Effective November 16, 2008, testing for anti Beta-2 glycoprotein I (IgG, IgM) antibodies and a new in-house antiphospholipid antibody panel will be performed in Special Testing. Testing for anti-cardiolipin antibodies (IgG, IgA, IgM) will remain unchanged. Criteria for the diagnosis of antiphospholipid syndrome are outlined below under “Interpretation.”

Anti Beta-2 glycoprotein I antibodies (IgG, IgM)

Specimen: 5 mL, gold top tube
BRL external preparation: Allow sample to clot completely at room temperature. Separate serum from cells ASAP and keep refrigerated
Performed: Results available within 2 days of receipt by lab (excludes weekend)
Test methodology: ELISA (Binding Site)
Reference range:
- Anti-β_2_ GPI (IgG) < 20 U/mL negative
- Anti-β_2_ GPI (IgG) > 20 U/mL positive
- Anti-β_2_ GPI (IgM) < 10 U/mL negative
- Anti-β_2_ GPI (IgM) > 10 U/mL positive

Anti-phospholipid antibody panel

Panel includes: Anti Beta-2 glycoprotein I antibodies (IgG, IgM)
Anticardiolipin antibodies (IgG, IgA and IgM)
Specimen: 5 mL, gold top tube
BRL external preparation: Allow sample to clot completely at room temperature. Separate serum from cells ASAP and keep refrigerated
Performed: At Royal Oak Laboratory with results available within 2 days of receipt by lab (excludes weekend)
Test methodology: ELISA (Binding Site)
Interpretation: According to the most recent international consensus statement (see reference), the Antiphospholipid syndrome (APS) is present if at least one clinical criterion and one laboratory criterion are present. Clinical criteria include: 1) vascular thrombosis (arterial, venous, small vessel); 2) pregnancy morbidities with fetal loss).

Continued on back
Laboratory criteria: these must occur on 2 or more occasions, at least 12 weeks apart and include:

- Anticardiolipin antibodies positive with IgG > 40 GPL and/or IgM > 40 MPL (NOTE: IgA anticardiolipin antibodies are not currently considered to be a laboratory criterion)
- Anti-beta 2 glycoprotein I antibodies positive with IgG > 20 GPL and/or IgM > 10 MPL
- Lupus anticoagulant detected in plasma.

A diagnosis of APS is discouraged if less than 12 weeks or more than 5 years separates the positive laboratory and clinical criteria. NOTE: Anticardiolipin antibodies may occur following acute bacterial or viral infections and in syphilis. Patients with such a history, who test positive, should be retested in 6-8 weeks to exclude transient antibodies that are usually not clinically significant.

CPT Code: Beta-2 glycoprotein I antibodies: 86146 x 2
APL antibody panel: 86147 x 3, 86146 x 2


Effective Date: November 16, 2008

Submitted by: Elizabeth Sykes, MD, Medical Director, Auto Chemistry and Special Testing, Royal Oak
Yvonne Posey, MD, Assoc Medical Director, Auto Chemistry and Special Testing, Royal Oak
J. Douglas Ferry, PhD, Technical Director, Auto Chemistry and Special Testing, Royal Oak
CA 27-29 & CA 19-9 In-House Testing and New Reference Ranges

Effective January 27th 2008, testing for CA 27-29 and CA 19-9 will be performed in-house in Automated Chemistry. This change necessitates reference changes. Test details and specimen requirements are as follows:

**CA 27-29**

<table>
<thead>
<tr>
<th>Specimen</th>
<th>5mL, gold top tube</th>
</tr>
</thead>
<tbody>
<tr>
<td>BRL External Preparation</td>
<td>Allow sample to clot completely at room temperature. After clotting, separate serum from cells ASAP and keep refrigerated.</td>
</tr>
<tr>
<td>Performed</td>
<td>Tuesday and Friday</td>
</tr>
<tr>
<td>Reference Range</td>
<td>Less than 38.7 U/mL (old range &lt;41U/mL)</td>
</tr>
<tr>
<td>Test Methodology</td>
<td>Siemens Centaur (chemiluminescence immunoassay)</td>
</tr>
<tr>
<td>Interpretation</td>
<td></td>
</tr>
</tbody>
</table>

- The CA 27-29 assay is used as an aid in monitoring patients previously treated for stage II or III breast cancer. Serial testing in conjunction with other clinical methods is used for early detection of cancer recurrence and the management of metastatic breast cancer treatment.
- Results cannot be interpreted as absolute evidence of the presence or absence of malignant disease and should always be used in conjunction with other diagnostic and clinical procedures.
- This test should NOT be used for screening and should NOT be used interchangeably with other assay methods.

| CPT Code | 86300 |

**CA 19-9**

<table>
<thead>
<tr>
<th>Specimen</th>
<th>5 mL, gold top tube</th>
</tr>
</thead>
<tbody>
<tr>
<td>BRL External Preparation</td>
<td>Allow sample to clot completely at room temperature. After clotting, separate serum from cells ASAP and keep refrigerated.</td>
</tr>
<tr>
<td>Performed</td>
<td>Tuesday and Friday</td>
</tr>
<tr>
<td>Reference Range</td>
<td>Less than 35 U/mL (old range &lt;55U/mL)</td>
</tr>
<tr>
<td>Test Methodology</td>
<td>Siemens Centaur (chemiluminescence immunoassay)</td>
</tr>
<tr>
<td>Interpretation</td>
<td></td>
</tr>
</tbody>
</table>

- CA 19-9 is useful in monitoring pancreatic, hepatobiliary, gastric, hepatocellular and colorectal cancer.
- The CA 19-9 assay value, regardless of the level, should not be interpreted as absolute evidence of the presence or absence of malignant disease.
- Patients must possess the ability to express the Lewis blood group antigen or they will be unable to produce the CA 19-9 antigen.
- This test should NOT be used for screening and should NOT be used interchangeably with other assay methods.

| CPT Code | 86301 |
| Effective Date | January 27, 2008 |
| Submitted by |

J. Douglas Ferry, PhD, Technical Director, Chemistry and Special Testing, Royal Oak
Elizabeth Sykes, MD, Medical Director, Chemistry and Special Testing, Royal Oak
Ralph Zade, MD, Medical Director, Chemistry, Troy
CELIAC DISEASE SCREENING PANEL - REVISION

Effective November 16, 2008, the celiac disease screening panel will be revised to include only a Tissue transglutaminase antibody (IgA) and an IgA level. The endomysial antibody (IgA), which detects the same antigen measured by the Tissue transglutaminase antibody test, will no longer be part of the panel, although it is still an orderable test.

Selective IgA deficiency occurs more commonly in celiac disease (2-3%) than in the general population (0.2%) and is likely to lead to a false negative result when IgA antibody screens are used in the diagnosis of celiac disease. For this reason, an IgA level is being included in the revised panel. Patients with an IgA of < 7 mg/dL, who are suspected of having celiac disease, should be re-tested by the IgG-Tissue transglutaminase antibody test or referred to a gastroenterologist. Currently the IgG-Tissue transglutaminase antibody is a send-out test and will require a new order.

Specimen: 5 mL, gold top tube
BRL external preparation: Allow sample to clot completely at room temperature. Separate serum from cells ASAP and keep refrigerated
Performed: At Royal Oak Laboratory with results available within 2 days of receipt by lab (excludes weekend)
Test methodology: IgA – nephelometry (Beckman)
Tissue transglutaminase antibody – ELISA (Binding Site)
Reference ranges:
   IgA (adults): 85 – 385 mg/dL
   Tissue transglutaminase (IgA): < 4 U/mL negative
                  4 – 10 U/mL weak positive
                  > 10 U/mL positive
CPT codes: 83516
           82784
Effective Date November 16, 2008
Submitted by Elizabeth Sykes, MD, Medical Director, Auto Chemistry and Special Testing, Royal Oak
          J. Douglas Ferry, PhD, Technical Director, Auto Chemistry and Special Testing, Royal Oak
To: Medical Staff, William Beaumont Hospital

From: Bobby Boyanton, M.D. (RO)  B. Robinson-Dunn, Ph.D., DABMM (RO)
Paul A. Goodman, M.D. (Troy)  Vaishali Pansare, M.D. (Grosse Pointe)

Date: February 14, 2008

Re: Cerebrospinal fluid (CSF) testing for Lyme Disease

Lyme Disease (LD) is diagnosed by clinical assessment and demonstrating the presence of *B. burgdorferi*-specific IgM/G antibodies in serum with positive or equivocal results confirmed by western blot assay. Uncommonly the infection may involve the nervous system, so-called Neurologic Lyme Disease (NLD), which is confirmed by demonstrating intrathecal synthesis of *B. burgdorferi*-specific IgM/G antibodies.

In as much, NLD testing requires the simultaneous analysis of serum and CSF for antibody production and calculation of the “intrathecal antibody synthesis index” for proper test interpretation.

Clinical specimens for NLD testing should be sent to one of the Beaumont clinical laboratories for proper processing and shipping - MAYO Medical Laboratories will perform the analysis. If testing is clinically warranted, please contact the Send-Out Laboratory (248-551-9045), or visit the online Laboratory Test Directory (Lyme Disease, Neurologic) to ensure proper specimen collection. **Remember: NLD testing requires the simultaneous collection of serum and CSF.**

If there are additional questions, please contact Drs. Boyanton, Robinson-Dunn, Goodman, or Pansare through client services (1-800-551-0488) or your BRL representative.

References:


Critical Call Values for PT/INR Limited to INR

To simplify communicating critical values for protime (PT)/INR, calls to physicians for critical values will now be based solely on the INR.

Protime (PT) and international normalized ratio (INR) results are derived from a single clotting test. The INR is simply a calculation developed to ensure consistency between different instruments using different reagents.

**Specimen**

**SPECIAL HANDLING**
Collect: One 5 mL light blue Hemogard vacutainer (3.2% sodium citrate).
Tube must be full.

**Rejection Criteria**
Specimens containing clots, gross hemolysis, inappropriate volume, thawed or partially thawed are unacceptable and will not be tested.

**Specimen Transport**
Transport whole blood specimens to Coagulation Laboratory within 24 hours. Specimens should be kept at room temperature (20-25°C or 68-77°F). If not possible, the following procedure must be followed for accurate results:

1. Centrifuge the capped tube at 1500 x g for 15 minutes.
2. Transfer plasma with a plastic pipette into a plastic centrifuge tube, cap and centrifuge an additional 15 minutes at 1500 x g to obtain platelet poor plasma which has a platelet count less than 10 bil/L. Double-centrifuged specimens are critical for accurate results as platelet contamination may cause spurious results.
3. Immediately remove only the top two-thirds of the platelet-free sample and transfer it into a plastic tube.
4. Freeze the specimen immediately.
5. Transport frozen on DRY ICE. Specimens must remain frozen during transport.

**Performed**
7 days a week; 24 hours/day. Available on a Stat basis.

**Interpretation**
**Prothrombin times** are elevated in oral anticoagulant therapy where it is useful for monitoring Coumadin therapy, liver disease, some lupus like inhibitors, congenital deficiency of factors II, V, VII or X.

**CPT Code**
PT: 85610

**Effective Date**
August 4th, 2008

**Submitted by**
Marc Smith, MD, Medical Director, Royal Oak Coagulation Laboratory
Ming Xie, MD, Clinical Pathology, Troy
DISCONTINUED CLOT RETRACTION

ANNOUNCEMENT OF TEST CHANGE

Beaumont Hospitals – Royal Oak will no longer offer the clot retraction test, effective June 8, 2008 because the proper non-siliconized collection tubes are no longer available. Although clot retraction used to be a popular screening test for platelet defects (particularly Glanzmann’s thrombasthenia), more advanced tests such as Platelet Function Analysis (PFA) and optical platelet aggregation have greater sensitivity and specificity for detecting the same abnormalities, and are more compatible with current blood collection methods.

Effective Date
June 8, 2008

Submitted by
Marc Smith, MD, Medical Director, Coagulation
ELVIS* Herpes Simplex Virus (HSV) ID/Typing Test System

A rapid-based method for detecting HSV within 24-30 hours of receipt of clinical specimens in the Clinical Microbiology Laboratory, Beaumont Hospital, Royal Oak, will replace our conventional culture that has required up to 10 days for a final result. Co-infections cannot be reported with this assay; only HSV-1 or HSV-2 will be reported if present in clinical specimens.

NOTE: Antigen detection for HSV on primary specimens by direct fluorescent antibody (DFA) analysis will no longer be available.

*ELVIS = Enzyme-Linked Virus Inducible System

Synonyms
- HSV Culture

Performed
- Monday through Sunday

Test Methodology
- Detection of herpes simplex virus in genetically modified cells with confirmation of HSV 1 and HSV 2 by DFA testing with monoclonal reagents.

Interpretation
- By report

CPT Code
- 87255, 87140x2

Effective Date
- May 9, 2008

Submitted by
- Barbara Robinson-Dunn, Ph.D., DABMM, Technical Director, Clinical Microbiology
- Bobby L. Boyanton, M.D., Medical Director, Clinical Microbiology
**FIBRIN STABILIZING FACTOR**

Fibrin Stabilizing Factor specimens now may be kept at room temperature for up to 4 hours or submitted frozen. (Formerly these specimens were to be kept at room temperature for only 2 hours.)

**Synonyms**
- Factor 13, Factor XIII

**Specimen**
- Collect: One 5 mL light blue Hemogard vacutainer (3.2% sodium citrate).
- **Tube must be full.** It is imperative for the light blue tube to be full, Insufficient volumes will cause inaccurate results.

**BRL External Preparation**
- Transport whole blood specimens to Coagulation Laboratory at room temperature within 4 hours. If unable to transport to lab within 4 hours, freeze plasma according to the following:
  1. It is imperative for the light blue tube to be full. Insufficient volumes will cause inaccurate results.
  2. Centrifuge the capped tube at 1500 x g for 15 minutes.
  3. Transfer plasma with a plastic pipette into a plastic polypropylene centrifuge tube, cap and centrifuge an additional 15 minutes at 1500 x g to obtain platelet poor plasma which has a platelet count less than 10,000 bill/L. Double-centrifuged specimens are critical for accurate results as platelet contamination may cause spurious results.
  4. Immediately remove only the top two-thirds of the platelet-free sample and transfer it into a plastic tube.
  5. Freeze the specimen immediately.
  6. Transport frozen on DRY ICE. Specimens must remain frozen during transport.

**BRL Specimen Transport**
- Transport whole blood specimens to Coagulation Laboratory at room temperature within 4 hours or transport frozen plasma on DRY ICE. Specimens must remain frozen during transport.

**Rejection Criteria**
- Specimens containing clots, gross hemolysis, inappropriate volume, thawed or partially thawed, are unacceptable and will not be tested.

**Performed**
- Monday-Friday, dayshift

**Results available in 24 hours.**

**Test Methodology**
- Manual

**Interpretation**
- FSF is severely reduced in Factor XIII deficiency
- Present- FSF is detected in sample.
- Absent- No FSF is detected in sample.

**CPT Code**
- 85291

**Effective Date**
- June 8, 2008

**Submitted by**
- Marc Smith, MD, Medical Director, Coagulation
Free Testosterone Testing - Adult Males

Effective March 10, 2008, Free Testosterone testing for adult males (18 years or older) will be performed on site in Beaumont’s Special Testing Laboratory. The testing will still be performed by radioimmunoassay and the reference range will not change. Test details and specimen requirements are as follows:

<table>
<thead>
<tr>
<th>Specimen</th>
<th>5 mL, gold top tube</th>
</tr>
</thead>
<tbody>
<tr>
<td>BRL External Preparation</td>
<td>Allow sample to clot completely at room temperature. After clotting, separate serum from cells ASAP and keep refrigerated</td>
</tr>
<tr>
<td>Performed</td>
<td>Monday, Wednesday, Friday</td>
</tr>
</tbody>
</table>
| Reference Range | Males: 18-49 yrs: 0.95-4.30 ng/dL  
>50 yrs: 0.80-3.50 ng/dL |
| Test Methodology | Radioimmunoassay (analog method) |
| Interpretation | • Free testosterone assays aid in the diagnosis of gonadal and adrenal tumors, adrenal hyperplasia, hypopituitarism, and orchiectomy in adults.  
• Less than 4% of the circulating testosterone is free, 1-2% is bound to cortisol-binding globulin, 40% is loosely bound to albumin and the remainder to sex hormone binding globulin (SHBG). |
| CPT Code | 84590 |
| Effective Date | March 10, 2008 |
| Submitted by | J. Douglas Ferry, PhD, Technical Director, Chemistry and Special Testing, Royal Oak  
Elizabeth Sykes, MD, Medical Director, Chemistry and Special Testing, Royal Oak |
Free Testosterone Testing - Females and Children

Effective March 10, 2008, all requests for Free Testosterone levels in females and patients under the age of 18 years will be sent to ARUP Laboratories. ARUP performs this test by an LCMS/MS (tandem mass spectrometry) method with a calculated free testosterone level using sex hormone-binding globulin and albumin equilibrium binding constants. Current literature supports this approach for the determination of free testosterone levels in this patient population. Free testosterone levels in adult males will be moved to on-site testing using the same radioimmunoassay method that is currently being used for the send-out test, however, this method is not sufficiently sensitive to use routinely in females and patients under the age of 18 years. Testosterone by LCMS/MS with a calculated free fraction is suggested for women and children because of the improved sensitivity for total testosterone by this method. Test details and specimen requirements are as follows:

Specimen: 5 mL gold top (SST). Specimen should be collected between 6-10 AM.

BRL External Preparation: Allow sample to clot completely at room temperature. After clotting, separate serum from cells ASAP. Transport to lab refrigerated (2-8°C).

Performed: Sunday - Saturday

Reference Range:

<table>
<thead>
<tr>
<th>Female Free Testosterone, pg/mL</th>
<th>Male Free Testosterone, pg/mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-6 years: Less than 0.6 pg/mL</td>
<td>1-6 years: Less than 0.6 pg/mL</td>
</tr>
<tr>
<td>7-9 years: 0.6-1.8 pg/mL</td>
<td>7-9 years: 0.1-0.9 pg/mL</td>
</tr>
<tr>
<td>10-11 years: 0.1-3.5 pg/mL</td>
<td>10-11 years: 0.1-6.3 pg/mL</td>
</tr>
<tr>
<td>12-13 years: 0.9-6.8 pg/mL</td>
<td>12-13 years: 0.5-98.0 pg/mL</td>
</tr>
<tr>
<td>14-15 years: 1.2-7.5 pg/mL</td>
<td>14-15 years: 3-138.0 pg/mL</td>
</tr>
<tr>
<td>16-17 years: 1.2-9.9 pg/mL</td>
<td>16-17 years: 38.0-173.0 pg/mL</td>
</tr>
<tr>
<td>18-30 years: 0.8-7.4 pg/mL</td>
<td>Tanner Stage I: Less than or equal to 3.7 pg/mL</td>
</tr>
<tr>
<td>31-40 years: 1.3-9.2 pg/mL</td>
<td>Tanner Stage II: 0.3-21 pg/mL</td>
</tr>
<tr>
<td>41-51 years: 1.1-5.8 pg/mL</td>
<td>Tanner Stage III: 1.0-98.0 pg/mL</td>
</tr>
<tr>
<td>Postmenopausal: 0.6-3.8 pg/mL</td>
<td>Tanner Stage IV: 35.0-169.0 pg/mL</td>
</tr>
<tr>
<td>Tanner Stage I: Less than 2.2 pg/mL</td>
<td>Tanner Stage V: 41.0-239.0 pg/mL</td>
</tr>
<tr>
<td>Tanner Stage II: 0.4-4.5 pg/mL</td>
<td></td>
</tr>
<tr>
<td>Tanner Stage III: 1.3-7.5 pg/mL</td>
<td></td>
</tr>
<tr>
<td>Tanner Stage IV: 1.1-15.5 pg/mL</td>
<td></td>
</tr>
<tr>
<td>Tanner Stage V: 0.8-9.2 pg/mL</td>
<td></td>
</tr>
</tbody>
</table>

(See Reverse)
Test Methodology:  LCMS/MS

Interpretation:  Testosterone circulates in plasma approximately 97-98% protein bound, mainly to sex hormone binding globulin (SHBG) and albumin. The concentration of free testosterone is derived from a mathematical expression based on constants for the binding of testosterone to SHBG and albumin. Because SHBG is often low in women with hirsutism, free testosterone is elevated while total testosterone levels may be normal. Free testosterone levels are also useful in the evaluation of virilization, acne, amenorrhea and male hypogonadism.

CPT Code:  84402

Effective Date:  March 10, 2008

Submitted by:  Joan Wehby, MT, Coordinator, Send-Out Laboratory, Royal Oak and Troy
J. Douglas Ferry, PhD, Technical Director, Special Testing Laboratory
Yvonne F. Posey, MD, Medical Director, Send-Out Laboratory, Royal Oak
Fructosamine

Beginning June 8, 2008, testing for fructosamine will no longer be performed at a William Beaumont laboratory. Because the frequency of requests is low, the test will be sent out to ARUP Laboratories. Results should be available within 24 hours of receipt by ARUP Laboratories. Specimens will be sent out Monday through Friday. Because a specimen received late on Friday may not be sent out until Monday, turnaround time may be from one to four days. Results from ARUP should be numerically equivalent to our previous Beaumont laboratory results.

Although the clinical correlation of fructosamine with hyperglycemia is not as well established as that for hemoglobin A1c, fructosamine may be an alternative indicator of blood glucose control over the previous two to three weeks in cases when a hemoglobin A1c cannot be obtained. This is the case in patients with any degree of in-vivo hemolysis, acquired or hereditary, including those with certain hemoglobin variants (e.g. sickle cell disease, SC disease).

Synonyms: Glycosylated or glycated protein, glycosylated or glycated albumin

Instructions: Transport 0.5 mL of serum at 2-8 degrees C to ARUP

Specimen: One 5 mL SST tube

BRL External Preparation: None

BRL Specimen Transport: No special handling

Rejection Criteria: Hemolyzed specimen

Performed: Sunday through Saturday

Reference Range: Non-diabetic: 170-285 micromol/L

Test Methodology: Spectrophotometry

Interpretation: None

Reflex Testing: No

CPT Code: 82985

Effective Date: June 8, 2008

Submitted by: Elizabeth Sykes, M.D., Medical Director, Automated Chemistry, Royal Oak
Ralph Zade, M.D., Medical Director, Chemistry, Troy
Fructosamine

Beginning June 8, testing for fructosamine will no longer be performed at a William Beaumont laboratory. Because the frequency of requests is low, the test will be sent out to ARUP Laboratories. Results should be available within 24 hours of receipt by ARUP Laboratories. Specimens will be sent out Monday through Friday. Because a specimen received late on Friday may not be sent out until Monday, turnaround time may be from one to four days. Results from ARUP should be numerically equivalent to our previous Beaumont laboratory results.

Although the clinical correlation of fructosamine with hyperglycemia is not as well established as that for hemoglobin A1c, fructosamine may be an alternative indicator of blood glucose control over the previous two to three weeks in cases when a hemoglobin A1c cannot be obtained. This is the case in patients with any degree of in-vivo hemolysis, acquired or hereditary, including those with certain hemoglobin variants (e.g. sickle cell disease, SC disease).

Synonyms
Glycosylated or glycated protein, glycosylated or glycated albumin

Instructions
Transport 0.5 mL of serum at 2-8 degrees C to ARUP

Specimen
One 5 ml SST tube

BRL External Preparation
None

BRL Specimen Transport
No special handling

Rejection Criteria
Hemolyzed specimen

Performed
Sunday through Saturday

Reference Range
Non-diabetic: 170-285 micromol/L

Test Methodology
Spectrophotometry

Interpretation
None

Reflex Testing
No

CPT Code
82985

Effective Date
June 8, 2008

Submitted by
Raymond Karcher, Ph.D.
HLA-B*5701 SCREENING FOR ABACAVIR HYPERSENSITIVITY

The FDA recommends that genetic testing for HLA-B*5701 be performed prior to prescribing the reverse transcriptase inhibitor, Abacavir, to HIV patients. The presence of HLA-B*5701 is associated with a drug-induced hypersensitivity reaction to Abacavir that can be prevented with prior genetic screening.

Synonyms
HLA-B*5701 Screening

Specimen
Whole Blood: One 7 mL lavender top (EDTA) tube.

Specimen Preparation & Transport
After collection of whole blood, invert tube several times to ensure sufficient mixing with anti-coagulant. Deliver to HLA Laboratory at room temperature within 24 hours. Do not refrigerate or freeze.

Rejection Criteria
Specimens collected in a green (heparin), gold (serum separator), or red (clot) top tubes will not be tested.

Performed
HLA Laboratory (Royal Oak): Weekdays, 7:00 a.m.-5:00 p.m.

Test Methodology
Sequence Specific Priming (SSP) for HLA Class I genotyping.

Reference Range
Antigens present are reported.

Reference

Contacts
HLA Laboratory, Beaumont Hospital, Royal Oak

CPT Codes
83890, 83894, 83898, 83912
Reflex Testing: 83894, 83898

Effective Date
09/28/2008

Submitted by
Gabriel Maine, PhD, Director, HLA Laboratory
Bobby Boyanton, Jr MD, Medical Director, Microbiology
INHIBITOR (CIRCULATING ANTICOAGULANT) SCREEN

Beginning June 8, 2008, the collection requirements for the Inhibitor (Circulating Anticoagulant) Screen will be changed to two 5 mL light blue tubes (3.2% sodium citrate) from the original one tube.

Synonyms
Inhibitor, Lupus Anticoagulant

Specimen
Collect: Two 5 mL light blue tube (3.2% sodium citrate).
Tube must be full. It is imperative for the light blue tube to be full. Insufficient volumes will cause inaccurate results.

BRL External Preparation
Transport whole blood specimens to Coagulation Laboratory at room temperature within 4 hours. If unable to transport to lab within 4 hours, freeze specimen according to the following:
1. It is imperative for the light blue tube to be full. Insufficient volumes will cause inaccurate results.
2. Centrifuge the capped tube at 1500 x g for 15 minutes.
3. Transfer plasma with a plastic pipette into a plastic polypropylene centrifuge tube, cap and centrifuge an additional 15 minutes at 1500 x g to obtain platelet poor plasma which has a platelet count less than 10,000 bill/L. Double-centrifuged specimens are critical for accurate results as platelet contamination may cause spurious results.
4. Immediately remove only the top two-thirds of the platelet-free sample and transfer it into a plastic tube.
5. Freeze the specimen immediately.
6. Transport frozen on DRY ICE. Specimens must remain frozen during transport.

BRL Specimen Transport
Transport whole blood specimens to Coagulation Laboratory at room temperature within 4 hours of collection or transport frozen plasma on DRY ICE. Specimens must remain frozen during transport.

Rejection Criteria
Specimens containing clots, gross hemolysis, inappropriate volume, thawed or partially thawed are unacceptable and will not be tested.
This test will not be performed on patients receiving heparin or Coumadin.

Performed
Sunday - Saturday; 24 hrs/day

Result available in 4 hours.

Reference Range
Negative

Test Methodology
Change in optical density.

Interpretation
Immediate inhibitors are most often lupus-like inhibitors. All inhibitor screens that are positive for immediate inhibitor affecting the aPTT will automatically have a Platelet Neutralization Procedure (PNP) performed to prove phospholipid dependence.
Progressive inhibitors are most often specific factor inhibitors, such as Factor VIII inhibitors.
To exclude the presence of a Lupus Anticoagulant (i.e., lupus inhibitor), the International Society on Thrombosis and Hemostasis recommends that at least two different lupus anticoagulant sensitive tests are normal.
William Beaumont hospital offers three tests to exclude lupus anticoagulants.
These are the Inhibitor Screen, dilute Russell Viper Venom Time (dRVVT), and Hexagonal Phase Phospholipid.

CPT Code
85730x2, 85610x2, 85597

Effective Date
June 8, 2008

Submitted by
Marc Smith, MD, Medical Director, Coagulation
LABORATORY TESTING FOR VAGINOSIS / VAGINITIS
(VAGINOSIS SCREEN)

On September 18, 2007 the Division of Clinical Microbiology at William Beaumont Hospital - Royal Oak began utilizing an FDA approved, DNA probe-based test for the detection of the most common pathogens associated with vaginosis / vaginitis - *Gardnerella vaginalis* (BV - bacterial vaginosis), *Trichomonas vaginalis* (trichomoniasis), and *Candida* species (candidiasis). Since that time approximately 4,000 AFFIRM™ tests have been performed and the feedback from our primary care providers has been positive.

The AFFIRM™ test has numerous advantages, including a) the simultaneous detection of these microorganisms from a single vaginal swab, b) rapid turn-around-time, and c) sensitivity and specificity that are at least equivalent to routine culture and microscopy and much better than that of microscopy alone.

Effective May 12, 2008, the Clinical Microbiology Laboratory will STOP performing routine vaginal cultures for *Gardnerella vaginalis*, *Trichomonas vaginalis*, and *Candida* species. Cultures will still be accepted for *Neisseria gonorrhoeae* and Group B *Streptococcus*.

If there are any specific culture requests or additional questions, please contact Bobby L. Boyanton Jr., M.D., or Barbara Robinson-Dunn, Ph.D. through client services (1-800-551-0488) or your BRL representative.

Supplies for the AFFIRM™ test may be obtained through your BRL representative.
### Synonyms
AFFIRM™ Test

### Instructions
Prepare the patient as follows:
Place the patient in position for a pelvic examination. Insert an UNLUBRICATED speculum (WITHOUT JELLY) into the vagina to permit visualization of the posterior vaginal fornix.

### Specimen
**Internal:** See Specimen Collection Manual under Laboratory Services, Inside Beaumont
**External:** See literature provided by your BRL representative

### BRL External Preparation
The patient’s name and collection date must be written on the AFFIRM™ label which accompanies the Ambient Temperature Transport System (ATTS). Client must attach AFFIRM™ label around the top of the transport tube directly under the cap.
The collected specimen may be stored at room temperature (20-25°C or 68-77°F) or refrigerated (2-8°C or 36-46°F).

### BRL Specimen Transport
The AFFIRM™ VPIII Ambient Temperature Transport System (ATTS):
Transport at room temperature (20-25°C or 68-77°F) or refrigerated (2-8°C or 36-46°F) conditions.

### Rejection Criteria
- Any transport system other than the AFFIRM™ VPIII Ambient Temperature Transport System (ATTS)
- Specimen older than 72 hrs. old.
- Frozen specimen.

### Performed
Monday-Friday, 24 hours a day
Results available in one business day.

### Reference Range
Negative for Candida albicans, Gardnerella vaginalis, Trichomonas vaginalis

### Test Methodology
The AFFIRM™ VPIII Microbial Identification Test is based on the principles of nucleic acid hybridization.

### Interpretation
A positive result for Candida, Gardnerella, and/or Trichomonas means nucleic acid for Candida species (C. albicans, C. glabrata, C. kefyr, C. krusei, C. parapsilosis, C. tropicalis), G. vaginalis and/or T. vaginalis, respectively, is present in the sample and indicates that the patient has candidiasis, bacterial vaginosis, and/or trichomoniasis when consistent with clinical signs and symptoms. Simultaneous infections by more than one organism are common.

### CPT Code
87480 - Candida Species; 87510 - Gardnerella Vag.; 87660 - Trichomonas Vag.

### Effective Date
May 12, 2008

### Submitted by
Bobby L. Boyanton, Jr, MD, Medical Director, Microbiology
Barbara Robinson-Dunn, PhD, Technical Director, Microbiology
New Haptoglobin Assay

Effective June 8, 2008 the Haptoglobin assay will be moved from the Special Testing Laboratory (nephelometric method) to Automated Chemistry (turbidimetric method). The Automated Chemistry method will provide better Stat coverage with results available in less than two hours after sample receipt in the laboratory (24 hours/day, 7 days/week). Routine results will be available the same day. The new haptoglobin assay demonstrates good precision and patient results correlate well (r = 0.984) with our old method. The new reference range will be lowered to 40 –240 mg/mL.

Method

Turbidimetric

Test performed

24 hours/day, 7 days/wk

Results available

Routine / same day
Stats within 2 hours

Reference Range

40 –240 mg/dL

Effective Date

June 8, 2008

Submitted by

J. Douglas Ferry, Ph.D., Technical Director, Chemistry and Special Testing, Royal Oak
Elizabeth Sykes, M.D., Medical Director, Chemistry and Special Testing, Royal Oak
Ralph Zade, Jr., M.D., Medical Director, Chemistry, Troy
Suresh Gehani, M.D., Medical Director, Department of Laboratories, Grosse Pointe
New Reference Ranges for aPTT (Activated Partial Thromboplastin Time) and TT (Thrombin Time)

<table>
<thead>
<tr>
<th>Test</th>
<th>Old Reference Range</th>
<th>New Reference Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>aPTT (sec)</td>
<td>25-33</td>
<td>25-32</td>
</tr>
<tr>
<td>TT (sec)</td>
<td>15-17</td>
<td>15-18</td>
</tr>
</tbody>
</table>

Specimen
SPECIAL HANDLING
Collect: One 5 mL light blue Hemogard vacutainer (3.2% sodium citrate). Tube must be full.

Rejection Criteria
Specimens containing clots, gross hemolysis, inappropriate volume, thawed or partially thawed are unacceptable and will not be tested.

BRL Specimen Transport
Transport whole blood specimens to Coagulation Laboratory within 16 hours for aPTT and 4 hours for TT. Specimens should be kept at room temperature (20-25°C or 68-77°F). If not possible, the following procedure must be followed for accurate results:
1. Centrifuge the capped tube at 1500 x g for 15 minutes.
2. Transfer plasma with a plastic pipette into a plastic centrifuge tube, cap and centrifuge an additional 15 minutes at 1500 x g to obtain platelet poor plasma which has a platelet count less than 10 bil/L. Double-centrifuged specimens are critical for accurate results as platelet contamination may cause spurious results.
3. Immediately remove only the top two-thirds of the platelet-free sample and transfer it into a plastic tube.
4. Freeze the specimen immediately.
5. Transport frozen on DRY ICE. Specimens must remain frozen during transport.

Performed
7 days a week; 24 hours/day. Available on a Stat basis.

Interpretation
Activated partial thromboplastin times are elevated in classical hemophilia A and B, congenital deficiencies of factors II, V, VIII, IX, X and XI, XII, dysfibrinogenemia, disseminated intravascular coagulation, liver failure, congenital hypofibrinogenemia, and vitamin K deficiency.
Thrombin times are elevated in hepatic disease, DIC, afibrinogenemia, dysfibrinogenemia and macroglobulinemia.

CPT Code
PTT: 85730, TT: 85670

Effective Date
August 4th, 2008

Submitted by
Marc Smith, MD, Medical Director, Coagulation Laboratory, Royal Oak
Ming Xie, MD, Clinical Pathology, Troy
New Reference Ranges for PT (Prothrombin Time) and TT (Thrombin Time)

<table>
<thead>
<tr>
<th>Test</th>
<th>Old Reference Range</th>
<th>New Reference Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>PT (sec)</td>
<td>9.3-11.2</td>
<td>9.7-11.6</td>
</tr>
<tr>
<td>TT (sec)</td>
<td>14-18</td>
<td>15-17</td>
</tr>
</tbody>
</table>

**Specimen**

**SPECIAL HANDLING**
Collect: One 5 mL light blue Hemogard vacutainer (3.2% sodium citrate).
Tube must be full.

**Rejection Criteria**
Specimens containing clots, gross hemolysis, inappropriate volume, thawed or partially thawed are unacceptable and will not be tested.

**Specimen Transport**
Transport whole blood specimens to Coagulation Laboratory within 24 hours. Specimens should be kept refrigerated (2-8°C or 36-46°F) or room temperature (20-25°C or 68-77°F). If not possible, the following procedure must be followed for accurate results:

1. Centrifuge the capped tube at 1500 x g for 15 minutes.
2. Transfer plasma with a plastic pipette into a plastic centrifuge tube, cap and centrifuge an additional 15 minutes at 1500 x g to obtain platelet free plasma which has a platelet count less than 5,000/μL. Double-centrifuged specimens are critical for accurate results as platelet contamination may cause spurious results.
3. Immediately remove only the top two-thirds of the platelet-free sample and transfer it into a plastic tube.
4. Freeze the specimen immediately.
5. Transport frozen on DRY ICE. Specimens must remain frozen during transport.

**Performed**
7 days a week; 24 hours/day. Available on a Stat basis.

**Interpretation**

Prothrombin times are elevated in oral anticoagulant therapy, liver disease, some lupus like inhibitors, congenital deficiency of factor VII, X, V, or II.

Thrombin times are elevated in hepatic disease, DIC, afibrinogenemia, dysfibrinogenemia and macroglobulinemia.

**CPT Code**
PT: 85610, TT: 85670

**Effective Date**
February 13, 2008

**Submitted by**
Marc Smith, MD, Medical Director, Royal Oak Coagulation Laboratory
New Reference Range for Thyroglobulin Antibody (Anti-Tg) Test

The Special Testing Laboratory has lowered the reference range for the thyroglobulin antibody assay from $\leq 40\text{ IU/mL}$ to $\leq 20\text{ IU/mL}$. Elevated thyroglobulin antibody results are known to interfere with thyroglobulin immunometric assays causing falsely low thyroglobulin results. Therefore, thyroglobulin should be interpreted with caution when thyroglobulin antibody levels are $>20\text{ IU/mL}$. When monitoring thyroid cancer patients (post ablation therapy) thyroglobulin should be at or below the assay detection limit (0.5 ng/mL).

**Reference Range**

$\leq 20\text{ IU/mL}$

**Effective Date**

April 21, 2008

Note: Both thyroid peroxidase (TPO) antibody and thyroglobulin antibody (Anti-Tg) are typically ordered as a Thyroid Antibody Panel when testing patients for autoimmune disease. The Anti-TPO assay has not changed.

**Submitted by**

J. Douglas Ferry, PhD, Technical Director, Chemistry and Special Testing,
Royal Oak
Elizabeth Sykes, MD, Medical Director, Chemistry and Special Testing,
Royal Oak
Path Consult: Hematology

Pathology consults (Path consult), which consist of a CBC, differential and pathologist review, are useful when a hematologic abnormality is present and the clinician wants an in-depth interpretation of the hematology results by a pathologist before further action is taken. However, in order to comply with Medicare and other federal regulatory agencies, Path consults cannot be performed on normal peripheral bloods. Orders must contain an established diagnosis or signs/symptoms with the applicable ICD9 code entered with the order. In addition, the order must clearly state “pathology consult,” as other terms, such as hemogram, are not acceptable. Original specimens are stable for 8 hours at room temperature. Due to the deterioration of morphology on aged specimens, it is not appropriate to add a Path consult to a specimen received the prior day. Even though a CBC is reportable for 3 days and the instrument can still distinguish cell types, the cells undergo morphologic changes, in size, shape and granularity that do not allow for accurate morphologic interpretation. Thus, all requests for add-on Path consults will be rejected and a fresh specimen should be obtained for a Path consult when the CBC identifies abnormalities and pathologist review is requested.

Specimen

Whole blood: 4 mL lavender (EDTA) (Min: 2.0 mL lavender)
Capillary blood: 500 mcL lavender microtainer (EDTA) (Min: 300 mcL lavender)
Note: Effective 4/2/03, all INPATIENT Heme Path Consults require a Hem/Onc request. This does not apply to outpatient and BRL requests.

BRL External Preparation Storage:
Refrigerated (2-8 °C or 36-46 °F): 24 hours

BRL Specimen Transport
Transport refrigerated (2-8 °C or 36-46 °F).

Rejection Criteria
Specimens containing clots or insufficient volume are unacceptable and will not be tested. A slide review to pathologist must be ordered as a Path consult or it will be rejected. In order to ensure compliance with Medicare and other federal agencies, the Hematology Laboratory has instituted the written policy of not accepting requests for path consult of normal CBC/differentials.

Performed
Monday-Friday, dayshift
Reports available in 24 hrs.
Specimens received Friday afternoon through Sunday will have results available the following Monday.

CPT code
80502, 80505 and 80545

Effective Date
November 1, 2008

Submitted by
Ann Marie Blenc, MD, Medical Director, Hematology Royal Oak
Hongwei Ma, MD, Medical Director, Hematology Troy
Paroxysmal Nocturnal Hemoglobinuria (PNH) Screening Assay

Effective April 1, 2008, the William Beaumont Hospital Flow Cytometry Laboratory will be modifying our current testing panel for PNH. We will be adding FLAER analysis and evaluation of the GPI-linked antigens CD14 and CD24, to our testing panel for PNH in granulocyte and monocyte populations. In addition we will now offer analysis of red blood cells for CD59 expression or absence, as this can also help in the diagnosis of PNH and is important information in PNH patients being treated with eculizumab. For patients found to have PNH, the percentage of Type I, II and III RBC's, as well as the percentages of granulocyte and monocyte PNH clones will be reported so that patients can be followed more effectively.

Background: PNH is a disease that evolves from a hematopoietic stem cell defect in which a somatic mutation of an X-linked gene (PIG-A) results in a partial or absolute deficiency of GPI-linked proteins. Clinical manifestations include chronic intravascular hemolysis, bone marrow failure and life threatening thrombosis. A fluorescein labeled proaerolysin (FLAER) has been identified that binds directly to the GPI anchor and it has been shown to be more sensitive at detecting small populations of PNH clones.

Synonyms
PNH Screening Assay, PI Antigen, FLAER

Specimen
One 5 mL EDTA tube (lavender top)

BRL External Preparation
All specimen types must be received within 48 hours of collection

BRL Specimen Transport
Transport at room temperature (20-25°C or 68-77°F).

Rejection Criteria
Specimens received in the laboratory greater than 48 hours post collection and clotted specimens will not be tested.

Performed
Monday-Saturday (Blood must ARRIVE in Flow Cytometry by 1PM on Saturday.)
Results available in 1-2 days.

Reference Range
Normal, or percent of abnormal granulocytes, monocytes and red cells

Test Methodology
Immunophenotyping by multiparameter flow cytometry

Interpretation
This assay is reported as normal or abnormal. The percentage of granulocytes and monocytes showing decreased or absent expression of FLAER, CD14, CD24, and CD59, and the percentage of Type I, II and II red blood cells will be reported in abnormal patients.

CPT Code

Effective Date
April 1, 2008

Submitted by
Vonda Douglas-Nikitin MD, Medical Director
Flow Cytometry Laboratory
Phadia ImmunoCAP Allergy Update

Due to new scientific nomenclature standards, the genus and species name of the following allergens have been changed:

<table>
<thead>
<tr>
<th>Former Name</th>
<th>New Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Penicillium notatum</td>
<td>Penicillium chrysogenum*</td>
</tr>
<tr>
<td>Helminthosporium halodes</td>
<td>Setomelanomma rostrata</td>
</tr>
<tr>
<td>Fusarium moniliforme</td>
<td>Fusarium proliferatum*</td>
</tr>
<tr>
<td>Cephalosporium acremonium</td>
<td>Acremonium kiliense</td>
</tr>
</tbody>
</table>

*Two of these allergens with new names (P. chrysogenum and F. proliferatum) are also offered in the Comprehensive Mold Panel.

Effective date: Immediately
Submitted by: J. Douglas Ferry, PhD and Elizabeth Sykes, MD

In order to better serve our customers, we offer additional allergy panels:

**Region VII/Upper Respiratory Panel**

<table>
<thead>
<tr>
<th>Box Elder</th>
<th>Elm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cat Dander</td>
<td>House Dust (D. Farinae)</td>
</tr>
<tr>
<td>Cockroach</td>
<td>Oak</td>
</tr>
<tr>
<td>Cocksfoot</td>
<td>Outdoor Mold (A. Alternata)</td>
</tr>
<tr>
<td>Common Ragweed</td>
<td>Redtop Bent grass</td>
</tr>
<tr>
<td>Common Silver Birch</td>
<td>Rough Marsh Elder</td>
</tr>
<tr>
<td>Dog Dander</td>
<td>Total IgE</td>
</tr>
</tbody>
</table>

**Food Allergy Panel**

<table>
<thead>
<tr>
<th>Clam</th>
<th>Egg White</th>
<th>Fish, Cod</th>
<th>Maize, Corn</th>
<th>Milk</th>
<th>Peanut</th>
<th>Scallop</th>
<th>Shrimp</th>
<th>Soybean</th>
<th>Walnut</th>
<th>Wheat</th>
<th>Total IgE</th>
</tr>
</thead>
</table>

**Childhood Allergy Panel**

<table>
<thead>
<tr>
<th>Cat Dander</th>
<th>Cockroach</th>
<th>Dog Dander</th>
<th>Egg White</th>
<th>Fish, Cod</th>
<th>House Dust Mite (D. farinae)</th>
<th>Milk</th>
<th>Outdoor mold (A. Alternata)</th>
<th>Peanut</th>
<th>Soybean</th>
<th>Wheat</th>
<th>Total IgE</th>
</tr>
</thead>
</table>

Beaumont Laboratories
Beaumont Reference Laboratory (BRL)

Beaumont Hospitals
3601 West 13 Mile Road
Royal Oak, MI 48073-6769
1-800-551-0488
www.beaumonthospitals.com/labs

Beaumont Hospitals
3601 West 13 Mile Road
Royal Oak, MI 48073-6769
1-800-551-0488

Beaumont Laboratories
44201 Dequindre Road
Troy, MI 48098-1198
248-964-8030
www.beaumonthospitals.com/labs
SEMEN ANALYSIS

Effective July 27, 2008, semen analysis for fertility testing will be performed using an automated analyzer, the SQA-V analyzer. This will result in a change in reporting of several parameters which are listed below:

- Viscosity will be reported as normal or abnormal.
- Sperm Count will be reported only as million/mL
- Motility will be reported as sperm progressive motility only (%).
- Morphology will be reported as % normal.

We will continue to use the WHO 3rd edition for sperm morphology. Post vasectomy checks will not be affected by this change and will continue to be done manually.

**Instructions**

Semen Analysis for fertility testing must be prescheduled with the Beaumont Hospitals’ Appointment Center. Call (800) 328-8542 for instructions on collection and to schedule appointment for drop off of specimen.

**Specimen**

The sample should be collected after minimum of 48 hours but not more than seven days of sexual abstinence. For repeated sample, period of abstinence should be constant.

**Collect entire ejaculate in a sterile container.**

Container should be obtained at the Beaumont Hospitals’ Outpatient Laboratory or at one of the Beaumont Hospitals’ ambulatory sites.

**Specimen Transport**

Transport at 37°C (keep as close to body temperature as possible) within 45 minutes after collection.

**Rejection Criteria**

Samples collected in container with chemical or soap residues or in an ordinary latex condom (not issued by the laboratory) are not acceptable and must be re-collected. Insufficient specimen or specimens delivered more than 1 hour after collection may be cause for rejection.

See Reverse Side
<table>
<thead>
<tr>
<th>Reference Range</th>
<th>Appearance:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Color:</td>
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<td></td>
<td>Character:</td>
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<td>Liquefaction:</td>
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<td>Sperm Count:</td>
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<td></td>
<td>Motility:</td>
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<td></td>
<td>Morphology:</td>
</tr>
</tbody>
</table>

CPT Code 89320
Effective Date July 27, 2008
Submitted by Ann Marie Blenc, MD, Medical Director, Hematology Royal Oak
Ralph Zade, MD, Medical Director, Chemistry Troy
Sequential Screen – Prenatal Screening for Down Syndrome and ONTD

The sequential screen is being introduced by Special Testing on March 10th 2008. The sequential screen is very similar to the full integrated screen, in that for most women it requires both a 1st and 2nd trimester blood sample. However, unlike the full integrated screen it allows a woman with a very high risk of Down syndrome to be identified in the 1st trimester and therefore seek early diagnostic testing. Women with a negative risk in the 1st trimester will continue on to 2nd trimester testing, at which time a final Down syndrome risk will be reported. It is estimated that approximately 2/3rds of Down syndrome cases will be identified in the 1st trimester and a further 1/3rd in the 2nd trimester.

Studies indicate that the sequential screen performs almost as well as the full integrated screen, although for a given detection rate, the false positive rate is slightly higher for the sequential screen. Because the full integrated screen still yields the lowest false positive rate we will continue to offer this testing. Note that detection and false positive rates are better for both integrated and sequential screens than they are for the 2nd trimester Quad screen and the First trimester screen alone. It is essential that patients understand that these are screens and not diagnostic tests. Details of the sequential screen are as follows:

Instructions
A completed Prenatal Screening Requisition should be sent with the 1st trimester sample; the middle yellow copy of this requisition should be submitted with the subsequent 2nd trimester sample.

Specimen
Gold top tube (5 mL) and nuchal thickness measurement (by ultrasound) at 11 – 13 weeks gestational age.
Gold top tube (5 mL) at 15 – 20 weeks gestational age

BRL External Preparation
Allow sample to clot completely at room temperature. After clotting, separate serum from cells ASAP and keep refrigerated.

Performed
Mon, Wed, Fri - dayshift

Interpretation
Based on the nuchal thickness (NT) measurement, pregnancy-associated plasma protein A (PAPP-A) and patient age, the sequential screen is designed to identify women who are at a very high risk for carrying a Down syndrome fetus in the 1st trimester. A cut-off of 1 in 30 will be used to indicate whether the risk is increased.

If the Down syndrome risk is greater than 1 in 30, a final result that includes the calculated risk will be reported. Because of the early gestational age, a risk for open neural tube defect (ONTD) cannot be reported.

If the Down syndrome risk is less than 1 in 30, a report will be issued indicating that the laboratory has performed PAPP-A testing and that we are now waiting for the 2nd trimester sample. No Down syndrome risk will be included in the report.
Once a 2nd trimester sample is received, alpha fetoprotein, hCG, unconjugated estriol and inhibin A will be performed. A final report that includes risks for both Down syndrome and ONTD will be issued – this is analogous to the full integrated screen report. A final risk cut-off (2nd trimester) of 1 in 110 will be used for the sequential screen. The cut-off of 1 in 110 is also used for the integrated screen.

Using the risk cut-offs noted above (1 in 30 for 1st trimester and 1 in 110 for 2nd trimester), it is estimated that the false positive rate for Down syndrome using the sequential screen will be approximately 3 %, slightly greater than the current integrated screen (false positive rate for 2007 was 2.7%).

NOTE:
- If an NT cannot be performed, the test will be converted to a serum integrated screen.
- hCG will not be performed on the 1st trimester sample – studies have shown that it does not add significantly to sequential screen performance.
- Risks for Trisomy 18 (if greater than 1 in 100) and for Smith Lemli Opitz syndrome (if greater than 1 in 50) will be reported as they occur.
- We will continue only to accept NT measurements from Beaumont Fetal Imaging or from ultrasonographers who are approved by Clinical Pathology.

**CPT Code**
PAPP-A (84163), AFP (82105), uE3 (82677), hCG (84702), inhibin A (86336)

**Effective Date**
March 10th, 2008

**References**


**Submitted by**
Elizabeth Sykes, MD, Medical Director, Automated Chemistry and Special Testing, Royal Oak
Shiga Toxin Testing for Enterohemorrhagic *E. coli*

The Clinical Microbiology Laboratories at Beaumont Hospitals are pleased to announce the availability of testing for enterohemorrhagic *E. coli* by detection of Shiga toxin 1 and Shiga toxin 2. The results of this test will be completed within 24-30 hours of receipt of the specimen in the Microbiology Laboratory and will be available as a component of the routine stool culture. Use of the Shiga toxin assay will allow identification of infections due to many toxin-producing *E. coli* serotypes in addition to O157:H7. Specific culture based assays for enterohemorrhagic *E. coli* will be discontinued on June 7, 2008.

**Synonyms**
O157:H7, EHEC, Stool for *E. coli*, hemorrhagic *E. coli*

**Specimen**
Fecal specimen submitted in Cary-Blair transport medium

**Rejection Criteria**
Fecal specimens in any other transport medium (including formalin, PVA, SAF), and swab specimens

**Performed**
Seven days a week

**Reference Range**
Negative

**Test Methodology**
Immunochromatographic rapid test

**Interpretation**
By report

**CPT Code**
87015, 87427x2

**Effective Date**
June 8, 2008

**Submitted by**
Barbara Robinson-Dunn, Ph.D., DABMM, Technical Director, Clinical Microbiology, Royal Oak
Bobby L. Boyanton, M.D., Medical Director, Clinical Microbiology, Royal Oak
Paul Goodman, M.D., Medical Director of Microbiology, Troy
Suresh Gehani, M.D., Medical Director, Department of Laboratories, Grosse Pointe
New Test Announcement
UGT1A1 Genotyping for Irinotecan Toxicity/Gilbert Syndrome

The Molecular Pathology Laboratory in the Department of Clinical Pathology, Beaumont Hospital, Royal Oak, offers a new molecular diagnostic test for UGT1A1 genotyping. The test detects two polymorphisms in the UGT1A1 gene: the *1 (6TA) allele is the wild type (normal) allele; the *28 variant allele (7TA) encodes for an enzyme with decreased activity, resulting in decreased glucuronidation/deactivation of the active Irinotecan metabolite. Approximately 10% of Caucasians are homozygous for the variant allele. Patients treated with Irinotecan for colorectal cancer, are at increased risk of severe Irinotecan toxicity if they are homozygous for the variant allele.

The test is also used for the diagnosis of Gilbert Syndrome, characterized by chronic unconjugated hyperbilirubinemia.

Synonyms
Irinotecan toxicity genotyping
Gilbert Syndrome genotyping

Specimen
5-10 mL whole blood in EDTA (lavender top) tubes or ACD (yellow top) tubes.

Rejection Criteria
Specimens collected in heparin (green top), clot tubes, SST tubes, unlabeled tubes or frozen specimens can not be tested.

Performed
Weekly

Reference Range
Wild type (normal) genotype *1*1 (6TA/6TA)

Test Methodology
Genomic DNA analysis using Cleavase enzymes, signal amplification and FRET detection.

Interpretation
By report

Clinical Utility
The genotyping test helps identify patients at risk for Irinotecan toxicity; the test is also used for diagnosis of Gilbert Syndrome

CPT Code
83891x1; 83892x8; 83903x4; 83908x4; 83912x1

Effective Date
June 8, 2008

Submitted by
Domnita Crisan, MD, PhD. Medical Director, Molecular Pathology
aPTT (Activated Partial Thromboplastin Time) and Heparin aPTT

Special Note:
The reference range for the aPTT and Heparin aPTT will not change this year. However, the laboratory has noticed some confusion regarding the ordering of these two tests. Please note that both tests are performed with the same method. The reason for the two designations is the heparin aPTT order permits computer release of an expected out of range result. Please do not order both tests on the same patient, as this is redundant and causes delay in turn-around time for other patients.

Specimen
SPECIAL HANDLING
Collect: One 5 mL light blue Hemogard vacutainer (3.2% sodium citrate). Tube must be full.
Specimen Transport
Note for BRL Patients ONLY: Prolonged aPTTs in specimens greater than 16 hours old from patients NOT on anticoagulants should be verified by repeat analysis on a frozen specimen. Transport whole blood specimens to Coagulation Laboratory within 16 hours. Specimens should be kept at 2°C to 8°C or 18°C to 24°C. If not possible, see Lab Test Directory for further instructions.

Rejection Criteria
Specimens containing clots, gross hemolysis, inappropriate volume, thawed or partially thawed are unacceptable and will not be tested.

Performed
7 days a week; 24 hours/day. Routine: 2 hours. STAT: 30 minutes

Reference Range
aPTT: 25-33 seconds. Critical Value: >123.9 seconds

Test Methodology
Light Scatter (Sysmex CA 1500 Method)

Clinical Utility
The aPTT assay aids in the evaluation of the intrinsic coagulation system, screening for the presence of classical hemophilia A and B, screening for lupus anticoagulant, and screening for congenital deficiencies of factors II, V, VIII, IX, X and XII, XI, dysfibrinogenemia, disseminated intravascular coagulation, liver failure and congenital hypofibrinogenemia. The heparin aPTT is designated for monitoring of heparin anticoagulant therapy.

CPT Code
85730

Effective Date
February 13, 2008

Submitted by
Marc Smith, MD, Medical Director, Royal Oak Coagulation Laboratory
Chromogranin A (0080469) Test Kit Change

We recently received notice from ARUP Laboratories, Salt Lake City, Utah, regarding a change in the Chromogranin A test.

The changes are as follows:

ARUP Laboratories will change the test kit for Chromogranin A (0080469) on March 17, 2008. The new kit requires frozen specimens. Because of differences in the analytical components of the two kits, test results obtained with each cannot be used interchangeably. To facilitate a comparison and rebaselining of individual patient results, specimens received for Chromogranin A will be tested with both the old and new kits. Chromogranin A concentrations determined by each kit will be reported until March 16, 2008, or until the supply of old kits is exhausted.

Specimen
One 6 ml plain red or SST

Specimen Transport:
1 mL frozen serum (min: 0.5 mL)
Specimen must be frozen within 12 hours of collection.

Stability
Ambient: 12 hours
Refrigerated: Unacceptable
Frozen: 1 month

For any questions or concern, please contact ARUP Client Services at (800) 522-2787.

Please take the above information into consideration in managing your patients who are being followed with Chromogranin A levels. For any further questions or concerns, please contact Joan Wehby, MT (248-551-9730) or Yvonne Posey, MD (248-551-8032).

Effective Date March 17, 2008
Submitted by Joan Wehby, MT, Send-Out Coordinator
Yvonne Posey, MD, Pathologist, Clinical Chemistry
To: Medical and House Staff

From: Bobby L. Boyanton Jr., M.D.

Date: December 3, 2008

Re: HIV Viral Load Testing

On December 15, 2008 the Molecular Pathology Laboratory will switch PCR-based HIV-1 viral load testing platforms from the COBAS Amplicor HIV-1 Monitor Standard and Ultrasensitive assays (Roche Diagnostics Corporation) to the COBAS Ampliprep / COBAS TaqMan, FDA-approved assay (Roche Diagnostics Corporation).

The new test method offers the same standard of care sensitivity (50 cp/mL) coupled with a greater dynamic range for quantitation (48 to 10,000,000 cp/mL), in a single, consolidated, semi-automated platform.

The minimum sample volume for testing is 1.0 mL of EDTA-plasma.

There is NO need to re-baseline or re-calibrate your patients because of the exceptional degree of correlation between the new and previously utilized platforms.

Note: The final report will contain a comment succinctly reminding you of the change in testing methodology.

Sincerely,

Bobby L. Boyanton Jr., M.D.
Medical Director, Clinical Microbiology

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>December 15, 2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submitted by</td>
<td>Bobby L. Boyanton, Jr., M.D. - Medical Director, Clinical Microbiology</td>
</tr>
</tbody>
</table>
The 2006 Consensus Guidelines for the Management of Women with Abnormal Cervical Cancer Screening and HPV DNA Test Utilization: Comprehensive evidence-based guidelines were developed in 2001 to assist clinicians with the management of patients with cervical cytologic abnormalities. Recent follow-up data from the ASCUS/LSIL Triage Study (ALTS) and other studies have led the American Society for Colposcopy and Cervical Pathology to issue the 2006 Consensus Guidelines for the Management of Women with Abnormal Cervical Tests, published in October 2007. The intent of this summary is to facilitate provider education. These guidelines should never substitute for clinical judgment. Complete guidelines and management algorithms may be viewed online at www.asccp.org. Additional information has been published as a review in the American Journal of Obstetrics and Gynecology, 2007; 197 (4) 346-355.

Utilizing High-risk HPV DNA testing
Recommendations include:

- Routine cervical cancer screening for high risk HPV (human papillomavirus), in conjunction with a Pap test, for women 30 years or older. If both tests are negative, re-screen with both in three years.
- Initial management of women 21 years and older with a cytologic diagnosis of atypical squamous cells of undetermined significance (ASC-US).
- Initial management of women 21 and older with a cytologic diagnosis of atypical glandular cells (AGC) in conjunction with colposcopy, endocervical sampling and, if over 35 or clinically indicated, endometrial sampling.
- Subsequent management of women 21 and older with cytologic diagnoses of atypical squamous cells – cannot exclude a high grade squamous intraepithelial lesion (ASC-H), low grade squamous intraepithelial lesion (LSIL) or AGC when the initial colposcopy does not show cervical intraepithelial neoplasm (CIN) 2/3 or a glandular lesion.

Other highlights of the ASCCP 2006 Guidelines include:

- High-risk HPV testing in adolescents (defined as less than 21 years of age) with a cytologic diagnosis of ASC-US or LSIL should NOT be performed. Although this age group has a high prevalence of HPV infection, low-grade cytologic abnormalities and CIN 1 have a very low risk of developing into cervical carcinoma. The majority of these infections will regress spontaneously and are of little long-term clinical significance. If HPV testing is inadvertently performed, the results should not influence patient management.

Continued on back
HPV testing for the triage of postmenopausal women with LSIL is an acceptable patient management option. Some studies have found the prevalence of both HPV DNA positivity and CIN 2/3 decline with age in women with LSIL suggesting that post-menopausal women can be managed less aggressively.

HPV DNA testing is not appropriate for the initial triage of women with HSIL or alone for the initial workup of atypical glandular cells (AGC) or adenocarcinoma in-situ (AIS).

HPV testing may be used in the post-colposcopy management of low-grade abnormalities at 12 month intervals.

HPV testing may be used in the post-treatment management of HSIL and AIS at six to 12 month intervals as a test of cure (post treatment surveillance).

Testing for low-risk (non-oncogenic) HPV types has no role in routine cervical cancer screening or for the evaluation of women with abnormal cervical cytology.

Repeat high-risk (oncogenic) HPV DNA testing should generally not be done in less than 12 months. The only exception is the follow-up to atypical glandular cells-not otherwise specified (AGC-NOS) when no pathology is found at initial work-up in which case repeat testing at 6 months may be appropriate. See ASCCP Guidelines for recommendations on testing intervals.

Cervical Cytology (Pap Tests) and Obtaining HPV testing as an Adjunct

When an HPV test is requested at the time of the Pap test, the cytology service and molecular laboratory of Beaumont Laboratory Services will combine their findings on a single Pap/HPV report.

When an HPV test is ordered after the Pap results have been received at the clinician’s office, a separate HPV report will be delivered upon completion of the HPV testing.

The option of molecular testing for HPV from the same vial is available from the time of Pap procurement through 60 days after the date of collection.

Edward Bernacki, M.D.  
Vice Chairman Anatomic Pathology  
Director of Cytopathology-Royal Oak

Patrician Novak, D.O.  
Director of Cytopathology-Troy

Jeanne Jax, CT(ASCP)  
Supervisor of Cytology  
Anatomic Pathology, Royal Oak

Date: October 3, 2008
PROPER BLOOD COLLECTION FOR COAGULATION STUDIES

It is imperative that vacutainer tubes be filled completely in order to obtain accurate test results. This general rule applies to all laboratory studies, but is especially true for coagulation testing because the ratio of blood to anticoagulant (already added to the tube) has a direct impact on clotting times. For instance, a “short draw” of 70% can lead to an increase in the INR by up to 1 point. This degree of inaccuracy can have a significant impact on patient care as the therapeutic range for many patients on Coumadin may be 2.0-3.0 or 2.5-3.5, i.e. a difference of 1 point. In order to prevent erroneous results from being reported, Beaumont Hospitals’ Laboratories routinely cancels tests on tubes that are not filled properly.

Listed below are five simple rules that will help you or your office consistently obtain high quality specimens, and prevent cancellation of tests ordered on those specimens:

1. **Follow the recommended order of draw (see attached order of Draw sheet).** If a citrate tube is the only tube to be drawn, draw a discard tube first when collecting with a blood collection kit (butterfly tubing). 
   *Air from the blood collection set tubing will cause underfilling of the tube (i.e. “short draw”) and result in an incorrect blood-to-anticoagulant ratio.*

2. **Hold the tube in place until draw is completed.**
   *The citrate stopper on the newer BD Vacutainer® tubes is softer than previous ones, resulting in greater pushback forces. This can occlude or block flow of blood through the non-patient end. Holding the blue top citrate tube in place until it has completed the required draw volume and blood flow ceases will obviate these pushback forces.*

3. **Avoid using a non-sharps device to transfer sample from syringe to evacuated tube.**
   *Transferring samples from a syringe to an evacuated tube using a non-sharps device should be performed with caution as this may cause over or under filling of tubes.*

4. **Use product within shelf life.**

5. **Store tubes at 4-25°C (39-77ºF) as recommended.**


Effective Date: June 08, 2008
Submitted by: Marc Smith, MD, Medical Director, Coagulation
**Order of Draw * for Multiple Specimens**

**Collected with Evacuated Tubes during a Single Venipuncture**

Collect and fill blood culture bottle/evacuated tubes in the following order to minimize contamination from tube additives:

<table>
<thead>
<tr>
<th>CAP COLOR</th>
<th>DESCRIPTION/PURPOSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blue blood culture bottle **</td>
<td>a. Adult blood culture bottle (aerobic)</td>
</tr>
<tr>
<td>Lavender blood culture bottle</td>
<td>b. Adult blood culture bottle (anaerobic)</td>
</tr>
<tr>
<td>Yellow blood culture bottle</td>
<td>c. Pediatric blood culture bottle (aerobic)</td>
</tr>
<tr>
<td>**Yellow/Black **</td>
<td>Blood culture for Fungus or AFB; draw one tube for each culture. **</td>
</tr>
<tr>
<td>Royal Blue</td>
<td>Plastic, NO additive - for certain trace metals/elements. (Check label carefully.)</td>
</tr>
<tr>
<td>**Clear ***</td>
<td>NO additive. A discard tube drawn before light blue in situations described below. ***</td>
</tr>
<tr>
<td>Light Blue</td>
<td>Citrate – for Coagulation studies; fill to STOP line.</td>
</tr>
<tr>
<td>Gold (or Marbled)</td>
<td>Serum separator gel (SST) and clot activator – for most Chemistry &amp; Immunology</td>
</tr>
<tr>
<td>Red</td>
<td>Clot activator only - for drug testing</td>
</tr>
<tr>
<td>Green</td>
<td>Heparin – for HLA &amp; chromosomes</td>
</tr>
<tr>
<td>Lavender</td>
<td>EDTA – for Hematology &amp; Molecular</td>
</tr>
<tr>
<td>Pink</td>
<td>EDTA – preferred tube for Blood Bank</td>
</tr>
<tr>
<td><strong>Royal Blue (yellow label)</strong></td>
<td>Plastic, EDTA – for certain trace metals/elements. (Check label carefully.)</td>
</tr>
<tr>
<td>Tan</td>
<td>EDTA – for lead assays</td>
</tr>
<tr>
<td>Grey</td>
<td>Fluoride + Oxalate – for GTT</td>
</tr>
<tr>
<td>Yellow</td>
<td>Glass, ACD - for cell cultures</td>
</tr>
<tr>
<td><strong>Royal Blue</strong></td>
<td>Trypsin inhibitor/Bothrops Attox venom - for Fibrin Split Products (FSP)</td>
</tr>
</tbody>
</table>

**MIX ALL TUBES 6-8 TIMES BY GENTLE INVERSION**

* Order described above minimizes cross-contamination from tube additives. While collecting the blood, hold the tube horizontally or slightly downward to reduce carry-over effects.

** Normally, routine and fungal/AFB blood cultures are drawn first to reduce bacterial/fungal contamination. **EXCEPTION: Venous pH and ionized calcium are to be drawn before any tubes, including routine or fungal/AFB blood cultures.

*** Draw a clear top discard tube before drawing any light blue citrate tube in the following situations:

(a) Special coagulation tests (e.g., platelet function studies, clotting factors, D-dimer) are ordered.

(b) When a butterfly collection set is used and a light blue coagulation tube is the only tube to be collected.

(c) When a fungal culture, venous pH or ionized calcium is ordered along with coagulation studies.

NOTE: For routine coagulation tests (PT, PTT, fibrinogen and thrombin time), a discard tube is not necessary, if the coagulation tube is the first tube drawn.

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Department of Clinical Pathology - April, 2005; updated November, 2006
1, 25-Dihydroxy Vitamin D

Effective February 2, 2009 testing for 1, 25-dihydroxy vitamin D (1,25-(OH)₂ –D) will be performed by radioimmunoassay (RIA) in the Special Testing Lab (Royal Oak) and will not be sent out to ARUP reference laboratory. The Diasorin RIA method (used by both laboratories) is based on a polyclonal antibody that is specific to both 1,25–(OH) ₂ D₂ and 1,25-(OH) ₂ D₃. The correlation data showed good agreement between laboratories and the reference range will remain 17 – 57 pg/mL.

1, 25-dihydroxy vitamin D is the active form of vitamin D and is produced primarily in the kidney. Its measurement may be useful in the:

• assessment of vitamin D status in patients with kidney disease
• investigation of some patients with vitamin D deficiency where the cause is not clear and/or an inherited disorder is suspected (e.g. vitamin D-dependent rickets, end-organ resistance to 1, 25-dihydroxy vitamin D).
• differential diagnosis of hypercalcemia

This test should NOT be used as an initial screen for vitamin D deficiency nor to assess vitamin D toxicity. **25-hydroxy vitamin D is the appropriate test for initial assessment of vitamin D stores.**

**Synonyms**
Calcitriol Level

**Specimen**
One 5 mL serum (SST) preferred.

**BRL External Preparation**
Let specimen clot, then centrifuge.

**BRL Specimen Transport**
1 mL serum, refrigerated (2-8°C), (min. 0.8 mL).

**Rejection Criteria**
Specimens that are excessively hemolyzed will not be tested.

**Performed**
Monday and Wednesday (results available Tuesday and Thursday afternoons - performed at Royal Oak).

**Reference Range**
15-75 pg/mL

**Test Methodology**
Radioimmunoassay

**Interpretation**
1,25-Dihydroxy vitamin D is low in chronic kidney disease, hypoparathyroidism and low or normal in cases of vitamin D toxicity. 1,25-Dihydroxy vitamin D may be high in sarcoidosis, other granulomatous diseases, some malignancies and 1° hyperparathyroidism.

**CPT Code**
82652

**Effective Date**
February 2, 2009

**Submitted by**
Elizabeth Sykes, MD, Medical Director, Automated Chemistry and Special Testing
J. Douglas Ferry PhD, Bioscientific Staff, Automated Chemistry and Special Testing
Acute myeloid leukemia (AML) is a hematopoietic neoplasm characterized by excessive accumulation of myeloid blasts (>20%) in bone marrow, peripheral blood, and other tissues. The identification of specific cytogenetic abnormalities is diagnostic for specific AML subtypes and can be powerful predictors of prognosis and response to therapy. Overall, cytogenetic abnormalities are identified in approximately 55% of adults at diagnosis, with a range of 50-80%; however, only a subset of these chromosome changes is associated with clinical, morphological, and immunophenotypic specificity for a particular AML subtype. These are included in the WHO classification scheme under AML with recurrent genetic abnormalities and include: AML with t(8;21)(q22;q22); (AML1/ETO), AML with inv(16)(p13q22) or t(16;16)(p13;q22); (CBFβ/MYH11), acute promyelocytic leukemia [AML with t(15;17)(q22;q12); (PML/RARα) and variants], and AML with 11q23 (MLL) abnormalities.

The following FISH probes detect myeloid-associated abnormalities and are available:

- AML1/ETO fusion for t(8;21)
- CBFβ/MYH11 gene for inv(16)/t(16;16)
- CEP8 for chromosome 8 enumeration
- MLL gene rearrangement for t(11q23;var)
- PML/RARA for t(15;17)
- 20q11.2 (D20S108) deletion

Specimen
Bone marrow

Reference Range
Positive or negative for a neoplastic clone. An interpretative report will be provided

Interpretation
A positive FISH result indicates the presence of the chromosome abnormality. The presence of AML1/ETO fusion, CBFβ gene rearrangement, PML/RARα fusion, or MLL gene rearrangement is diagnostic for their respective WHO AML classifications.

CPT Codes
- 88271x2 DNA probe, each
- 88275x1 Interphase in situ hybridization, 100-300 cells

Effective Date
February 16, 2009

Submitted by
Mark Micale, PhD, Clinical Cytogenetics Laboratory Medical Director, Anatomic Pathology, Royal Oak
ANA Screen
ANA Titer
Anti Cardiolipin IgA
Anti Cardiolipin IgG
Anti Cardiolipin IgM
Anti-Cyclic Citrullinated Peptide
   CA19-9
   Gliadin IgA
   Gliadin IgG
   Herpes (HSV) 1 & 2 IgG
   Herpes (HSV) 1 & 2 IgM,
   HLA-B27
   Rubeola
   Thyroglobulin Antibody
   Transferrin

Grosse Pointe Beaumont Hospital Medical Staff:

ANA Screen, ANA Titer, Anti Cardiolipin IgA, Anti Cardiolipin IgG, Anti Cardiolipin IgM, Anti-Cyclic Citrullinated Peptide, CA19-9, Gliadin IgA, Gliadin IgG, Herpes (HSV) 1 & 2 IgG, Herpes (HSV) 1 & 2 IgM, HLA-B27, Rubeola, Thyroglobulin Antibody and Transferrin will be sent to Beaumont Reference Laboratories at Royal Oak instead of ARUP Laboratories. These results can be viewed on EPIC OneChart. Patients’ results include the reference ranges.

Specimen collection, reference ranges and interpretation are available at “Inside Beaumont Online” by clicking on <References> and <Lab Test Directory> or at: www.beaumonthospitals.com/labtestdirectory

For any questions, contact BRL (Beaumont Reference Laboratory) Customer Service at 1-800-551-0488.

Effective Date  Tuesday, May 26, 2009
Submitted by  Suresh Gehani, M.D.
   Medical Director, Grosse Pointe Laboratories
Isabel Gauss, MS, MT (ASCP)
   Administrative Director, Grosse Pointe Laboratories
BURKITT'S AND BURKITT'S-LIKE LYMPHOMA, FLUORESCENCE IN SITU HYBRIDIZATION (FISH) ANALYSIS

The identification of specific chromosome abnormalities has emerged as one of the most important criteria for categorizing B-cell lymphomas. Specifically, in Burkitt's and Burkitt's-like lymphomas, three translocations are identified: t(8;14)(q24;q32), t(2;8)(q11;q24), and t(8;22)(q24;q11). While most cases demonstrate the common t(8;14) that repositions the C-MYC proto-oncogene next to the promoter for the Ig heavy chain gene at 14q32, 15-20% of cases will be associated with one of the two variant translocations. These translocations result in juxtaposition of C-MYC next to either the Ig kappa locus at 2q11 or Ig lambda locus at 22q11. All these rearrangements place the C-MYC gene under the transcriptional regulatory mechanisms of the respective Ig genes, resulting in constitutive overexpression of C-MYC leading to malignant transformation. The identification of one of these abnormalities is a requirement to make a diagnosis of either Burkitt's or Burkitt's-like lymphoma.

This assay can be performed on a bone marrow biopsy, lymph node touch preparation, or a paraffin-embedded tissue section. A MYC gene rearrangement probe is used initially to confirm MYC gene rearrangement in the sample. If positive, a tri-color dual fusion IGH/MYC/CEP8 FISH probe that recognizes juxtaposition of IGH and MYC genes is utilized. If this assay provides a negative result, Ig kappa and Ig lambda rearrangement probes are used to identify the less common t(2;8) or t(8;22), respectively.

Specimen
Bone marrow, lymph node touch preparation, or paraffin-embedded tissue section

Reference Range
Positive or negative for a neoplastic clone. An interpretative report will be provided.

Interpretation
A positive FISH result indicates the presence of the respective rearrangement. Initially, the MYC gene rearrangement probe and IGH/MYC probe can be run simultaneously if requested. If MYC is rearranged, but no IGH/MYC juxtaposition is identified, the Ig Kappa and Ig lambda probes are used.

CPT Codes
For MYC gene rearrangement 88271x1 DNA probe, each
For IGH/MYC 88271x3
For Ig Kappa or Ig Lambda 88271x1
For all assays 88275x1 Interphase in situ hybridization, 100-300 cells

Effective Date
February 16, 2009

Submitted by
Mark Micale, PhD, Clinical Cytogenetics Laboratory Medical Director, Royal Oak
CBC Differential

In specimens with low white blood cell counts, i.e. below 1.0x10^9 bil/L, an automated instrument count is most useful. For unflagged instrument results, this automated differential count is the most accurate, precise and reproducible count the laboratory can provide on a low WBC sample. If an instrument differential is not recovered, the laboratory performs a buffy coat differential. Although buffy coat preparations do provide a greater number of cells for review, this is a manipulated specimen for which no control or reference ranges are available. Thus, the significance of rare abnormal cells on these preparations is not known and may be misleading. In addition, the preparation of buffy coat differentials is labor intensive and can cause a significant delay in reporting differential results.

Thus, starting June 28, 2009, the laboratories at Royal Oak and Troy will no longer perform buffy coat differentials. If an automated differential is not available due to a low WBC count, instrument flags, etc., we will perform and report a manual differential on the first specimen with a WBC <1.0 bil/L, based on the available cellularity, primarily to look for abnormal cells. However, repeat differentials on the same patient admission or encounter will not be performed when the WBC count is <1.0 bil/L and we are unable to obtain an automated differential. Only a CBC will be reported and charged in these instances.

Synonyms
CBC/DIFF, CBC/D, Hemogram

Specimen
Whole blood: 4 mL lavender (EDTA) (Min: 2.0 mL lavender)
Capillary blood: 500 mcL lavender microtainer (EDTA) (Min: 300 mcL lavender)

BRL External Preparation
Original specimens are stable for 8 hours at room temperature (20-25°C or 68-77°F). Refrigerated specimens (2-8°C or 36-46°F) are stable for 72 hours.

Rejection Criteria
Specimens containing clots or insufficient volume are unacceptable and will not be tested.

Performed
7 days a week, 24 hours a day
Stat results available in 30 minutes; 60 minutes if further verification is necessary.
Routine results available in 90 minutes.

Reflex Testing
If abnormalities are detected that fall outside laboratory approved parameters, a pathology review of the smear will be performed.

CPT Code
85025

Effective Date
June 28, 2009

Submitted by
Ann Marie Blenc, MD, Medical Director, Royal Oak
Hongwei Ma, MD, Medical Director, Troy
CHEMO CBC AND CHEMO CBC WITH DIFFERENTIAL

Currently, critical CBC and differential values are called to the ordering physician on all patients. However, it is expected that oncology patients receiving chemotherapy will have decreased white blood cell counts, neutrophil counts, and platelet counts. Thus, beginning June 28, 2009, the Hematology Departments at Royal Oak and Troy will offer a Chemo CBC and Chemo CBC with differential. These tests are identical to a regular CBC or CBC with differential, with the exception that physicians will not receive calls for critical values (i.e. white blood cell counts, neutrophil counts, and platelet counts). Critical hemoglobin levels however will continue to be called to the ordering physician.

Specimen

Whole blood: 4 mL lavender (EDTA) (Min: 2.0 mL lavender)
Capillary blood: 500 mcL lavender microtainer (EDTA) (Min: 300 mcL lavender)

BRL Specimen Transport

Transport refrigerated (2-8°C or 36-46°F).

Rejection Criteria

Specimens containing clots or insufficient volume are unacceptable and will not be tested

Performed

Sunday-Saturday (24 hrs/day)
Stat results available in 30 minutes; 60 minutes if further verification is necessary.
Routine results available in 90 minutes.

Test Methodology

SYSMEX XE-2100

Reflex Testing

If abnormalities are detected that fall outside laboratory approved parameters, a pathology review of the smear will be performed.

CPT Code

85025

Effective Date

6/28/2009

Submitted by

Ann Marie Blenc, MD, Medical Director, Hematology, Royal Oak
Hongwei Ma, M.D., Medical Director, Troy
CHRONIC LYMPHOCYTIC LEUKEMIA FISH PANEL, 
FLUORESCENCE IN SITU HYBRIDIZATION (FISH) ANALYSIS

B-cell chronic lymphocytic leukemia (B-CLL) is the most common leukemia in North America. The identification of certain chromosome abnormalities in this disease has both diagnostic and prognostic implications. Unfortunately, the yield of cytogenetic abnormalities by conventional analysis in CLL is relatively low because of the low in vitro mitotic activity of tumor cells. Utilization of a CLL FISH panel increases this yield dramatically. In one study, the detection rate was increased from 16% (conventional analysis) to 75% (FISH). Therefore, this multiplex FISH assay is a necessary supplement to conventional cytogenetic analysis in this disease. As both a diagnostic and prognostic assay, this should be performed on all new cases of CLL. The CLL FISH panel consists of two DNA probe sets that recognize the ATM gene, chromosome 12 alpha-satellite region, D13S319 locus at 13q14.3, LAMP1 gene at 13q34, and p53 gene at 17p13.1.

Specimen: Bone marrow or peripheral blood

Reference Range: Positive or negative for a neoplastic clone. An interpretative report will be provided.

Interpretation: A neoplastic clone is detected when the percent of cells with any given chromosome abnormality exceeds the threshold (normal reference range) established for each probe. Patients with a chromosome 17p (p53 gene) deletion have the poorest prognosis, followed by patients with chromosome 11q (ATM gene) deletions, those with trisomy 12, and those with a normal karyotype. The best prognosis is associated with a chromosome 13q (D13S319, LAMP1 gene) deletion.

CPT Codes:
- 88271x5 DNA probe, each
- 88275x2 Interphase in situ hybridization, 100-300 cells

Clinical Reference:

Effective Date: February 16, 2009

Submitted by: Mark Micale, PhD, Clinical Cytogenetics Laboratory Medical Director, Anatomic Pathology, Royal Oak
Chronic myelogenous leukemia (CML) was the first hematological disorder to be associated with a specific chromosome abnormality, the t(9;22)(q34;q11.2) which generates the Philadelphia chromosome (truncated chromosome 22). The molecular consequence of this translocation is fusion of the 3’ segment of the Abelson (ABL) proto-oncogene on chromosome 9q34 to the 5’ segment of the BCR gene on chromosome 22q11.2, producing a chimeric 210 kDa BCR/ABL fusion gene product. At diagnosis, over 90% of CML patients will demonstrate the t(9;22)(q34;q11.2) by conventional cytogenetic analysis. The remaining cases either present a submicroscopic rearrangement or a variant t(V;9;22) translocation. In these cases, FISH analysis can readily detect the BCR/ABL fusion, and failure to do so would suggest that another myeloproliferative disorder, such as chronic neutrophilic leukemia, should be considered.

This assay utilizes a dual color dual fusion (DCDF) BCR/ABL FISH probe that provides the highest sensitivity (approximately 98-99%) with the lowest number of false positive and false negative rates. The ABL probe extends from a region centromeric of the ASS gene, through the ABL gene, and distal to a region telomeric of the last ABL exon. The LSI BCR probe is composed of two separate genomic targets spanning a region which begins 5’ of the BCR gene and ends at a point well distal to BCR, with an intervening gap in coverage of 300 kb. BCR/ABL fusion generates a double fusion (yellow or orange/green) signal pattern because both the der(9) [ABL/BCR] and der(22) [BCR/ABL] loci are detected. The D-FISH BCR/ABL probe will detect translocations occurring at the typical major breakpoint cluster region (M-BCR) that generates the p210 product, but will also identify a breakpoint in the μ region (μ-BCR) which produces a larger fusion protein (p230) rarely observed in CML as well as a breakpoint in the minor breakpoint region (m-BCR) producing the shorter fusion product (p190) most often observed in Ph+ ALL. This probe can also identify a deletion of the ASS gene which has been associated in some studies with a shortened chronic phase and decreased overall survival. BCR/ABL FISH analysis of peripheral blood specimens is a common practice for routinely monitoring CML patients.

Specimen: Bone marrow or peripheral blood
Reference Range: Positive or negative for a neoplastic clone. An interpretative report will be provided
Interpretation: A positive FISH result indicates the presence of the Philadelphia chromosome and the t(9;22)(q34;q11.2). In the routine monitoring of CML patients, reverse transcriptase polymerase chain reaction (RT-PCR) is the most sensitive method for identifying a very small clone of cells with a BCR/ABL fusion and could be considered if the results of this test are negative.
CPT Codes: 88271x2 DNA probe, each
8275x1 Interphase in situ hybridization, 100-300 cells
Effective Date: February 16, 2009
Submitted by: Mark Micale, PhD, Clinical Cytogenetics Laboratory Medical Director, Anatomic Pathology, Royal Oak
Creatinine – Result Reported to Two (2) Decimal Places

The National Kidney Foundation recommends using a creatinine value with two (2) decimal places to calculate the estimated glomerular filtration rate (eGFR). In order to comply, we must also report the serum creatinine in this way. This update does not reflect any change in laboratory precision or accuracy in the measurement of serum creatinine.

The change will become effective on May 10th 2009. At that time, all creatinine values (serum and urine) will be reported to two decimal places. Calculations used for timed urine collections and ratios, such as the albumin to creatinine ratio, will be unaffected and will continue to be reported with the same number of decimal places they have been.

This change in reporting applies only to Royal Oak and Troy Laboratories and not to the Grosse Pointe Laboratory.

Effective Date May 10, 2009

Submitted by Elizabeth Sykes, MD, Medical Director, Automated Chemistry and Special Testing, Royal Oak
Suresh Gehani, MD, Medical Director, Department of Laboratories, Grosse Pointe
Ralph Zade, MD, Medical Director, Chemistry, Troy
Serum Creatinine – Result Reported to Two (2) Decimal Places

The National Kidney Foundation recommends using a creatinine value with two (2) decimal places to calculate the estimated glomerular filtration rate (eGFR). In order to comply, we must also report the serum creatinine in this way. The update does not reflect any change in laboratory precision or accuracy in the measurement of serum creatinine.

The change will become effective on May 10th for Royal Oak and Troy Laboratories, but NOT for Radiology Bedside BUN/creatinine testing. Grosse Pointe Laboratory will be making the change shortly and will notify physicians at that time.

Effective Date      May 10, 2009

Submitted by       Elizabeth Sykes, MD, Medical Director, Automated Chemistry and Special Testing, Royal Oak
                   Suresh Gehani, MD, Medical Director, Department of Laboratories, Grosse Pointe
                   Ralph Zade, MD, Medical Director, Chemistry, Troy
Flow Cytometric Assessment for T-cell Clonality: TCR-Vβ Analysis

Effective immediately, the Flow Cytometry Laboratory will be implementing a new antibody panel for T-cell receptor beta variable domain (TCR-Vβ) analysis in the evaluation of abnormal T-cell populations. This new antibody panel will be added by the hematopathologists, as deemed necessary, after the initial identification of an abnormal T-cell population by routine flow cytometric testing methods. TCR-Vβ analysis will not be orderable as a stand-alone test; however, clinicians should be aware of the test and its significance since the results may be discussed in the flow cytometric reports.

TCR-Vβ repertoire analysis utilizes antibodies against gene products of the variable domain of T-cell receptor β (TCR-Vβ). A panel of antibodies against different TCR-Vβ segments is evaluated to determine if there is expansion of a single variable region domain. This expansion indicates that segment is clonally rearranged. TCR-Vβ repertoire analysis holds a number of advantages over conventional evaluation for T-cell gene rearrangement by PCR, in that the determination of T-cell clonality in that it is much more rapid and easier to perform. TCR-Vβ analysis can also be used in combination with other antibodies to more selectively target a neoplastic subset in a larger non-neoplastic T-cell population, thereby providing valuable quantitative information.

It is important to note that proper utilization of this test requires phenotypic and/or morphologic evidence of abnormal T-cell process, and necessitates interpretation of the results within the framework of the overall immunophenotypic, morphologic and clinical picture. Therefore this test should not be used as an initial screening tool for T-cell neoplasia. If T-cell neoplasia is suspected clinical, the flow cytometric test to order is “hematolymphoid neoplasm” with the reason for testing clearly stated. For peripheral blood specimens, a hematopathology consultation for morphologic screening can also be performed. If an aberrant T-cell population is identified with the initial flow cytometric antibody panel utilized in the hematolymphoid neoplasm test, then Vbeta analysis can be performed to further evaluation for T-cell clonality.

Effective Date: December 14, 2009
Submitted by: Vonda Douglas-Nikitin, MD
Medical Director, Flow Cytometry Laboratory
**Heparin aPTT**

**EFFECTIVE DATE: FEBRUARY 26, 2009**

The new heparin aPTT therapeutic range will be 48-71 seconds. Please note that the nomogram distributed last year will no longer be valid when the new heparin therapeutic range is in effect. Forms containing the new nomogram (below) will be distributed February 26th. Note that the nomogram applies to the Royal Oak Campus ONLY.

**Specimen**

Collect: One 5 mL light blue Hemogard vacutainer (3.2% sodium citrate). **Tube must be full.**

**Rejection Criteria**

Specimens containing clots, gross hemolysis, inappropriate volume, thawed or partially thawed are unacceptable and will not be tested.

**Reference Range**

Heparin aPTT: 25-31 seconds

Therapeutic Range: 48-71 seconds is comparable to 0.3-0.7 U/mL.

Panic Value: > 123.9 seconds

**Interpretation**

**Heparin Sliding Scale**

**Beaumont Hospitals: Royal Oak Campus Dosing Nomogram**

For Continuous Infusion Unfractionated Heparin (Therapeutic Anticoagulation)

<table>
<thead>
<tr>
<th>Heparin level (units/mL)</th>
<th>Heparin aPTT (seconds)</th>
<th>Dosage Adjustment</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ .17</td>
<td>&lt; 40</td>
<td>bolus 3000 units, increase 150 units/hr</td>
</tr>
<tr>
<td>0.18-0.23</td>
<td>40-43</td>
<td>increase by 100 units/hr</td>
</tr>
<tr>
<td>0.24-0.29</td>
<td>44-47</td>
<td>increase by 50 units/hr</td>
</tr>
<tr>
<td><strong>0.30-0.70</strong></td>
<td><strong>48-71</strong></td>
<td>NO CHANGE</td>
</tr>
<tr>
<td>0.71-0.78</td>
<td>72-76</td>
<td>decrease drip by 30 units/hr</td>
</tr>
<tr>
<td>0.79-0.88</td>
<td>77-82</td>
<td>decrease drip by 50 units/hr</td>
</tr>
<tr>
<td>0.89-0.97</td>
<td>83-87</td>
<td>decrease drip by 100 units/hr</td>
</tr>
<tr>
<td>0.98-1.11</td>
<td>88-95</td>
<td>hold heparin for one hour, decrease by 150 units/hr</td>
</tr>
<tr>
<td>&gt;1.11</td>
<td>&gt;95</td>
<td>hold heparin for one hour, decrease by 200 units/hr</td>
</tr>
</tbody>
</table>

CPT Code 85730

Effective Date February 26, 2009

Submitted by Marc D. Smith, M.D., Medical Director, Coagulation Laboratory, Royal Oak
HYPEREOSINOPHILIC SYNDROME/SYSTEMIC MAST CELL DISEASE, FLUORESCENCE IN SITU HYBRIDIZATION (FISH) ANALYSIS

Idiopathic hypereosinophilic syndrome (HES) is a rare hematologic disorder characterized by persistent eosinophilia without any identifiable primary etiology and is associated with organ damage secondary to tissue infiltration. If bone marrow blasts >5% are detected with or without concurrent identification of a clonal cytogenetic abnormality, a diagnosis of chronic eosinophilic leukemia is made. Systemic mast cell disease (SMCD) is a clinically heterogenous disorder associated with accumulation of mast cells. This may be limited to skin or may be extracutaneous, and is often associated with eosinophilia. A subset of patients with CES and SMCD have benefited from treatment with imatinib mesylate which appears to target a fusion tyrosine kinase FIP1L1/PDGFRα. This fusion gene is the consequence of a cryptic 800kb interstitial deletion within chromosome band 4q12, identified in around 40-60% of patients with HES/CEL. Identification of this chromosome rearrangement, therefore, has important implications for proper management. Because the submicroscopic del(4q) is not observed in conventional cytogenetic analysis, a FISH assay to identify it is necessary. Deletion of the CHIC2 (cysteine-rich hydrophobic domain 2) gene, which lies between the FIP1L1 and PDGFRα loci in band 4q12, is a surrogate marker for FIP1L1/PDGFRα fusion and is an effective target for a FISH assay to detect this rearrangement. This assay utilizes a tri color LSI 4q12 rearrangement probe that detects deletion of the CHIC2 gene.

Specimen
Bone marrow or peripheral blood

Reference Range
Positive or negative for a neoplastic clone. An interpretative report will be provided.

Interpretation
A positive FISH result indicates deletion of the CHIC2 gene which lies between the FIP1L1 and PDGFRα loci in band 4q12. Deletion of this gene is thus a surrogate marker for FIP1L1/PDGFRα fusion. Because of the genetic heterogeneity of these disorders, a negative result does not preclude the diagnosis of either HES or SMCD.

CPT Codes
88271x1 DNA probe, each
88275x1 Interphase in situ hybridization, 100-300 cells

Clinical References


Effective Date
February 16, 2009

Submitted by
Mark Micale, PhD, Clinical Cytogenetics Laboratory Medical Director, Royal Oak
Identification of Respiratory Viruses by R-Mix Too
Viral Culture

Beaumont Laboratory Services, Division of Clinical Microbiology is pleased to announce the availability of testing for viral respiratory agents by an improved, rapid culture method. Viruses that can be detected by this technique include influenza A, influenza B, respiratory syncytial virus, adenovirus, parainfluenza 1, parainfluenza 2, and parainfluenza 3. Approximately 80% of the positive results will be detected following 24 hours of incubation. For those specimens negative at 24 hours, final results will be available following another 24 hours of incubation. Introduction of this culture method into the laboratory has reduced the total time required for incubation of viral respiratory cultures by 8-12 days.

Synonyms:     Flu, Colds, URI, influenza-like illnesses.

Specimen:     NP swabs, throat swabs (included with an NP swab), NP wash, nasal aspirate (not a nasal swab), Leuken’s aspirates, sputum (least preferred specimen), bronchial lavages, bronchial washes, tracheal aspirates and ungu tissue.

NOTE: Swab specimens must be submitted in M4RT viral transport medium.

Rejection Criteria:     Respiratory swab specimens not submitted in M4RT viral transport medium.

Performed:     Seven days a week; testing performed at Royal Oak.

Reference Range:     Negative

Test Methodology:     Viral culture using two cell lines in a shell vial.

Interpretation:     The presence or absence of each respiratory virus will be reported.

CPT Code:     87254 x 7

Effective Date:     February 1, 2009

Submitted by:     Barbara Robinson-Dunn, Ph.D., DABMM, Technical Director, Clinical Microbiology, Royal Oak; Bobby L. Boyanton, M.D., Medical Director, Clinical Microbiology, Royal Oak; Paul Goodman, M.D., Medical Director, Microbiology Laboratory, Troy; Suresh Gehani, M.D., Medical Director, Department of Laboratories, Grosse Pointe
MICRODELETION/MICRODUPLICATION SYNDROME, FLUORESCENCE IN SITU HYBRIDIZATION (FISH) ANALYSIS

Several dysmorphic genetic syndromes are associated with small deletions that lead to a form of genetic imbalance known as segmental aneusomy. These are thus referred to as segmental aneusomy syndromes or contiguous gene syndromes. These deletions produce a clinically recognizable phenotype that consists of features associated with haploinsufficiency of the genes in the deleted region. Recent evidence has revealed that the chromosome breakpoints in these disorders lie within low-copy repeated DNA sequences and that aberrant recombination between nearby copies of these repetitive sequences can result in deletions that span several hundred to several thousand kilobase pairs. This research has also uncovered that this genetic mechanism can generate microduplications of the same regions (microduplication syndromes). These rearrangements are sometimes detected unequivocally with high-resolution cytogenetic analysis; however, a more definitive test is fluorescence in situ hybridization (FISH). A deletion can be identified by either metaphase or interphase FISH analysis, while duplication of the region is most often identified by interphase FISH analysis. A FISH assay for each of the following genomic disorders is offered:

<table>
<thead>
<tr>
<th>Disorder</th>
<th>Chromosome Region</th>
<th>Targeted Gene or Probe</th>
</tr>
</thead>
<tbody>
<tr>
<td>DiGeorge Syndrome/Velocardiofacial syndrome</td>
<td>22q11.2</td>
<td>TUPLE1</td>
</tr>
<tr>
<td>Prader-Willi/Angelman syndrome</td>
<td>15q11q13</td>
<td>SNRPN</td>
</tr>
<tr>
<td>Williams syndrome</td>
<td>7q11.23</td>
<td>ELN</td>
</tr>
<tr>
<td>Wolf-Hirschhorn syndrome</td>
<td>4p16.3</td>
<td>WHSC1</td>
</tr>
<tr>
<td>Smith-Magenis syndrome</td>
<td>17p11.2</td>
<td>SMS</td>
</tr>
<tr>
<td>Miller-Dieker syndrome</td>
<td>17p13.3</td>
<td>LIS1</td>
</tr>
</tbody>
</table>

The utilization of these FISH assays requires some clinical suspicion of the disorder so that the correct DNA probe is used. Other probes are available and can be run on a case-by-case basis. Please contact the lab for further details. Concurrent conventional cytogenetic analysis is also strongly recommended to identify other chromosome abnormalities.

**Specimen** Peripheral blood, amniotic fluid, or chorionic villi

**Reference Range** Positive or negative for deletion or duplication of the gene in question.

**Interpretation** A positive FISH result indicates deletion or duplication of the targeted gene. A negative result cannot completely rule out a diagnosis due to another genetic cause or gene mutation. Chromosome microarray analysis may be recommended as a follow-up study. Any patient with a positive FISH result should be referred for clinical genetic evaluation and genetic counseling.

**CPT Codes**
- 88271x2 DNA probe, each
- 88273x1 Metaphase in situ hybridization, 10-30 cells
- 88275x1 Interphase in situ hybridization, 100-300 cells (DiGeorge/VCFS only)

**Effective Date** February 16, 2009

**Submitted by** Mark Micale, PhD, Clinical Cytogenetics Laboratory Medical Director, Royal Oak
MYELODYSPLASTIC SYNDROME FISH PANEL,
FLUORESCENCE IN SITU HYBRIDIZATION (FISH) ANALYSIS

Bone marrow cytogenetic analysis is a standard practice in the evaluation of a patient with suspected myelodysplastic syndrome (MDS) and is considered an independent predictor of clinical outcome, overall survival, and progression to acute leukemia. Conventional cytogenetic analysis has identified chromosome abnormalities in approximately 40-70% of de novo MDS cases and in 95% of therapy-related MDS at diagnosis, with no abnormality specific for a particular MDS subtype with the exception of the chromosome 5q deletion. Recurrent chromosome changes in MDS include loss of chromosomes 5 or 7, deletions of chromosomes 5q or 7q, trisomy 8, and chromosome 20q deletion. Loss of the Y chromosome is also relatively common in MDS, but this may be an age-related artifact in many patients.

The primary utility of FISH analysis in MDS is based on the finding that 15-20% of MDS patients demonstrate a normal karyotype, yet possesses one or more clonal abnormalities of prognostic and/or therapeutic significance when analyzed by FISH. In addition, the subset of MDS patients positive for one or more abnormalities by FISH but with a normal karyotype has demonstrated an increase in bone marrow blasts, an increased rate of leukemic transformation, and a poorer prognosis. Based on this and other studies, most advocate the use of an MDS FISH panel on the diagnostic specimen. The MDS FISH panel includes probes to detect -5/-5q-, -7/-7q-, trisomy 8, chromosome 20q deletion, chromosome 11q deletion (MLL gene), and chromosome 13q deletion.

Specimen  Bone marrow

Reference Range  Positive or negative for a neoplastic clone. An interpretative report will be provided

Interpretation  A positive FISH result indicates the presence of the chromosome abnormality. A good prognosis is predicted with a normal karyotype, del(5q) or del(20q); an intermediate prognosis with trisomy 8; and a poor prognosis with chromosome 7 abnormalities and MLL gene deletion.

CPT Codes

88271x5  DNA probe, each
88275x3  Interphase in situ hybridization, 100-300 cells

Clinical Reference

Effective Date  February 16, 2009
Submitted by  Mark Micale, PhD, Clinical Cytogenetics Laboratory Medical Director, Anatomic Pathology, Royal Oak
MYXOID LIPOSARCOMA, SYNOVIAL SARCOMA, EWING'S SARCOMA

FLUORESCENCE IN SITU HYBRIDIZATION (FISH) ANALYSIS

Solid tumor cytogenetics can be an invaluable tool for diagnosing tumors of equivocal morphology. Unfortunately, as compared with hematological malignancies that are readily amenable to chromosome analysis, solid tumors present unique challenges, which can preclude an accurate cytogenetic diagnosis using conventional techniques. These include: 1) unpredictable growth of neoplastic cells in tissue culture, 2) overgrowth of neoplastic cells by "reactive" non-neoplastic cells, 3) destruction of tumor cultures by bacterial or fungal infection, and 4) failure of cells to grow in culture due to tissue non-viability. Fluorescence in situ hybridization (FISH) can overcome these problems as the assay can be performed on paraffin embedded tissue sections, which provides an opportunity to correlate cytogenetic events with morphology. Of course, these assays can also be performed on cultured cell preparations and can provide a definitive answer provided that the cells growing in culture are neoplastic.

The diagnosis of three solid tumors, in particular, can be aided by FISH analysis. These include myxoid liposarcoma, synovial sarcoma, and Ewing's sarcoma. Myxoid liposarcoma (as well as round cell liposarcoma) is associated with the t(12;16)(q13;p11) which leads to fusion of the CHOP gene at 12p13 and the FUS gene at 16p11. Synovial sarcoma is associated in more than 90% of cases with the t(X;18)(p11.2;q11.2) that results in fusion of the SYT gene on chromosome 18 with one of two genes on the X chromosome (SSX1 or SSX2). Ewing's sarcoma is associated with rearrangement of the EWSR1 gene on chromosome 22q with one of several partner genes, the most common being the FLI1 gene on chromosome 11 as a result of the t(11;22)(q24;q12).

Three solid tumor FISH assays are offered:

- **CHOP** gene rearrangement associated with t(12;16) in myxoid liposarcoma
- **SYT** gene rearrangement (18q11.2) in synovial sarcoma
- **EWSR1** gene rearrangement for t(v;22q) in Ewing's sarcoma

**Specimen**
Tumor biopsy for culture, paraffin tissue section with concurrent H/E slide

**Reference Range**
Positive or negative for a neoplastic clone. An interpretative report will be provided

**Interpretation**
A neoplastic clone is detected when the percent of cells with an abnormal probe hybridization pattern indicative of gene rearrangement exceeds the threshold (normal reference range) established for each probe.

**CPT Codes**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>88271x1</td>
<td>DNA probe, each</td>
</tr>
<tr>
<td>88275x1</td>
<td>Interphase in situ hybridization, 100-300 cells</td>
</tr>
</tbody>
</table>

**Effective Date**
March 11, 2009

**Submitted by**
Mark Micale, PhD, Clinical Cytogenetics Laboratory Medical Director, Anatomic Pathology, Royal Oak
New Reference Ranges for aPTT (Activated Partial Thromboplastin Time),
PT (Prothrombin Time) and TT (Thrombin Time)

EFFECTIVE DATE: FEBRUARY 26, 2009

<table>
<thead>
<tr>
<th>Test</th>
<th>Old Reference Range</th>
<th>New Reference Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>aPTT (sec)</td>
<td>25-32</td>
<td>25-31</td>
</tr>
<tr>
<td>PT (sec)</td>
<td>9.7-11.6</td>
<td>9.6-11.4</td>
</tr>
<tr>
<td>TT (sec)</td>
<td>15-18</td>
<td>15-19</td>
</tr>
</tbody>
</table>

Rejection Criteria
Specimens containing clots, gross hemolysis, inappropriate volume, 
thawed or partially thawed are unacceptable and will not be tested.

Performed
7 days a week, 24 hours a day
   Routine: 2 hours
   STAT: 30 minutes

Interpretation
The aPTT, PT and TT are useful in the evaluation of the intrinsic (aPTT) 
and extrinsic (PT) coagulation system as well as fibrinogen activity (TT). 
These tests also aid in screening for classical hemophilia A and B, other 
congenital factor deficiencies, dysfibrinogenemia, lupus anticoagulant, 
congenital hypofibrinogenemia, disseminated intravascular coagulation, 
liver failure and vitamin K deficiency. Coumadin should be monitored 
with the international normalized ratio (INR), calculated from the PT. 
Heparin should be monitored with the heparin aPTT assay.

CPT Code
aPTT: 85730, PT: 85610, TT: 85670

Effective Date
February 26, 2009

Submitted by
Marc D. Smith, MD, Medical Director, Coagulation Laboratory, Royal Oak
NON-HODGKIN'S LYMPHOMA

FLUORESCENCE IN SITU HYBRIDIZATION (FISH) ANALYSIS

The majority of non-Hodgkin’s lymphomas (NHL) demonstrate clonal chromosomal abnormalities that often cause relocation of oncogenes to the vicinity of highly active promoter/enhancer elements of immunoglobulin or T-cell receptor genes in B-cell or T-cell lymphoma, respectively, and result in deregulation of the oncogene. Conventional cytogenetic analysis is not always possible in lymphomas due to the lack of fresh tissue and small biopsy specimens. FISH can be used to establish the diagnosis in viable and fixed tissue and to assess the involvement of bone marrow by lymphoid tumor. As unfixed tissue may not be available, FISH on paraffin-embedded tissue sections can be an invaluable technique to identify genetic aberrations in lymphoid malignancies, as can FISH analysis of touch imprint specimens.

In NHL, a wide variety of translocation partner chromosomes are involved with 14q32, the site of the IgH gene. These translocations are associated with certain histopathologic subtypes, and therefore can be of diagnostic and prognostic value in these disorders. The most frequent translocation in B-cell NHL, (14;18)(q32;q21), juxtaposes the BCL2 proto-oncogene at 18q24 to the IgH locus in follicular lymphoma, and to a lesser extent diffuse large B-cell lymphoma. The t(11;14)(q13;q32), associated with mantle cell lymphoma, involves a breakpoint within the BCL1 gene locus at 11q13 that results in relocation of the cyclin D1 (CCND1) gene next to the promoter for the IgH gene causing overexpression of CCND1. The BCL6 gene at 3q27 is involved in a number of variant translocations in 30-40% of diffuse large cell lymphomas. Rearrangements of the anaplastic lymphoma kinase (ALK) gene on chromosome 2p23, often associated with the t(2;5)(p23;q35), are observed in anaplastic large cell lymphoma. FISH assays offered for NHL include:

<table>
<thead>
<tr>
<th>CPT Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>88271x2</td>
<td>IGH/BCL2 fusion FISH for t(14;18) (DNA probe, each)</td>
</tr>
<tr>
<td>88271x2</td>
<td>IGH/CCND1 fusion FISH for t(11;14) (DNA probe, each)</td>
</tr>
<tr>
<td>88271x1</td>
<td>BCL6 gene rearrangement for t(3q27;var) (DNA probe, each)</td>
</tr>
<tr>
<td>88271x1</td>
<td>CCND1 (BCL1) gene rearrangement for t(14q32;var) (DNA probe, each)</td>
</tr>
<tr>
<td>88271x1</td>
<td>ALK gene rearrangement for t(2p23.2;var) in anaplastic large cell lymphoma (DNA)</td>
</tr>
<tr>
<td>88275x1</td>
<td>For all lymphoma FISH probes listed above (100-300 interphase nuclei examined)</td>
</tr>
</tbody>
</table>

Specimen | Bone marrow, lymph node paraffin tissue section, lymph node touch preparation
Reference Range | Positive or negative for a neoplastic clone. An interpretative report will be provided
Interpretation | Identification of a characteristic cytogenetic abnormality along with morphological and immunophenotypic analysis can establish the specific type of lymphoma present. Studies have shown that the sensitivity of FISH for detecting lymphoma-associated chromosome translocations is higher and more specific than PCR, owing in part to the large genomic region over which some of the translocation breakpoints are spread, precluding their detection by molecular methods in a highly sensitive fashion.

Effective Date | March 11, 2009
Submitted by | Mark Micale, PhD, Clinical Cytogenetics Laboratory Medical Director, Anatomic Pathology, Royal Oak
**Nucleophosmin 1 Gene Mutation**

The Molecular Pathology Laboratory has developed a new test for detection of Nucleophosmin 1 (NPM1) mutation in acute myeloid leukemia (AML).

<table>
<thead>
<tr>
<th>Synonyms</th>
<th>NPM1 mutation</th>
</tr>
</thead>
</table>
| Specimen | **Blood:** 5-10 mL whole blood in EDTA (lavender top) or ACD (yellow top) tubes.  
**Bone marrow aspirate:** 0.5-1.0 mL in EDTA (lavender top) tubes. |
| **Outreach External Preparation** | Specimens are stable at room temperature (20-25°C or 68-77°F) up to 72 hours. |
| **Outreach Specimen Transport** | Transport at room temperature (20-25°C or 68-77°F). |
| **Rejection Criteria** | Specimens collected in heparin (green top), clot tubes, SST tubes, unlabeled tubes or frozen specimens will not be tested. |
| **Performed** | Once a week  
Results will be available in 7-10 days. |
| **Reference Range** | Negative (no mutations) |
| **Test Methodology** | PCR (polymerase chain reaction) of genomic DNA. |
| **Interpretation** | Positivity for NPM1 mutation is a good prognosis indicator and also serves as a marker of the leukemic clone in monitoring patients with AML for residual or recurrent leukemia. This is particularly important in AML with normal cytogenetics in which NPM1 positivity is seen in 60% of cases |
| **CPT Code** | 83891, 83898, 83909, 83912 |

**Effective Date**
October, 25, 2009

**Submitted by**
Domnita Crisan, MD, PhD  
Medical Director, Molecular Pathology Laboratory, Royal Oak
PATHOLOGIST SMEAR REVIEW WITH CBC-DIFF

ROYAL OAK CAMPUS

As of June 28, 2009, the Hematology Lab at Royal Oak will begin offering a simplified peripheral smear review to all ordering physicians. This will only be available for inpatients with abnormal CBC findings, as peripheral smear reviews cannot be performed on patients with normal CBC results. When a peripheral smear review is ordered, a brief interpretation/comment of the peripheral blood findings will be entered directly into the electronic medical record by a hematopathologist. The more detailed and comprehensive pathology consult will continue to be available only to Hematology/Oncology physicians or on an outpatient basis.

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Whole blood: 4 mL lavender (EDTA) (Min: 2.0 mL lavender)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Capillary blood: 500 mcL lavender microtainer (EDTA) (Min: 300 mcL lavender).</td>
</tr>
</tbody>
</table>

| Rejection Criteria | Specimens containing clots or insufficient volume are unacceptable and will not be tested. In order to ensure compliance with Medicare and other federal agencies, the Hematology Laboratory has instituted the written policy of not accepting requests for path consults on normal CBC/differentials. |

<table>
<thead>
<tr>
<th>Performed</th>
<th>Monday-Friday, dayshift</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Reports available in 24 hrs.</td>
</tr>
<tr>
<td></td>
<td>Specimens received Friday afternoon through Sunday will have results available the following Monday.</td>
</tr>
</tbody>
</table>

| CPT Code          | 85025, 85060 |

| Effective Date    | June 28, 2009 |

| Submitted by      | Ann Marie Blenc, MD, Medical Director, Hematology, Royal Oak |

www.beaumonthospitals.com/labs
PATHOLOGY CONSULTATION PANELS FOR COAGULATION

Beaumont Laboratory, Royal Oak now offers five coagulation testing panels, each of which will be accompanied by a pathologist interpretation. The five panels, entitled Coagulation Consultation for Pathology, include:

1) Anti-phospholipid antibodies
2) Bleeding diathesis
3) Prolonged clotting time
4) Thrombophilia/hypercoagulability
5) von Willebrand disease

Each panel will include a basic number of tests (see below), however tests may be added or excluded at the pathologist’s discretion based on prior or concurrent laboratory results.

It is expected that these panels will expedite work-up for complex coagulopathies or thrombotic risk factors. In addition, the pathologist will be able to order multiple tests on a single specimen, limiting the amount of blood to be drawn from the patient.

Please note that platelet studies are not included in these panels due to the considerable difference in allowable pre-analytic time for coagulation studies vs. platelet studies (4 hours for the latter). However, platelet studies may be ordered concurrently by the physician. In addition, if the pathologist considers platelet studies necessary to complete the work-up, it will be mentioned in the interpretation.

Also note that the thrombophilia/hypercoagulation panel includes multiple tests that should not be ordered in patients with an acute thrombotic event, as they can be falsely decreased. Moreover, many of these tests do not influence the initial treatment or prophylaxis. Therefore, the thrombophilia panel should NOT be ordered on inpatients.

Coagulation Consultation for Pathology, anti-phospholipid antibodies

Basic Panel: Protime (PT), activated partial thromboplastin time (PTT), hexagonal phase phospholipid, antiphospholipid antibody panel

SPECIAL HANDLING
Collect: Eight 5 mL light blue Hemogard Vacutainer (3.2% sodium citrate) and one 5 mL serum separator tube. TUBES MUST BE FULL.
Preparation: For sodium citrate tubes, see sodium citrate aliquot preparation below*. For serum separator tubes, use antiphospholipid antibody protocols.

Coagulation Consultation for Pathology, bleeding diathesis

Basic Panel: PT, PTT, CBC, von Willebrand evaluation

SPECIAL HANDLING
Collect: Eight 5 mL light blue Hemogard Vacutainer (3.2% sodium citrate) and one 4 mL lavender (EDTA). TUBES MUST BE FULL.
Preparation: For sodium citrate tubes, see sodium citrate aliquot preparation below*. For EDTA tubes, use CBC protocols.

~ continued on the reverse side ~
Coagulation Consultation for Pathology, prolonged clotting time

**Basic Panel:** Inhibitor/anticoagulant screen, thrombin time

**SPECIAL HANDLING**

**Collect:** Eight 5 mL light blue Hemogard Vacutainer (3.2% sodium citrate).

**TUBES MUST BE FULL.**

**Preparation:** See sodium citrate aliquot preparation below*.

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Coagulation Consultation for Pathology, thrombophilia/hypercoagulability

(for outpatients ONLY. Discontinuation of anticoagulant therapy, if possible, is highly recommended prior to testing)

**Basic Panel:** PT, PTT, activated protein C resistance, protein C activity, protein S activity, antithrombin III, factor VIII activity, hexagonal phase phospholipid, factor V genotyping, prothrombin genotyping, antiphospholipid antibody panel, homocysteine

**SPECIAL HANDLING**

**Collect:** Nine 5 mL light blue Hemogard Vacutainer (3.2% sodium citrate), one 5 mL serum separator tube and one 5 mL whole blood lavender (EDTA).

**TUBES MUST BE FULL.**

**Preparation:** For sodium citrate tubes, see sodium citrate aliquot preparation below* For serum separator tubes, use antiphospholipid antibody protocols. For EDTA tubes use factor V genotyping protocols.

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Coagulation Consultation for Pathology, von Willebrand disease

**Basic Panel:** PT, PTT, von Willebrand antigen, ristocetin cofactor, factor VIII

**SPECIAL HANDLING**

**Collect:** Eight 5 mL light blue Hemogard Vacutainer (3.2% sodium citrate).

**TUBES MUST BE FULL.**

**Preparation:** See sodium citrate aliquot preparation below*.

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*Sodium Citrate Aliquot Preparation (very important)

Transport whole blood specimens to Coagulation Laboratory within 4 hours. Specimens must be kept at room temperature (20-25°C or 68-77°F).

If not possible, the following procedure must be followed for accurate results:

1. Centrifuge the capped tubes at 1500 x g for 15 minutes.
2. Transfer plasma with plastic pipette into a plastic polypropylene centrifuge tube, cap and centrifuge an additional 15 minutes at 1500 x g to obtain platelet poor plasma which has a platelet count less than 10 bil/L. Plasma with a platelet count of less than 10 bil/L is critical for accurate results.
3. Immediately remove only the top two-thirds of the platelet-poor plasma and aliquot it into eight (nine for thrombophilia/hypercoagulability panel) plastic tubes. Send these plastic tubes as frozen aliquots.
4. Freeze (-20°C or below (-4°F or below)) the specimens immediately.
5. Transport frozen on DRY ICE. Specimens must remain frozen during transport.

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Rejection Criteria

Specimens containing clots, gross hemolysis, inappropriate volume, thawed or partially thawed are unacceptable and will not be tested.

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Performed

Test performed at least once a week. Specimen may be submitted at any time. The coagulation laboratory will store the specimen. Results available in 72 hrs.

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CPT Code

80502 (additional codes depending on tests chosen by pathologist)

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Effective Date

May 11, 2009

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Submitted by

Marc D. Smith, M.D., Medical Director, Coagulation
PEDIATRIC B-CELL ACUTE LYMPHOBLASTIC LEUKEMIA FISH PANEL, FLUORESCENCE IN SITU HYBRIDIZATION (FISH) ANALYSIS

The identification of recurrent chromosomal aberrations as prognostic markers in childhood acute lymphoblastic leukemia (ALL) has had a major impact on efforts to cure this disease, and for this reason is a major component, along with immunophenotype, of the WHO classification of ALL. Approximately 80% of ALL cases demonstrate clonal chromosome abnormalities. The remaining cases either present a normal karyotype or cannot be analyzed due to a variety of factors such as poor chromosome morphology and the apoptotic tendency of ALL blasts in culture. For this reason, FISH has become an important tool for the assessment of genetic aberrations in ALL.

Many clinical trials, including those established by the Children’s Oncology Group (COG), require all newly diagnosed ALLs to undergo both conventional cytogenetic testing as well as molecular cytogenetic characterization for risk-stratification utilizing a FISH panel to identify TEL/AML1 and BCR/ABL fusion; MLL gene rearrangement; and chromosome 4, 10, and 17 triple trisomy.

Specimen Bone marrow

Reference Range Positive or negative for a neoplastic clone. An interpretative report will be provided

Interpretation High hyperdiploidy defines a distinct subset characterized by a favorable prognosis. More specifically, hyperdiploid ALL with simultaneous trisomy of chromosomes 4, 10, and 17 have the least treatment failure and the best clinical outcome. The most common translocation in pediatric pre-B ALL is t(12;21)(p13;q22) which is recognized in up to 30% of childhood B-precursor ALL, but is rare or absent in infants and in adults with ALL. The t(12;21) is associated with a good prognosis. The Ph chromosome, t(9;22)(q34;q11.2) with BCR/ABL fusion, is observed in approximately 5% of children and is associated with a poor prognosis. Translocations of 11q23, causing rearrangements of the MLL gene, predict a clinically aggressive disease with a poor prognosis. Another recurrent translocation in ALL, the t(1;19)(q23;p13.3), is seen in approximately 5% of adult and childhood ALL and encodes the fusion protein E2A/PBX1. This was previously thought to represent a poor prognostic marker, but intensification of therapy in pediatric patients has overcome its effects on outcome.

CPT Codes
- 88271x8 DNA probe, each
- 88275x4 Interphase in situ hybridization, 100-300 cells


Effective Date February 16, 2009
Submitted by Mark Micale, PhD, Clinical Cytogenetics Laboratory Medical Director, Anatomic Pathology, Royal Oak
PEDIATRIC BONE MARROWS – Royal Oak

As of April 1, 2009, pediatric bone marrows will be interpreted by the hematopathologists in the Department of Clinical Pathology and reported in EPIC. All bone marrows (pediatric and adult) should be ordered in EPIC, as either Bone Marrow Biopsy or Bone Marrow Biopsy Bilateral. The order options, Pediatric Bone Marrow Exam and Pediatric Bone Marrow Exam – Bilateral, will no longer be available. The bone marrow procedure will continue to be performed by the pediatric hematologists/oncologists.

<table>
<thead>
<tr>
<th>Rejection Criteria</th>
<th>Additional orders (cytogenetics, flow cytometry) may be cancelled if insufficient aspirate is obtained.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Performed</td>
<td>Monday-Friday, day shift</td>
</tr>
<tr>
<td></td>
<td>Report available in 48 hours.</td>
</tr>
<tr>
<td>Test Methodology</td>
<td>Specimen procurement by needle aspiration and biopsy</td>
</tr>
<tr>
<td></td>
<td>Bone marrow aspiration smears: routine Wright/Giemsa stain; staining for iron.</td>
</tr>
<tr>
<td></td>
<td>Bone marrow biopsy and aspirate clot sections: routine H&amp;E staining, special stains, immunohistochemical stains, stains for iron.</td>
</tr>
<tr>
<td>Interpretation</td>
<td>By pathologist report.</td>
</tr>
<tr>
<td>Effective Date</td>
<td>April 1, 2009</td>
</tr>
<tr>
<td>Submitted by</td>
<td>Ann Marie Blenc, MD, Medical Director, Hematology, Royal Oak</td>
</tr>
</tbody>
</table>
Phlebotomy procedure and avoidance of high serum potassium

During phlebotomy:

- Do NOT leave tourniquet on for extended period (ideally less than 1 minute)
- Avoid fist clenching
- Follow correct order of draw
- Allow tube(s) to fill completely
- GENTLY invert tubes 5-6 times. Do NOT mix vigorously.

Following blood draw for serum separator tubes:

- Allow blood to clot for 30 – 60 minutes at room temperature
- Centrifuge for 10 – 15 minutes (do NOT shorten this time by stopping centrifuge)
- Gently invert centrifuged serum separator tube – if serum appears pink or red, the tube must be re-centrifuged immediately.
Beaumont Laboratories
Beaumont Reference Laboratory (BRL)

PLASMA CELL MYELOMA FISH PANEL,
FLUORESCENCE IN SITU HYBRIDIZATION (FISH) ANALYSIS

Conventional cytogenetic analysis in plasma cell myeloma (PCM) is difficult due to patchy bone marrow infiltration and low proliferation of the malignant plasma cells. An abnormal karyotype is found in 30-40% of cases, more often in advanced stages than in newly diagnosed patients. Two distinct cytogenetics groups are recognized: a hyperdiploid group with 47 chromosomes or greater observed in around 60% of cases and a nonhyperdiploid group with 46 chromosomes or less, observed in the remaining 40%. Nonhyperdiploid PCM has a higher prevalence of \(IgH/14q32\) translocations, monosomy 13/13q deletion, and 17p deletion. Clinically, this cytogenetics classification is valuable, since FISH analysis has demonstrated that chromosome aberrations can be found in the majority of PCM cases. This myeloma FISH panel includes enumeration probes for chromosomes 3, 9, and 15 to screen for ploidy, as well as probes to detect monosomy 13/13q deletion, \(p53\) gene deletion, and common \(IgH\) translocations. This methodology yields significant prognostic information for risk assessment and treatment stratification in patients with PCM.

Specimen

Bone marrow

Reference Range

Positive or negative for a neoplastic clone. An interpretative report will be provided.

Interpretation

Loss of chromosome 13/13q- is associated with shorter survival, lower response rates to treatment, and is considered an independent prognostic variable. Gain of chromosomes 3, 9, and 15 is found in >90% of hyperdiploid cases. Hyperdiploid PCM patients seem to have a better outcome than nonhyperdiploid patients. Three major specific \(IgH\) translocations, t(11;14)(q13;q32), t(4;14)(p16.3;q32), and (14;16)(q32;q23), are identified in PCM. The t(4;14) and t(14;16) are cryptic translocations found in less than 15% of patients and can only be detected accurately utilizing the \(FGFR3/IgH\) and \(MAF/IgH\) FISH dual fusion FISH probes, respectively (which can be performed reflexively). Both the t(4;14) and t(4;16) are associated with hypodiploidy, an adverse disease outcome with shorter survival, and aggressive clinical features. The t(11;14) is associated with a favorable prognosis. Deletion of 17p13 (\(p53\) gene) also confers a negative risk factor in PCM.

CPT Codes

88271x5 DNA probe, each
88275x3 Interphase in situ hybridization, 100-300 cells

Clinical Reference

Dewald GW et al. (2005) Relationship of patient survival and chromosome anomalies detected in metaphase and/or interphase cells at diagnosis of myeloma. Blood 106(10), 3553-3558.

Effective Date

February 16, 2009

Submitted by

Mark Micale, PhD, Clinical Cytogenetics Laboratory Medical Director, Anatomic Pathology, Royal Oak

Beaumont Laboratory Services
Anatomic Pathology
1-800-551-0488
www.beaumonthospitals.com/labs

468 Cadieux
Grosse Pointe, MI 48230
313-343-1637

3601 West 13 Mile Road
Royal Oak, MI 48073-6769
248-898-9060

44201 Dequindre Road
Troy, MI 48085-1198
248-964-4100
**Platelet Associated Antibody Assay (IgG and IgM)**

The Flow Cytometry Laboratory has made changes in the testing and reporting of the platelet associated antibody assay for idiopathic thrombocytopenia purpura (ITP). The test will now separately assay for IgG and IgM platelet associated antibody. Previously, a cocktail containing IgG, IgM and IgA antibodies was utilized as a screen and reported without specific delineation as to the antibody subtype. IgM platelet associated antibody was previously assayed separately only if the antibody screening assay for IgG, IgM and IgA was positive. The Flow Cytometry Laboratory will now be performing and reporting IgG and IgM platelet associated antibodies as individual results on all samples tested. Results will be reported as negative, equivocal, weakly positive or positive. The IgM platelet associated antibody assay will no longer be available as a stand alone test since it is incorporated into the new platelet associated antibody test.

<table>
<thead>
<tr>
<th>Synonyms</th>
<th>PAIg, anti platelet antibody, flow cytometry for ITP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specimen</td>
<td>Three 5 mL EDTA tubes</td>
</tr>
<tr>
<td>BRL External Preparation</td>
<td>The specimen should arrive in the laboratory within 24 hours of collection.</td>
</tr>
<tr>
<td>BRL Specimen Transport</td>
<td>Transport and store at room temperature</td>
</tr>
<tr>
<td>Rejection Criteria</td>
<td>Specimens received in the laboratory greater than 24 hours after collection.</td>
</tr>
<tr>
<td>Performed</td>
<td>Tuesdays and Thursday (Results available in 1-5 days)</td>
</tr>
<tr>
<td>Reference Range</td>
<td>Negative IgG, Negative IgM</td>
</tr>
<tr>
<td>Test Methodology</td>
<td>Flow cytometry</td>
</tr>
<tr>
<td>Interpretation</td>
<td>Results for IgG and IgM reported as negative, equivocal, weakly positive or positive.</td>
</tr>
<tr>
<td>CPT Code</td>
<td>86023 (IgG), 88023 (IgM)</td>
</tr>
<tr>
<td>Effective Date</td>
<td>May 10, 2009</td>
</tr>
<tr>
<td>Submitted by</td>
<td>Vonda Douglas-Nikitin MD, Medical Director, Flow Cytometry</td>
</tr>
</tbody>
</table>
Platelet LUMI Aggregation

Reference Range Change

Please note that the reference range for the ADP agonist in our LUMI aggregation profile has changed from 0.64 - 1.26 to 0.30 - 0.93 mcM.

Instructions for Outpatients

Patients must make an appointment through the Appointment Center (248-577-9700). The patient must be registered and have his/her blood drawn at Royal Oak, preferably at the Rose Cancer Center.

Patients should not eat, drink, smoke, or exercise the morning of the appointment. Do not drink alcohol the day before or the day of your appointment. Anti-platelet drugs (e.g. Plavix, aspirin) should be discontinued seven days prior to the appointment unless assessment of the anti-platelet drug is the reason for the study. It is important that the patient bring a list of all the medications that he/she has taken within the last seven days including herbals, over-the-counter medications, and prescription medications. A physician's written order is also necessary.

Inpatient Specimens

Do not collect before 7:00 a.m.; must be received before noon, Monday-Friday.

Test Methodology

Aggregation, optical PRP

Reference Ranges (mcM)

ADP: 0.3-0.93; Collagen: 0.5-1.4; TRAP: 0.4-1.2.

Interpretation

An interpretive pathologist’s report is included with results.

Clinical Utility

This assay aids in the evaluation of the platelet release reaction and dense granule storage pool disorder.

CPT Code

85576 per agonist (x7)

Effective Date

February 1, 2009

Submitted by

Marc D. Smith, M.D., Medical Director, Coagulation Laboratory, Royal Oak
While many causes of spontaneous miscarriage have been identified, a chromosome abnormality is observed in up to half of all cases. Aneuploidy, the gain or loss of a chromosome, as well as triploidy (69 chromosomes instead of the normal diploid content of 46 chromosomes) accounts for the majority of these cases. Up to 95% of all chromosome aneuploidy identified prenatally involves gain of chromosomes 13, 18, or 21, along with the X and Y chromosomes. In addition, aneuploidy of these chromosomes accounts for over 80% of all chromosome abnormalities in liveborn infants.

While standard cytogenetic analysis of amniotic fluid or chorionic villi remains the gold standard for fetal chromosome evaluation, it requires 7-12 days for a final result to be obtained. In certain clinical situations such as advanced maternal age, advanced gestational age, or the presence of an ultrasound anomaly strongly suggestive of aneuploidy, a technique to rapidly identify aneuploidy of chromosomes 13, 18, 21, X, and Y may be helpful. Utilization of a FISH panel to enumerate chromosomes 13, 18, 21, X, and Y applied to either uncultured amniocytes (obtained by amniocentesis) or chorionic villi (obtained by CVS) can provide a result in 1-2 business days. In addition, this test may be useful when rapid evaluation of possible aneuploidy in a newborn is required.

**Specimen**
Amniotic fluid or chorionic villi

**Reference Range**
Positive or negative for chromosome aneuploidy. An interpretative report will be provided

**Interpretation**
Aneuploidy is detected when the percentage of nuclei with an abnormality exceeds the threshold (normal reference range) established for each probe. The parents of an aneuploid conception have an increased risk of up to 1% beyond the age-related risk for aneuploidy in future pregnancies. It is recommended that decision-making regarding clinical management of the fetus should be based on two of the following: positive FISH results, confirmatory chromosome analysis, or consistent clinical information.

**CPT Codes**
88271 DNA probe, each
88274 Interphase in situ hybridization, 25-99 cells

**Clinical Reference**

**Effective Date**
February 16, 2009

**Submitted by**
Mark Micale, PhD, Clinical Cytogenetics Laboratory Medical Director, Anatomic Pathology, Royal Oak
Products of conception (POC) refer to tissues present in a fertilized gestation that are collected at the time of pregnancy termination or abortion. These tissues include chorionic villi, fetal membranes, and fetal tissue. While many causes of spontaneous miscarriage have been identified, a chromosome abnormality is observed in up to half of all cases. Thus, cytogenetic examination of POC tissues is important to ascertain a potential cause of the pregnancy loss. Chromosome aneuploidy, the gain or loss of chromosomes, is a major cause of early fetal demise. The gain of a chromosome (trisomy) accounts for a large percentage of aneuploidy identified in miscarried fetuses, most commonly involving chromosomes 13, 16, 18, 21, and 22. Other common numerical chromosome abnormalities identified in miscarriages include loss of the X chromosome (Turner syndrome) and triploidy (69 chromosomes instead of the normal diploid content of 46 chromosomes).

Conventional cytogenetic analysis of POC tissue will often identify aneuploidy as the cause of pregnancy loss; however, 20% of such specimens fail to grow in culture. Without further evaluation, a common potential cause of the fetal demise will fail to be identified. A FISH panel has been developed to evaluate this subset of patients. Utilizing paraffin-embedded tissue sections made at the time of pathological evaluation of the POC tissue, DNA probes to enumerate chromosomes 13, 16, 18, 21, 22, X, and Y are utilized. This test is only performed on tissue sections known to contain fetal tissue or chorionic villi.

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Paraffin-embedded tissue section</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference Range</td>
<td>Positive or negative for chromosome aneuploidy. An interpretative report will be provided</td>
</tr>
<tr>
<td>Interpretation</td>
<td>Aneuploidy is detected when the percentage of nuclei with an abnormality exceeds the threshold (normal reference range) established for each probe. An aneuploid conception is associated with an increased risk of up to 1% beyond the age-related risk for aneuploidy in future pregnancies.</td>
</tr>
<tr>
<td>CPT Codes</td>
<td>88271x4 DNA probe, each 88275 Interphase in situ hybridization, 100-300 cells</td>
</tr>
<tr>
<td>Effective Date</td>
<td>February 16, 2009</td>
</tr>
<tr>
<td>Submitted by</td>
<td>Mark Micale, PhD, Clinical Cytogenetics Laboratory Medical Director, Anatomic Pathology, Royal Oak</td>
</tr>
</tbody>
</table>
Reporting of Epstein Barr Virus (EBV) Serology

Effective Monday June 29, 2009, quantitative results will replace the current qualitative reporting of Epstein Barr virus (EBV) serology. Cut-offs used to determine negative, equivocal or positive results are:

<table>
<thead>
<tr>
<th>Test</th>
<th>Cut-off Range</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>EBV-VCA, IgG (U/mL)</td>
<td>≤ 17.9</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>18.0 – 21.9</td>
<td>Equivocal</td>
</tr>
<tr>
<td></td>
<td>≥ 22.0</td>
<td>Positive</td>
</tr>
<tr>
<td>EBV-VCA, IgM (U/mL)</td>
<td>≤ 35.9</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>36.0 – 43.9</td>
<td>Equivocal</td>
</tr>
<tr>
<td></td>
<td>≥ 44.0</td>
<td>Positive</td>
</tr>
<tr>
<td>EBV-EA  (U/mL)</td>
<td>≤ 8.9</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>9.0 – 10.9</td>
<td>Equivocal</td>
</tr>
<tr>
<td></td>
<td>≥ 11.0</td>
<td>Positive</td>
</tr>
<tr>
<td>EBNA    (U/mL)</td>
<td>≤ 17.9</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>18.0 – 21.9</td>
<td>Equivocal</td>
</tr>
<tr>
<td></td>
<td>≥ 22.0</td>
<td>Positive</td>
</tr>
</tbody>
</table>

In addition, comments that accompany results have been modified. The new comments are as follows:

**EBV-VCA, IgG**
EBV-VCA IgG is first detectable within 1-2 weeks of onset of symptoms. Antibody levels will decline somewhat after clinical illness but remain detectable throughout the patient's lifetime. If results are negative or equivocal and infection is suspected, a 2nd sample should be collected in no less than 1-2 weeks.

**EBV-VCA, IgM**
The presence of EBV-VCA IgM usually denotes a primary infection with peak levels usually being present at the onset of clinical symptoms. EBV-VCA IgM levels persist for 2-3 months following a primary infection. Levels may also be in the low-positive range in reactivated infections but this occurs in only a minority of cases (< 5%). If results are negative or equivocal and infection is suspected, a 2nd sample should be collected in no less than 1-2 weeks.

**EBV-EA**
EBV-EA antibodies are usually present during acute infections and may be undetectable 3-6 months after clinical illness. They may also be elevated in reactivated infections (usually low-positive) and occur in asymptomatic individuals. Cross-reactivity has been reported with some specimens containing antibody to HIV.

**EBNA**
Antibodies to EBV nuclear antigens are rarely present in acute infection and are usually first detected 3-4 weeks after the onset of symptoms. EBNA antibody levels persist throughout the patient's life-time, however they may be undetectable in immunodeficient patients.

**Effective Date:** Monday, June 29, 2009

**Submitted by:** Elizabeth Sykes, MD, Medical Director, Clinical Chemistry & Special Testing
STONE FORMER PANEL – INTERPRETATION CHANGE

The stone former panel interpretation that has accompanied the lab results for a number of years has been eliminated from the report. This change became effective at the recent Misys roll-over on December 13th, 2009. The remainder of the stone former panel is unchanged and abnormal results will still be underlined.

Submitted by: Elizabeth Sykes, MD, Medical Director, Automated Chemistry and Special Testing, Royal Oak

Raymond Karcher, PhD, Bioscientific Staff, Clinical Chemistry, Royal Oak
Troponin I – Reference Range and Sodium – Critical Values
Changes Effective October 25, 2009

TROTONIN I – Royal Oak and Troy Labs

New ranges:

- < 0.06 ng/mL  Normal
- 0.06 – 0.19 ng/mL  Indeterminate for myocardial damage
- ≥ 0.2 ng/mL  Indicates or highly suggestive of myocardial damage (critical value)

This change allows us to better comply with recommendations from the AHA on diagnosis of myocardial infarction. The change means that more Troponin I results will be positive. However it is important to remember that an elevated troponin is not specific for acute ischemia and can be seen in several conditions affecting the myocardium. The following comment is attached to all troponin results:

NOTE: Troponin I is elevated in acute coronary syndromes with myocardial necrosis as well as ST elevation MI. Increases are also associated with direct myocardial damage (myocarditis, pericarditis, contusion, cardioversion), myocardial strain (CHF, pulmonary hypertension, pulmonary embolus) and demand ischemia (sepsis, hypotension, atrial fibrillation). Troponin may also be elevated with renal failure, intracranial hemorrhage and amyloidosis. The mechanism for the latter elevations is unclear. An elevated troponin level is a predictor for poor outcome, regardless of its cause.

Laboratory methods: Currently Royal Oak and Troy Labs use the Siemens Centaur for troponin I testing. Grosse Pointe uses a different method (Abbott Architect) and will not be making any range changes.

References:


SODIUM (All Laboratories)

The critical values for pediatric patients are being changed to those listed below. Adult critical values will remain unchanged. Values listed will be in use at Grosse Pointe, Royal Oak and Troy.

New pediatric (0-17yr) critical: 125 mmol/L
120 mmol/L

Sodium criticals: 160 mmol/L

Effective Date: November 25, 2009
Submitted by:

Elizabeth Sykes, MD, Medical Director, Automated Chemistry and Special Testing, Royal Oak
Suresh Gehani, MD, Medical Director, Department of Laboratories, Grosse Pointe
Ralph Zade, MD, Medical Director, Chemistry, Troy
UN-CENTRIFUGED BLOOD SAMPLES

For Outreach Clients:

Effective immediately, blood samples that are received un-centrifuged with serum or plasma not properly separated from the red cells, will not be tested for the following:

- Potassium
- Glucose
- LD

If it is determined that the blood remained un-centrifuged for longer than 18 to 24 hours, other tests may also be canceled. Such decisions will be made on an individual basis.

The final laboratory report will state that the collection tube was received un-centrifuged and will suggest repeat testing if clinically indicated.

Effective Date: January 19, 2009

Submitted by: Elizabeth Sykes, MD, Medical Director, Automated Chemistry and Special Testing, Royal Oak
ATTENTION PHYSICIANS AND OFFICE MANAGERS

– UPDATED POLICY –

UN-CENTRIFUGED SERUM SEPARATOR TUBES RECEIVED BY LAB –

Why have a policy?

It is essential that gold-top/SST tubes are centrifuged as soon as the blood has clotted (clotting takes 30 – 60 mins). Centrifugation allows the gel to separate red cells, white cells and platelets from the serum. If cells remain in contact with serum, cell contents (e.g. potassium, LD, AST) leak into the serum, or because the cells are metabolically active they utilize glucose. Consequently the following changes start to occur within 2-4 hours from blood collection:

- Potassium increases
- Glucose decreases
- Other tests are affected after longer periods (e.g. LD, CO2, phosphate, TSH)

What is the updated policy?

<table>
<thead>
<tr>
<th>Un-centrifuged tube collected less than 24 hours prior to receipt:</th>
<th>Routine Chemistry tests performed. The following cautionary note will be reported with results: “Tube received unspun – may elevate K and LD and lower gluc.”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Un-centrifuged tube collected 25-48 hours prior to receipt:</td>
<td>Only selected chemistry tests (e.g. BUN, creatinine) can be performed; others will be canceled (e.g. electrolytes).</td>
</tr>
<tr>
<td>Un-centrifuged tube that has been frozen, exposed to excessive heat or collected more than 48 hours prior to receipt:</td>
<td>All tests will be canceled.</td>
</tr>
</tbody>
</table>

In summary, in order to cause as little inconvenience to you and your patients, it is essential that your staff:

- Centrifuges the gold-top/SST tube as soon as the blood has clotted (clotting takes approximately 30-60 mins).
- Does NOT centrifuge before clotting has occurred.
- Documents the time of blood collection on the requisition form.

Effective Date
August 3, 2009

Submitted by
Elizabeth Sykes, MD, Medical Director, Automated Chemistry and Special Testing, Royal Oak
Grosse Pointe Beaumont Hospital Medical Staff:

Alphafetoprotein (tumor marker, non-pregnant), Cortisol (serum), DHEA Sulfate, Free & Total Testosterone (male only), Insulin (fasting), and RBC Folate will be sent to Beaumont Reference Laboratories at Royal Oak instead of ARUP Laboratories. These results can be viewed on EPIC OneChart.

Specimen collection, reference ranges and interpretation can be seen on “Inside Beaumont Online” by clicking on <References> and <Lab Test Directory> or at: www.beaumonthospitals.com/labtestdirectory

Patients’ results include the reference ranges.

For any questions, contact BRL (Beaumont Reference Laboratory) Customer Service at 1-800-551-0488.

Effective Date Monday, May 11, 2009
Submitted by Suresh Gehani, M.D.,
    Medical Director, Grosse Pointe Laboratories
Isabel Gauss, MS, MT (ASCP)
    Administrative Director, Grosse Pointe Laboratories
Bordetella pertussis Testing

The purpose of this document is to delineate the specimen collection requirements for the laboratory-based detection of *B. pertussis*.

Pertussis (whooping cough) is an acute infectious illness of the respiratory tract primarily caused by *B. pertussis* - a fastidious microorganism that requires special collection procedures and growth media for recovery by culture. Because *B. pertussis* is difficult to recover by culture, molecular-based testing (i.e., polymerase chain reaction [PCR]) is now the preferred testing modality. Culture-based testing should be reserved for instances where there is a need for antimicrobial susceptibility testing.

Molecular Testing (PCR) - Preferred Testing Modality:

Order: Bordetella pertussis by PCR (Outreach Order Code: 83024)
Collect: Nasopharyngeal swab, place into liquid Amies WITHOUT Charcoal.

Transport: Maintain at room / refrigerated temperature. Do NOT Freeze.

Culture-Based Testing

Order: Bordetella pertussis culture (Outreach Order Code: 42059)
Collect: Two nasopharyngeal swabs (use separate swabs for each nostril), place immediately into Amies WITH Charcoal transport medium.
Transport: Maintain at room temperature. Do NOT Freeze or Refrigerate.

NOTE: Collection supplies (swab and transport media) are CURRENTLY OUT OF STOCK. Until supplies are available, please order *B. pertussis* by PCR and ensure that the specimen is appropriately collected.

For additional information, please contact Client Services (1-800-551-0488, option 5).

Effective Date
December 17, 2009

Submitted by
Bobby Boyanton, M.D., Medical Director, Microbiology, Royal Oak

Beaumont Laboratory
Outreach
1-800-551-0488

468 Cadieux
Grosse Pointe, MI 48230
313-343-1637

3601 West 13 Mile Road
Royal Oak, MI 48073-6769
1-800-551-0488

44201 Dequindre Road
Troy, MI 48085-1198
248-964-8030

www.beaumonthospitals.com/labs
**C. trachomatis and N. gonorrhoeae: Test Requests, Specimen Collection and Testing**

**To:** Grosse Pointe Medical Staff and BRL Physicians

Testing for *C. trachomatis* and *N. gonorrhoeae* may be performed by PCR or culture; the choice of testing modality relies entirely on three variables: 1) location or source from which the specimen will be obtained, 2) method of specimen collection and transportation to the laboratory, and 3) downstream testing modality.

Laboratories **MUST** know the source of the patient sample to guarantee compliance with regulatory agencies and ensure that the test is being performed by the correct methodology. There are **NO** exceptions to this.

The following table clarifies *C. trachomatis* and *N. gonorrhoeae* testing to ensure that each specimen will be collected, transported, and tested appropriately. **NOTE:** antimicrobial susceptibility testing is only available for *N. gonorrhoeae* if testing is performed by culture.

<table>
<thead>
<tr>
<th>Gonorrheae Testing</th>
<th>Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient</strong></td>
<td><strong>Source/Site</strong></td>
</tr>
<tr>
<td>Male</td>
<td>Urethral Swab</td>
</tr>
<tr>
<td>Female</td>
<td>Endocervical Swab</td>
</tr>
<tr>
<td>Male/Female</td>
<td>All other sources</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chlamydia Testing</th>
<th>Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient</strong></td>
<td><strong>Source/Site</strong></td>
</tr>
<tr>
<td>Male</td>
<td>Urethral Swab</td>
</tr>
<tr>
<td>Female</td>
<td>Endocervical Swab</td>
</tr>
<tr>
<td>Male/Female</td>
<td>All other sources</td>
</tr>
</tbody>
</table>

For additional information, please utilize the online test directory - Inside Beaumont.
Changes in Reporting of Flow Cytometry Results

Beginning December 13, 2009 the Flow Cytometry Laboratory will utilize a new software system, Tamtron, for reporting of flow cytometric results on three tests- Hematolymphoid Neoplasm, Paroxysmal Nocturnal Hemoglobinuria (PNH) and ZAP-70. After this date, these tests will appear under a different heading in the EPIC and Misys systems. The previous headings as reported by test name will no longer contain the completed report, but will merely represent a placeholder for tracking and accessioning purposes. The completed reports will available under the general heading “Flow Cytometry Report”.

In EPIC, flow cytometry results will be available in two places under Results Review (see summary below). Results for the tests “Hematolymphoid Neoplasm, PNH screen and ZAP-70” will now appear under “Anatomic Pathology” in the “Anatomic Path Reports” tab. All other flow cytometry tests will appear under “Clinical Pathology” in the “Flow Cytometry” tab. Results on all flow cytometry tests will still be available in under the “Lab” tab in Chart Review. Completed reports will not appear in EPIC or Misys until they are finalized by the pathologist. These changes in reporting will have no impact on the time to interpretation or reporting of results. The flow cytometry tests should still be ordered under their specific names (Hematolymphoid Neoplasm, PNH, ZAP-70) as was done previously.

New format for flow cytometry reporting in EPIC “Results Review”:
Anatomic Pathology/Anatomic Path Report tabs:
- Hematolymphoid Neoplasm (leukemia, lymphoma, MDS, myeloma evaluation)
- ZAP-70 Evaluation (for known chronic lymphocytic leukemia only)
- Paroxysmal Nocturnal Hemoglobinuria (PNH) Screen

Clinical Pathology/Flow Cytometry tabs:
- Lymphocyte Subset Quantitation
- CD4 Absolute counts
- Platelet Associated Antibody (IgG and IgM)
- HLA B27 screen
- Fetal RBC Assay (FMH)
- Transplant Monitoring (OKT3)
- Flow Crossmatch

Effective Date: December 13, 2009
Submitted by: Vonda Douglas-Nikitin, MD
Medical Director, Flow Cytometry
CRYOGLOBULIN AND CRYOFIBRINOGEN – ROYAL OAK ONLY

Effective Monday, March 2, 2009, blood collection for cryoglobulin and cryofibrinogen testing will only be performed Monday to Friday, 6 a.m. to 3 p.m. This policy applies to both Royal Oak inpatients and Royal Oak outpatients. The change is being implemented to improve collection and transportation of these blood samples that need to be kept at 37°C prior to lab processing.

Beaumont Reference Lab clients should note that they must send patients to the outpatient lab for testing. It is not possible to collect and process a blood sample appropriately in a physician’s office or at a draw site.

This change does not affect patients at the Troy or Grosse Pointe hospitals.

Effective Date: Monday, March 2, 2009
Submitted by: Elizabeth Sykes, MD, Medical Director
Automated Chemistry and Special Testing, Royal Oak
Group A Streptococcus Testing Update for Throat Specimens

The primary cause of bacterial pharyngitis in the United States is Group A Streptococcus, *S. pyogenes* (GAS), accounting for ~30% of cases in children and ~10% of cases in adults. Penicillin or comparable β-lactam antibiotics remain the mainstay of treatment. Macrolides and clindamycin may be effective treatment options, but should be reserved for patients with penicillin allergy or intolerance. Because antimicrobial resistance to the macrolide class of antibiotics has been reported and varies geographically, susceptibility testing for this drug class remains an option at Beaumont Laboratories.

**Effective October 1, 2009,** the Clinical Microbiology Laboratories at Beaumont Hospitals will cease routine antimicrobial susceptibility testing (AST) on isolates of GAS from throat sources. AST will only be performed if requested at the time of specimen submission or following telephone communication with Client Services.

**Question:** How do I order the correct option?

**Answer:** We’ve made it easy for you. Each requisition has been updated with two ordering options as depicted below:

**MICROBIOLOGY TESTS**

<table>
<thead>
<tr>
<th>Code</th>
<th>Test Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>42023</td>
<td>Strep A Culture without susceptibility (Throat Only)</td>
</tr>
<tr>
<td>42363</td>
<td>Strep A Culture w/ susceptibility</td>
</tr>
</tbody>
</table>

- [ ] throat
- [ ] anus/rectal

**Question:** I submitted the specimen and realized I checked the wrong box; how do I resolve the issue?

**Answer:** Contact Client Services and your issue will be resolved.

If you have any questions, please contact Client Services (1-800-551-0488, option 5).
Influenza A nH1N1 (2009) by RT-PCR

The Molecular Pathology Laboratory at Beaumont Hospitals (Royal Oak) now offers a specific test for the detection of influenza A nH1N1 (2009), formerly called “Swine Flu”. The test uses the principle of real-time reverse transcriptase PCR (RT-PCR) to 1) detect all types of influenza A viruses, and 2) more specifically detect the influenza A nH1N1 (2009) "Swine Flu" virus.

When to Order:  
Primary Test: Patient with influenza-like-illness.  
Reflex Test: Patient with a previously tested nasopharyngeal swab specimen shown to be positive for influenza A by a rapid antigen test or cell culture. Patients shown to be positive for influenza A by the Respiratory Virus Panel (RVP) test do NOT need to be confirmed by the influenza A nH1N1 (2009) RT-PCR assay as the RVP test can distinguish between seasonal influenza A viruses and the nH1N1 (2009) influenza A virus.

What to Order: Influenza A nH1N1 (2009) by RT-PCR (Outreach order code 65445). For reflex testing, contact Client Services (1-800-551-0488, option 5) to add on the test.

What to Collect: Nasopharyngeal swab(s) (rayon, Dacron, flocked), placed into viral transport medium (M4-RT, M5, or universal transport media [UTM]) and refrigerated until received in the laboratory.

Lab Information: Performed daily (Results usually available within 24 hours). Specimen must be received in the molecular laboratory by 8:00 am to be tested the same day.

Possible Results and Accompanying Interpretations:

1) Negative: Influenza A Not Detected; Influenza A viruses were not detected in this specimen.

2) Positive: Influenza A nH1N1 (2009) Detected: Testing reveals the presence of influenza A nH1N1 (2009). If therapy is clinically indicated, nH1N1 (2009) remains susceptible to oseltamivir (Tamiflu) and zanamivir (Relenza). NOTE: This assay cannot exclude the simultaneous presence of seasonal influenza A viruses when influenza A nH1N1 (2009) is detected. Seasonal influenza A viruses may not be susceptible to these antiviral agents.

3) Positive: Influenza A (Seasonal, NOT nH1N1 (2009)) Detected; Test results indicate the presence of seasonal influenza A virus, not influenza A nH1N1 (2009). This assay does not differentiate between different sub-types of seasonal influenza A virus.

4) Positive: Influenza A Detected (See Comment); Testing reveals the presence of influenza A virus. However, due to low levels of virus in this specimen, we CANNOT determine whether seasonal influenza A or nH1N1 (2009) influenza A is present.

For additional information, please contact Client Services (1-800-551-0488, option 5).

Effective Date  November 11, 2009
Submitted by  
Bobby L. Boyanton, M.D., Medical Director, Microbiology, Royal Oak
Domnita Crisan, M.D., Ph.D., Medical Director, Molecular Pathology, Royal Oak

www.beaumonthospitals.com/labs
Influenza Testing Recommendations (Updated November 16, 2009)

First and foremost, please consider whether testing is medically necessary. Unless persons with mild illness belong to a high-risk group for complications (see below, High Risk Groups for Severe Influenza) testing or treatment may not be needed. Secondly, since shortages of test supplies, swabs and viral transport media are anticipated for the upcoming influenza season, these supplies must be preserved whenever possible. Finally, the CDC recently reported the inability of rapid antigen tests (RATs) to detect influenza A, with sensitivities of 40-83% when compared to PCR or viral culture. Therefore, if RATs are negative, another test will be necessary to determine the cause of the influenza-like illness. If testing is to be done, the following approach is recommended (also see included Algorithm):

**Specimen Collection:** All swabs (rayon, Dacron, flocked) must be placed into viral transport medium (M4-RT, M5, or universal transport media [UTM]) and refrigerated until received in the laboratory.

**Nasopharyngeal (NP) Specimens:**
1) Non-urgent testing: (Order ONLY one of the following tests)

   **NOTE:** Rapid Antigen Testing for Influenza A is NOT Recommended for Non-Urgent Testing

   a) *Respiratory Virus Panel (RVP) by PCR.* (Outreach order code 65425)
      - **Performed** (Mon – Sat, results available in 24 – 48 hours).
      - **Detects** influenza A with sub-typing, influenza B, RSV A/B, human metapneumovirus, adenovirus, rhinovirus/enterovirus, and parainfluenza viruses 1, 2, 3.
      - **Note:** If RVP result is “influenza A, unable to subtype as seasonal H1 or seasonal H3”, there is a high probability (>99%) of nH1N1 (2009) influenza A virus infection, formerly called “Swine Flu”. In this situation, you DO NOT need to order the *Influenza A nH1N1* (2009) by RT-PCR test.
      - **Limitation:** The RVP by PCR test can NOT rule out a co-infection with nH1N1 (2009) influenza A if seasonal influenza A, subtype H1 or H3 is detected. However, it will be able to detect a co-infection with other respiratory viruses.
      - **When to order:** if you suspect the patient may be infected with respiratory viruses other than influenza A, or if you suspect co-infection with influenza A and other respiratory viruses.

   b) *Influenza A nH1N1 (2009) by RT-PCR.* (Outreach Order Code 65445)
      - **Performed** (Mon – Sun, results available in 24 hours)
      - **Detects** all types of influenza A viruses and specifically determines if the nH1N1 (2009) influenza A virus is present.
      - **Limitation:** This assay can NOT exclude the simultaneous presence of seasonal influenza A viruses when influenza A nH1N1 (2009) is detected. This assay can NOT sub-type seasonal influenza A viruses. This assay can NOT detect influenza B virus.
      - **When to order:** if you suspect the patient may be infected solely with an influenza A virus and/or the nH1N1 (2009) influenza A virus.

Continued on Back
Continued from Front

2) **Urgent testing: (RAT):**
   a) Rapid Antigen Test (RAT): Order *influenza A/B EIA*. (Outreach Order Code 42289)
      - **Performed** (Mon – Sun, results available same day)
      - **Detects** influenza A and influenza B viruses
      - **Limitation**: Rapid Antigen Tests are insensitive and can miss up to 50% of patients that are truly infected with an influenza virus. For this reason, please note the following test result scenarios and the proposed “reflex” testing recommendations if you desire to order rapid antigen tests
      - **Result Scenarios**:
        1) If RAT is positive for influenza A, is sub-typing needed to facilitate management (treatment, infection control measures, prophylaxis)?
           i. If **Yes** and there is **NO concern** for co-infection with other respiratory viruses, please order Influenza A nH1N1 (2009) by RT-PCR.
           ii. If **Yes** and there **IS concern** for co-infection with other respiratory viruses, please order Respiratory Virus Panel (RVP) by PCR.
           iii. If **No**, no further action is required.
        2) If RAT is negative for influenza A/B and the patient is quite ill or in a high-risk group for complications, then order RVP by PCR to determine if a viral etiology is present.
        3) If the result is positive for influenza B, further testing is NOT needed.

Non-NP Specimens (BAL, bronchial washing, lung biopsy, sputum, etc.)
1) Order comprehensive viral culture: (results available in 24 – 48 hours)
2) **Detects** influenza A, influenza B, RSV, adenovirus, and parainfluenza viruses 1, 2, 3.

**High Risk Groups for Severe Influenza**

- Child <5 years
- Adult >65 years
- Pregnant women
- Immunocompromised host
- Long term care facility resident
- Chronic underlying disease
- Persons <19 years of age and on chronic aspirin therapy

Continued on Next Page
Influenza A Antiviral Drug Susceptibility (2008-2009 Influenza Season)**

<table>
<thead>
<tr>
<th>Antiviral Drug</th>
<th>nH1N1 (2009) “Swine”</th>
<th>Seasonal A/H1N1</th>
<th>Seasonal A/H3N2</th>
</tr>
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<tbody>
<tr>
<td>Oseltamivir (Tamiflu)</td>
<td>Sensitive</td>
<td>Resistant</td>
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</tr>
<tr>
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<td>Sensitive</td>
</tr>
<tr>
<td>Amantadine/Ramantadine</td>
<td>Resistant</td>
<td>Sensitive</td>
<td>Resistant</td>
</tr>
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</table>

** Note:
- Current Antiviral Drug Susceptibility Data from the CDC demonstrates that oseltamivir (Tamiflu) and zanamivir (Relenza) are effective for treatment of nH1N1 (2009) influenza A.
- Antiviral Drug Susceptibility Data for seasonal influenza A (H1N1 and H3N2) for the 2009 to 2010 influenza A seasonal is NOT available at this time.

Additional information: [http://www.cdc.gov/h1n1flu](http://www.cdc.gov/h1n1flu)


If you have questions, please contact Client Services (1-800-551-0488, option 5).

Effective Date November 11, 2009
Submitted by Bobby L. Boyanton, M.D., Medical Director, Clinical Microbiology, Royal Oak
Barbara Robinson-Dunn, Ph.D., Technical Director, Clinical Microbiology, Royal Oak
Domnita Crisan, M.D., Ph.D., Medical Director, Molecular Pathology, Royal Oak
Testing Desired (Y/N)?

Is molecular sub-typing needed to facilitate management - treatment, infection control measures, prophylaxis (Y/N)?

Urgent or Routine?

Is another test needed to exclude a viral respiratory infection (Y/N)?

Rapid Antigen Test (Flu A/B)

Order Respiratory Viral Panel by PCR
(NP Swab Only, M4-RT, M5, UTM)

RVP Outcome Possibilities for Influenza A:
1) *Positive: seasonal influenza A H1 detected
2) *Positive: seasonal influenza A H3 detected
3) Positive: influenza A detected, unable to subtype as seasonal H1 or seasonal H3. There is a high probability (>99%) of nH1N1 (2009) influenza A infection. Influenza A nH1N1 (2009) by RT-PCR is NOT needed in this situation.

* If outcome 1 or 2 is present, the RVP can not rule-out co-infection with novel H1N1 (2009), but can determine if co-infection with other respiratory viruses is present.

Order Either Test - NOT BOTH
1) Influenza A nH1N1 (2009) by RT-PCR
2) Respiratory Viral Panel by PCR

Note: Rapid Antigen Testing Not Needed
Influenza Testing Recommendations

First and foremost, please consider whether testing is medically necessary. Unless persons with mild illness belong to a high-risk group for complications (see below, High Risk Groups for Severe Influenza) testing or treatment may not be needed. Secondly, since shortages of test supplies, swabs and viral transport media are anticipated for the upcoming influenza season, these supplies must be preserved whenever possible. Finally, the CDC recently reported the inability of rapid antigen tests (RATs) to detect influenza A with sensitivities 40-83% when compared to PCR or viral culture. Therefore, if RATs are negative, another test will be necessary to determine the cause of the influenza-like illness. If testing is to be done, the following approach is recommended (See Attached Algorithm):

Specimen Collection: All swabs (rayon, Dacron, flocked) must be placed into viral transport medium (M4-RT, M5, or universal transport media [UTM]) and refrigerated until received in the laboratory.

Nasopharyngeal (NP) Specimens:
1) Non-urgent testing: Order Respiratory Virus Panel (RVP) by PCR.
   a) Testing performed (Mon – Sat, results available in 24 – 48 hr).
   b) Detects influenza A with sub-typing, influenza B, RSV A/B, human metapneumovirus, adenovirus, rhinovirus/enterovirus, and parainfluenza viruses 1, 2, 3.
   c) If RVP result is “influenza A, unable to subtype as seasonal H1 or seasonal H3”, there is a high probability (>99%) of novel H1N1 (2009) “Swine Flu” infection.

2) Urgent testing (RAT): Order influenza A/B EIA.
   a) Testing performed (Mon – Sun, results available same day)
   b) If RAT is positive for influenza A, is sub-typing needed to facilitate management (treatment, infection control measures, prophylaxis)?
      i. If Yes, please order RVP by PCR (by contacting Client Services)
      ii. If No, no further action is required.
   c) If RAT is negative for influenza A/B and the patient is quite ill or in a high-risk group for complications, then order RVP by PCR (by contacting Client Services) to determine if a viral etiology is present.
   d) If RAT is positive for influenza B, further testing is NOT needed.

3) Limitation: The RVP can not rule out a co-infection with the novel H1N1 (2009) influenza A “swine flu” virus if seasonal influenza A (seasonal H1 or seasonal H3) is detected.

Non-NP Specimens (BAL, bronchial washing, lung biopsy, sputum, etc.)
1) Order comprehensive viral culture: (results available in 24 to 48 hr)
2) Viruses detected: influenza A, influenza B, RSV, adenovirus, and parainfluenza viruses 1, 2, 3.

Please See Back
High Risk Groups for Severe Influenza

- Child <5 years
- Adult >65 years
- Pregnant women
- Immunocompromised host
- Long term care facility resident
- Chronic underlying disease
- Persons <19 years of age and on chronic aspirin therapy

### Influenza A Antiviral Drug Susceptibility

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<td>Sensitive</td>
<td>Resistant</td>
</tr>
</tbody>
</table>

If you have questions, please contact Client Services (1-800-551-0488, option 5).

Additional information: [http://www.cdc.gov/h1n1flu](http://www.cdc.gov/h1n1flu)

No Further Action

Signs/Symptoms of Influenza Like Illness

Testing Desired (Y/N)?

Yes

Rapid Antigen Test (Flu A/B)
(Physician Office or Laboratory)

Urgent or Routine?

Urgent

Flu B (+)

No Further Action

Flu A (+)

RVP (Respiratory Viral Panel)
Nasopharyngeal Swab Only

Is another test needed to exclude a viral respiratory infection (Y/N)?

Yes

Flu A/B (-)

Is molecular sub-typing needed to facilitate management - treatment, infection control measures, prophylaxis (Y/N)?

Yes

RVP Outcome Possibilities for Influenza A:
1) Flu A H1*: seasonal Flu A H1
2) Flu A H3*: seasonal Flu A H3

* Note: If outcome 1 or 2 is present, the RVP can not rule-out co-infection with novel H1N1 (2009) “Swine flu”.

No

Rapid Antigen Testing Not Needed

Perform RVP (See below)

Routine

Flu A/B (-)

No

No Further Action

Routine

No Further Action
Flowchart:

1. **Signs/Symptoms of Influenza Like Illness**
2. **Testing Desired (Y/N)?**
   - Yes
     - **Urgent or Routine?**
       - **Urgent**
         - **Rapid Antigen Test (Flu A/B)**
           - (Physician Office or Laboratory)
           - **Flu B (+)**: No Further Action
           - **Flu A (+)**: Is molecular sub-typing needed to facilitate management - treatment, infection control measures, prophylaxis (Y/N)?
             - Yes: **RVP (Respiratory Viral Panel)** Nasopharyngeal Swab Only
             - No: No Further Action
           - **Flu A/B (-)**: Is another test needed to exclude a viral respiratory infection (Y/N)?
             - Yes: **RVP (Respiratory Viral Panel)** Nasopharyngeal Swab Only
             - No: No Further Action
       - **Routine**
         - Perform RVP (See below)
         - Rapid Antigen Testing Not Needed
3. **Flu A (+)**: Perform RVP (See below)
4. **Flu B (+)**: No Further Action
5. **No**
6. **No Further Action**

**RVP Outcome Possibilities for Influenza A:**

1) Flu A H1*: seasonal Flu A H1
2) Flu A H3*: seasonal Flu A H3

* Note: If outcome 1 or 2 is present, the RVP **cannot** rule-out co-infection with novel H1N1 (2009) “Swine flu”.
Laboratory Guidance: Testing for Influenza H1N1 (Swine Flu)

1. A specific test for Swine Flu is not available.

2. If a specimen contains influenza B, it is not "Swine Flu".

3. At this time, Swine Flu should only be suspected in persons with symptoms compatible with influenza and
   a. Who have traveled to an area or resides in an area where there are confirmed cases of Swine influenza A (H1N1) OR
   b. Who have close contact to a confirmed case of Swine influenza A (H1N1) while the case was ill.

4. Three assays are available to test NP specimens:
   a. Influenza A and B rapid antigen test - results available rapidly (24/7) but not as sensitive as culture or the molecular assay - test performed at all three sites (BLS test code 42289).
   b. Comprehensive virus culture - most results available in 24-48 hours, available Monday through Sunday - test performed at Royal Oak (BLS test code 42330).
   c. Respiratory virus panel (molecular test) - results available in 24 hours, Monday-Saturday - test performed at Royal Oak (BLS test code 65425).

5. The appropriate specimen consists of two (2) nasopharyngeal (NP) swabs.

6. Appropriate Transport Media:

<table>
<thead>
<tr>
<th>Test</th>
<th>Royal Oak</th>
<th>Troy</th>
<th>Grosse Pointe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rapid antigen</td>
<td>M4-RT viral transport</td>
<td>Stuart’s bacterial transport</td>
<td>M5 viral transport</td>
</tr>
<tr>
<td></td>
<td>Amies bacterial transport</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comprehensive viral culture</td>
<td>M4-RT</td>
<td>M4-RT</td>
<td>M4-RT</td>
</tr>
<tr>
<td>Molecular-respiratory virus panel</td>
<td>M4-RT</td>
<td>M4-RT</td>
<td>M4-RT</td>
</tr>
</tbody>
</table>

NOTE:
   a. Nasal swabs are **inappropriate** for viral respiratory testing and will not produce accurate results.
   b. Swab specimens that are received in bacterial transport media (Amie’s or Stuart’s) are only appropriate for rapid antigen testing. These specimens **CANNOT** be used for viral culture or molecular testing!

Continued on other side
7. The county public health epidemiologist must give approval before specimens can be sent to MDCH for suspect cases of Swine Flu. Specimens that test positive for influenza A will not be accepted for further testing at MDCH (to differentiate seasonal influenza A from Swine influenza A) unless the requesting physician contacts an epidemiologist at the local county public health department with information about the patient including a travel history and contact with other persons who have compatible illnesses.

8. IMPORTANT: NP swab specimens must be collected in physician offices. The patient Service Centers are not prepared to collect these specimens.


Should you have any questions about this information, please do not hesitate to contact:

Barbara Robinson-Dunn, Ph.D., D(ABMM), Technical Director, Clinical Microbiology, Royal Oak
Bobby L. Boyanton, M.D., Medical Director, Clinical Microbiology, Royal Oak
Paul Goodman, M.D., Medical Director, Microbiology Laboratory, Troy
Suresh Gehani, M.D., Medical Director, Department of Laboratories, Grosse Pointe
Jeffrey D. Band, M.D., Corporate Epidemiologist

Effective Date April 30, 2009
New Serum Protein Electrophoresis / Monoclonal Gammopathy Evaluation Procedure

Beginning Monday October 26, 2009, the procedure for protein electrophoresis changed from our current gel-based zone electrophoresis to capillary electrophoresis. This results in a change in reference ranges as follows:

<table>
<thead>
<tr>
<th>Fraction</th>
<th>Current Reference Range (g/dL)</th>
<th>New Reference Range (g/dL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albumin</td>
<td>3.91-5.06</td>
<td>3.42-4.86</td>
</tr>
<tr>
<td>Alpha-1 globulins</td>
<td>0.12-0.24</td>
<td>0.22-0.41</td>
</tr>
<tr>
<td>Alpha-2 globulins</td>
<td>0.64-1.01</td>
<td>0.55-1.09</td>
</tr>
<tr>
<td>Beta globulins</td>
<td>0.61-1.08</td>
<td>0.53-1.01</td>
</tr>
<tr>
<td>Gamma globulins</td>
<td>0.69-1.38</td>
<td>0.80-1.65</td>
</tr>
</tbody>
</table>

Capillary electrophoresis is a more reproducible and rapid method for measuring serum protein components than gel-based zone electrophoresis. There may be a slight shift in monoclonal quantitation between the old and new method. The smaller monoclonal proteins (<1.0 g/dL) may be slightly increased and the larger monoclonal proteins (>2.0 g/dL) may be slightly decreased, by approximately 7%. Please consider re-establishing a baseline value in patients with known monoclonal gammopathies. There is also a change in the test menus available so that tests ordered through Royal Oak, Troy, and Grosse Pointe are consistent. The available tests for ordering are as follows:

1) Protein Electrophoresis, Serum:

This test includes capillary protein electrophoresis only. While this method is as sensitive as the former gel-based zone electrophoresis, it is less sensitive than immunofixation electrophoresis for detecting small monoclonal gammopathies. This test is suitable for screening for large monoclonal gammopathies, but if a monoclonal gammopathy is suspected clinically, recommend ordering the Serum Monoclonal Gammopathy Evaluation.
2) Immunofixation Electrophoresis, Serum:

This test includes immunoglobulin quantitations (IgG, A, M, kappa and lambda) and an immunofixation electrophoresis. If a monoclonal protein is detected, the peak cannot be quantitated by this method. The immunoglobulin quantitations alone may or may not be helpful depending on how much polyclonal immunoglobulin of a particular isotype is present.

3) Monoclonal Gammopathy Evaluation, Serum:

This test includes Serum Protein Electrophoresis and Serum Immunofixation Electrophoresis. Immunoglobulin Quantitations (Immunoglobulins G, A, M, kappa and lambda) will be included for 1) the initial evaluation of a patient with a new monoclonal gammopathy, 2) the initial evaluation of a patient with hypogammaglobulinemia, 3) as needed for those monoclonal gammopathies positioned such that other proteins obscure the monoclonal protein and 4) when immunoglobulin quantitations are requested as a separate order.

4) Immunoglobulins, Quantitative:

Includes IgG, A and M. This test does not reflex to a serum protein electrophoresis.

Effective Date October 26, 2009
Submitted by Yvonne Posey, MD, Assistant Medical Director, Special Testing, Royal Oak
Ralph Zade, MD, Medical Director, Clinical Chemistry, Troy
Suresh Gehani, MD, Medical Director, Department of Laboratories, Grosse Pointe
Off-Site Reference Laboratory Tests

The Beaumont Laboratory Services provides physicians and patients the ability to obtain highly specialized testing, of which most tests are performed on site. However, many tests will be sent to off-site reference laboratories (referred to as send-out tests). Not uncommonly, these requests are for tests that are not part of our laboratory test menu, or are included in our test menu as Patient Responsibility.

The category of Patient Responsibility billing permits Beaumont Laboratory Services to support the diagnostic needs of your outpatients (including BRL) by sending tests to off-site reference laboratories that otherwise would not be available through Beaumont. Such tests are listed as Patient Responsibility in our Laboratory Test Directory (LTD) which may be accessed online at www.beaumonthospitals.com/labtestdirectory.

If you are planning to order a test in the Patient Responsibility billing category, please call the laboratory, 248-551-9045, prior to sending the patient to be drawn. We will supply the necessary documents to obtain testing. Since reimbursement from insurances differ, we will encourage patients to contact the outside testing laboratory to ensure preauthorization is obtained when needed. This will not only avoid a delay in testing but will also ensure the patient is aware of any cost for which they may be held responsible.

By policy, only tests included in the Beaumont Lab Test Directory are orderable through our laboratory. If there is a test that you would like added to the LTD you may submit a request. Please forward your request, in writing, to the Clinical Practice Council, c/o Mark D. Kolins, MD, Chief Medical Executive of Beaumont Laboratory Services, 3601 W. 13 Mile Road, Royal Oak, MI 48073. Tests will be reviewed by the Clinical Practice Council; submitters will be offered the opportunity to present a test’s clinical utility to the council.

We appreciate your cooperation and we are ready to help provide the needed testing for your patients.

Respectfully,

Mark D. Kolins, MD
Chief Medical Executive
Beaumont Laboratory Services

Effective Date: Tuesday, April 14, 2009
OUTREACH SPECIMEN LABELING REQUIREMENTS

REMINDER: Beaumont Laboratory requires two identifiers for all specimens submitted for testing at any Beaumont laboratory.

Why are we requiring this? It's a matter of patient safety. Every day, specimens are received with crack and peel label only; without a patient name; labeling that does not match the requisition; or no labeling at all. Improperly labeled or unlabeled specimens cause delays in receiving your test results and may lead to medical errors in patient diagnosis and treatment.

Reference: The Joint Commission, National Patient Safety goals, NPSG 1 - Patient Identification, Two Patient Identifiers

What are the consequences if specimens are not labeled correctly? Effective January 1, 2010, specimens that are not correctly labeled will be discarded, with the exception of those specimen types classified as “irretrievable” (e.g., fresh tissue, bone marrow, products of conception, biopsy, FNA, or any fluids including amniotic, CSF, synovial).

What are the acceptable identifiers?
- Patient’s Full Name (handwritten clearly)
- Birth Date (handwritten clearly – example A below)
- Crack and Peel Label (for specimens submitted with a Beaumont Laboratory Outreach requisition form – example B below)
- Patient Identification (patient’s Beaumont ID number or last 4 digits of SSN)

Are there any additional labeling requirements? Yes, there are additional labeling requirements for the following specimens:
- Drug Levels – should indicate peak/trough and time of draw
- Blood Cultures – indicate number of culture (#1, #2, #3, etc.) and time of collection
- Glucose Tolerance Test – indicate fasting, 1 hr, 2hr, etc.
- Blood Bank (pink EDTA tubes for ABO, Rh and antibody screens):
  - Patient’s Full Name (first and last; spelled correctly and written clearly);
  - Crack and Peel Label - OR - Patient’s Beaumont ID number; AND
  - Date of Collection

Effective Date: November 11, 2009
Submitted by: Mark D. Kolins, MD, Chief Laboratory Medical Executive, Beaumont Laboratory
Physicians Notice

In its compliance guidance for clinical laboratories, the Office of the Inspector General (OIG) recommends that all clinical laboratories distribute a physician notice to its ordering clients at a minimum once per year. In an effort to comply with these recommendations, Beaumont Laboratory is providing this Physicians Notice delineating the guidelines used by Beaumont Laboratory for submitting claims to Medicare, Medicaid, and other federally funded healthcare programs.

Medicare Medical Necessity

The Centers for Medicare and Medicaid (CMS) and the OIG recognize that physicians and other authorized individuals must be able to order any test that they believe are appropriate for the treatment or diagnosis of their patients. As the physician, you may order any test(s), including screening tests that you believe are appropriate for the treatment of your patients. Each test must be accompanied with a valid ICD-9 code or narrative (i.e., diagnosis, signs, symptoms or clinical complaint). Use of outdated terminology (e.g., SMAC, SMA21, Chem 12, etc.) or wording that is subject to multiple interpretations (e.g., Liver Function Test [LFT], Fasting Lipid Test [FLT], FLP, etc.) when ordering lab tests requires that our Customer Service staff contact your office for clarification. In an effort to reduce interruptions that these calls have on your practice, laboratory requisition forms are designed to assist you in communicating diagnostic information to the highest degree of accuracy and completeness at the time the test is ordered. However, Medicare will only pay for tests that are covered, reasonable, and necessary for the individual patient given his or her clinical condition.

For Beaumont Laboratory to bill Medicare, you must specify a valid, medically appropriate ICD-9 code (or provide a narrative diagnostic information), which is supported by the patient’s medical record, for each test that you order, including all tests listed as part of organ or disease-oriented panels.

National Coverage Determinations (NCD), Local Coverage Determination (LCD), and Limited Coverage Tests

The Centers for Medicare and Medicaid Services (CMS) has 23 National Coverage Determinations (NCD’s) regarding clinical laboratory tests. The following National Coverage Determinations (NCD’s) were developed by the Centers for Medicare and Medicaid Services and became effective November 25, 2002. They are binding on all Medicare carriers and supersede existing carrier local medical review policies (LCD’s). CMS updates NCD’s on a quarterly basis and can be accessed on CMS’s Clinical Labs Center using the following web address: http://www.cms.hhs.gov/center/clinical.asp.

Advance Beneficiary Notice

The Medicare program will allow the laboratory to bill the patient for denied services only if an Advance Beneficiary Notice (ABN) is forwarded to the laboratory with the test requisition. The ABN must be completed by the ordering physician and signed by the patient; the ABN is intended to inform the patient that Medicare will not pay for the services that it determines to be not reasonable and necessary under Section 1862(a)(1) of the Medicare Lab. Medicare does not pay for:

1) tests that are limited coverage unless the ICD-9 code supports medical necessity;
2) tests that are considered noncovered;
3) tests that exceed frequency limits established by Medicare; or
4) tests that are for experimental or research use

Medical Laboratory Fee Schedule:

CMS provides you with the Clinical Labs Center website to communicate information specific to Clinical Laboratories. To view the laboratory fee schedule for year 2007 go to: http://www.cms.hhs.gov/ClinicalLabFeeSched/01_overview.asp

Additionally, Medicaid reimbursement will be equal to, or less than Medicare reimbursement.

American Medical Association (AMA) Approved Organ or Disease Oriented Panels

The American Medical Association (AMA) has grouped certain tests into panels for coding purposes only. If one orders tests in addition to those specifically indicated for a particular panel, those tests are billed separately in addition to the panel code. A valid diagnosis code must be provided for each AMA-approved panel ordered. Individual components of these panels may be ordered separately. When ordering tests for Medicare or Medicaid patients, the physician should:
1) Only order those tests that he or she believes are medically necessary for each patient.
2) Be aware that using a customized panel/profile may result in ordering tests for which Medicare or Medicaid will deny payment.
3) Order individual tests or a less inclusive panel/profile if all analytes in the panel/profile are not medically necessary.
4) Understand that the U.S. Department of Health and Human Services, Office of Inspector General takes the position that a physician who orders medically unnecessary tests may be subject to civil penalties.

Reflex Testing
Reflex testing occurs when initial test results are positive or outside normal parameters and indicate that a second related test or further testing is medically appropriate. Mandated testing criteria set by government or accrediting agencies, relevant practices in laboratory medicine, and avoidance of performing unnecessary testing help dictate, which tests are subject to reflexive testing. Upon results of an initial laboratory test, reflex tests will be performed as outlined based on, “ALGORITHMS FOR REFLEX TESTS” located on Inside Beaumont or on the internet at: Laboratory Resources | Beaumont Hospitals. Some reflex testing may result in additional charges. If you DO NOT want reflex testing, please clearly communicate this request on the laboratory test requisition form and contact Customer Services at 800-551-0488 or 248-551-1155.

Screening Pap Tests
The College of American Pathologists, the accrediting organization for the Laboratory, requires that providers of cervicovaginal specimens be periodically notified that screening Pap tests are performed to primarily test for squamous cancers and its precursors and can have associated false negative or false positive results. Liquid based preparations may decrease but will not eliminate all false negative results. Regular sampling and follow-up of unexplained clinical signs and symptoms are recommended to minimize false negative results.

Physician Clinical Consultants
Beaumont has a professional staff of over forty pathologists and Ph.D. scientists specializing in all areas of laboratory medicine. Our medical staff is available to discuss laboratory testing questions including ordering and interpretation or contact Mark Kolins, M.D., Chief Laboratory Medical Executive and Clinical Professor, Clinical Pathology.

Questions
Please feel free to contact Customer Service at 800-551-0488 or 248-551-1155 if you should have any further questions.

Submitted by: Sherri D’Anna, Quality Assurance Coordinator, Beaumont Laboratory

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Serum IgG, IgA, IgM, C3, C4, Vitamin D and Ureaplasma Cultures

Grosse Pointe Beaumont Hospital Medical Staff:

Serum IgG, IgA, IgM, C3, C4, Vitamin D and Ureaplasma Cultures will be sent to Beaumont Reference Laboratories at Royal Oak instead of ARUP Laboratories. These results can be viewed on EPIC OneChart.

Specimen collection, reference ranges and interpretation can be seen on “Inside Beaumont Online” by clicking on <References> and <Lab Test Directory> or at: www.beaumonthospitals.com/labtestdirectory
Patients’ results include the reference ranges.

For any questions, contact BRL (Beaumont Reference Laboratory) Customer Service at 1-800-551-0488.

Effective Date April 27, 2009
Submitted by Suresh Gehani, M.D.,
Medical Director, Grosse Pointe Laboratories
Isabel Gauss, MS, MT (ASCP)
Administrative Director, Grosse Pointe Laboratories
SPECIMEN LOCK BOX USAGE GUIDELINES

GENERAL SPECIMEN LOCK BOX USE:
- The Beaumont Laboratory lock box is provided for your convenience to leave laboratory specimens for pickup only after your office closes.
- It is recommended these boxes be placed in a protected area, preferably inside the building, to minimize environmental exposures and public access. (Location will be agreed upon at account set-up with your client representative.)
- Please keep the boxes locked at all times. Each lock box is provided with a key.
- WHEN OUTSIDE TEMPERATURE IS GREATER THAN 90°F: Take a cold pack from freezer. Wrap the cold pack in paper toweling and place in the bottom of the box. (Wrapping will prevent the specimen from resting directly on the cold pack.)
- Keep CULTURES farthest away from any type of cold pack.

IMPORTANT NOTES:
1. When the Beaumont Laboratory courier arrives at your office and there are no specimens available for pick up, they will leave a visible yellow flag in the door of your box. Please do NOT put specimens in a flagged box without calling Courier Services for an additional pick-up.
2. If the OFFICE IS CLOSING EARLY, please notify Beaumont Laboratory Courier Services at 1-800-551-0488.
3. Beaumont Home Care specimens should be dropped off regularly throughout the day at various specified locations.

BEAUMONT LABORATORY SPECIMEN INTEGRITY PRACTICES:
- When outside temperatures are 32°F or less, Beaumont Laboratory couriers will pick-up specimens within two hours of your posted office closing hours.
- When outside temperatures exceed 90°F at office closing time, include a cold pack with specimens in the box as described above under General Use.
- For specimens requiring serum/plasma centrifugation and freezing, put frozen specimen in provided frozen specimen container and then place in lock box.

REMEMBER:
- Wrap cold pack in paper toweling before placing in the box.
- Keep CULTURES farthest away from any type of cold pack.
- Lock the box.
- Call Beaumont Laboratory Courier Services if the office is closing early.

COURIER INFORMATION:
- General courier hours are Mon-Fri 8 am - 9 pm; Sat 8 am - 7 pm; Sun 9 am - 4 pm.
- Specimen pick up times are individual per client. Please schedule with your Beaumont Laboratory client representative.
- Questions/Concerns? Call 1-800-551-0488.

Effective Date: May 29, 2009
Submitted by: Mark D. Kolins, MD, Chief Laboratory Medical Executive, Beaumont Laboratory
Donald Henderson, Administrative Director, Clinical Pathology
THERAPEUTIC APHERESIS SERVICE (PLASMApheresis – APHERESIS)  

COVERAGE CHANGE AT THE ROYAL OAK CAMPUS

As of October 1, 2009, the therapeutic apheresis service (plasmapheresis – apheresis) will be managed under the Division of Nephrology with Dr. Francis Dumler as the Medical Director. Due to the closing of the Donor / Apheresis Center on 1 South Tower, all outpatient apheresis patients' procedures will be performed in the Acute Hemodialysis Unit (5th Floor Central Tower).

For all apheresis requests (outpatient scheduling and inpatient consults) after September 30, 2009, please contact the Acute Hemodialysis Unit at (Phone: 248-898-1666) or contact Dr. Dumler (Phone: 248-551-1010 or Beeper 21468).

For all emergent apheresis procedures or consults (i.e. plasma exchanges, red cell exchange, platelet reduction, leukocyte reduction, etc), please contact Drs. Francis Dumler or H. Gampala Reddy via the page operator (Therapeutic Apheresis Service On Call Roster) or the urgent apheresis beeper (54646).

Effective Date: October 1, 2009
Submitted by: Peter A. Millward, MD
Medical Director, Blood Bank, Royal Oak
Warfarin (Coumadin) Hyper-Responsiveness Genotyping (CYP2C9 Genotyping):

- One in five of Caucasians do not metabolize warfarin normally and are at significantly increased risk for preventable bleeding complications.

- Over anticoagulation can be life threatening.

- Current data demonstrates that patients on warfarin have a significant risk of hemorrhagic complications (0.25%-0.8% for fatal hemorrhage, 1.1%-4.9% for major hemorrhage and 6.2%-15% for minor hemorrhagic events).

- Determining the optimal therapeutic window of an individual patient can be challenging because of the wide variability in the response to a dose of warfarin.

- This variability is due to genetic factors affecting warfarin metabolism. The main gene associated with warfarin metabolism is the CYP2C9 gene.

- Polymorphisms (variants) in the CYP2C9 gene are associated with hyper-responsiveness to standard coumadin doses and an increased risk of significant and preventable bleeding complications.

- Testing is available at Beaumont Laboratory Services for the most common polymorphisms (variants) that have been associated with warfarin hyper-responsiveness.

- Testing is performed on a peripheral blood sample.

- Testing is performed in Clinical Pathology, Beaumont Hospital, Royal Oak, MI and the turnaround time is less than 7 days.

- Further questions may be directed to Dr. Domnita Crisan, Molecular Pathology, Royal Oak.

Effective Date January 14, 2009
Submitted by Emily Volk, MD, Beaumont Hospital, Troy
Domnita Crisan, MD, PhD, Beaumont Hospital, Royal Oak
WHAT BLOOD COLLECTION PRODUCT SHOULD YOU USE?

FACTS:
- The “gold standard” for routine venipunctures is the straight blood collection needle used in combination with a blood collection holder.
- Blood collection set needles (also known as “butterflies” or “wingsets”) have similar gauge sizes as straight needles. (Healthcare workers and patients often perceive the shorter needle length to be a smaller puncture size and to “hurt” less.)
- Butterfly needles are responsible for the majority of needle stick exposures in phlebotomists.
- A needle that is too small (i.e., 23G or 25G) increases the chance of a hemolyzed specimen and erroneous test results. This could result in a request for redraw.

Therefore, select the most appropriate blood collection system that will not compromise specimen quality or patient and phlebotomist safety.

### COMMON VENIPUNCTURE NEEDLE TYPES WITH GAUGE, PUNCTURE SIZE, AND TYPICAL USE

<table>
<thead>
<tr>
<th>IMAGE</th>
<th>GAUGE &amp; PUNCTURE SIZE</th>
<th>NEEDLE TYPE</th>
<th>TYPICAL USE</th>
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</table>
| ![Image](image1.png) | 21 .032” | BD Eclipse™ – attaches to BD holder for multi-sample collection | - The “gold standard” for routine venipunctures  
- Recommended as the “first line” product.  
- Patients with normal veins. |
| ![Image](image2.png) | 22 .028” | BD Eclipse™ – attaches to BD holder for multi-sample collection | - Older children  
- Adult patients with small or difficult veins. |
| ![Image](image3.png) | 23 .025” | BD Safety-Lok™ – attaches to BD multi-sample holder or syringe* | - Veins of infants and children  
- Difficult or hand veins of adults  
*Requires additional luer adapter for multi-sample holder or syringe transfer device to fill tubes. |
| ![Image](image4.png) | 25 .020” | BD Safety-Lok™ – attaches to BD syringe**. Should not be used on multi-sample holder. | - Should be used rarely  
- Tiny veins of premature infants and other neonates  
**Requires additional syringe transfer device to fill tubes. |

PLEASE NOTE:
For most patients, the straight 21G and 22G needles are a reasonable substitute for a 23G blood collection set because they require less additional steps and equipment, have an easier safety mechanism activation, have a lower needle stick incidence and help reduce healthcare costs.

Ask your laboratory representative for additional literature on the use of these products.

Effective Date: April 30, 2009
Submitted by:
Mark D. Kolins, MD, Chief Laboratory Medical Executive, Beaumont Laboratory Services
Keith Reynolds, MT(ASCP), Phlebotomy Supervisor, Clinical Pathology – Royal Oak
Nancy Ramirez, MS, MT(ASCP)SH, Education Coordinator, Clinical Pathology – Royal Oak
Anti-Double Stranded DNA Antibody Testing

Effective September 26th, all samples that test borderline or positive for anti-double stranded DNA antibodies by ELISA will also be tested by indirect immunofluorescence (IFA – IgG specific) using Crithidia luciliae as substrate. Results of samples that are positive by IFA will be reported with a titer using dilutions up to 1:640. IFA is generally considered more specific but less sensitive than ELISA for the detection of antibodies to double stranded DNA. There will be no changes to specimen requirements.

ELISA reference range:  
- < 30 IU/mL  Negative
- 30 – 75 IU/mL  Borderline
- > 75 IU/mL  Positive

IFA reference range:  
- < 1:10  Negative

Testing performed:  
- ELISA  Mon, Wed, Fri
- IFA  Tues, Thurs

Effective:  September 26, 2010

Submitted by:  Elizabeth Sykes, MD, Medical Director, Automated Chemistry and Special Testing, Royal Oak
Gabriel Maine, PhD, Technical Director, Special Testing, Royal Oak
Auto-Antibody Reference Range Changes

Effective June 28, 2010, reference ranges for the auto-antibody tests indicated below will change. Our supplier will soon discontinue manufacturing the testing reagents, prompting the selection of another vendor. All tests will continue to be performed by enzyme-linked immunosorbent assay (ELISA). No changes are being made to specimen collection requirements. Beaumont’s Special Testing Laboratory has independently validated the products from the new vendor.

### NEW REFERENCE RANGES

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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Negative:</td>
<td>≤ 0.90</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indeterminate:</td>
<td>0.91-1.09</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive:</td>
<td>≥ 1.10</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Effective: June 28, 2010

Submitted by: Gabriel Maine, PhD, Technical Director, Special Testing, Royal Oak
Elizabeth Sykes, MD, Medical Director, Automated Chemistry and Special Testing, Royal Oak
BK VIRUS QUANTITATION – URINE AND SERUM

On June 28, 2010, Beaumont Laboratory (Molecular Pathology) will begin BK viral load testing on urine and serum specimens.

Note the following advantages of testing being performed at Beaumont Laboratory:

1. NO need to re-baseline your patients - internal correlation studies demonstrated near perfect correlation between the Beaumont Laboratory and current reference laboratory (Focus Diagnostics) methods.

2. NO change in current specimen collection and handling requirements:
   • Minimum sample volume: Urine (1.0 mL), Serum (0.5 mL)

3. Result (copies/mL) will be reported in both integer and scientific notation formats.

4. Urine and Serum specimens will be ordered and reported separately, so that result trending based upon specimen source will now be possible.

5. Faster turn around time as compared to our current reference laboratory:
   • Testing will be performed on Tuesday and Friday
   • Results available within 24 hours

For complete specimen collection and handling instructions, please refer to the on-line Laboratory Test Directory:
   • Internal URL: http://beaunet.beaumont.edu/portal/pls/portal/lab.lab_pkg.lab_list
   • External URL: http://beaumonthospitals.com/labtestdirectory

If you need additional information, please contact Client Services at 1-800-551-0488, option 5.

Effective Date: June 28, 2010

Submitted by: Bobby L. Boyanton Jr., M.D., Medical Director, Clinical Microbiology, Associate Medical Director, Molecular Pathology
Dilip Samarapungavan, MD, MRCP, Medical Director, Multi-Organ Transplantation
Changes - Glucose Reference Ranges, GTT Availability, Acetone Order

The following changes will take place at the time of the June 27, 2010 Misys roll-over:

GLUCOSE REFERENCE RANGES

Lab glucose testing

Unless specifically ordered as a “fasting glucose”, all laboratory glucose results will be reported with the following reference ranges. The fasting range will be used to trigger an abnormal flag.

- Fasting glucose: 60 – 99 mg/dL
- Random glucose: 60 – 139 mg/dL

Glucose meter testing

Results from glucose meters will be reported with the random range of 60 – 139 mg/dL and this range will be used to trigger an abnormal flag. In addition, the following note will be attached to the result:

“If this is a fasting glucose, reference range is 60-99 mg/dL. Glucose meter results should not be used for the diagnosis of diabetes.”

Pregnancy Glucose Tolerance Test

The 3 hour pregnancy GTT (100 g glucola) will be reported with the most recent ADA recommended cut-offs. Diagnosis of gestational diabetes requires the patient to have 2 abnormal results.

- Fasting: < 95 mg/dL
- 1 hour: < 180 mg/dL
- 2 hour: < 155 mg/dL
- 3 hour: < 140 mg/dL

IN-PATIENT (NON-PREGNANT) GLUCOSE TOLERANCE TESTING

Glucose tolerance testing for non-pregnant patients will NOT be performed on in-patients. It is recommended that GTTs be performed on patients who are not acutely ill and who are eating a regular diet containing at least 100 g carbohydrate/day for at least 3 days prior to the GTT.

ACETONE (SERUM) CHANGE AT ROYAL OAK

Requests for “acetone” at Royal Oak will be automatically converted to beta hydroxybutyrate. The current “acetone” test is qualitative – it measures primarily acetoacetate and some acetone, but does not detect beta hydroxybutyrate. If a specific acetone level is required, the “Toxic Serum Alcohol Screen” should be ordered.

Effective Date: June 27, 2010

Submitted By: Elizabeth Sykes, MD, Medical Director, Automated Clinical Chemistry and Special Testing, Royal Oak
Beatrice Muglia, MD, Chemistry, Grosse Pointe
Ralph Zade, Jr., MD, Chemistry, Troy
**Clostridium difficile TESTING UPDATE**

On **November 1, 2010**, Beaumont Laboratory will rely solely upon **real-time PCR** for the detection of **toxigenic Clostridium difficile** using the FDA-approved BD GeneOhm Cdiff assay.

The new test offers the following **advantages**:

1) Exceptional sensitivity (>95%) and specificity (>95%).

2) Quick Results: Testing performed every 8 hours, 7 days per week.

3) No change in specimen collection requirements:
   
   a. Liquid or soft stool in a sterile container **without preservatives**
   
   b. Specimen handling:
      - Maintain specimen at **room temperature** up to 48 hours
      - Maintain specimen at **refrigeration temperature** up to 5 days

4) No need for serial testing (i.e., 1 test per day for 3 days, etc.).

**Special circumstances where testing will NOT be performed:**

1) Stool specimens that do NOT conform to the shape of the collection container.

2) Specimens obtained during endoscopy procedures.

3) Repeat stool specimens if the patient had a previous real-time PCR test performed within 7 days.

Exceptions require approval by the Medical Director or Technical Director of the Microbiology Laboratory.

For complete specimen collection and handling instructions, please refer to the on-line Laboratory Test Directory:

- **Internal URL**: [http://beaunet.beaumont.edu/portal/pls/portal/lab.lab_pkg.lab_list](http://beaunet.beaumont.edu/portal/pls/portal/lab.lab_pkg.lab_list)

If you need additional information, please contact client services (1-800-551-0488, option 5).

---

**Effective Date**
November 1, 2010

**Submitted by**
Bobby L. Boyanton, M.D., Medical Director, Clinical Microbiology; Associate Medical Director, Molecular Pathology, Royal Oak
Barbara Robinson-Dunn, Ph.D., Technical Director, Clinical Microbiology, Royal Oak
**Clostridium difficile TESTING UPDATE – DECEMBER 2010**

Beaumont Laboratory switched from enzyme immunoassay (EIA) to **real-time PCR** as the sole testing modality for detecting **toxigenic Clostridium difficile** on November 1, 2010. The purpose of this memorandum is to 1) highlight the impact of this new test, and 2) clarify your questions about specimen collection and handling, testing frequency, and rejection criteria.

**Highlights of this highly sensitive and specific test are as follows:**

1) Detection Rate has doubled: 11% by EIA vs. 22% by real-time PCR

2) Improved turn-around-time: (testing intervals)
   a. Monday – Friday (every 8 hours); Weekends (every 12 hours)

3) Improved Utilization of Beaumont Staff:
   a. **Cessation of Serial Testing.** There is NO longer a need to order, collect, and test a stool specimen each day over a two to three day period.
   b. No change in specimen collection requirements:
      - liquid or soft stool in a **sterile** container **without preservatives**
      - maintain stool at **room temperature** up to 48 hours
      - maintain stool at **refrigeration temperature** up to 5 days

**ENDOSCOPY-collected stool specimens WILL be tested.** A comment will be added to the report, reminding the care provider as to the nature of collection.

**Circumstances where testing will NOT be performed:**

1) Stool specimens that do NOT conform to the shape of the collection container.

2) Repeat stool specimens if the patient had a previous real-time PCR test within 7 days.
   Remember - “Serial testing” is no longer needed with real-time PCR testing.

Exceptions to the above require approval by the Medical Director or Technical Director of the Microbiology Laboratory.

For complete specimen collection and handling instructions, please refer to the on-line Laboratory Test Directory:

- Internal URL: [http://beaunet.beaumont.edu/portal/pls/portal/lab.lab_pkg.lab_list](http://beaunet.beaumont.edu/portal/pls/portal/lab.lab_pkg.lab_list)
- External URL: [http://beaumonthospitals.com/labtestdirectory](http://beaumonthospitals.com/labtestdirectory)

If you need additional information, please contact Customer Services (1-800-551-0488, option 5).

Bobby L. Boyanton Jr., M.D.  
Medical Director, Microbiology  
Assoc. Medical Director, Molecular Pathology

Barbara Robinson-Dunn, Ph.D.  
Technical Director, Microbiology
FECAL LACTOFERRIN (LEUKO EZ VUE)

On July 12, 2010, Beaumont Laboratory will begin using the Fecal Lactoferrin test in place of the Fecal Leukocyte test for the determination of neutrophils in fecal specimens. The Fecal Lactoferrin test provides faster turn around time and improved neutrophil detection sensitivity, which facilitates the differentiation of inflammatory and non-inflammatory intestinal disorders.

Important Notes:

1. The Fecal Lactoferrin test requires the collection fresh stool (No Preservatives)
2. The Fecal Leukocyte (WBC) test requires preserved stool (SAF)
3. The Fecal Lactoferrin test will yield a false positive result for patients who are breast-feeding. In this situation, the Fecal Leukocyte test MUST be ordered.

Common Questions and Answers for the Fecal Lactoferrin Test:

Test Order: Fecal Lactoferrin.

Sample Collection: Fresh stool, placed into a clean, air-tight container with NO preservatives.

Sample Handling: Send to the Laboratory at room or refrigerated temperature.

What happens if I accidentally order the Fecal Leukocyte test? The Laboratory will still perform the Fecal Leukocyte test; however, this test should be reserved for breast-feeding patients.

For additional information, please utilize the following resources:

On-line Laboratory Test Directory:
- Internal URL: http://beaunet.beaumont.edu/portal/pls/portal/lab/lab_pkg.lab_list
- External URL: http://beaumonthospitals.com/labtestdirectory

Contact Client Services at 1-800-551-0488, option 5.

Effective Date: July 12, 2010

Submitted By:
- Bobby L. Boyanton Jr., M.D.
  Medical Director, Clinical Microbiology, Royal Oak
  Associate Medical Director, Molecular Pathology, Royal Oak
- Barbara Robinson-Dunn, Ph.D., D(ABMM)
  Technical Director, Clinical Microbiology, Royal Oak
- Paul Goodman, M.D.
  Medical Director, Microbiology, Troy
- Vaishali Pansare, M.D.
  Director, Microbiology, Grosse Pointe

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www.beaumonthospitals.com/labs
HBV VIRAL LOAD TESTING - UPDATE

During the month of September 2010, the Molecular Pathology Laboratory will switch HBV viral load testing platforms from the COBAS Amplicor HBV Monitor Test to the FDA-approved COBAS TaqMan HBV Test (Roche Diagnostics Corporation).

This new test method offers the following:

- improved **sensitivity** *(29 IU/mL)*
- greater dynamic range for **quantitation** *(29 to 110,000,000 IU/mL).*
- **NO need to re-baseline or re-calibrate your patients**

Specimen Collection Summary:

- **acceptable specimens:** EDTA-plasma or serum.
- **minimum sample volume** is **1.0 mL**.

Special Note:

This will be a seamless transition to you and your patients.

There will be **NO need to re-baseline or re-calibrate your patients**, as correlation studies performed by our laboratory have demonstrated exceptional correlation between the new and previously utilized methods.

**Effective Date:** September 8, 2010

**Submitted By:** Bobby L. Boyanton Jr., M.D.
Medical Director, Clinical Microbiology
HCV VIRAL LOAD TESTING – UPDATE

On December 6, 2010, the Molecular Pathology Laboratory will switch HCV viral load testing platforms from the Versant HCV RNA 3.0 assay (Siemens) to the FDA-approved, COBAS AmpliPrep/TaqMan HCV Test (Roche).

This new test method offers the following advantages:

- Improved sensitivity (43 IU/mL)
- Greater dynamic range for quantitation (43 to 69,000,000 IU/mL)
- NO need to re-baseline or re-calibrate your patients

Specimen Collection Summary:

- Acceptable specimens: serum or plasma
- Minimum sample volume: 1.1 mL of serum or plasma
- Separate serum or plasma (centrifuge) within 6 hours of collection

For complete specimen collection and handling instructions, please refer to the “on-line” Laboratory Test Directory:

Internal URL: http://beaunet.beaumont.edu/portal/pls/portal/lab.lab_pkg.lab_list
External URL: http://beaumonthospitals.com/labtestdirectory

Special Note:

This will be a seamless transition to you and your patients.

There will be NO need to re-baseline or re-calibrate your patients, as correlation studies performed by our laboratory have demonstrated exceptional agreement between the new and previously utilized methods.

If you need additional information, please contact client services (1-800-551-0488, option 5).

Effective Date: December 6, 2010

Submitted By: Bobby L. Boyanton Jr., M.D.
Medical Director, Microbiology
Associate Medical Director, Molecular Pathology

Domnita Crisan, M.D., Ph.D.
Medical Director, Molecular Pathology
Heparin Platelet Factor 4 Antibody testing

On October 15th, the new Beaumont Heparin Induced Thrombocytopenia (HIT) algorithm will be implemented. This involves changes in EPIC ordering and laboratory testing.

Ordering in EPIC:

- At the time of ordering, the physician will be asked to input the 4Ts score. Hyperlinks to guideline documents will be shown during the ordering process. Details on the 4Ts score can also be found on the Inside Beaumont web site at References, All References, Anticoagulation Resources, Clinical Practice Guidelines, 4Ts scoring.

Beaumont Lab’s approach to Platelet Factor 4 Antibody testing:

- Heparin platelet factor 4 antibody testing will be performed by ELISA and the optical density (OD) result, together with the likelihood of having a serotonin release assay (SRA) positive result, will be reported. The ELISA is being changed to the IgG specific assay from the polyclonal assay currently in use.

- Cut-off times for ELISA testing: 11 am - Monday to Friday
  10 am - Saturday/Sunday.

- OD result and follow-up:

  Less than 0.4  Negative - no further action taken

  Between 0.4 and 1.99  Sample automatically sent out for SRA to Blood Center for Wisconsin

  Equal to or greater than 2.0  No further action will be taken because the likelihood of HIT is very high. An OD result of ≥ 2.0 will represent a critical value and will be called to the nursing unit or physician.

- SRA results should be available 1 – 4 days following the initial request. SRA testing is only performed on weekdays and therefore samples sent out from Beaumont on Friday will not be available until late Monday.

- SRA only requests – if an order for only an SRA is received, the physician may be contacted to determine whether the order is appropriate (as outlined in the new algorithm).

Effective Date: October 15, 2010
Submitted by: Elizabeth Sykes, MD, Medical Director, Automated Chemistry and Special Testing, Royal Oak

References:
Warkentin TE Br J Hematol 2003;121:535-55
Warkentin TE, Linkins LA J Throm Haemost 2010 PMID 20403090
Influenza Testing Recommendations - 2010

Information from the CDC and the World Health Organization indicates that nH1N1 (2009) influenza A, seasonal influenza A H3N2 and influenza B are currently circulating globally and likely to be seen in Michigan this viral respiratory season. Fortunately, these three viruses are still predominantly susceptible to oseltamivir (Tamiflu) and zanamivir (Relenza). Therefore, molecular sub-typing should not be needed unless seasonal influenza A H1N1 is identified.

Note: The sensitivity of rapid antigen tests is suboptimal (40% to 60% detection), therefore if testing is necessary, please consider the use of PCR or viral culture. If testing is necessary, the following approach is recommended (also see included Algorithm):

Specimen Collection: All swabs (rayon, Dacron, flocked) must be placed into viral transport medium (M4-RT, M5, or universal transport media [UTM]) and refrigerated until received in the laboratory.

Nasopharyngeal (NP) Specimens:
1) Non-urgent testing: (Order ONLY one of the following tests)

   NOTE: Rapid Antigen Testing for Influenza A is NOT Recommended for Non-Urgent Testing

   a) *Respiratory Virus Panel (RVP) by PCR*. (Outreach order code 65425)
      - **Performed** (Mon – Sat, results available in 24 – 48 hr).
      - **Detects** influenza A with sub-typing, influenza B, RSV A/B, human metapneumovirus, adenovirus, rhinovirus/enterovirus, and parainfluenza viruses 1, 2, 3.
      - **Note:** If RVP by PCR result is “influenza A, unable to subtype as seasonal H1 or seasonal H3”, there is a high probability (>99%) of nH1N1 (2009) influenza A virus infection, formerly called “Swine Flu”. In this situation, you do NOT need to order the *Influenza A nH1N1(2009)* by RT-PCR test.
      - **Limitation:** The RVP by PCR test can NOT rule out a co-infection with nH1N1 (2009) influenza A if seasonal influenza A, subtype H1 or H3 is detected. However, it will be able to detect a co-infection with other respiratory viruses.
      - **When to order RVP by PCR:** If you suspect the patient may be infected with respiratory viruses other than influenza A, or if you suspect co-infection with influenza A and other respiratory viruses.

   b) *Influenza A nH1N1 (2009) by RT-PCR*. (Outreach Order Code 65445)
      - **DO NOT order at this time**
      - **We DO NOT anticipate a clinical need for this test during the 2010 – 2011 viral respiratory season.**
      - **If utilization of this test becomes clinically necessary, healthcare providers will be immediately notified.**

Continued on Back
Continued from Front

2) **Urgent testing: (RAT):**
   a) Rapid Antigen Test (RAT): Order *influenza A/B EIA.* (Outreach Order Code 42289)
      - **Performed** (Mon – Sun, results available same day)
      - **Detects** influenza A and influenza B viruses
      - **Limitation:** Rapid Antigen Tests are insensitive and can miss up to 50% of patients that are truly infected with an influenza virus. For this reason, please note the following test result scenarios and the proposed additional testing recommendations if you desire to order rapid antigen tests
      - **Result Scenarios:**
        1) If RAT is positive for influenza A, is another test needed for the following indications: 1) sub-typing to facilitate management (treatment, infection control measures, prophylaxis), or 2) detect co-infection with other respiratory viruses.
           i. If **Yes**, please order RVP by PCR (Outreach order code 65425).
           ii. If **No**, no further action is required.
        2) If RAT is negative for influenza A/B and the patient is quite ill or in a high-risk group for complications, then order RVP by PCR (Outreach order code 65425) to determine if a viral etiology is present.
        3) If the result is positive for influenza B, further testing is NOT needed.

**Non-NP Specimens (BAL, bronchial washing, lung biopsy, sputum, etc.)**
1) Order comprehensive viral culture: (Outreach Order Code 42365).
2) **Performed** (Mon – Sun, results available in 24 – 48 hr).
3) **Detects** influenza A, influenza B, RSV, adenovirus, and parainfluenza viruses 1, 2, 3.

**High Risk Groups for Severe Influenza**

- Child <5 years
- Adult >65 years
- Pregnant women
- Immunocompromised host
- Long term care facility resident
- Chronic underlying disease
- Persons <19 years of age and on chronic aspirin therapy

Continued on next page
Influenza Antiviral Drug Susceptibility (2009-2010 Influenza Season)**

<table>
<thead>
<tr>
<th>Antiviral Drug</th>
<th>Seasonal A H3N2</th>
<th>nH1N1 (2009) “Swine”</th>
<th>Seasonal B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oseltamivir (Tamiflu)</td>
<td>Sensitive</td>
<td>Sensitive</td>
<td>Sensitive</td>
</tr>
<tr>
<td>Zanamivir (Relenza)</td>
<td>Sensitive</td>
<td>Sensitive</td>
<td>Sensitive</td>
</tr>
<tr>
<td>Amantadine/Ramantadine</td>
<td>Resistant</td>
<td>Resistant</td>
<td>Resistant</td>
</tr>
</tbody>
</table>

** Note:
- Current Antiviral Drug Susceptibility Data from the CDC demonstrates that oseltamivir (Tamiflu) and zanamivir (Relenza) are effective for treatment of most nH1N1 (2009) influenza A.
- Sporadic isolates of nH1N1 influenza A may be resistant to oseltamivir (Tamiflu).

Additional information:  [http://www.cdc.gov/flu](http://www.cdc.gov/flu)


If you have questions, please contact Client Services (1-800-551-0488, option 5).

Effective Date: October 10, 2010
Submitted by: Bobby L. Boyanton, M.D., Medical Director, Clinical Microbiology; Associate Medical Director, Molecular Pathology, Royal Oak
Barbara Robinson-Dunn, Ph.D., Technical Director, Clinical Microbiology, Royal Oak

(See Algorithm on back page)
Influenza Like Illness

Testing Desired?
Yes
- Urgent or Routine?
  - Urgent
    - Rapid Antigen Test (RAT) for Flu A/B
      - Flu A (+)
        - No Further Action
      - Flu B (+)
        - No Further Action
    - No Further Action. Molecular sub-typing NOT needed at this time.
  - Routine
    - No

Order:
Respiratory Viral Panel by PCR (NP Specimens)
or
Comprehensive Virus Culture (Non-NP Specimens)
(Rapid Antigen Test Not Needed)

Order:
Respiratory Viral Panel by PCR (NP Swab Only, M4-RT, M5, UTM)

RVP Outcome Possibilities for Influenza A

1) *Positive: seasonal influenza A H1 detected
2) *Positive: seasonal influenza A H3 detected
3) Positive: influenza A detected, unable to subtype as seasonal H1 or seasonal H3. There is a high probability (>99%) of nH1N1 (2009) influenza A infection. Influenza A nH1N1 (2009) by RT-PCR is NOT needed in this situation.

* If outcome 1 or 2 is present, the RVP cannot rule-out co-infection with novel H1N1 (2009), but can determine if co-infection with other respiratory viruses is present.

Effective: October 10, 2010
MPL Gene Mutation

The Molecular Pathology Laboratory has developed a new test for detection of MPL Gene Mutations in myeloproliferative neoplasms.

| Specimen                        | Blood: 5-10 mL whole blood in EDTA (lavender top) or ACD (yellow top) tubes  
|                                | Bone marrow aspirate: 0.5-1.0 mL in EDTA (lavender top) tubes  
| Outreach External Preparation  | Specimens are stable at room temperature (20-25°C or 68-77°F) up to 72 hours.  
| Outreach Specimen Transport    | Transport at room temperature (20-25°C or 68-77°F).  
| Rejection Criteria             | Specimens collected in heparin (green top), clot tubes, SST tubes, unlabeled tubes or frozen specimens will not be tested.  
| Performed                      | Once a week  
|                                | Results will be available in 7-10 days  
| Reference Range                | Negative for MPL mutations  
| Test Methodology               | Real Time PCR with allelic discrimination.  
| Interpretation                 | Mutations in the MPL gene have been reported in 5-8% of patients with primary myelofibrosis and 1-3% of patients with essential thrombocythemia. MPL is a member of the hematopoietin gene superfamily and encodes the thrombopoietin receptor, facilitating global hematopoiesis and megakaryocyte growth and differentiation. Both mutations at W515 are gain of function mutations and induce initiating events in myeloproliferative neoplasms. Their detection in cases that are JAK2 and BCR-ABL negative, facilitates the diagnosis of myeloproliferative neoplasms.  
| CPT Code                       | 83891, 83898, 83896x2, 83912  
| Effective Date                 | September 26, 2010  
| Submitted by                   | Domnita Crisan, MD, PhD  
|                                | Medical Director, Molecular Pathology Laboratory, Royal Oak  

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www.beaumonthospitals.com/labs
New Reference Ranges for aPTT (Activated Partial Thromboplastin Time), Heparin aPTT and PT (Prothrombin Time)

EFFECTIVE DATE: FEBRUARY 23, 2010

<table>
<thead>
<tr>
<th>Test</th>
<th>Old Reference Range</th>
<th>New Reference Range</th>
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</thead>
<tbody>
<tr>
<td>aPTT (sec)</td>
<td>25-31</td>
<td>25-32</td>
</tr>
<tr>
<td>and heparin aPTT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PT (sec)</td>
<td>9.6-11.4</td>
<td>9.6-11.5</td>
</tr>
</tbody>
</table>

Rejection Criteria
Specimens containing clots, gross hemolysis, inappropriate volume, thawed or partially thawed are unacceptable and will not be tested.

Performed
7 days a week, 24 hours a day
- Routine: 2 hours
- STAT: 30 minutes

Interpretation
The aPTT and PT are useful in the evaluation of the intrinsic (aPTT) and extrinsic (PT) coagulation system. These tests also aid in screening for classical hemophilia A and B, other congenital factor deficiencies, dysfibrinogenemia, lupus anticoagulant, congenital hypofibrinogenemia, disseminated intravascular coagulation, liver failure and vitamin K deficiency. Coumadin should be monitored with the international normalized ratio (INR). Heparin should be monitored with the heparin aPTT assay at Royal Oak and Troy.

Specimen Transport
Transport whole blood specimens to Coagulation Laboratory within 24 hours. Specimens should be kept room temperature (20-25°C or 68-77°F) for optimal results.

CPT Code
aPTT: 85730, PT: 85610

Effective Date
February 23, 2010 after 12:00pm

Submitted by
Marc D. Smith, MD, Medical Director, Coagulation Laboratory, Royal Oak
Ming Xie, MD, Medical Director, Hematology, Troy
LeiLei Chen, MD, Medical Director, Hematology, Grosse Pointe

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www.beaumonthospitals.com/labs
**Platelet Associated Antibody Assay for Immune-mediated Thrombocytopenia (ITP) (IgG & IgM)**

The Platelet Associated Antibody Assay will be temporarily sent out due to a reagent problem. Please be sure to take note of the new specimen collection time and testing guidelines listed below.

<table>
<thead>
<tr>
<th>Synonyms</th>
<th>ARUP Test Code 95614</th>
</tr>
</thead>
<tbody>
<tr>
<td>Instructions</td>
<td>Send specimens to laboratory at room temperature as soon as possible.</td>
</tr>
<tr>
<td>Specimen Collection Criteria</td>
<td>Two 5 mL Lavender EDTA</td>
</tr>
<tr>
<td>Physician Office/Draw Site Specimen Preparation</td>
<td>Store at room temperature. <strong>Collect Monday-Thursday. Specimens collected on Friday must be in the lab by 11 am due to short specimen stability.</strong></td>
</tr>
<tr>
<td>Rejection Criteria</td>
<td>Clotted, hemolyzed, refrigerated or frozen samples will not be tested. Specimens greater than 24 hours old cannot be sent to the referral lab for testing.</td>
</tr>
<tr>
<td>Reference Range</td>
<td>IgG: Negative, IgM: Negative</td>
</tr>
<tr>
<td>Test Methodology</td>
<td>Flow Cytometry</td>
</tr>
<tr>
<td>CPT Code</td>
<td>86023 x2</td>
</tr>
<tr>
<td>Effective Date</td>
<td>03/30/2010</td>
</tr>
<tr>
<td>Submitted by</td>
<td><strong>Vonda Douglas-Nikitin, MD</strong>, Medical Director, Flow Cytometry, Royal Oak</td>
</tr>
</tbody>
</table>

*Beaumont Laboratory*

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[www.beaumonthospitals.com/labs](http://www.beaumonthospitals.com/labs)
Reference Range Changes

Tissue Transglutaminase (IgA) Antibodies
Gliadin (IgG, IgA) Antibodies
Cyclic Citrullinated Peptide (IgG/IgA) Antibodies

Effective March 28, 2010, reference ranges for antibodies to Tissue Transglutaminase (IgA), Gliadin (IgG, IgA) and Cyclic Citrullinated Peptide (IgG/IgA) will change. Our reagent supplier will soon discontinue manufacturing these products, prompting the selection of another vendor. All tests will continue to be performed by enzyme-linked immunosorbent assay (ELISA). No changes are being made to specimen collection requirements. Beaumont’s Special Testing Laboratory has independently validated the products from the new vendor.

Tissue Transglutaminase (IgA) Antibodies

- Negative: < 20 units
- Weak Positive: 20-30 units
- Moderate-Strong Positive: > 30 units

IgA antibodies to tissue transglutaminase (tTG) serve as one of the criteria for diagnosing celiac disease. The new test system provides a relative sensitivity and specificity of 93% and 92%, respectively.

Gliadin (IgG, IgA) Antibodies

- Negative: < 20 units
- Weak Positive: 20-30 units
- Moderate-Strong Positive: > 30 units

Testing for IgG and IgA antibodies specific for gliadin is also used to aid in diagnosing celiac disease. Deamidation of gliadin by the tissue transglutaminase enzyme promotes enhanced binding by anti-gliadin antibodies. The new assays utilize deamidated gliadin peptides bound to a polystyrene surface of a microtiter plate, resulting in test systems with higher diagnostic accuracy for celiac disease when compared to standard anti-gliadin assays.

CCP (IgG/IgA) Antibodies

- Negative: < 20 units
- Weak Positive: 20-39 units
- Moderate Positive: 40-59 units
- Strong Positive: ≥ 60 units

Antibodies to cyclic citrullinated peptide (CCP) are found in patients with rheumatoid arthritis. The new test system is equally specific compared to other kits, but the sensitivity is improved by ~5%. That is due to the inclusion of additional CCP epitopes and the simultaneous screening of IgG and IgA antibodies. Regarding the latter, some patients with rheumatoid arthritis harbor CCP-specific IgA antibodies in the absence of IgG.

Effective: March 28, 2010
Submitted by: Gabriel Maine, PhD, Technical Director, Special Testing, Royal Oak
Elizabeth Sykes, MD, Medical Director, Automated Chemistry and Special Testing, Royal Oak
Reflex Monospot Testing

The Hematology Laboratory will no longer be performing a reflex monospot test when atypical lymphocytes are identified on a CBC differential.

Although atypical lymphocytes are usually seen on a peripheral blood smear when a patient has infectious mononucleosis, this finding is very non-specific and can be related to other infections (CMV, toxoplasmosis, measles, mumps, roseola, rubella) and drug reactions, among others. Thus, a monospot is better ordered directly by the treating physician who knows the clinical history. This will decrease unnecessary testing and false positive results.

When atypical lymphocytes are present, we will add a comment to the report suggesting the possibility of infectious mononucleosis and recommend monospot testing if the clinical presentation is consistent with this diagnosis.

Effective Date 06/01/2010
Submitted By
Ann Marie Blenc, MD, Medical Director, Hematology, RO
Hongwei Ma, MD, Medical Director, Hematology, Troy
LeiLei Chen, MD, PhD, Medical Director, Hematology, Grosse Pointe
Varicella Zoster Virus (VZV) testing by PCR

The Molecular Pathology Laboratory is critically low on VZV reagents due to its recent discontinuation by our current manufacturer.

To maintain our commitment to continuity of care, the following events will occur beginning June 2, 2010:

1. The remaining reagents at Beaumont Laboratory will be reserved solely for critical specimens (i.e. cerebrospinal fluid).
2. All routine specimens (i.e. skin lesions, etc.) will be sent to our reference laboratory, Mayo Medical Laboratories, for analysis.

Note: For specimens being forwarded to our reference laboratory, there will be minimal impact on turn-around-time, and there is no anticipated alteration in test performance (i.e. sensitivity, specificity).

We thank you very much for your continued support and cooperation.

We anticipate resolution of this issue within 2 to 3 weeks as we locate another manufacturer for these reagents.

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<tr>
<th>Effective Date</th>
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<tbody>
<tr>
<td>Submitted by</td>
<td>Bobby L. Boyanton Jr., M.D.</td>
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<tr>
<td></td>
<td>Medical Director, Microbiology</td>
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<td></td>
<td>Associate Medical Director, Molecular Pathology</td>
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</tbody>
</table>
VIRAL TRANSPORT MEDIUM

Effective immediately, Beaumont Laboratories will switch from M4RT viral transport medium (Remel) to Universal Viral Transport (UVT, Becton-Dickinson) for all viral specimens requiring specialized transport medium.

Guidelines for Use:

1. Place all swab specimens, vesicle aspirates and small pieces of tissue or stool into UVT.
2. Fluids (e.g. CSF, urine) and bulk specimens (eg. large amounts of stool, autopsy tissue) can be placed into sterile, leakproof containers.
3. Label appropriately, refrigerate and deliver or arrange for delivery to laboratory.

Information on UVT:

1. Two different types of UVT are available.
   a. For nasopharyngeal (NP) specimens, order the Viral NP Collection Kit containing:
      i. a 3 mL tube of viral transport medium
      ii. one sterile, nylon, flocked, flexible, mini-tip swab with a scored plastic shaft.
   b. For all other specimens that must be submitted in viral transport medium, order the General Purpose (non-NP) Viral Collection Kit. This contains the following:
      i. a 3 mL tube of viral transport medium
      ii. one sterile nylon, flocked, regular swab with a scored plastic shaft
      iii. one sterile nylon, flocked flexible mini-tip swab with a scored plastic shaft. (This cannot be used for NP specimens as the shaft of the swab is not flexible.)
2. Flocked swabs are recommended for all viral specimens. Flocked swabs collect better specimens; thus, more cells are available for culture or molecular assay.
3. Store uninoculated UVT at 2-25°C until use.
4. Inoculated transport medium should be refrigerated at 2-8°C and transported expeditiously.
5. UVT can be used for culture or assay of viruses, *Chlamydia trachomatis*, *Ureaplasma* and *Mycoplasma*.
   a. MycoTrans will be discontinued once supplies have been depleted.
   b. In all other respects, UVT should be used in the same way as M4RT was used.
   c. UVT and Universal Transport Medium (UTM) are essentially the same product but distributed by different manufacturers. Both are acceptable for testing at Beaumont Laboratories.

For additional information, please contact: Client Services (1-800-551-0488, option 5).

Effective Date 11/03/2010
Submitted by Bobby L. Boyanton, M.D., Medical Director, Clinical Microbiology, Assoc. Med. Dir., Molecular Pathology, Royal Oak
Barbara Robinson-Dunn, Ph.D., D(ABMM), Technical Director, Clinical Microbiology, Royal Oak
2010 Microtainer

Beaumont Laboratory will be switching from the current K2 EDTA microtainer to a longer K2 EDTA microtainer with a tube extender. This extra length allows space for a bar coded patient identifier and direct sampling on the automation line improving patient safety. The blood collection and sample requirements will remain the same.

Effective Date: February 1, 2011
Submitted by: Mark Kolins, M.D.
Peripheral Blood and Body Fluid Differential Update
Grosse Pointe Campus

The Grosse Pointe Hematology Department will discontinue the enumeration of the "Band" cell category when reporting either a peripheral blood or body fluid differential. The bands will be enumerated with the segmented neutrophils. This is due to inter-laboratory and interobserver variability in distinguishing bands from segmented neutrophils, and there is lack of specificity of bandemia. This initiative is to further standardize reporting criteria of the differential tests with the Royal Oak and Troy campuses.

Specimen collection, reference ranges and interpretation can be seen on “Inside Beaumont Online” by clicking on <References> and <Lab Test Directory> or at: www.beaumonthospitals.com/labtestdirectory

Effective Date  May 3, 2011
Submitted by  Suresh Gehani, M.D.
Chief of Pathology, Grosse Pointe Laboratory
LeiLei Chen, M.D.
Medical Director, Hematology, Grosse Pointe Laboratory
Cindy Kopenski MT(ASCP)SH
Supervisor, Hematology, Grosse Pointe Laboratory
REFERENCE RANGE CHANGES – GROWTH HORMONE AND IRON/TIBC

Effective Date: November 28, 2011

I. Growth Hormone (Fasting reference ranges)
   Adult male: 0.1 – 3.0 ng/mL
   Adult female: 0.1 – 8.0 ng/mL

Reference ranges have not been established for children

The new Growth Hormone assay is standardized to the Recombinant Second International Standard 98/574. In-house comparison studies indicate that the new assay results read approximately 17% lower than the old assay – this should be taken into consideration if patients are being monitored or if cut-offs are being used in stimulation/suppression testing.

Arginine Stimulation Test: The normal cut-off expected after arginine stimulation in adult patients is updated to 4.7 ng/mL.

II. Iron, TIBC and Percent Saturation for Royal Oak and Troy ONLY
   The updated ranges are listed below. There is no change to the Grosse Pointe range.

   Iron:  
   Male 45 – 160 mcg/dL  
   Female 30 – 160 mcg/dL

   Total iron binding capacity:  
   Male 228 – 417 mcg/dL  
   Female 228 – 417 mcg/dL

   Percent Saturation:  
   Male 15 – 55 %  
   Female 15 – 55 %

Submitted: November 17, 2011
Submitted by: Elizabeth Sykes, MD, Medical Director, Automated Chemistry and Special Testing, Royal Oak
Gabriel Maine, PhD, Bioscientific Staff, Special Testing, Royal Oak
Vivek Kumar, PhD, Bioscientific Staff, Automated Chemistry and Special Testing, Royal Oak
Ralph Zade, MD, Medical Director, Chemistry, Troy
PTH Sample Requirement Update
Royal Oak and Troy Campuses

Effective Date: September 28, 2011

The sample requirement for PTH testing (includes calcium) has been updated as follows:

**Collect:** Two 5 mL gold-top SST

**PTH tube:**

1. One 5 mL gold-top SST (minimum whole blood 4 mL, minimum serum 2.0 mL)
2. Allow the specimen to clot 30-60 minutes on ice.
3. Centrifuge the tube and immediately separate serum from cells.
4. Transfer serum to plastic transport tube. Immediately freeze serum (-20°C or -4°F or below).
5. Store frozen.

**Calcium:**

1. One 5 mL gold-top SST (minimum whole blood 4 mL, minimum serum 0.5 mL)
2. Allow the specimen to clot 30-60 minutes.
3. Centrifuge the tube and immediately separate serum from cells.
4. Refrigerate (2-8°C or 36-46°F) the centrifuged gold-top tube prior to pick-up by courier. Room temperature is acceptable for maximum of 2 hours.

Please contact Beaumont Laboratory’s Customer Service at 1-800-551-0488 if you have any questions or need additional information.

Date: October 19, 2011

Submitted by: Elizabeth Sykes, MD, Medical Director, Automated Chemistry, Royal Oak
Ralph Zade, MD, Medical Director, Chemistry
CA 19-9 Reagent Lot Problem

Effective Date: October 19, 2011

We were recently informed by Siemens Healthcare Diagnostics that reagent lots in use at Beaumont from July 18, 2011 to the current date yielded results that were on average 15.0% lower than those obtained with earlier reagent lots (at a level of 37 U/mL).

However, it is our practice to perform a lot-to-lot comparison, and results from July 2011 were acceptable. In addition, please note that the impact of Siemens findings should be interpreted in the context of biological variation observed in a given individual during monitoring. Biological variation for CA 19-9 is reported to range from 16.2% to 27.2% (Ref. 1, 2, 3).

Therefore, we believe the negative bias observed by Siemens may not significantly alter the course of management of patients. In addition, Siemens assures us that future lots of CA 19-9 reagent should not vary significantly from the current one in use.

Please contact Beaumont Laboratory’s Customer Service at 1-800-551-0488 if you have any questions or need additional information.

References:
CHANGE IN HPV TEST MENU

Effective Date: September 8, 2011

With implementation of the new state-of-the-art Soft Laboratory Information System, there is a change in the HPV test order menu on the Beaumont Laboratory Cytology Requisition (form #6624 061311 0S5). This change is in accordance with ASCCP guidelines for HPV DNA test utilization and to better serve you and your patients.

The new test menu includes the following:

- HPV if ASC-US
- HPV ANY INTERPRETATION
- HPV ONLY (NO PAP)

The previously offered "HPV if ASC-US/ASC-H/LGSIL/HGSIL" and "HPV if ABNORMAL" are no longer available.

Should a physician’s clinical judgment suggest HPV DNA testing outside of the recommended guidelines, the physician or physician’s office should call Beaumont Laboratory’s Client Services (248-551-1155) to “ADD-ON” HPV test, once they have reviewed the cytology report. A verbal request to Client Services will be treated as an order in this scenario. The Thin Prep vials are stored in the Cytology Laboratory for 60 days after receipt of the specimen and HPV DNA testing can be performed during this 60-day period.

Date Submitted: September 15, 2011

Submitted by: Edward Bernacki, MD
Medical Director, Cytopathology, Royal Oak

Said Hafez Khayyata, MD
Medical Director, Cytology, Troy

Vaishali Pansare, MD
Medical Director, Cytology, Grosse Pointe

Statement on Human Papillomavirus DNA Test Utilization* †

Diane Solomon, MD1; Jacalyn L. Papillo, CT (ASCP)2; and Diane D. Davey, MD3, for the Cytopathology Education and Technology Consortium (CETC)

Testing for carcinogenic or high-risk human papillomavirus (HPV) DNA has proven usefulness in cervical cancer screening and in many aspects of the clinical management of cervical cancer prevention. However, inappropriate testing increases costs without benefit and potentially results in the overtreatment of women. This statement was developed by the Cytopathology Education and Technology Consortium (CETC) and has been endorsed by additional professional medical societies. It is intended as a concise, convenient summary of clinical indications for HPV DNA test utilization based on the 2002 American Cancer Society screening recommendations1 and interim guidance,2 and the 2006 American Society for Colposcopy and Cervical Pathology (ASCCP) consensus management guidelines.3,4 Circumstances in which HPV DNA testing is considered appropriate and those in which such testing is generally not appropriate are outlined below. This statement and Figure 1 are intended to serve as educational tools and references with which to improve the management of women and reduce the inappropriate use of HPV tests.

1. High-risk (oncogenic) HPV DNA testing is appropriate in the following circumstances:

1.1. Routine cervical cancer screening in conjunction with cervical cytology (dual testing or co-testing) for women aged ≥30 years:

1.1.1. For women who are cytology negative but HPV positive, repeat both tests in 12 months (As of March 2009, the US Food and Drug Administration approved an HPV type 16/18 genotyping test; as per ASCCP guidelines,3,4 HPV 16/18-positive women aged ≥30 years are referred directly for colposcopy.)
1.1.2. For women who are both cytology and HPV negative, repeat both tests only after a 3-year interval.

1.2. Initial triage management of women aged ≥21 years with a cytologic result of atypical squamous cells of undetermined significance (ASC-US).

1.3. Initial triage management of postmenopausal women with a cytologic result of low-grade squamous intraepithelial lesion (LSIL).

1.4. Postcolposcopy management of women of any age with an initial cytologic result of atypical glandular cells (AGC)* or atypical squamous cells, cannot exclude high-grade squamous intraepithelial lesion (ASC-H) (when the initial workup does not identify a high-grade lesion).

1.5. Postcolposcopy management of women aged ≥21 years with initial cytologic results of ASC-US or LSIL (when the initial colposcopy does not identify a high-grade lesion).

1.6. Post-treatment surveillance.

*Note that for a finding of AGC, HPV testing is not to be used for triage to decide whether to refer for colposcopy; however, HPV testing may be performed at the time of colposcopy to guide postcolposcopy management.

2. High-risk (oncogenic) HPV DNA testing is generally not appropriate in the following situations:

2.1. Routine cervical cancer screening in women aged <30 years.

2.2. Routine screening with HPV testing and cervical cytology more often than every 3 years for women aged ≥30 years whose tests were negative at the time of last screening (see 1.1.2 above).

2.3. Initial triage or management of adolescents (aged ≤20 years) with any abnormal cytologic result. Furthermore, if HPV testing is inadvertently performed, the results should not be used to influence patient management.

2.4. Initial triage of LSIL (except for postmenopausal women; see 1.3 above).

2.5. Initial triage of ASC-H, high-grade squamous intraepithelial lesion (HSIL), or AGC*/adenocarcinoma in situ (AIS) in women of any age.

3. Repeat high-risk (oncogenic) HPV DNA testing should generally not be performed within <12 months:

3.1. Exceptions include as a follow-up to AGC, not otherwise specified (AGC NOS) when no pathology is found at the time of the initial workup and as follow-up after treatment for cervical intraepithelial neoplasia grades 2 and 3 (CIN 2,3). See the ASCCP guidelines for specific recommendations concerning testing intervals.

4. Testing for low-risk (nononcogenic) HPV types has no role in routine cervical cancer screening or for the evaluation of women with abnormal cervical cytology.

Endorsed by the American Cancer Society
American Society for Clinical Pathology#
ASCCP
American Society of Cytopathology#
American Society for Cytotechnology#
College of American Pathologists#
International Academy of Cytology#
Papanicolaou Society of Cytopathology#

#Indicates a member of the CETC.
The intent of this summary is to facilitate provider education and to encourage the appropriate utilization of HPV testing. Clinical judgment should always be used when applying a guideline to an individual patient because it is impossible to develop guidelines that will apply to all situations. Links to the 2006 ASCCP Consensus Guidelines, as well as management algorithms, are available on the ASCCP website at http://www.asccp.org/consensus/cytological.shtml accessed on April 22, 2009.

References


Group B Streptococcus (GBS) - TESTING UPDATE  
Effective Date: August 15, 2011

Group B Streptococcus (GBS) or *Streptococcus agalactiae*, remains the leading cause of neonatal morbidity and mortality in the United States. Since 2002, the Centers for Disease Control and Prevention has recommend antepartum screening cultures at 35 to 37 weeks gestation to predict women likely to be colonized with GBS at the time of delivery so that appropriate antibiotic therapy could be provided to prevent neonatal GBS disease. Recently updated CDC guidelines now support the concomitant use of molecular-based methods to facilitate the detection of women colonized with GBS.

Effective August 15, 2011, Beaumont Laboratory will begin using a highly sensitive detection protocol that incorporates LIM-broth enriched culture followed by real-time PCR detection of GBS. If GBS is identified, antimicrobial susceptibility testing (penicillin, erythromycin, clindamycin, vancomycin) will automatically be performed at no additional cost. Our primary goal is to provide the most sensitive GBS detection method available, while minimizing expense to your patients and the healthcare system.

Frequently asked questions:
1) Will the test name change?
   Yes. The old test name “Group B Strep Culture” will be discontinued.
   The new test name will be “Group B Strep Screen”.
2) Will there be a change in the specimen collection and handling requirements?
   NO. Continue to submit vaginal-rectal swabs placed into bacterial transport medium.
3) When will the specimens be tested?
   24 hours per day, 7 days per week.
4) Will there be a change in the turn-around-time of test results?
   YES. For women not colonized with GBS, test results will be available 1 to 2 days sooner.
   For women colonized with GBS, test results will be available in 2 to 3 days.

For complete specimen collection and handling instructions or additional information, please refer to the on-line Laboratory Test Directory:
   Internal URL: http://beaunet.beaumont.edu/portal/pls/portal/lab.lab_pkg.lab_list
   External URL: http://www.beaumont.edu/labtestdirectory

If you need additional information, please contact Customer Service (1-800-551-0488, option 5).

Date Submitted: July 27, 2011

Submitted By:

Bobby L. Boyanton Jr., M.D.  Barbara Robinson-Dunn, Ph.D., D(ABMM)
Medical Director, Microbiology, Royal Oak  Technical Director, Microbiology,
Assoc. Medical Director, Molecular Pathology, Royal Oak  Royal Oak

Vaishali Pansare M.D.  Paul Goodman, MD,
Medical Director, Cytology/Microbiology,  Medical Director, Microbiology,
Grosse Pointe  Grosse Pointe

Beaumont Laboratory  
Customer Service  
1-800-551-0488
Reticulin Antibody – Test Discontinued

Reticulin antibody testing was introduced several years ago for the investigation of celiac disease. However, with the introduction of more specific tests, it is no longer considered useful and will no longer be available as of June 27, 2011.

Recommended initial testing for most patients suspected of having celiac disease:

- **Celiac disease panel:***
  - Tissue transglutaminase antibodies (IgA)
  - Total IgA level

  **NOTE:** For patients that are IgA deficient, tissue transglutaminase antibodies (IgG) should be ordered.

Other tests available:

- Tissue transglutaminase antibodies (IgA) alone
- Gliadin antibodies, deamidated (IgG and IgA)
- Endomysial antibodies (IgA)

**Effective Date**
June 27, 2011

**Submitted by**
Elizabeth Sykes, MD
Medical Director, Automated Chemistry and Special Testing

Gabriel Maine, PhD
Technical Director, Special Testing
ESTRADIOL – NEW REFERENCE RANGES

Effective Wednesday, June 15th, Beaumont Laboratory Automated Chemistry will start using the new Siemens estradiol immunoassay, which is traceable to ID GC-MS (isotope dilution gas chromatography-mass spectrometry). There will be no change in specimen requirements; however, reference ranges will change to the following:

**Females**
- Follicular: 20 – 144 pg/mL
- Mid cycle: 64 – 357 pg/mL
- Luteal: 56 – 214 pg/mL
- Post-menopausal: ≤ 32 pg/mL

**Males**
- ≤ 40 pg/mL

Effective Date: June 15, 2011
Submitted by: Elizabeth Sykes, MD, Medical Director, Chemistry, Royal Oak
Vivek Kumar, PhD, Technical Director, Chemistry, Royal Oak
Molecular Testing Update: *Chlamydia trachomatis* and *Neisseria gonorrhoeae*

Effective June 6, 2011, Beaumont Laboratory will begin using the FDA-approved Becton Dickinson ProbeTec Q™ amplified DNA assays on the VIPER XTR System for the qualitative detection of *Chlamydia trachomatis* (Ct) and *Neisseria gonorrhoeae* (Ng) from genitourinary specimens. The impact of this change from our current molecular test should be minimal.

**Benefits of this Change:**
1) Ability to test male and female urine for both Ct and Ng
2) Ability to test liquid-based cytology (PreservCyt or SurePath) – this feature should be available in the fourth quarter of 2011. You will receive notice when this becomes available.

**Anticipated Changes:**
1) We will systematically transition all clients to Becton Dickinson (BD) specific collection and transportation kits.

**Why is it necessary to change collection and transportation kits?**

BD-specific kits facilitate optimal specimen stability during transportation and maximize the speed at which the laboratory can provide results to the client.

The following BD-specific kits will be provided to all clients:
- Female Endocervical Collection Kit
- Male Urethral Collection Kit
- Urine Preservative Kit

**Special Note:** Currently used collection and transport kits (M4-RT, UTM, UVT) and clean-catch urine will still be accepted. Specimens received in other collection and transport kits are NOT acceptable and will be rejected.

For complete specimen collection and handling instructions, please refer to the on-line Laboratory Test Directory:

| Internal URL: | http://beaunet.beaumont.edu/portal/pls/portal/lab.lab_pkg.lab_list |
| External URL: | http://beaumonthospitals.com/labtestdirectory |

If you need additional information, please contact Customer Services (1-800-551-0488, option 5).

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| Submitted by   | Bobby L. Boyanton Jr., M.D., Medical Director, Microbiology, Assoc. Medical Director, Molecular Pathology
|                | Domnita Crisan, M.D., Ph.D., Medical Director, Molecular Pathology |
Creatine Kinase Test Change
for Grosse Pointe Campus Only

Effective May 25, 2011 Beaumont Grosse Pointe will begin using a new methodology for Creatine Kinase which will result in a reference range change. These changes have been made to standardize with Beaumont Royal Oak and Troy.

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<tr>
<th>OLD REFERENCE RANGES</th>
<th>NEW REFERENCE RANGES</th>
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<tr>
<td>Male : 35-232 U/L</td>
<td>Male: 40-230 U/L</td>
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<tr>
<td>Female: 21-215 U/L</td>
<td>Female: 30-150 U/L</td>
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Specimen collection, reference ranges and interpretation can be seen on “Inside Beaumont Online” by clicking on <References> and <Lab Test Directory> or at: www.beaumonthospitals.com/labtestdirectory

<table>
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<tr>
<th>Effective Date</th>
<th>May 25, 2011</th>
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| Submitted by  | Beatrice Muglia, MD, Medical Director, Chemistry  
Suresh Gehani, MD, Medical Director, Grosse Pointe Laboratories |
Alcohol Test Change
for Grosse Pointe Campus Only

Effective May 25, 2011 Beaumont Grosse Pointe will begin using a new methodology for Alcohol testing. The new reference range will be ≤ 10 mg/dl. In addition, results will be reported in mg/dL, rather than in percentages as was the previous practice. These changes have been made to standardize with Beaumont Royal Oak and Troy.

<table>
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<tr>
<th>OLD REFERENCE RANGE</th>
<th>NEW REFERENCE RANGE</th>
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<tr>
<td>Not Detectable %</td>
<td>≤10 mg/dL</td>
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Additionally, there will be a new critical value for the ages listed below:

Critical Value:
0-12 years: > 50 mg/dL
≥ 13 years: >250 mg/dL

Specimen collection, reference ranges and interpretation can be seen on “Inside Beaumont Online” by clicking on <References> and <Lab Test Directory> or at: www.beaumonthospitals.com/labtestdirectory

Effective Date
May 25, 2011

Submitted by
Beatrice Muglia, MD, Medical Director, Chemistry
Suresh Gehani, MD, Medical Director, Grosse Pointe Laboratories
How to Collect a Quality Sample
Preventing QNS Collections

What is QNS?
QNS is the abbreviation used for “Quantity Not Sufficient”. Laboratory specimens are reported as QNS when:

- There is not enough specimen for the laboratory to perform the requested test(s).
- The amount of blood collected into the tube does not meet the proper blood: anticoagulant ratio. Improper anticoagulant ratios can result in the reporting of inaccurate test results.

What causes QNS?

- The use of expired tubes with decreased vacuum (i.e. there is insufficient vacuum to fill properly)
- Difficult patient draws
- Not ensuring tube is completely filled before removal from needle and tube holder

How can QNS specimens be prevented?

- For most serum and plasma tests, check to be certain that the tube is at least half full. 
  Note: Certain coagulation tests (e.g., PT, aPTT, TT, Fibronogen) require a 90% to 100% full tube in order to achieve the proper blood-to-anticoagulant ratio.

What labs are primarily affected?

A variety of laboratory tests are adversely affected, resulting in invalid results. QNS specimens should be redrawn.

Examples of testing adversely affected by the QNS status

- **Coagulation**: Prolonged clotting times for PT, aPTT, TT and fibrinogen
- **Hematology**: Reduced MCV, HCT; Falsely decreased RBC, WBC, PLT counts; Changes in leukocyte morphology

Effective Date: May 23, 2011
Submitted by: Grace Bostic, Quality Assurance Coordinator, Clinical Pathology, RO
Elizabeth Sykes, MD, Medical Director, Clinical Chemistry, RO
How to Prepare a Quality Sample: Preventing Hemolysis

What are hemolyzed specimens?
Hemolysis occurs when the red cells are damaged during sample collection causing them to rupture. Hemolyzed serum or plasma is pale pink to red rather than the normal clear straw or pale yellow color.

What causes a specimen to be hemolyzed?
- Mixing tubes too vigorously
- Exposure to heat
- Using a needle with too small of a bore necessary for the venipuncture
- Using too large a tube when using a butterfly needle
- Not allowing sufficient time for alcohol to dry on puncture site
- Leaving the tourniquet on for longer than one minute

How can hemolyzed specimens be prevented?
- For routine collections, use a 20-22 gauge needle
- Do not remove the needle from the vein with the vacuum tube engaged
- Do not collect a specimen in a hematoma
- Do not centrifuge the specimen for a prolonged period of time
- Draw the sample gently and evenly

What labs are primarily affected?
A variety of laboratory tests are adversely affected, resulting in invalid results. The sample must then be redrawn causing discomfort for the patient and extra nurse and technologist time.

Examples of adverse outcomes associated with hemolyzed specimens
- Chemistry: Increased $K^+$, $Mg^{2+}$, AST/ALT
- Hematology: Decreased RBC count
- Blood Bank: Inaccurate testing

Effective date: May 18, 2011
Submitted by: Grace Bostic, Quality Assurance Coordinator, Clinical Pathology, RO
Elizabeth Sykes, MD, Medical Director, Clinical Chemistry, RO
How to Collect a Quality Sample
Prevent Clotting with Anticoagulant Tubes

What are clotted specimens?
An inappropriately clotted blood specimen is one in which clotting occurs in a tube containing an anticoagulant. A specimen clots when there is not adequate mixing of the anticoagulant in the tube.

What causes a specimen to be clotted?
- Inadequate mixing of the tubes
- No mixing of tubes
- Use of expired blood collection tubes

How can clotted specimens be prevented?
- Gently invert each blood specimen 6-8 times to allow adequate mixing of the blood. Mix blood IMMEDIATELY after collection.
- Fill all blood collection tubes to the fill line. (This step prevents the dilution of the blood components, which can result in altered results).

What labs are primarily affected?
A variety of laboratory tests are adversely affected, resulting in invalid test results. (This then requires the collection of another specimen from the patient).

Examples of adverse outcomes associated with clotted specimens
- Coagulation: Prolonged clotting times for PT, aPTT, TT and fibrinogen
- Hematology: Erroneous WBC count and RBC indices; Decreased platelet count

Effective date: May 18, 2011
Submitted by: Grace Bostic, Quality Assurance Coordinator, Clinical Pathology, RO
Elizabeth Sykes, MD, Medical Director, Clinical Chemistry, RO
Discontinuation of Lactate Dehydrogenase (LDH) Isoenzyme Testing

Lactate dehydrogenase (LD) isoenzymes are no longer offered at William Beaumont Hospital. This test was developed in the past as an aid in the diagnosis of acute myocardial infarction. LD isoenzyme testing has largely been replaced by cardiac troponin – a test that is still abnormal 7-10 days post-infarction but has significantly greater specificity for myocardial damage than the elevated LD1/LD2 isoenzyme ratio.

The National Academy of Clinical Biochemists, the American Association for Clinical Chemistry, the American College of Cardiology, the American Heart Association, and the American College of Emergency Physicians have for over a decade, recommended cardiac troponin as the test of choice for the diagnosis of acute myocardial infarction. The National Academy of Clinical Biochemists and the American Association for Clinical Chemistry have recommended that LD isoenzyme testing no longer be performed because more rapid, less labor intensive and more specific testing is available.

LD isoenzymes have also been used as an aid in identifying patients with hepatic/skeletal muscle injury (elevated LD5 +/- LD4) and hemolysis (elevated LD1/LD2 ratio). Again, more rapid, less labor intensive and more specific tests are available. See chart below.

<table>
<thead>
<tr>
<th>LD Isoenzyme Pattern</th>
<th>Interpretation</th>
<th>Alternate Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>LD1/LD2 Elevation</td>
<td>Acute Myocardial Infarction</td>
<td>Troponin</td>
</tr>
<tr>
<td></td>
<td>Hemolysis</td>
<td>Haptoglobin</td>
</tr>
<tr>
<td>LD4/LD5 or LD5 Elevation</td>
<td>Hepatic and/or Skeletal Muscle Injury</td>
<td>Hepatic Panel and/or Creatine Kinase (CK)</td>
</tr>
</tbody>
</table>

All other patterns are too non-specific for comment.

If you have any further questions or need additional information, please contact Beaumont Laboratory Customer Service at 1-800-551-0488 and ask for one of the following:

- Yvonne Posey, MD
- Elizabeth Sykes, MD
- Special Testing Department

Submitted by: Yvonne Posey, MD, Associate Director, Special Testing
Elizabeth Sykes, MD, Medical Director, Special Testing
Effective date: May 6, 2011
The following tests will be performed at Beaumont Laboratory, Royal Oak instead of ARUP Laboratories.

<table>
<thead>
<tr>
<th>TEST</th>
<th>SIROLIMUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>TUBE TYPE</td>
<td>4mL Lavender-whole blood</td>
</tr>
<tr>
<td>REFERENCE RANGE</td>
<td>Trough Therapeutic Range: 5.0-15.0 ng/mL</td>
</tr>
<tr>
<td></td>
<td>Critical Value: &gt;30 ng/mL</td>
</tr>
<tr>
<td>METHODOLOGY</td>
<td>LC/MS/MS-Tandem Liquid Chromatography/Mass Spectrometry</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TEST</th>
<th>MYCOPHENOLIC ACID</th>
</tr>
</thead>
<tbody>
<tr>
<td>TUBE TYPE</td>
<td>7mL plain red top tube. Do not centrifuge specimen. Do not aliquot. Transport refrigerated</td>
</tr>
<tr>
<td>REFERENCE RANGE</td>
<td>Trough: 1.5-5.0 mcg/mL</td>
</tr>
<tr>
<td>METHODOLOGY</td>
<td>LC/MS/MS-Tandem Liquid Chromatography/Mass Spectrometry</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TEST</th>
<th>TACROLIMUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>TUBE TYPE</td>
<td>4mL Lavender-whole blood</td>
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<tr>
<td>REFERENCE RANGE</td>
<td>Therapeutic range: (0-3 months post transplant): 8-16 ng/mL</td>
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<tr>
<td></td>
<td>Therapeutic range: (&gt;3 months post transplant): 5-15 ng/mL</td>
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<td>Critical Value: &gt;20 ng/mL</td>
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<td>METHODOLOGY</td>
<td>LC/MS/MS-Tandem Liquid Chromatography/Mass Spectrometry</td>
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<table>
<thead>
<tr>
<th>TEST</th>
<th>CYCLOSPORINE A</th>
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<tbody>
<tr>
<td>TUBE TYPE</td>
<td>4mL Lavender-whole blood</td>
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<tr>
<td>REFERENCE RANGE</td>
<td>Therapeutic Range (0-3 months post transplant): 200-400 ng/mL</td>
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<td></td>
<td>Therapeutic Range (3-12 months post transplant): 100-300 ng/mL</td>
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<tr>
<td></td>
<td>Therapeutic Range (&gt;1 yr. post Transplant): 100-200 ng/mL</td>
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<tr>
<td></td>
<td>Critical Value: &gt;500 ng/mL</td>
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<tr>
<td>METHODOLOGY</td>
<td>LC/MS/MS-Tandem Liquid Chromatography/Mass Spectrometry</td>
</tr>
</tbody>
</table>

Specimen collection, reference ranges and interpretation can be seen on “Inside Beaumont Online” by clicking on <References> and <Lab Test Directory> or at: www.beaumonthospitals.com/labtestdirectory

Effective Date: May 2, 2011

Submitted by: Suresh Gehani, M.D.
Chief of Pathology, Grosse Pointe Laboratory
Pregnancy 2 hr Glucose Tolerance (75g)

The American Diabetes Association (ADA) has recently recommended that patients who are not diagnosed with overt diabetes or gestational diabetes (GDM) at the initial prenatal visit should undergo screening for gestational diabetes at 24-28 weeks of gestation using a 2 hour glucose tolerance test (GTT) with 75g Glucola. However, this approach is not currently recommended by ACOG. Until there is general agreement within the obstetrician community, we will offer both this new pregnancy tolerance test and the previously-recommended tests.

Patient Preparation
Testing is to be performed in the morning after an overnight fast of at least 8 hours. At Beaumont draw sites, we will continue to test the patient’s fasting glucose prior to administration of Glucola. If the glucose is greater than 140 mg/dL, the GTT will be canceled.

Interpretation
The ADA recommends that a diagnosis of gestational diabetes is made when any one of the following glucose values is exceeded:
- Fasting ≥ 92 mg/dL
- 1 Hour ≥ 180 mg/dL
- 2 Hour ≥ 153 mg/dL

Reference: Diabetes Care 34:S62-S69, 2011

Tests currently available for glucose intolerance in pregnancy:
- Pregnancy 2 hr Glucose Tolerance (75g)
- Pregnancy 3 hr Glucose Tolerance (100 g)
- 50 g Glucola screen performed at any time of day, regardless of food intake.

Submitted by: Grosse Pointe:
Beatrice Muglia, MD, Medical Director, Chemistry

Royal Oak:
Elizabeth Sykes, MD, Medical Director, Automated Chemistry and Special Testing

Troy:
Ralph Zade, MD, Medical Director, Chemistry

Effective date: April 4, 2011
Protocol for Blood Samples that Appear to be Contaminated with IV Fluid

Clinical Pathology sometimes receives blood samples that, based on prior patient results, appear to be contaminated with IV fluids. However, since Lab personnel are not aware of the patient’s status, it is difficult to be certain that IV contamination has occurred. Therefore, when IV contamination seems possible:

- The lab technologist will notify the nurse of possible contamination and report all results together with the following comment:

  “Possible specimen contamination with IV fluid, IV medication or TPN solution. Interpret results with caution. If clinically indicated, suggest repeat for this test and any others obtained at original draw time. RN # ---- alerted.”

- The nurse must review with physician and decide whether a redraw is required.

- If the initial result is a critical result, the lab technologist will document the critical call.

- If it is decided that the sample was contaminated with IV fluid, the physician or nurse may call the Lab to cancel the result:
  
  Grosse Pointe: (313) 473-1808
  Royal Oak: (248) 551-1155
  Troy: (248) 964-8070

Submitted: Grosse Pointe:
Beatrice Muglia, MD, Medical Director, Chemistry
Suresh Gehani, MD, Medical Director, Grosse Pointe Laboratories

Royal Oak:
Elizabeth Sykes, MD, Medical Director, Automated Chemistry and Special Testing
Mark Kolins, MD, System Chair, Pathology and Laboratory Medicine

Troy:
Ralph Zade, MD, Medical Director, Chemistry
David Grossman, MD, Medical Director, Troy Laboratories

Effective: March 31, 2011
Changes in Specimen Requirements for Vitamin B6 and Vitamin B2

Changes are as follows:

<table>
<thead>
<tr>
<th>TEST</th>
<th>OLD TUBE TYPE</th>
<th>NEW TUBE TYPE</th>
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</thead>
<tbody>
<tr>
<td>Vitamin B6</td>
<td>Lavender</td>
<td>Green (Sodium or Lithium Heparin)</td>
</tr>
<tr>
<td>Vitamin B2</td>
<td>Lavender</td>
<td>Green (Sodium or Lithium Heparin)</td>
</tr>
</tbody>
</table>

For Vitamin B6:

- Patient should fast overnight
- Collect one 6mL green (sodium or lithium heparin) tube
- Separate plasma from cells as soon as possible, indicating if specimen is serum or plasma (heparin) on pour over tube and Freeze ASAP.

For Vitamin B2:

- Collect one 6mL green (sodium or lithium heparin) tube
- Separate plasma from cells as soon as possible, indicating if specimen is serum or plasma (heparin) on pour over tube
- Freeze ASAP

Effective Date: March 8, 2011
Submitted by: Lisa Rupkus, Send Out Coordinator, Beaumont Laboratory, Royal Oak
Intact PTH (Intact Human Parathyroid Hormone) - UPDATE

Specimen Collection

- One 5 mL gold-top SST or red top tube
- Minimum volume: whole blood 4 mL or 2.0 mL serum

Physician Office/Drawsite Specimen Preparation

- Allow the specimen to clot 20 minutes. Centrifuge the tube and separate serum from cells immediately.
- Freeze (-20°C/-4°F or below) serum immediately. Store Frozen.

Preparation for Courier Transport

- Transport frozen (-20°C/-4°F or below).

Rejection Criteria

- Samples from draw sites or physician offices that have not been processed and frozen, as indicated above.
- PTH will not be added on to an existing serum sample that has not been frozen.

Submitted By: Elizabeth Sykes, M.D.,
Medical Director, Automated Chemistry and Special Testing

Effective Date: February 24, 2011
Effective **February 14, 2011**, the Special Testing Laboratory will offer the QuantiFERON-TB (QFT-TB) test. QFT-TB provides an assessment of cell-mediated immunity to peptide antigens that simulate *Mycobacterium tuberculosis* proteins. T lymphocytes from individuals with active or latent tuberculosis infection (LTBI) will secrete interferon gamma (IFNγ) when stimulated *in vitro* by those antigenic components. The QFT-TB test system measures mycobacterium-specific IFNγ release as an endpoint for determining exposure to *M. tuberculosis*. In comparison to the Tuberculin Skin Test (TST), QFT-TB exhibits a similar specificity for excluding LTBI (99.8% QFT-TB vs. 99.8% TST) but an increased sensitivity for confirming LTBI (89% QFT-TB vs. 76% TST).

**Recommended Indications for QFT-TB Testing:**

**In Health Care Workers (HCWs) for evaluation of:**
- Latent tuberculosis infection (LTBI) in foreign born HCWs and individuals who have been vaccinated with BCG.
- LTBI in new HCWs over 50 years of age.
- LTBI in HCWs with chronic medical conditions.
- HCWs that have converted their TST and do not have an identified exposure.

**Patients – it may be appropriate to test the following individuals for LTBI:**
- Compromised by disease (e.g. malignancy, connective tissue disorders)
- Compromised by medications (e.g. glucocorticoids, anti-TNF)
- Dialysis patients and transplant population (donor/recipient)
- When TB is suspected and the TST is negative

**Test Limitations:**
- QFT-TB has only limited advantages over TST in individuals who are not foreign born, have not been vaccinated with BCG, or in immunocompromised patients where the test is less sensitive.
- QFT-TB does not distinguish between active and latent tuberculosis infection.

**QFT-TB Collection and Testing Information**

**Specimen Collection Information**
- **Collection Days:** Monday-Thursday Only
- **Draw Sites:**
  1. Occupational Health Services (Troy, MI): 6:30 am – 5:00 pm
  2. Medical Office Building Outpatient Laboratory (WBH - Royal Oak, MI):
     Monday: 7:00 am – 7:00 pm, Tuesday – Thursday: 7:00 am – 6:00 pm
- **Collection Tubes:**
  - Nil Tube (negative control): Used to assess basal level of IFNγ in plasma.
  - TB Antigen Tube: Used to assess TB-specific cell mediated immunity.
  - Mitogen Tube (positive control): Non-specific stimulator used to assess overall immune responsiveness.

**Testing Information**
- QFT-TB assay will be performed **once per week on Tuesday**.
- **Testing Methodology:** ELISA (Assayed analyte - IFNγ)
- **Results:**
  1. Negative - *M. tuberculosis* infection not likely.
  2. Indeterminate for TB antigen responsiveness.
  3. Positive - *M. tuberculosis* infection likely.

Submitted By: Gabriel Maine, PhD - Technical Director, Special Testing (Royal Oak)
Elizabeth Sykes, MD - Medical Director, Automated Chemistry & Special Testing (Royal Oak)
Jeffrey Band, MD - Chair, Corporate Epidemiology
Changes in Source Patient Testing Following Occupational Exposures

Effective February 1, 2011, the order for SOURCE patient testing following exposures will change and will only be available as a stat panel named:

**HIV 1/2 (Rapid)/Hepatitis Source Patient Panel**
(searchable in EPIC under Source Patient Testing)

The panel includes:
- HIV 1/2 (Rapid) Antibody Test (Source Patient)
- Source Hepatitis B Surface Antigen
- Source Anti Hepatitis C Virus

These tests should be performed on the SOURCE of the exposure and NOT on the EXPOSED person.

Notify the Emergency Center (at Grosse Pointe, Royal Oak, or Troy) and/or Occupational Health Services at 248-733-7300 immediately. Tests performed on the exposed person will be ordered as indicated by the Emergency Center or Occupational Health Services.

When ordering the **HIV 1/2 (Rapid)/Hepatitis Source Patient Panel**, a prompt will appear as a reminder that Form 553 (Employee Illness/Accident Form) must be filled out for the EXPOSED person. The EXPOSED person should proceed immediately with this form to the Emergency Center or Occupational Health Services for follow-up instructions and counseling.

Specimen Requirements:
- Two 5 mL SST (gold-top)
- Deliver specimen immediately to Stat Lab (Royal Oak), Microbiology (Troy) or Microbiology (Grosse Pointe)

Effective Date: February 1, 2011

Submitted by:

**Grosse Pointe:**
Beatrice Muglia MD, Medical Director, Chemistry
Vaishali Pansare MD, Medical Director, Cytology/Microbiology

**Royal Oak:**
Yvonne Posey, MD, Associate Director, Automated Chemistry and Special Testing
Elizabeth Sykes, MD, Medical Director, Automated Chemistry and Special Testing

**Troy:**
Paul Goodman, MD, Medical Director, Microbiology
Ralph Zade, MD, Medical Director, Chemistry
Lactate Dehydrogenase Test Change  
For the Grosse Pointe Campus Only

Effective June 1, 2011 Beaumont Grosse Pointe will begin using a new methodology for Lactate Dehydrogenase which will result in a reference range change. These changes have been made to standardize with Beaumont Royal Oak and Troy.

<table>
<thead>
<tr>
<th>OLD REFERENCE RANGE</th>
<th>NEW REFERENCE RANGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>SEX</td>
<td>AGE</td>
</tr>
<tr>
<td>M</td>
<td>0-1 M</td>
</tr>
<tr>
<td>M</td>
<td>1M – 1Y</td>
</tr>
<tr>
<td>M</td>
<td>1Y-16Y</td>
</tr>
<tr>
<td>M</td>
<td>16Y-19Y</td>
</tr>
<tr>
<td>M</td>
<td>19Y-UNL</td>
</tr>
<tr>
<td>M</td>
<td>10Y-12Y</td>
</tr>
<tr>
<td>M</td>
<td>16Y-18Y</td>
</tr>
<tr>
<td>F</td>
<td>0-1 M</td>
</tr>
<tr>
<td>F</td>
<td>1M – 1Y</td>
</tr>
<tr>
<td>F</td>
<td>1Y-16Y</td>
</tr>
<tr>
<td>F</td>
<td>16Y-19Y</td>
</tr>
<tr>
<td>F</td>
<td>19Y-UNL</td>
</tr>
<tr>
<td>F</td>
<td>10Y-12Y</td>
</tr>
<tr>
<td>F</td>
<td>16Y-18Y</td>
</tr>
</tbody>
</table>

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If you have questions, please contact Client Services (1-800-551-0488, option 5).

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>June 1, 2011</th>
</tr>
</thead>
</table>
| Submitted by   | Beatrice Muglia, MD, Medical Director, Chemistry  
Suresh Gehani, MD, Medical Director, Grosse Pointe Laboratories |
Physicians Notice

In its compliance guidance for clinical laboratories the Office of the Inspector General (OIG) recommends that all clinical laboratories distribute a physician notice to its ordering clients at a minimum once per year. In an effort to comply with these recommendations, Beaumont Laboratory is providing this Physicians Notice delineating the guidelines used by Beaumont Laboratory for submitting claims to Medicare, Medicaid and other federally funded healthcare programs.

Clinical Laboratory Improvement Amendments (CLIA) Brochures

The Centers for Medicare and Medicaid Services (CMS) has several brochures to help explain the Clinical Laboratory Improvement Amendments (CLIA) regulation requirements including one on how to report concerns about a Laboratory's Operations to CMS. To access one or more of these brochures go to: CLIA Brochures Clinical Laboratory Improvement Amendments (CLIA). The CLIA Complaints brochure is also posted on the Laboratory’s web site under Laboratory Compliance Resources.

Medicare Medical Necessity

The Centers for Medicare and Medicaid Services (CMS) and the OIG recognize that physicians and other authorized individuals must be able to order any test that they believe are appropriate for the treatment or diagnosis of their patients. As the physician, you may order any test(s), including screening tests that you believe are appropriate for the treatment of your patients. Each test must be accompanied with a valid ICD-9 code or narrative (i.e., diagnosis, signs, symptoms or clinical complaint). Use of outdated terminology (e.g., SMAC, SMA21, Chem 12, etc.) or wording that is subject to multiple interpretations (e.g., Liver Function Test [LFT], Fasting Lipid Test [FLT], FLP, etc.) when ordering lab tests requires that our Customer Service staff contact your office for clarification. In an effort to reduce interruptions that these calls have on your practice, laboratory requisition forms are designed to assist you in communicating diagnostic information to the highest degree of accuracy and completeness at the time the test is ordered. However, Medicare will only pay for tests that are covered, reasonable, and necessary for the individual patient given his or her clinical condition.

For Beaumont Laboratory to bill Medicare, you must specify a valid, medically appropriate ICD-9 code (or provide a narrative diagnostic information), which is supported by the patient’s medical record, for each test that you order, including all tests listed as part of organ or disease-oriented panels.

National Coverage Determinations (NCD), Local Coverage Determination (LCD), and Limited Coverage Tests

The Medicare Coverage Database (MCD) contains all 23 National Coverage Determinations (NCDs) outlined in the chart below as well as Local Coverage Determinations (LCDs), local policy articles, and proposed NCD decisions. The 23 National Coverage Determinations developed by the Centers for Medicare and Medicaid Services are updated on a quarterly basis and published in the NCD Coding Policy Manual. You can download the current NCD and LCD related information at: Medicare Coverage Database – Centers for Medicare & Medicaid Services.

<table>
<thead>
<tr>
<th>Test Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alpha-fetoprotein</td>
<td>Blood Counts</td>
</tr>
<tr>
<td>Carcinomembryonic Antigen</td>
<td>Collagen Crosslinks, Any Method</td>
</tr>
<tr>
<td>Fecal Occult Blood</td>
<td>Gamma Glutamyl Transferase</td>
</tr>
<tr>
<td>Hepatitis Panel/Acute Hepatitis Panel</td>
<td>HIV-1 or HIV-2 Quantification</td>
</tr>
<tr>
<td>Hepatitis Panel/Acute Hepatitis Panel</td>
<td>Human Chorionic Gonadotropin</td>
</tr>
<tr>
<td>Human Immunodeficiency Virus Testing (HIV Diagnosis)</td>
<td>Lipids Testing</td>
</tr>
<tr>
<td>Prolactin Specific Antigen</td>
<td>Prothrombin Time</td>
</tr>
<tr>
<td>Thyroid Testing</td>
<td>Serum Iron Studies</td>
</tr>
<tr>
<td>Tumor Antigen by Immunoassay CA-19-9</td>
<td>Tumor Antigen by Immunoassay CA-15-3/CA27.29</td>
</tr>
<tr>
<td>Tumor Antigen by Immunoassay CA-15-3/CA27.29</td>
<td>Urine Culture, Bacterial</td>
</tr>
</tbody>
</table>

Advance Beneficiary Notice

The Medicare program will allow the laboratory to bill the patient for denied services only if an Advance Beneficiary Notice (ABN) is forwarded to the laboratory with the test requisition. The ABN must be completed by the ordering physician and signed by the patient; the ABN is intended to inform the patient that Medicare will not pay for the services that it determines to be not reasonable and necessary under Section 1862(a)(1) of the Medicare Lab. Medicare does not pay for:

1) tests that are limited coverage unless the ICD-9 code supports medical necessity;
2) tests that are considered noncovered;
3) tests that exceed frequency limits established by Medicare; or
4) tests that are for experimental or research use.

Medical Laboratory Fee Schedule

CMS provides you with the Clinical Labs Center website to communicate information specific to Clinical Laboratories. To access the current laboratory fee schedule go to: Fee Schedule Clinical Laboratory Fee Schedule. Additionally, Medicaid reimbursement will be equal to, or less than Medicare reimbursement.
American Medical Association (AMA) Approved Organ or Disease Oriented Panels

The American Medical Association (AMA) has grouped certain tests into panels for coding purposes only. If one orders tests in addition to those specifically indicated for a particular panel, those tests are billed separately in addition to the panel code. A valid diagnosis code must be provided for each AMA-approved panel ordered. Individual components of these panels may be ordered separately.

1) Only order those tests that he or she believes are medically necessary for each patient.
2) Be aware that using a customized panel/profile may result in ordering tests for which Medicare or Medicaid will deny payment.
3) Order individual tests or a less inclusive panel/profile if all analytes in the panel/profile are not medically necessary.
4) Understand that the U.S. Department of Health and Human Services, Office of Inspector General takes the position that a physician who orders medically unnecessary tests may be subject to civil penalties.

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>BUN</td>
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<td>CBC</td>
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<td></td>
</tr>
<tr>
<td>Direct Bilirubin</td>
<td>82249</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hepatitis A Antibody, IgM</td>
<td>86709</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>Hepatitis B Surface Antigen</td>
<td>87340</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>LDL Cholesterol</td>
<td>83718</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HDL Cholesterol</td>
<td>83719</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Reflex Testing

Reflex testing occurs when initial test results are positive or outside normal parameters and indicate that a second related test or further testing is medically appropriate. Mandated testing criteria set by government or accrediting agencies, relevant practices in laboratory medicine, and avoidance of performing unnecessary testing help dictate which tests are subject to reflexive testing. Upon results of an initial laboratory test, reflex tests will be performed as outlined based on, "ALGORITHMS FOR REFLEX TESTS" located on Inside Beaumont on the Laboratory Services web page, under Reference Guides or on the internet at: http://www.beaumonthospitals.com/laboratory-resources

Some reflex testing may result in additional charges. If you DO NOT want reflex testing, please clearly communicate this request on the laboratory test requisition form and contact Customer Services at 800-551-0488 or 248-551-1155.

Screening Pap Tests

The College of American Pathologists, the accrediting organization for the Laboratory, requires that providers of cervicovaginal specimens be periodically notified that screening Pap tests are performed to primarily test for squamous cancers and its precursors and can have associated false negative or false positive results. Liquid based preparations may decrease but will not eliminate all false negative results. Regular sampling and follow-up of unexplained clinical signs and symptoms are recommended to minimize false negative results.

Physician Clinical Consultants

Beaumont has a professional staff of over forty pathologists and Ph.D. scientists specializing in all areas of laboratory medicine. Our medical staff is available to discuss laboratory-testing questions including ordering and interpretation or contact Mark Kolins, M.D., System Chair, Pathology and Laboratory Medicine, directly at 248-551-8030.

Please feel free to contact Customer Service at 800-551-0488 or 248-551-1155 if you should have any further questions. Thank you.
New Reference Range for PT (Prothrombin Time)

Effective Date: FEBRUARY 1, 2012

<table>
<thead>
<tr>
<th>Test</th>
<th>Old Reference Range</th>
<th>New Reference Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>PT (sec)</td>
<td>9.6-11.5</td>
<td>9.3-12.4</td>
</tr>
</tbody>
</table>

Rejection Criteria
Specimens containing clots, gross hemolysis, inappropriate volume, thawed or partially thawed are unacceptable and will not be tested.

Performed
7 days a week, 24 hours a day
- Routine: 2 hours
- STAT: 30 minutes

Interpretation
The Prothrombin Time is useful in the evaluation of the extrinsic pathway of coagulation. This test also aids in screening congenital factor deficiencies (II, V, VII, X), dysfibrinogenemia, congenital hypofibrinogenemia, disseminated intravascular coagulation, liver failure and vitamin K deficiency. Coumadin should be monitored with the international normalized ratio (INR).

Specimen Transport
Transport whole blood specimens to Coagulation Laboratory within 24 hours. Specimens should be kept room temperature (20-25°C or 68-77°F) for optimal results.

CPT Code
PT: 85610

Effective date
February 1, 2012 after 12pm

Submitted by
Marc D. Smith, MD, Medical Director, Coagulation Lab, Royal Oak
Ming Xie, MD, Medical Director, Hematology, Troy
LeiLei Chen, MD, Medical Director, Hematology, Grosse Pointe
OVA & PARASITE EXAMINATION
FOR GROSSE POINTE CAMPUS ONLY

Effective Date: February 6, 2012

Beaumont Health System, Grosse Pointe Medical Staff:

The above listed test will be sent to Beaumont Laboratory at Royal Oak. Patient’s results include the reference ranges and can be viewed on EPIC OneChart.

Specimen collection, reference ranges and interpretation are available at “Inside Beaumont Online” by clicking on <References> and <Lab Test Directory> or at: www.beaumonthospitals.com/latestdirectory

For any questions, contact Beaumont Laboratory Customer Service at 1-800-551-0488.

Date Submitted: January 27, 2012

Submitted by: Vaishali Pansare M.D.
Medical Director, Beaumont Laboratory Grosse Pointe

Isabel Gauss, MT (ASCP)
Administrative Director, Beaumont Laboratory Grosse Pointe
Cerebrospinal Fluid (CSF) Specimen Collection and Labeling Requirements:
Grosse Pointe Only

The protocol for proper CSF collection requires that an aliquot of CSF be placed in sequentially numbered and properly labeled sterile tubes as the fluid is collected. A CSF collection kit is available for collection of all cerebrospinal fluids. The kit contains four separate sterile tubes labeled with numbers 1-4 as shown below. Specimens are usually collected in four sterile tubes, which are labeled 1, 2, 3 and 4 in the order in which they are withdrawn.

The typical protocol for CSF specimen collection is as follows:

Please note that when ordering more than one test, the volumes need to be added up. Each tube holds a maximum of 8 ml.

- Tube 1 = CSF Protein, Glucose 1-2 mL required
- Tube 1 = CSF Oligoclonal Banding (includes IgG)* 1.5 mL required
- Tube 1 = CSF Myelin Basic Protein 1 mL required
**There is no need to use viral transport media with CSF as it usually contains enough protein for protection of any viruses that might be present.**

**CSF orders should be placed in EPIC prior to obtaining the specimen!**

**CSF tubes must be walked to the Main Laboratory in the lower level - STAT. Do not send CSF via the pneumatic tube.**

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**Tube 2 = Microbiology/Serology Studies**
- Tube 2 = CSF Routine Bacterial Culture 1 mL
- Tube 2 = CSF Fungal Culture 2 mL
- Tube 2 = CSF Viral Culture** 2 mL
- Tube 2 = CSF Mycobacterial Culture 5 - 7 mL
- Tube 2 = CSF Bacterial Antigen Detection 0.5 mL
- Tube 2 = CSF Cryptococcal Ag 0.5 mL

**Special Testing**
- Tube 2 = CSF Arbovirus IgM Panel 2.0 mL
- Tube 2 = CSF HSV PCR 1.0 mL
- Tube 2 = CSF Enterovirus PCR 1.0 mL
- Tube 2 = CSF Syphilis VDRL 0.5 mL

- Tube 3 = CSF Cell Count 1 mL required
- Tube 3 = CSF Flow Cytometry for Lymphoproliferative Disorder 1 mL required

- Tube 4 = Cytology Studies 1 mL required
- Tube 4 = Hold 1 mL required

* Blood (gold SST tube) is also required

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Specimen collection, reference ranges and interpretation can be seen on “Inside Beaumont Online” by clicking on <References> and <Lab Test Directory> or at: www.beaumonthospitals.com/labtestdirectory

If you have questions, please contact Client Services (1-800-551-0488, option 5).

---

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>02-08-2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submitted by</td>
<td>Vaishali Pansare, M.D., Pathology Chief / Medical Director, Laboratory, Beaumont Grosse Pointe</td>
</tr>
</tbody>
</table>
BLOOD CULTURES – TESTING UPDATE

Effective Date: March 5, 2012

More than 200,000 episodes of bloodstream infections occur annually in the United States. Optimal therapy for these infections is based on rapid detection of growth, identification of the isolate(s) and performance of \textit{in vitro} antimicrobial susceptibility testing. In order to achieve the most rapid growth and detection with blood cultures, the Clinical Microbiology Laboratories of Beaumont Health System will implement state-of-the-art blood culture equipment, the Bactec FX system.

On March 5, 2012, the Clinical Microbiology Laboratories at Royal Oak, Troy and Grosse Pointe will begin using this equipment for blood cultures. Growth in the FX system may be detected up to \textbf{four hours faster} than with other blood culture equipment currently in use. While the procedure for venipuncture will remain the same, \textbf{this change will necessitate a switch to glass bottles until plastic blood culture bottles are available in June 2012.} Additionally, it will no longer be necessary to use an angel wing adaptor during venipuncture as a vacutainer can be used.

Frequently asked questions:

1) \textbf{Will the test name change?}
   No. You will still order “Culture, Blood”

2) \textbf{Will there be a change in specimen collection and handling?}
   a) Yes. The new bottles are different from the old bottles and the old bottles will not work in the new equipment. The stock of old bottles will be reduced leading up to March 5, 2012 and should continue to be used until depleted after that date. They will be replaced with new bottles.
   b) Blood can be obtained with a syringe or with a butterfly apparatus attached to a vacutainer on the bottle.
   c) There are specific requirements when sending bottles through the pneumatic tube systems in the hospitals. \textit{Bottles must be placed into plastic carriers in a biohazard bag and padded with foam for transport in the pneumatic tube system.}

3) \textbf{Will there be a change in the turn-around-time for results?}
   Yes. If blood is collected with the optimal volumes of 8-10 mL/bottle for adults and 1-3 mL for pediatrics (<80 lb child), positive results can be detected more rapidly.

4) \textbf{What will happen if I incorrectly submit a blood culture in the old bottles?}
   They will be tested, however, results may not be available as rapidly as with the FX system. If you do not have the new Bactec bottles, contact Beaumont Laboratory Customer Service.

For complete specimen collection and handling instructions or additional information, please refer to the on-line Laboratory Test Directory:

Internal URL: \url{http://employee.beaumont.edu/portal/pls/portal/docs/997615.PDF}
External URL \url{http://beaumont.edu/labtestdirectory}

If you need additional information, please contact Customer Service (1-800-551-0488, option 5).

Date Submitted: February 16, 2012
Submitted By:
Royal Oak:
B. Robinson-Dunn, Ph.D., D(ABMM)
Technical Director, Microbiology
B. L. Boyanton, M.D.
Medical Director, Microbiology
Associate Medical Director, Molecular Pathology

Troy:
Paul Goodman, MD
Medical Director, Microbiology

Grosse Pointe:
Vaishali Pansare, MD
Medical Director, Cytology/Microbiology

http://www.beaumont.edu/labs
MICROBIOLOGY CULTURE REQUESTS FOR
SPECIMENS SUBMITTED IN SALINE RINSED FORMALIN CONTAINERS

Effective Date: March 9, 2012

POLICY: Tissue specimens received in formalin containers that have been rinsed and subsequently filled with saline will NOT be accepted for microbiological culture testing.

The reasons for this policy are as follows:

• **Formalin is a fixative or “pickling agent”**
  1. It preserves (i.e. kills) bacteria, yeasts, molds, etc.
  2. Residual formalin in the “rinsed-out” container, in the form of vapor or leaching from the internal surface of the container or lid, will dissolve into the saline solution. This will adversely impact the ability of the microbiology laboratory to cultivate microorganisms – this will lead to false negative culture results.

• **Laboratory safety policies . . . . .**
  1. Are enforced by regulatory agencies (i.e. OSHA, MIOSHA, CLIA, CAP, etc.)
  2. Prohibit laboratory staff from “smelling” the liquid within containers; therefore, laboratory staff cannot verify that saline is present in the container.

• **Contamination Concerns**
  1. The “rinsing process” may create a non-sterile environment – this may lead to false positive culture results.

**PROPER COLLECTION:** Place the tissue specimen into a sterile container with a small amount of sterile non-bacteriostatic saline (the concomitant use of sterile gauze is optional).

For complete specimen collection and handling instructions, please refer to the “on-line” Laboratory Test Directory:

Internal URL: [http://beaunet.beaumont.edu/portal/pls/portal/lab.lab_pkg.lab_list](http://beaunet.beaumont.edu/portal/pls/portal/lab.lab_pkg.lab_list)

External URL: [http://beaumonthospitals.com/labtestdirectory](http://beaumonthospitals.com/labtestdirectory)

If you need additional information, please contact Client Services (1-800-551-0488, option 5).

Submitted Date: February 20, 2012

Submitted By:
Royal Oak:
Barbara Robinson-Dunn, Ph.D., D(ABMM)
Technical Director, Microbiology

Bobby L. Boyanton Jr., M.D.
Medical Director, Microbiology Associate
Medical Director, Molecular Pathology

Troy:
Paul Goodman, MD
Medical Director, Microbiology

Grosse Pointe:
Vaishali Pansare, MD
Medical Director, Cytology/Microbiology
REFERENCE RANGES
Changes to Ammonia, Pseudocholinesterase and Sweat Chloride
Lower Limit Change to Alkaline Phosphatase Isoenzymes
Cutoff Change to Lecithin/Sphingomyelin (L/S) and Phosphatidylglycerol (PG)

Effective Date: March 9, 2012

Establishment of New Reference Ranges
Ammonia and pseudocholinesterase reference range changes are the result of method changes and/or method re-evaluation. The sweat chloride reference range changes (Royal Oak only) are due to new data indicating that these reference ranges in infants under 6 months old are too high and needed adjustment to a lower level so as not to miss the diagnosis in a significant number of infants.

<table>
<thead>
<tr>
<th>Performed At</th>
<th>Analyte</th>
<th>Old Range</th>
<th>New Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>RO/Troy</td>
<td>Ammonia</td>
<td>10-60 micromoles/L</td>
<td>11-35 micromoles/L</td>
</tr>
<tr>
<td>RO Only</td>
<td>Pseudocholinesterase</td>
<td>4.5-13.3 kU/L</td>
<td>4.9-11.9 kU/L</td>
</tr>
<tr>
<td>RO Only</td>
<td>Sweat Chloride (age 0-6 months)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Normal</td>
<td>&lt;40 mmol/L</td>
<td>&lt;30 mmol/L</td>
</tr>
<tr>
<td></td>
<td>Intermediate</td>
<td>40-59 mmol/L</td>
<td>30-59 mmol/L</td>
</tr>
</tbody>
</table>

There is no change in the reference interval for sweat chloride levels in patients greater than 6 months old.

Establishment of Lower Limit for Alkaline Phosphatase Isoenzymes
Because of the limited clinical utility of measuring alkaline phosphatase isoenzyme levels when the total alkaline phosphatase level is well within the normal range, alkaline phosphatase isoenzymes will no longer be performed when the total alkaline phosphatase level is less than or equal to 80 U/L.

Change in Lecithin/Sphingomyelin (L/S) ratio cutoff and Phosphatidylglycerol (PG) presence in amnionic fluid for determining fetal lung maturity in diabetic and non-diabetic pregnancies
The interpretative comment for L/S ratio and PG in amnionic fluid has changed.

Previous comment:
In the diabetic woman, a PG of trace or greater is required for maturity. In the non-diabetic woman, an L/S ratio of greater than or equal to 2.0 and/or a PG of trace or greater is considered mature.

New comment:
An L/S ratio of greater than or equal to 2.0 and/or a PG of trace or greater is considered mature.

This change follows the recommendation by ACOG (American College of Obstetrics and Gynecology) in which studies indicate no difference in the L/S ratio or PG in diabetic vs. non-diabetic pregnancies.

Date Submitted: March 9, 2012

Submitted by:
Royal Oak:
Yvonne Posey, MD, Associate Director, Automated Chemistry and Special Testing
Elizabeth Sykes, MD, Medical Director, Automated Chemistry and Special Testing
Troy:
Paul Goodman, MD, Medical Director, Microbiology
Ralph Zade, MD, Medical Director, Chemistry
HBV VIRAL LOAD TESTING – UPDATE

Effective Date: March 12, 2012

On March 12, 2012, the Molecular Pathology Laboratory will update HBV viral load testing to an automated instrument (Roche COBAS AmpliPrep / COBAS TaqMan HBV Test, v2.0.)

This new test offers the following advantages:
- Improved sensitivity (20 IU/mL)
- Greater dynamic range for quantitation (20 to 170,000,000 IU/mL)
- NO need to re-baseline or re-calibrate your patients

Specimen Collection Summary:
- Acceptable specimens: serum or plasma
- Minimum sample volume: 1.1 mL of serum or plasma
- Separate (centrifuge) serum or plasma from cells within 6 hours of collection

For complete specimen collection and handling instructions, please refer to the “on-line” Laboratory Test Directory:

Internal URL: http://beaunet.beaumont.edu/portal/pls/portal/lab.lab_pkg.lab_list
External URL: http://beaumonthospitals.com/labtestdirectory

Special Note:
This will be a seamless transition to you and your patients.

There will be NO need to re-baseline or re-calibrate your patients - correlation studies performed by our laboratory have demonstrated exceptional agreement between the new and previously utilized tests.

If you need additional information, please contact Client Services (1-800-551-0488, option 5).

Submitted Date: February 27, 2012

Submitted By: Bobby L. Boyanton Jr., M.D.
Medical Director, Microbiology
Associate Medical Director, Molecular Pathology

Domnita Crisan, M.D., Ph.D.
Medical Director, Molecular Pathology

Beaumont Laboratory
Customer Service
1-800-551-0488

468 Cadieux
Grosse Pointe, MI 48230

3601 West 13 Mile Road
Royal Oak, MI 48073-6769

44201 Dequindre Road
Troy, MI 48085-1198

http://www.beaumont.edu/labs
MYCOPLASMA SEROLOGICAL TESTING

Effective March 19, 2012, *Mycoplasma pneumoniae* IgG and IgM testing will be performed by enzyme-linked immunosorbent assay (ELISA). No changes are being made to specimen collection requirements. The testing was previously performed by indirect immunofluorescence. However, the vendor recently discontinued distributing the required reagents, prompting the change in test methodology. Beaumont Laboratory has independently verified appropriate performance of the new test systems.

REFERENCE RANGES
*Mycoplasma pneumoniae* IgG
*Mycoplasma pneumoniae* IgM

<table>
<thead>
<tr>
<th>Index Ratio</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 0.90</td>
<td>Negative</td>
</tr>
<tr>
<td>0.91 – 1.09</td>
<td>Equivocal</td>
</tr>
<tr>
<td>≥ 1.10</td>
<td>Positive</td>
</tr>
</tbody>
</table>

Submitted date: February 23, 2012
Submitted by: Gabriel Maine, PhD
Technical Director, Special Testing, Royal Oak

Elizabeth Sykes, MD
Medical Director, Special Testing, Royal Oak
FUNGUS CULTURES
FOR GROSSE POINTE CAMPUS ONLY

Effective Date: March 26, 2012

Beaumont Health System, Grosse Pointe Medical Staff:

The above listed test will be sent to Beaumont Laboratory at Royal Oak. Patient's results include the reference ranges and can be viewed on EPIC OneChart.

Specimen collection, reference ranges and interpretation are available at “Inside Beaumont Online” by clicking on <References> and <Lab Test Directory> or at: www.beaumonthospitals.com/latestdirectory

For any questions, contact Beaumont Laboratory Customer Service at 1-800-551-0488.

Date Submitted: March 15, 2012

Submitted by: Vaishali Pansare M.D., Medical Director, Beaumont Laboratory Grosse Pointe
Isabel Gauss, MT (ASCP), Administrative Director, Beaumont Laboratory Grosse Pointe
Flow Cytometry for Hematolymphoid Neoplasm, CSF

Effective Date: 03/28/2012

Flow Cytometry for Hematolymphoid Neoplasm orders that are to be performed on cerebrospinal fluid specimens will now be orderable as a separate test. This test should be ordered in EPIC as “Flow Cytometry for Hematolymphoid Neoplasm, CSF”.

<table>
<thead>
<tr>
<th>Synonyms</th>
<th>Flow Cytometry for Hematolymphoid Neoplasm, FHEMC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Instructions</td>
<td>In EPIC, when ordering Flow Cytometry for Hematolymphoid Neoplasm on a CSF specimen, order “Flow Cytometry for Hematolymphoid Neoplasm, CSF”.</td>
</tr>
<tr>
<td>Performed</td>
<td>Monday-Saturday</td>
</tr>
<tr>
<td>Test Methodology</td>
<td>Immunophenotyping by multiparameter flow cytometry</td>
</tr>
<tr>
<td>Interpretation</td>
<td>The antigen panel is determined by the clinical history and/or review of stained slides. The antigen expression is reviewed with available slides and provided clinical history to determine a differential diagnosis or final diagnosis.</td>
</tr>
<tr>
<td>Date Submitted</td>
<td>March 12, 2012</td>
</tr>
</tbody>
</table>
| Submitted by              | Vonda Douglas-Nikitin MD Medical Director, Flow Cytometry  
James Huang MD Associate Director, Flow Cytometry |
GROUP A CULTURE WITH / WITHOUT SUSCEPTABILITY
STOOL CULTURE / INCLUDING SHIGA TOXIN TESTING
PIN WORM PADDLES
CATH TIP CULTURE
FOR GROSSE POINTE CAMPUS ONLY

Effective Date: April 9, 2012

Beaumont Health System, Grosse Pointe Medical Staff:

The above listed test will be sent to Beaumont Laboratory at Royal Oak. Patient’s results include the reference ranges and can be viewed on EPIC OneChart.

Specimen collection, reference ranges and interpretation are available at “Inside Beaumont Online” by clicking on <References> and <Lab Test Directory> or at: www.beaumonthospitals.com/latestdirectory

For any questions, contact Beaumont Laboratory Customer Service at 1-800-551-0488.

Date Submitted: March 30, 2012

Submitted by:

Vaishali Pansare M.D. , Medical Director, Beaumont Laboratory Grosse Pointe
Isabel Gauss, MT (ASCP), Administrative Director, Beaumont Laboratory Grosse Pointe
New Critical Values Added
Asparate Aminotransferase (AST) and Lactic Acid

Critical Values have been added for two analytes:

Effective Date: Immediately

Asparate Aminotransferase (AST) >2000
Lactic Acid >3.9

Date Submitted | 4/23/2012
---|---
Submitted by | Mark Kolins, MD, System Chair, Pathology & Laboratory Medicine
| Elizabeth Sykes, MD, Vice Chief, Clinical Pathology, Chemistry
| Ralph Zade, MD, Chemistry, Troy
| Beatrice Muglia, MD, Chemistry, Grosse Pointe
Hyponatremia Panel – Royal Oak only

Effective Date: April 25, 2012

The hyponatremia panel has been set up to provide rapid result turn around time and consistency of testing equipment (by direct potentiometry) for patients being treated for hyponatremia. It may also be of use in patients with a possible diagnosis of pseudohyperkalemia (due to high platelets or white cells). The panel will automatically be treated as Stat and the sample should be sent to the Stat Lab. Details are as follows:

<table>
<thead>
<tr>
<th>Test Included</th>
<th>Sodium, Potassium, Chloride</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tube Type</td>
<td>Green top (Li heparin)</td>
</tr>
<tr>
<td></td>
<td>Minimum whole blood – 2.0 mL</td>
</tr>
<tr>
<td>Performed</td>
<td>Stat Lab by direct potentiometry (blood gas analyzers)</td>
</tr>
<tr>
<td>Reference Range</td>
<td>No changes</td>
</tr>
<tr>
<td>Availability</td>
<td>Sunday-Saturday, 24 hours a day</td>
</tr>
<tr>
<td></td>
<td>Results available within 15 minutes after receipt in lab.</td>
</tr>
<tr>
<td>Date Submitted</td>
<td>04/25/2012</td>
</tr>
<tr>
<td>Submitted by</td>
<td>Elizabeth Sykes, MD, Medical Director, Automated Chemistry and Special Testing</td>
</tr>
</tbody>
</table>
CRYSTAL ANALYSIS

Effective Date: Immediately

Please use the following guidelines when collecting samples for Crystal Analysis. 1.0 mL (Min: 0.5 mL) synovial fluid in sodium heparin (green) vacutainer tube, preferred. Crystal identification should not be performed on EDTA (lavender) tubes, as powdered EDTA may produce false positive results. Specimens collected in a red top tube are no longer acceptable due to the presence of a clot activator in the collection tube.

<table>
<thead>
<tr>
<th>Synonyms</th>
<th>Crystals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specimen Collection Criteria</td>
<td>1.0 mL (Min: 0.5 mL) synovial fluid in sodium heparin (green) vacutainer tube, preferred. Specimens collected in a red top tube are no longer acceptable due to the presence of a clot activator in the collection tube.</td>
</tr>
<tr>
<td>Specimen Preparation for Courier Transport</td>
<td>Transport refrigerated (2-8°C or 36-46°F).</td>
</tr>
<tr>
<td>Rejection Criteria</td>
<td>Specimens received in bags, bottles, or syringes will not be tested. Specimens collected in powdered sodium EDTA, (lavender), oxalate, lithium heparin tubes, or red tubes with clot activator will not be tested due to possible specimen interference.</td>
</tr>
<tr>
<td>Performed</td>
<td>Sunday - Saturday, 24 hours a day Results available in 4 hours.</td>
</tr>
<tr>
<td>Reference Range</td>
<td>Absent</td>
</tr>
<tr>
<td>Date Submitted</td>
<td>4-14-2012</td>
</tr>
</tbody>
</table>

Submitted by

<table>
<thead>
<tr>
<th>Name</th>
<th>Hospital</th>
<th>Phone 1</th>
<th>Phone 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hematology Laboratory</td>
<td>RO</td>
<td>(248) 551-8050</td>
<td></td>
</tr>
<tr>
<td>Noelle Procopio</td>
<td>RO</td>
<td>(248) 551-8081</td>
<td></td>
</tr>
<tr>
<td>Ann Marie Blenc, M.D.</td>
<td>RO</td>
<td>(248) 551-8023(248) 992-2671</td>
<td></td>
</tr>
<tr>
<td>Hematology/Coagulation LaboratoryTroy</td>
<td>Troy</td>
<td>(248) 964-8040</td>
<td></td>
</tr>
<tr>
<td>Mary Wyrzykowski</td>
<td>Troy</td>
<td>(248) 964-8008</td>
<td></td>
</tr>
<tr>
<td>Hongwei Ma, M.D.</td>
<td>Troy</td>
<td>(248) 964-4105</td>
<td></td>
</tr>
<tr>
<td>Hematology/Coagulation</td>
<td>GP</td>
<td>(313) 473-1809</td>
<td></td>
</tr>
<tr>
<td>Cynthia Kopenski</td>
<td>GP</td>
<td>(313) 473-1809</td>
<td></td>
</tr>
<tr>
<td>Lei Lei Chen, M.D.</td>
<td>GP</td>
<td>(313) 473-1615(248) 992-1234</td>
<td></td>
</tr>
</tbody>
</table>
MRSA CULTURE  
VRE CULTURE  
STAPH AUREUS CULTURE  
FOR GROSSE POINTE CAMPUS ONLY

Effective Date: April 30, 2012

Beaumont Health System, Grosse Pointe Medical Staff:

The above listed test will be sent to Beaumont Laboratory at Royal Oak. Patient’s results include the reference ranges and can be viewed on EPIC OneChart.

Specimen collection, reference ranges and interpretation are available at “Inside Beaumont Online” by clicking on <References> and <Lab Test Directory> or at: www.beaumonthospitals.com/latestdirectory

For any questions, contact Beaumont Laboratory Customer Service at 1-800-551-0488.

<table>
<thead>
<tr>
<th>Date Submitted:</th>
<th>April 18, 2012</th>
</tr>
</thead>
</table>
| Submitted by:   | Vaishali Pansare M.D., Medical Director, Beaumont Laboratory Grosse Pointe  
Isabel Gauss, MT (ASCP), Administrative Director, Beaumont Laboratory Grosse Pointe |
CYP2C19 Genotyping

Effective Date: May 1, 2012

The Molecular Pathology Laboratory in the department of Clinical Pathology will offer testing of CYP2C19 genotype, a pharmacogenomics assay for patients treated with Clopidogrel.

<table>
<thead>
<tr>
<th>Synonyms</th>
<th>CYP2C19 Genotyping for Clopidogrel/Plavix</th>
</tr>
</thead>
<tbody>
<tr>
<td>Instructions</td>
<td>Collect 5-10 mL whole blood in EDTA (lavender top) or ACD (yellow top) tubes</td>
</tr>
<tr>
<td>Physician Office/Draw Site Specimen Preparation</td>
<td>Specimens are stable at room temperature up to 72 hours. Specimens may be refrigerated (2°-8°C or 36°-46°F). Do not freeze specimens.</td>
</tr>
<tr>
<td>Specimen Preparation for Courier Transport</td>
<td>Transport at room temperature (20°-25°C or 68°-77°F)</td>
</tr>
<tr>
<td>Rejection Criteria</td>
<td>Specimens collected in heparin (green top), clot tubes, SST tubes, unlabeled tubes or frozen specimens will not be tested.</td>
</tr>
<tr>
<td>Performed</td>
<td>Once a week. Results will be available in 7-10 days.</td>
</tr>
<tr>
<td>Reference Range</td>
<td>Wild type (Normal) genotype CYP2C19 *1 *1</td>
</tr>
<tr>
<td>Test Methodology</td>
<td>Genomic DNA extracted from the patient’s peripheral blood is used for PCR amplification and multiplexed hybridization to detect the following CYP2C19 gene alleles: *1 (Normal/wild type), *2 → *10, *13 and *17.</td>
</tr>
<tr>
<td>Interpretation</td>
<td>Based on the genotype, patients are phenotypically categorized as extensive (normal) metabolizers, intermediate metabolizers, poor metabolizers, and ultrarapid metabolizers. The test reports will provide genotype/phenotype/therapy correlations and also information on drug-drug interactions and their effects on CYP2C19 activity and Clopidogrel metabolism.</td>
</tr>
<tr>
<td>CPT Code</td>
<td>83891, 83900, 83901, 83892, 83856, 83909</td>
</tr>
<tr>
<td>Date Submitted</td>
<td>April 5, 2012</td>
</tr>
<tr>
<td>Submitted by</td>
<td>Domnita Crisan, MD, PhD Medical Director, Molecular Pathology Laboratory</td>
</tr>
</tbody>
</table>
GIARDIA ANTIGEN
CRYPTOSPORIDIUM ANTIGEN
INSECT IDENTIFICATION
FOR GROSSE POINTE CAMPUS ONLY

Effective Date: May 14, 2012

Beaumont Health System, Grosse Pointe Medical Staff:

The above listed test will be sent to Beaumont Laboratory at Royal Oak. Patient’s results include the reference ranges and can be viewed on EPIC OneChart.

Specimen collection, reference ranges and interpretation are available at “Inside Beaumont Online” by clicking on <References> and <Lab Test Directory> or at: www.beaumonthospitals.com/labtestdirectory

For any questions, contact Beaumont Laboratory Customer Service at 1-800-551-0488.

<table>
<thead>
<tr>
<th>Date Submitted:</th>
<th>May 3, 2012</th>
</tr>
</thead>
</table>
| Submitted by:   | Vaishali Pansare M.D., Medical Director, Beaumont Laboratory Grosse Pointe  
                  Isabel Gauss, MT (ASCP), Administrative Director, Beaumont Laboratory Grosse Pointe |
## Pediatric Path Consult

**Effective Date: June 1, 2012**

All peripheral smear reviews should be ordered as Path Consult Hematology, which will be interpreted in the clinical pathology department by board certified hematopathologists. Official reports will be distributed to ordering physicians and available in oneChart. As of June 1, 2012, the term “pediatric pathology consults” will no longer be used nor available.

### Rejection Criteria

<table>
<thead>
<tr>
<th>Specimens containing clots or insufficient volume are unacceptable and will not be tested. A slide review to pathologist must be ordered as a Pathology Consult or it will not recognized as an order and therefore not performed. In order to ensure compliance with Medicare and other federal regulatory agencies, the Hematology Laboratory has instituted the written policy of not accepting requests for Pathology Consults to review normal CBC/differential results.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Due to the deterioration of morphology on aged specimens, it is not appropriate to add a Path Consult to an EDTA specimen that was received on a previous day. All requests for an add-on Path Consult should be re-directed at obtaining a fresh specimen. In addition, Path Consults are only available more frequently than once per week if approved by a pathologist.</td>
</tr>
</tbody>
</table>

### Performed

- Monday-Friday, dayshift
- Reports available in 24 hours.
- Specimens received Friday afternoon through Sunday will have results available the following Monday.

### Interpretation

- By pathologist report.

### CPT Code

- 85025, 85046, 80502

### Date Submitted

- May 22, 2012

### Submitted by

- Ann Marie Blenc, MD
BRAF MUTATION ANALYSIS

Effective Date: July 1, 2012

BRAF Mutation Analysis is now being offered by the Advanced Diagnostics Laboratory. This test is ordered in SoftPath as MBRFG (BRAF Mutation Analysis) and must be accompanied by a written requisition from the requesting physician.

<table>
<thead>
<tr>
<th>Synonyms</th>
<th>BRAF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Instructions</td>
<td>Requesting physician’s written requisition must accompany the order. Order test in Soft Path: MBRFG – BRAF Mutation Analysis. If the sample is an outside block, the test is ordered in Soft Lab using the same code. BRAF testing can be performed on many tumors, especially thyroid papillary carcinomas, colon cancers, lung cancers and melanomas. Melanomas that are positive in house for BRAF mutations will be sent out for confirmatory testing.</td>
</tr>
<tr>
<td>Specimen Collection Criteria</td>
<td>Formalin fixed paraffin embedded specimens (paraffin block) or alcohol fixed cytology slide preparations</td>
</tr>
<tr>
<td>Rejection Criteria</td>
<td>Inadequate tumor as ascertained by pathologist</td>
</tr>
<tr>
<td>Performed</td>
<td>Monday-Friday</td>
</tr>
<tr>
<td>Test Methodology</td>
<td>Shifted Termination Assay, a proprietary technology of the Trimgen Corporation (Sparks MD)</td>
</tr>
<tr>
<td>Interpretation</td>
<td>Wild-type or BRAF mutation present with specific mutation listed (V600E, V600A and V600G)</td>
</tr>
<tr>
<td>CPT Codes</td>
<td>83890, 83907, 83892, 83898x3, 83914, 83909.</td>
</tr>
<tr>
<td>Date Submitted</td>
<td>July 16, 2012</td>
</tr>
<tr>
<td>Submitted by</td>
<td>Mitual B. Amin, Director, Advanced Diagnostics Laboratory Anatomic Pathology - Royal Oak, Beaumont Laboratory</td>
</tr>
</tbody>
</table>
Effective Monday, July 24th, Beaumont Lab will introduce a new HIV 1/2 testing algorithm. The initial screen is a 4th generation assay that detects both HIV-1 p24 antigen and antibodies to HIV-1 (groups M and O) and HIV-2. The new screen will detect acute HIV infection, on average 7 to 10 days earlier than the previously used antibody-only screen.

Positive screen confirmation antibody testing to distinguish HIV-1 from HIV-2 will be performed in-house within 24 hours of initial testing. Western blots (currently a send-out test) will no longer be ordered. Rarely, additional molecular-based confirmation testing for HIV-1 and/or HIV-2 will be performed (Send Out) as delineated in the algorithm below. All test results will be included in a single report with a final interpretation.

Specimen type: Serum: Gold top (5 mL)
Test Name: HIV 1/2 Testing Algorithm (SOFT Code: HIV4G)
Initial screen performed: Monday – Saturday, day and midnight shifts
Sunday – dayshift only
Confirmation testing: Monday – Sunday, dayshift

Submitted: Elizabeth Sykes, MD, Medical Director, Automated Chemistry and Special Testing
Bobby Boyanton, MD, Medical Director, Microbiology; Associate Medical Director, Molecular Pathology
Barbara Robinson-Dunn, PhD, D(ABMM), Technical Director, Microbiology

---

**HIV 1/2 TESTING ALGORITHM**

1. **HIV-1 p24 antigen**
   - **Reactive**
     - **Antibody Confirmation Procedure**
       - **HIV-1 and HIV-2 Ab Reactive**
         - Additional molecular-based testing (Send-Out)
       - **Non-reactive**
         - Additional molecular-based testing (Send-Out)
   - **Non-reactive**
     - **HIV-2 Ab Reactive**
       - Additional molecular-based testing (Send-Out)
     - **HIV-1 Ab Reactive**
       - **STOP HIV-1 infection confirmed**

2. **HIV-1/2 antibodies**
   - **Reactive**
     - **Antibody Confirmation Procedure**
       - **HIV-1 and HIV-2 Ab Reactive**
         - Additional molecular-based testing (Send-Out)
       - **Non-reactive**
         - Additional molecular-based testing (Send-Out)
   - **Non-reactive**
     - **STOP No further testing**
URINE CULTURE
FOR GROSSE POINTE CAMPUS ONLY

Effective Date: July 30, 2012

Beaumont Health System, Grosse Pointe Medical Staff:

The above listed test will be sent to Beaumont Laboratory at Royal Oak. Patient’s results include the reference ranges and can be viewed on EPIC OneChart.

Specimen collection, reference ranges and interpretation are available at “Inside Beaumont Online” by clicking on <References> and <Lab Test Directory> or at: www.beaumonthospitals.com/labtestdirectory

For any questions, contact Beaumont Laboratory Customer Service at 1-800-551-0488.

<table>
<thead>
<tr>
<th>Date Submitted</th>
<th>July 19, 2012</th>
</tr>
</thead>
</table>
| Submitted by    | Vaishali Pansare, M.D.  
                 | Medical Director, Beaumont Laboratory Grosse Pointe |
|                 | Isabel Gauss, MT (ASCP)  
                 | Administrative Director, Beaumont Laboratory Grosse Pointe |
Human Immunodeficiency Virus Genotyping for Drug Resistance (HIV-1 Genotyping) REVISED

Effective Date: August 3, 2012

The Molecular Pathology Laboratory has updated its database of HIV genome mutations related to drug resistance according to TRUGENE HIV-1 new Guideline Rules Version 17.0.

There is no change in RT-PCR and DNA sequencing methodology and no change in specimen requirements.

Highlights include:
- Resistance interpretation rules are added for the newly introduced Reverse Transcriptase Inhibitor Rilpivirine. Results for this drug appear on the TRUGENE HIV-1 Resistance Report.
- L74V alone and Y115F alone are upgraded to full Resistance for the Reverse Transcriptase Inhibitor Abacavir (ABC).
- E138K alone is upgraded to full Resistance for the Reverse Transcriptase Inhibitor Etravirine (ETR).

Date Submitted: August 3, 2012

Submitted by: Domnita Crisan, MD, PhD
Medical Director, Molecular Pathology Laboratory

Bobby Boyanton, MD
Medical Director, Microbiology Laboratory
HIV-1 VIRAL LOAD TESTING – UPDATE

Effective Date: August 06, 2012

On August 06, 2012, the Molecular Pathology Laboratory will enhance HIV-1 viral load testing by implementing a dual-target real-time PCR test. This new test targets two highly conserved regions of the HIV-1 genome (LTR and gag), thereby mitigating the effect of mutations within the HIV-1 genome on the HIV-1 viral load. This new test detects all clinically significant HIV-1 groups and subtypes with full subtype coverage and quantification of HIV-1 groups (O and M).

Advantages of New Test (Roche COBAS Ampliprep/COBAS TaqMan HIV test, version 2.0)
- Dual-Target quantification (minimize chance of mutation effects)
- Improved lower limit of quantification (20 copies / mL)
- Same upper limit of quantification (10,000,000 copies / mL)

Specimen Collection Summary:
- Acceptable specimens: serum or plasma
- Minimum sample volume: 1.1 mL of serum or plasma
- Separate (centrifuge) serum or plasma from cells within 6 hours of collection

For complete specimen collection and handling instructions, please refer to the “on-line” Laboratory Test Directory:
  Internal URL: http://beunet.beaumont.edu/portal/pls/portal/lab.lab_pkg.lab_list
  External URL: http://beaumonthospitals.com/labtestdirectory

Special Note:
This will be a seamless transition to you and your patients. There will be NO need to re-baseline or re-calibrate your patients - correlation studies performed by our laboratory have demonstrated exceptional agreement between the new and previously utilized test.

If you need additional information, please contact Client Services (1-800-551-0488, option 5).

July 10, 2012
Bobby L. Boyanton Jr., M.D.
Medical Director, Microbiology
Associate Medical Director, Molecular Pathology

Domnita Crisan, M.D., Ph.D.
Medical Director, Molecular Pathology
HELICOBACTER PYLORI UREA BREATH TEST

Effective Date: August 6, 2012

The Urea Breath test is for the analysis of pre- and post-breath samples to detect C13 (isotopic, nonradioactive). The urea breath test may be used for the diagnosis and treatment follow-up of H. pylori infection. Specimens are only accepted from our Outreach Physician Client offices. Patient must be 18 years or older.

<table>
<thead>
<tr>
<th>Synonyms</th>
<th>Urea Breath Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scheduling</td>
<td>Specimens are only accepted from our Outreach Physician Client Offices. Call Customer Service for supplies @ 800-551-0488 option 5.</td>
</tr>
</tbody>
</table>
| Patient Preparations              | Patients with PKU disease should consult their physician. Solution contains phenylalanine. Patients should abstain from the following 2 weeks prior to testing:  
  a. Antibiotics  
     i. Zegerid  
     ii. Prilosec  
     iii. Prilosec OTC  
     iv. Prevacid  
     v. Aciphex  
     vi. Protonix  
     vii. Nexium  
  b. Proton Pump inhibitors  
     i. Zegerid  
     ii. Prilosec  
     iii. Prilosec OTC  
     iv. Prevacid  
     v. Aciphex  
     vi. Protonix  
     vii. Nexium  
  c. Bismuth preparations (Pepto Bismol) |
| Testing                           | Patients will exhale in a small bag for the pre-breath sample. Patient will drink solution and wait 15 minutes. Patient will exhale in small bag for post-breath sample. |
| Performed                         | Specimens sent to Laboratory Corporation of America. Results available in 3 business days. |
| Reference Range                   | Negative                                                                        |
| Date Submitted                    | 09/11/2012                                                                      |
| Submitted by                      | Dr. Yvonne Posey, M.D. – Medical Director of Send Outs  
                               Dr. Elizabeth Sykes, M.D – Medical Director of Automated Chemistry. |
Lamellar Body Count on Amniotic Fluid to Replace Abbott FLM II (Fetal Lung Maturity II) Testing

Effective Date: 8/07/2012

Effective August 7, 2012, the Lamellar Body Count (LBC) will replace the Abbott FLM II test. The Abbott FLM II test is no longer being manufactured.

Lamellar bodies represent the storage form of pulmonary surfactant. Surfactant is produced by Type II pneumocytes and is excreted from the fetal lung into the amniotic fluid as early as 32 weeks of gestation. Surfactant levels increase as the lungs mature forming a phospholipid monolayer over the alveoli that decreases surface tension and therefore keeps the lungs from collapsing completely with expiration. Failure to produce sufficient surfactant results in neonatal respiratory distress syndrome (RDS). This is a leading cause of morbidity and mortality in newborns, especially those born prematurely. The counting of lamellar bodies in amniotic fluid is a reflection of the amount of surfactant being produced by the fetus and is used to predict fetal lung maturity and assess the risk of development of neonatal RDS. Lamellar bodies are similar in size to platelets (2 - 10 fl) and can be accurately quantified on a hematology analyzer using the platelet channel.

| Specimen Collection Criteria | A minimum of 7 mL of amniotic fluid collected by transabdominal amniocentesis is preferred. Vaginal pool specimens should be avoided when possible. |
| Specimen Preparation for Courier Transport | **Inpatient:** The specimen should be transferred to the laboratory immediately after collection in a sterile container.  
**Outpatient:** If it cannot be transported immediately, then refrigerate, call for a STAT pick-up and transport to the laboratory within 4 hours of collection. **DO NOT CENTRIFUGE. DO NOT FREEZE.** |
| Rejection Criteria | Grossly bloody specimens (that is specimens having more than 1% v/v of blood), meconium-stained (green-colored) specimens, specimens containing obvious mucus or contaminated specimens will not be tested. Frozen or centrifuged specimens will not be tested for LBC. |
| Performed | Monday-Sunday. Specimen must be received in the Special Testing Laboratory before noon Monday-Friday for LSPG testing to be performed the same day. |
| Reference Range | Amniotic Fluid Lamellar Body Count (LBC):  
LBC > 55,000/mcL is predictive of fetal lung maturity  
LBC ≤ 55,000/mcL is suggestive of fetal lung immaturity. |
| Interpretation | An immature LBC is not reliable in predicting fetal lung immaturity. Therefore, all LBC results less than 55,000/mcL will be tested for a lecithin:sphingomyelin ratio and phosphatidyl glycerol (L/S-PG).  
100 percent of specimens (N=195) with a LBC > 55,000/mcL had an L/S > 2.0 (mature). Specimens with a LBC of ≥ 55,000/mcL will NOT be analyzed for L/S-PG. |
| Date Submitted | July 24, 2012 |
| Submitted by | Yvonne Posey, M.D., Associate Director, Automated Chemistry and Special Testing  
Ann Marie Blenc, M.D., Director, Hematopathology |
Thyroid Stimulating Immunoglobulin

Effective Date: August 20, 2012

Effective 8-20-12 the reference range for the Thyroid Stimulating Immunoglobulin will change.

<table>
<thead>
<tr>
<th>Performed</th>
<th>ARUP Laboratories</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference Range</td>
<td>Old Reference Ranges</td>
</tr>
<tr>
<td></td>
<td>Negative - 109% basal activity or less.</td>
</tr>
<tr>
<td></td>
<td>Indeterminate - 110-129% basal activity</td>
</tr>
<tr>
<td></td>
<td>Positive - 130% basal activity or greater</td>
</tr>
<tr>
<td></td>
<td>New Reference Ranges</td>
</tr>
<tr>
<td></td>
<td>Negative - 122% basal activity or less.</td>
</tr>
<tr>
<td></td>
<td>Positive - 123% basal activity or more</td>
</tr>
<tr>
<td>Test Methodology</td>
<td>Quantitative Bioassay/Quantitative Chemiluminescent</td>
</tr>
<tr>
<td></td>
<td>Immunoassay</td>
</tr>
<tr>
<td>Interpretation</td>
<td>Positive results (111 percent or greater) are consistent with Graves disease but do not always correlate with the presence and severity of hyperthyroidism. Antibodies to the Thyroid Stimulating Hormone Receptor (TSHR) may be stimulating, blocking, or neutral. Stimulating antibodies mimic the action of TSH and cause hyperthyroidism (Graves disease). This test determines the net effect of all TSHR antibody types present in the serum specimen.</td>
</tr>
<tr>
<td>Date Submitted</td>
<td>August 3, 2012</td>
</tr>
<tr>
<td>Submitted by</td>
<td>Yvonne Posey, MD  Medical Director, Send Outs</td>
</tr>
</tbody>
</table>
Aminolevulinic Acid, Urine

Effective Date: August 30, 2012

As of August 30, 2012, this test will be sent to ARUP Laboratories.

<table>
<thead>
<tr>
<th>Synonyms</th>
<th>ALA (Aminolevulinic Acid) , DALA (Delta-Aminolevulinic Acid) , AIP (Acute Intermittent Porphyria) , ALA Dehydratase Deficiency Porphyria (ADP) , HCP (Hereditary Coproporphyria) , VP (Variegate Porphyria)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Instructions</td>
<td>Refrain from alcohol consumption for at least 24 hours prior to collection.</td>
</tr>
<tr>
<td>Specimen Collection</td>
<td>Collect a 24 Hour urine with no preservative. Refrigerate the 24 Hour specimen during the collection period.</td>
</tr>
<tr>
<td>Criteria</td>
<td></td>
</tr>
<tr>
<td>Physician Office/Draw</td>
<td>Samples should be kept refrigerated (2-8°C or 36-46°F).</td>
</tr>
<tr>
<td>Site Specimen Preparation</td>
<td></td>
</tr>
<tr>
<td>Specimen Preparation</td>
<td>Transport entire 24 hour urine collection refrigerated (2-8°C or 36-46°F).</td>
</tr>
<tr>
<td>for Courier Transport</td>
<td></td>
</tr>
<tr>
<td>Rejection Criteria</td>
<td>Urine collected with any type of preservative will not be tested.</td>
</tr>
<tr>
<td>Performed</td>
<td>ARUP Laboratories, Salt Lake City, UT</td>
</tr>
<tr>
<td>Reference Range</td>
<td>0-35 umol/L</td>
</tr>
<tr>
<td>Test Methodology</td>
<td>Quantitative Ion Exchange Chromatography/Spectrophotometry</td>
</tr>
<tr>
<td>Interpretation</td>
<td>Increased ALA concentration is associated with exposure to alcohol, lead, and a variety of other agents. Massive elevation of ALA occurs in the acute porphyrias and hereditary tyrosinemia.</td>
</tr>
<tr>
<td>CPT Code</td>
<td>82135</td>
</tr>
<tr>
<td>Date Submitted</td>
<td>September 12, 2012</td>
</tr>
<tr>
<td>Submitted by</td>
<td>Yvonne Posey, M.D. Medical Director, Send Outs, Royal Oak Laboratory</td>
</tr>
</tbody>
</table>
New Effective Date: September 11, 2012

for

Chlamydia trachomatis & Neisseria gonorrhoeae – Nucleic Acid Amplification Testing Update: ThinPrep PreservCyt Liquid Cytology Specimens

and

Change to In-House Measurement of Testosterone in Women and Children by LCMS/MS

Due to unforeseen issues, Beaumont Laboratory must delay the change in the following testing:

Chlamydia trachomatis & Neisseria gonorrhoeae – Nucleic Acid Amplification Testing Update: ThinPrep PreservCyt Liquid Cytology Specimens

Scheduled change: September 4, 2012
Revised date: September 11, 2012

Change to In-House Measurement of Testosterone in Women and Children by LCMS/MS

Scheduled change: September 4, 2012
Revised date: September 11, 2012

Please call Beaumont Laboratory Customer Service at 1-800-551-0488 Option 5 with any questions.

Date Submitted: August 30, 2012
Submitted by: Mark Kolins, MD
Systems Chair, Pathology and Laboratory Medicine
Beaumont Laboratory
Effective September 11, 2012, ThinPrep specimens are acceptable for *Chlamydia trachomatis* (Ct) and/or *Neisseria gonorrhoeae* (Ng) testing. Such testing requires the laboratory to retrieve a 0.5-mL aliquot from the ThinPrep specimen prior to cytology and/or HPV testing. It is therefore imperative to correctly order Ct and/or Ng testing as the laboratory will NOT be able to perform the test(s) after the ThinPrep specimen has been processed for cytology and/or HPV testing.

**HOW TO ORDER TESTING ON THE THINPREP SPECIMEN:**

**Requisition-Based Ordering:**
1) New Cytology Requisition
   a. These are being distributed by Beaumont Laboratory.
   b. Please check the appropriate box indicating that Ct and/or Ng testing is requested.
2) Old Cytology Requisition
   a. Clearly write on the requisition that Ct and/or Ng testing is requested.
   b. Circle the written request or use a highlighter.

**Electronic-Based Ordering:**
1) Each client will need to update their own electronic medical record/ordering system using the “compendium” of recommended updates provided by Beaumont Laboratory.
2) Beaumont Laboratory will automatically update Atlas, Emdeon and LabTest.
3) Once updated, you will need to answer a few ask-at-order-entry questions – this information will be present on the printed requisition that accompanies the ThinPrep specimen to the laboratory.

**Important Notes:**
- Ct and/or Ng test results will be reported separately. Results will NOT be included on the combined Pap/HPV report.
- Confirmation testing for *Neisseria gonorrhoeae* is NOT available for ThinPrep specimens at this time. If indicated, an additional endocervical swab or urine specimen will be required.

**Other Notes:**
- Endocervical swabs and urine specimens are still acceptable for stand-alone-testing - *Neisseria gonorrhoeae* confirmation testing is routinely performed on these specimens.

For complete specimen collection instructions, please refer to the on-line Laboratory Test Directory:
Internal URL: [http://beaunet.beaumont.edu/portal/pls/portal/lab.lab_pkg.lab_list](http://beaunet.beaumont.edu/portal/pls/portal/lab.lab_pkg.lab_list)
External URL: [http://beaumonthospitals.com/labtestdirectory](http://beaumonthospitals.com/labtestdirectory)

If you need additional information, please contact Customer Services (1-800-551-0488, option 5).
Change to In-House Measurement of Testosterone in Women and Children by LCMS/MS

Effective Date: September 11, 2012

Effective September 11, 2012, Beaumont Laboratories will introduce the following tests for assessing testosterone levels using LCMS/MS:

<table>
<thead>
<tr>
<th>Soft Code</th>
<th>Current Testosterone Assay</th>
<th>New Testosterone Assay</th>
</tr>
</thead>
<tbody>
<tr>
<td>TESTF</td>
<td>Testosterone, Total, Women and Children</td>
<td>Testosterone, Total, Females or Children</td>
</tr>
<tr>
<td>TESTT</td>
<td>Testosterone, Free, Women and Children (includes SHBG)</td>
<td>Testosterone, Free and Bioavailable, Females (or Children) (includes SHBG and albumin)</td>
</tr>
<tr>
<td></td>
<td>Testosterone, Bioavailable, Women and Children (includes SHBG and albumin)</td>
<td></td>
</tr>
</tbody>
</table>

Sample Requirements: One 5 mL SST or Red top tube (1 mL pediatric minimum).

Specimen Preparation: Separate serum from cells within 2 hours of collection.

Test Availability: Monday-Friday. Report available the following day.

Transport and Storage: Refrigerated (2-8°C or 36-46°F): 1 week.

Reference Range: By report.

Test Methodology: High Performance Liquid Chromatography/Tandem Mass Spectrometry, Total Testosterone
Chemiluminescent Immunoassay, Sex Hormone Binding Globulin (SHBG)
Spectrophotometry, Albumin

The Testosterone, Free and Bioavailable, Females (or Children) report includes:
- Measurement of total testosterone by LCMS/MS
- Measurement and reporting of sex hormone binding globulin (SHBG) and albumin (ALB), the primary testosterone binding proteins
- Calculation of free, % free, bioavailable and % bioavailable testosterone concentrations using a modified version of the Vermeulen equation

Continued on other side
Continued from Front Page 2

Change to In-House Measurement of Testosterone in Women and Children by LCMS/MS

Test Information
Accurate measurement of total testosterone and its bound and unbound sub-fractions in women are important in the assessment of hyperandrogenic states such as hirsutism, acne, polycystic ovarian syndrome, congenital adrenal hyperplasia and androgen secreting tumors. There is additional value in the assessment of pediatric growth, precocious and delayed puberty, hypogonadism and unexplained virilization in children under the age of 18 years. Over the years a variety of approaches have been developed with mixed success to assist in diagnosis. Among these are measurement of total testosterone, unbound (free) testosterone, bioavailable testosterone, androgen indices, and measurement of various binding proteins. This has resulted in numerous test combinations, which when combined with the complexities of gender and age has caused considerable confusion and resulted in efforts on the part of a number of professional associations and the CDC to advocate and sponsor focused recommendations and programs for more accurate testosterone testing.1

Total Testosterone
Testosterone measurement in women and children has been an analytical challenge due to the relatively low concentrations observed in these populations. Further difficulties have involved concerns over the specificity of available immunoassays for testosterone, particularly at low levels.1,2 A third issue has been the existence of testosterone in both a protein bound (presumably inactive) and an unbound (theoretically active) form. Beaumont Laboratories can now address these problems with a new methodology designed to measure total testosterone at low levels commonly seen in women and children.

Free (Unbound) Testosterone
Free testosterone concentrations are frequently about 2%, of the total concentration, but may vary due to changes in concentrations of its binding proteins, the concentration of endogenous competitors for binding sites, renal status and hepatic disease. Sex hormone binding globulin (SHBG) is a low capacity, high affinity protein that accounts for about 60-80% of the bound testosterone in women and 40-50% in men.6 Albumin is a high capacity, low affinity protein that binds the remainder of the testosterone with the exception of a small fraction that remains unbound or free. When SHBG concentrations are high, more of the testosterone is in the bound state and less testosterone is available for biological activity and the % free testosterone is decreased. When SHBG concentrations are low, more testosterone is in the free state and the % free is elevated. Changes in binding protein concentrations in theoretical models typically do not change the concentration of free testosterone but may cause a fluctuation in total concentrations in that metabolism of testosterone is considered to be controlled by the % of the total that is free. In such a circumstance, the use of total testosterone measurements as an assessment of hormonal status may be misleading and a more appropriate measure may be the free testosterone concentration. Reporting the total testosterone, the concentrations of binding proteins, and an estimate of the free testosterone concentration is likely to permit a rational evaluation of a patient’s hormonal status.

Continued on next page
Bioavailable (Free and Albumin-bound) Testosterone
Testosterone that is not bound to sex hormone binding globulin is referred to as bioavailable testosterone. It consists of the sum of the albumin-bound and unbound testosterone concentrations. This typically represents about 20-30 % of the total circulating testosterone in women and 50-60% in males. Bioavailable testosterone is not easily measured and the reported result in this test combination is based on a calculation derived from the measurement of total testosterone by LCMS/MS, SHBG and albumin concentrations in serum.5

The Testosterone, Free and Bioavailable, Females (or Children) report includes:
• Measurement of total testosterone by LCMS/MS3
• Measurement and reporting of sex hormone binding globulin (SHBG) and albumin (ALB), the primary testosterone binding proteins
• Calculation of free, % free, bioavailable and % bioavailable testosterone concentrations using a modified version of the Vermeulen equation4,6

References:

Please contact Beaumont Laboratory Customer Service at 1-800-551-0488 for further information.

Date Submitted: August 27, 2012
Submitted by: Yvonne Posey, M.D., Associate Director, Automated Chemistry
John Wilson, PhD, Bioscientific Staff
Elizabeth Sykes, M.D., Medical Director, Automated Chemistry
Karen Leonard, MT(ASCP)
Valerie Peterson, MT(ASCP)
Anti-HU Antibody, Anti-Ri Antibody, and Anti-YO Antibody

Effective Date: Immediately

The methodology for the Anti-Hu, Anti-Ri, and Anti-Yo antibodies is being changed from Immunoblot to IFA with reflex to titer and Western Blot. Specimen collection, processing and transport will be unchanged.

<table>
<thead>
<tr>
<th>Performed</th>
<th>Monday, Wednesday, and Friday</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference Range</td>
<td>Negative</td>
</tr>
<tr>
<td>Test Methodology</td>
<td>IFA with reflex to titer and Western Blot</td>
</tr>
<tr>
<td>CPT Code</td>
<td>86255</td>
</tr>
<tr>
<td>Date Submitted</td>
<td>09/11/2012</td>
</tr>
<tr>
<td>Submitted by</td>
<td>Yvonne Posey, MD Medical Director, Send Outs</td>
</tr>
</tbody>
</table>
Motor and Sensory Neuropathy Evaluation and Motor Neuropathy Evaluation

Effective Date: Immediately

The Motor & Sensory Neuropathy Evaluation and the Motor Neuropathy Evaluation test will be sent to ARUP Laboratories under the test name of Motor and Sensory Neuropathy Evaluation.

<table>
<thead>
<tr>
<th>Specimen Collection Criteria</th>
<th>Collect 1 5mL Red top or Gold SST</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician Office/Draw Site Specimen Preparation</td>
<td>Separate serum from cells within 2 hours of collection. Transfer 2 mL serum to a Standard Transport Tube. (Min: 1 mL)</td>
</tr>
<tr>
<td>Specimen Preparation for Courier Transport</td>
<td>Storage/Transport Temperature: Refrigerated</td>
</tr>
<tr>
<td>Rejection Criteria</td>
<td>Any sample other than serum</td>
</tr>
<tr>
<td>Performed</td>
<td>ARUP Laboratories (Test Code 51224)</td>
</tr>
<tr>
<td>Reference Range</td>
<td>See Chart on other side</td>
</tr>
<tr>
<td>Test Methodology</td>
<td>Semi-Quantitative Enzyme-Linked Immunosorbent Assay/ Semi-Quantitative Indirect Fluorescent Antibody/ Qualitative Immunoblot</td>
</tr>
<tr>
<td>Note</td>
<td>ANNA antibodies are screened by IFA. If the IFA screen is 1:10, then a titer and immunoblot (Hu and Ri) will be added. Additional charges apply.</td>
</tr>
<tr>
<td>CPT Code</td>
<td>83516X5 Asialo-GM1; 83516 MAG IgM ELISA; 83516 SGPG IgM; 86255 ANNA; if reflexed add 86256 ANNA titer and 83516 Immunoblot</td>
</tr>
<tr>
<td>Date Submitted</td>
<td>September 11, 2012</td>
</tr>
<tr>
<td>Submitted by</td>
<td>Yvonne Posey, MD, Medical Director, Sendouts Lab</td>
</tr>
</tbody>
</table>

Continued on other side
### Components and Reference Intervals

<table>
<thead>
<tr>
<th>Components</th>
<th>Reference Interval</th>
</tr>
</thead>
</table>
| Asialo-GM1 Antibodies, IgG/IgM                  | 29 IV or less: Negative  
                                          30-50 IV: Equivocal  
                                          51-100 IV: Positive  
                                          101 IV or greater: Strong Positive |
| GM1 Antibodies, IgG/IgM                         | 29 IV or less: Negative  
                                          30-50 IV: Equivocal  
                                          51-100 IV: Positive  
                                          101 IV or greater: Strong Positive |
| GD1a Antibodies, IgG/IgM                        | 29 IV or less: Negative  
                                          30-50 IV: Equivocal  
                                          51-100 IV: Positive  
                                          101 IV or greater: Strong Positive |
| GD1b Antibodies, IgG/IgM                        | 29 IV or less: Negative  
                                          30-50 IV: Equivocal  
                                          51-100 IV: Positive  
                                          101 IV or greater: Strong Positive |
| GQ1b Antibodies, IgG/IgM                        | 29 IV or less: Negative  
                                          30-50 IV: Equivocal  
                                          51-100 IV: Positive  
                                          101 IV or greater: Strong Positive |
| Myelin Associated Glycoprotein (MAG) Antibody, IgM | Less than 1000 TU                                      |
| Sulfate-3-Glucuronyl Paragloboside (SGPG) Antibody, IgM | Less than 1.00 IV                                     |
| Neuronal Nuclear Antibody (ANNA) IgG Screen, by IFA | < 1:10                                                  |
| Neuronal Nuclear Antibody (ANNA) Titer IgG by IFA, Serum | < 1:10 No antibody detected.                           |
| Neuronal Nuclear Antibody IgG, Immunoblot Anti-Hu | Negative                                               |
| Neuronal Nuclear Antibody IgG, Immunoblot Anti-Ri | Negative                                               |
Urinalysis - Bilirubin Confirmation

Effective Date: 09/24/2012

Siemens has informed us that the Ictotest reagent tablets, used to confirm a positive bilirubin by dipstick, are currently unavailable. We have been advised that the reagent may not be available until November. Once our current stock is depleted and until the problem is rectified, if a urine dipstick is positive for bilirubin, the following comment will be added to the urinalysis result.

“Positive bilirubin by dipstick- unable to exclude color interference. Suggest clinical correlation.”

This applies to the urinalysis – bilirubin testing performed at Beaumont Laboratory, Royal Oak, Troy and Grosse Pointe.

Date Submitted: September 21, 2012
Submitted by: Elizabeth Sykes, MD Medical Director Chemistry, Royal Oak
Hongwei Ma, MD, Medical Director Hematology, Troy
LeiLei Chen, MD, PhD, Medical Director Chemistry, Grosse Pointe
Lymphocyte Subset Quantitation and CD4 Absolute Count

Effective Date: September 27, 2012

Effective September 27, 2012, the Flow Cytometry Laboratory tests “Lymphocyte Subset Quantitation” and “CD4 Absolute Count” will institute a time limitation of 24 hours from collection to specimen processing. Specimens for these tests must be received in the Flow Cytometry Laboratory within 24 hours of blood draw. As a result, specimens will be accepted Monday-Friday and will not be accepted weekend days (Saturday or Sunday) or Beaumont Health System recognized holidays. This change is being instituted in response to updated product recommendations sent out by the manufacturer.

For further information, please contact Beaumont Laboratory Customer Service at 1-800-551-0488 and ask to speak to the Flow Cytometry Supervisor, Nancy Fine, or the Laboratory Medical Director, Dr. Vonda Douglas-Nikitin.

<table>
<thead>
<tr>
<th>Synonyms</th>
<th>CD4:CD8 ratio Lymphocyte subsets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Instructions</td>
<td>Please deliver tests immediately to flow cytometry laboratory</td>
</tr>
<tr>
<td>Specimen Collection Criteria</td>
<td>No change. 4 mL whole blood, lavender (EDTA) tubes accepted. Specimens should not be drawn on weekend days (Saturday/Sunday) or on Beaumont Health System recognized holidays.</td>
</tr>
<tr>
<td>AMENDED:</td>
<td>CHANGED: Specimens should be processed within 24 hours of collection.</td>
</tr>
<tr>
<td>Physician Office/Draw Site Specimen Preparation</td>
<td></td>
</tr>
<tr>
<td>Specimen Preparation for Courier Transport</td>
<td>No change. Transport at room temperature (20-25°C or 68-77°F)</td>
</tr>
<tr>
<td>AMENDED:</td>
<td>CHANGED: Specimens received in the Flow Cytometry Laboratory that are more than 24 hours from the time of the blood draw will be rejected.</td>
</tr>
<tr>
<td>Rejection Criteria</td>
<td></td>
</tr>
<tr>
<td>Performed</td>
<td>No change. Monday-Friday, and Saturday until noon</td>
</tr>
<tr>
<td>Test Methodology</td>
<td>Flow Cytometry</td>
</tr>
<tr>
<td>Date Submitted</td>
<td>September 27, 2012</td>
</tr>
<tr>
<td>Submitted by</td>
<td>Vonda K. Douglas-Nikitin, M.D., Medical Director, Flow Cytometry Laboratory</td>
</tr>
</tbody>
</table>
Outpatient Critical Results: After Hours Communication

Effective Date: October 1, 2012

Beginning on Monday, October 1, 2012, Beaumont Laboratory will utilize physicians’ answering services for notification of outpatient critical laboratory results. It will be the responsibility of the answering service, as a member of the physician's care team, to relay these results to the ordering physician as they have been instructed.

We encourage physicians to contact their answering service providers and instruct them on how they want to handle this information.

Date Submitted: September 28, 2012
Submitted by: Mark Kolins, MD
System Chair, Beaumont Laboratory
Amino Acids, Plasma

Effective Date: October 3, 2012

Effective October 3, 2012, the reference lab changed the reference values for the Amino Acid, Plasma profile. Also, an additional 17 amino acids were added to the profile as follows:

- 1-Methylhistidine
- 3-Methylhistidine
- Alpha-aminoadipic Acid
- Anserine
- Aspartic Acid
- Beta-aminoisobutyric Acid
- Carnosine
- Cystathioine
- Ethanolamine
- Gamma-aminobutyric acid
- Homocitruline
- Hydroxyllysine
- Hydroxyproline
- Phosphoethanolamine
- Phosphoserine
- Sarcosine
- Tryptophan.

Specimen collection and processing will remain unchanged.

<table>
<thead>
<tr>
<th>Reference Range</th>
<th>See next page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Methodology</td>
<td>Quantitative Analysis by Liquid Chromatography-Tandem Mass Spectometry (LC-MS/MS)</td>
</tr>
<tr>
<td>CPT Code</td>
<td>82139</td>
</tr>
<tr>
<td>Date Submitted</td>
<td>10/16/2012</td>
</tr>
</tbody>
</table>
| Submitted by          | Yvonne Posey, MD  
  Medical Director, Send Outs |
<table>
<thead>
<tr>
<th>Old Plasma Amino Acid Reference Ranges (nmol/mL)</th>
<th>New Plasma Amino Acid Reference Ranges (nmol/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Premature 1-31 days</td>
<td>32 days-23 months</td>
</tr>
<tr>
<td>Alanine 212-504</td>
<td>131-710</td>
</tr>
<tr>
<td>Allo-isoleucine &lt;2</td>
<td>&lt;2</td>
</tr>
<tr>
<td>Alpha-Aminoadipic Acid</td>
<td>&lt;4</td>
</tr>
<tr>
<td>Alpha-Aminoadipic Acid</td>
<td>&lt;4</td>
</tr>
<tr>
<td>Arginine 34-96</td>
<td>6-140</td>
</tr>
<tr>
<td>Argininosuccinic Acid &lt;1</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Beta-Alanine 0</td>
<td>0-10</td>
</tr>
<tr>
<td>Beta-Aminobutyric Acid &lt;2</td>
<td>2-10</td>
</tr>
<tr>
<td>Carnosine 13-13</td>
<td>13-13</td>
</tr>
<tr>
<td>Citrulline 20-87</td>
<td>10-45</td>
</tr>
<tr>
<td>Cystathionine &lt;2</td>
<td>&lt;2</td>
</tr>
<tr>
<td>Cystine 15-70</td>
<td>17-98</td>
</tr>
<tr>
<td>Ethanolamine &lt;70</td>
<td>&lt;70</td>
</tr>
<tr>
<td>Glutamic Acid 107-276</td>
<td>62-620</td>
</tr>
<tr>
<td>Homocitrulline &lt;5</td>
<td>&lt;5</td>
</tr>
<tr>
<td>Hydroxynitrile &lt;4</td>
<td>&lt;4</td>
</tr>
<tr>
<td>Hydroxyproline 8-61</td>
<td>7-35</td>
</tr>
<tr>
<td>Isoleucine 23-85</td>
<td>26-91</td>
</tr>
<tr>
<td>Leucine 151-220</td>
<td>48-160</td>
</tr>
</tbody>
</table>

Continued on next page
Continued from previous page

## Reference Ranges (continued)

<table>
<thead>
<tr>
<th>Old Plasma Amino Acid Reference Ranges (nmol/mL)</th>
<th>New Plasma Amino Acid Reference Ranges (nmol/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methionine</td>
<td>37-91</td>
</tr>
<tr>
<td>Ornithine</td>
<td>77-212</td>
</tr>
<tr>
<td>Phenylalanine</td>
<td>98-213</td>
</tr>
<tr>
<td>Phosphoethanolamine</td>
<td>&lt;6</td>
</tr>
<tr>
<td>Phosphoserine</td>
<td>&lt;109</td>
</tr>
<tr>
<td>Proline</td>
<td>92-310</td>
</tr>
<tr>
<td>Sarcosine</td>
<td>&lt;5</td>
</tr>
<tr>
<td>Taurine</td>
<td>151-411</td>
</tr>
<tr>
<td>Tryptophan</td>
<td>17-75</td>
</tr>
<tr>
<td>Tyrosine</td>
<td>147-420</td>
</tr>
</tbody>
</table>
LUBRICANT USE INTERFERES WITH PAP TEST ADEQUACY

Effective Date: Immediately

The Thin Prep Pap test (HOLOGIC, Inc) is the preferred method for Pap test at the Beaumont Laboratory. There are many advantages of using liquid based methodology compared to conventional Pap smears, which include better cellular yield and preservation.

Rate of unsatisfactory smears obtained with Thin Prep Pap test is less than 2%. Some physicians and laboratories have reported an increase in unsatisfactory specimen rate with lubricant use due to the presence of interfering substances called carbomers.

Sample Collection Options for Lubricating the Speculum:
1. Luke warm water: This protocol has the least risk to the quality of the Pap sample collected.

2. Lubricant Gels: If lubricant must be used due to patient discomfort or other circumstances, lubricant should be used sparingly and applied only to the exterior sides of the speculum blades, avoiding contact with the tip of the speculum. When lubricant is used in excess, it can adversely affect the Pap sample. Hologic evaluated a variety of popular lubricants and found those containing carbomer or carbopol polymers (thickening agents) interfere with the Thin Prep Pap test when found in the sample vial. Hologic recognizes the varying availability of different types of lubricants and recommends that, if used, any lubricant should be applied sparingly.

<table>
<thead>
<tr>
<th>Date Submitted</th>
<th>October 15, 2012</th>
</tr>
</thead>
</table>
| Submitted by   | Edward Bernacki, M.D., Director of Cytology, Beaumont Laboratory Royal Oak  
                 Said Hafez-Khayyata, M.D., Director of Cytology, Beaumont Laboratory Troy  
                 James Liu, M.D., Director of Cytology, Beaumont Laboratory Grosse Pointe |
Amino Acids, Urine Quantitative

Effective Date: October 31, 2012

Effective October 31, 2012, the reference lab will be changing the reference values for the Amino Acid, Urine Quantitative profile. Also, an additional 13 amino acids will be added to the profile as follows:

- Alloisoleucine
- Anserine
- Argininosuccinic Acid
- Aspartic Acid
- Ethanolamine
- Gamma-amino-n-butyric acid
- Homocitruline
- Hydroxylysine
- Hydroxyproline
- Phosphoethanolamine
- Phosphoserine
- Sarcosine
- Tryptophan

Specimen collection and processing will remain unchanged.

<table>
<thead>
<tr>
<th>Reference Range</th>
<th>See next two pages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Methodology</td>
<td>Quantitative Analysis by Liquid Chromatography-Tandem Mass Spectometry (LC-MS/MS)</td>
</tr>
<tr>
<td>CPT Code</td>
<td>82139</td>
</tr>
<tr>
<td>Date Submitted</td>
<td>October 12, 2012</td>
</tr>
<tr>
<td>Submitted by</td>
<td>Yvonne Posey, MD</td>
</tr>
<tr>
<td></td>
<td>Medical Director Send Outs</td>
</tr>
</tbody>
</table>

Continued
## Reference Ranges

<table>
<thead>
<tr>
<th>Old Urine Amino Acid Reference Range's (nmol/mL)</th>
<th>New Plasma Amino Acid Reference Ranges (nmol/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Premature</td>
</tr>
<tr>
<td>Alanine</td>
<td>1320-4040</td>
</tr>
<tr>
<td>1-Methylhistidine</td>
<td></td>
</tr>
<tr>
<td>3-Methylhistidine</td>
<td></td>
</tr>
<tr>
<td>Alanine</td>
<td></td>
</tr>
<tr>
<td>Alpha-Aminoadipic Acid</td>
<td>70-460</td>
</tr>
<tr>
<td>Alpha-Aminoadipic Acid</td>
<td></td>
</tr>
<tr>
<td>Alpha-Aminoadipic Acid</td>
<td></td>
</tr>
<tr>
<td>Arginine</td>
<td>190-820</td>
</tr>
<tr>
<td>Arginine</td>
<td></td>
</tr>
<tr>
<td>Arginine</td>
<td></td>
</tr>
<tr>
<td>Asparagine</td>
<td></td>
</tr>
<tr>
<td>Asparagine</td>
<td></td>
</tr>
<tr>
<td>Beta-Alanine</td>
<td>1020-3500</td>
</tr>
<tr>
<td>Beta-Alanine</td>
<td></td>
</tr>
<tr>
<td>Beta-Alanine</td>
<td></td>
</tr>
<tr>
<td>Beta-Aminoisobutyric Acid</td>
<td>50-470</td>
</tr>
<tr>
<td>Citrulline</td>
<td>240-1320</td>
</tr>
<tr>
<td>Cystathionine</td>
<td>260-1160</td>
</tr>
<tr>
<td>Cystine</td>
<td>480-1690</td>
</tr>
<tr>
<td>Cystine</td>
<td></td>
</tr>
<tr>
<td>Cystine</td>
<td></td>
</tr>
<tr>
<td>Glutamic Acid</td>
<td>380-3760</td>
</tr>
</tbody>
</table>

Beaumont Laboratory
Customer Service
1-800-551-0488
## Reference Ranges (continued)

<table>
<thead>
<tr>
<th>Old Urine Amino Acid Reference Range's (nmol/mL)</th>
<th>New Plasma Amino Acid Reference Ranges (nmol/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Premature</strong></td>
<td><strong>&lt;12 months</strong></td>
</tr>
<tr>
<td><strong>1-31 days</strong></td>
<td><strong>13-35 months</strong></td>
</tr>
<tr>
<td><strong>32 days-23 months</strong></td>
<td><strong>3-6 years</strong></td>
</tr>
<tr>
<td><strong>2-18 years</strong></td>
<td><strong>7-8 years</strong></td>
</tr>
<tr>
<td><strong>&gt;=19 years</strong></td>
<td><strong>9-17 years</strong></td>
</tr>
<tr>
<td><strong>&gt;=18 years</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Glutamine</strong></td>
<td><strong>Glutamine</strong></td>
</tr>
<tr>
<td>520-1700</td>
<td>139-2985</td>
</tr>
<tr>
<td>393-1042</td>
<td>263-2979</td>
</tr>
<tr>
<td>670-1562</td>
<td>152-1325</td>
</tr>
<tr>
<td>369-1014</td>
<td>164-1125</td>
</tr>
<tr>
<td>190-510</td>
<td>188-1365</td>
</tr>
<tr>
<td><strong>Glycine</strong></td>
<td><strong>Glycine</strong></td>
</tr>
<tr>
<td>7840-16423</td>
<td>362-18614</td>
</tr>
<tr>
<td>3023-11148</td>
<td>627-6914</td>
</tr>
<tr>
<td>897-4500</td>
<td>412-5705</td>
</tr>
<tr>
<td>987-4500</td>
<td>449-4492</td>
</tr>
<tr>
<td>730-4160</td>
<td>316-4249</td>
</tr>
<tr>
<td><strong>Histidine</strong></td>
<td><strong>Histidine</strong></td>
</tr>
<tr>
<td>1240-7240</td>
<td>145-3833</td>
</tr>
<tr>
<td>908-2528</td>
<td>427-3398</td>
</tr>
<tr>
<td>815-7090</td>
<td>230-2635</td>
</tr>
<tr>
<td>644-2430</td>
<td>268-2147</td>
</tr>
<tr>
<td>460-1430</td>
<td>134-1983</td>
</tr>
<tr>
<td><strong>Homocitruline</strong></td>
<td><strong>Homocitruline</strong></td>
</tr>
<tr>
<td>&lt;295</td>
<td>&lt;71</td>
</tr>
<tr>
<td>11-158</td>
<td>&lt;62</td>
</tr>
<tr>
<td>&lt;33</td>
<td>&lt;30</td>
</tr>
<tr>
<td><strong>Hydroxylysine</strong></td>
<td><strong>Hydroxylysine</strong></td>
</tr>
<tr>
<td>&lt;150</td>
<td>&lt;57</td>
</tr>
<tr>
<td>&lt;34</td>
<td>&lt;26</td>
</tr>
<tr>
<td>&lt;31</td>
<td>&lt;12</td>
</tr>
<tr>
<td><strong>Hydroxyproline</strong></td>
<td><strong>Hydroxyproline</strong></td>
</tr>
<tr>
<td>&lt;2536</td>
<td>&lt;89</td>
</tr>
<tr>
<td>&lt;46</td>
<td>&lt;19</td>
</tr>
<tr>
<td>&lt;19</td>
<td>&lt;22</td>
</tr>
<tr>
<td><strong>Isoleucine</strong></td>
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<td><strong>&gt;=18 years</strong></td>
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GROUP-A STREP REFLEX TESTING  
Grosse Pointe Campus Only

Effective Date: 11-1-2012

The Infectious Diseases Society of America (IDSA) recommends culture confirmation of a negative Group A Streptococcus antigen screen (rapid test) by culture in pediatric population due to false negative screens.
In order to comply with the IDSA, as well as College of American Pathologists (CAP) guidelines, there will be a change at Grosse Pointe regarding this test starting November 1st, 2012.

Current practice at Grosse Pointe:
Negative Group A Strep screen is reported as negative, without reflex to culture. If a physician needs a culture, it must be ordered.

Change in practice at Grosse Pointe:
All negative Group A Streptococcal screens (rapid test) in patients younger than 16 years will be reflexed to culture testing. Laboratory staff will automatically order the culture.

Specimen collection:
Collect the sample using the red top routine culture swab (red top swab containing Amies transport).

<table>
<thead>
<tr>
<th>Date Submitted</th>
<th>September 25, 2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submitted by</td>
<td>Vaishali Pansare, M.D., Medical Director, Beaumont Laboratory Grosse Pointe</td>
</tr>
</tbody>
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GROUP-A STREP REFLEX TESTING

Effective Date: November 1, 2012

The Infectious Diseases Society of America (IDSA), with support from the College of American Pathologists (CAP), recommends culture confirmation of all negative Group A Streptococcus (GAS) antigen tests for pediatric patients due to false negative results.

To comply with IDSA and CAP guidelines, Beaumont Laboratory will adopt the following changes and reporting scenarios for the GAS rapid antigen test (GAS-RAT) on November 1, 2012:

1. Patient is ≥ 16 years old and has a negative GAS-RAT result:
   Report: Negative

2. Patient is < 16 years old and has a negative GAS-RAT result:
   a. Only one swab was submitted for testing:
      Report: Negative.
      Comment: The presence of Group A Strep cannot be entirely ruled out by antigen testing. Please submit a throat swab specimen for Culture, Group A Strep, as endorsed by the IDSA, 2012 Guidelines for Group A Streptococcal Pharyngitis.
   b. Two swabs were submitted for testing:
      Report: Negative.
      Comment: Reflex culture confirmation testing will be performed as endorsed by the IDSA, 2012 Guidelines for Group A Streptococcal Pharyngitis. See separate report for Culture, Group A Strep test results.

3. Patient is any age and has an indeterminate GAS-RAT result:
   a. Only one swab was submitted for testing:
      Result: Unable to interpret results.
      Comment: Please submit a throat swab specimen for Culture, Group A Strep, as endorsed by the IDSA, 2012 Guidelines for Group A Streptococcal Pharyngitis.
   b. Two swabs were submitted for testing:
      Result: Unable to interpret results.
      Comment: Reflex culture testing will be performed as endorsed by the IDSA, 2012 Guidelines for Group A Streptococcal Pharyngitis. See separate report for Culture, Group A Strep test results.

Date Submitted: October 17, 2012

Submitted by:
Royal Oak:
B. Robinson-Dunn, Ph.D., D(ABMM)
Technical Director, Microbiology

Royal Oak:
B. L. Boyanton, M.D.
Medical Director, Microbiology
Associate Medical Director, Molecular Pathology

Grosse Pointe:
Vaishali Pansare, MD
Medical Director, Cytology/Microbiology

Troy:
Elizabeth Wey, M.D.
Medical Director, Microbiology
Allergen-Specific IgE Testing

Effective Date: November 6, 2012

The following changes will be made to the allergen-specific IgE test menu:

1. **Expansion of the Region 7 upper respiratory panel:** 25 allergens + total IgE

   **Allergens Tested**
   - Aspergillus fumigatus
   - Bermuda grass
   - Box elder
   - Cat dander
   - Cladosporium herbarum
   - Cockroach
   - Cocksfoot (Orchard grass)
   - Common ragweed
   - Common silver birch
   - Cottonwood
   - D. farinae
   - D. pteronyssinus
   - Dog dander
   - Elm
   - Moutain cedar
   - Mulberry
   - Nettle
   - Oak
   - Penicillium notatum
   - Redtop bentgrass
   - Rough marshelder
   - Russian thistle/Saltwort
   - Timber grass
   - White ash

2. **New individual allergens offered:**
   - Ovalbumin
   - Ovomucoid
   - Egg white components
   - Mulberry
   - Nettle
   - Moutain cedar
   - White Ash

3. **The mold panel will only test for allergen-specific IgE.** Allergen specific-IgA and IgG will no longer be included as part of the mold panel

**Ordering and Specimen Collection Criteria:**
- All allergens can be ordered individually or as part of a panel.
- Tube type: 5 mL SST (gold-top, serum separator)
- **One** filled 5 mL SST tube is sufficient to test up to 20 individual allergens.
- Minimum specimen collection requirements for panels indicated above:
  - Region 7 upper respiratory panel (25 allergens + total IgE): **Two** 5 mL SST tubes
  - Mold panel: **One** 5 mL SST tube (8 allergens)

**Date Submitted:** November 1, 2012

**Submitted by:** Gabriel Maine, PhD
- Technical Director, Special Testing, Royal Oak
- Elizabeth Sykes, MD
- Medical Director, Special Testing, Royal Oak
FECAL LACTOFERRIN and FECAL Leukocyte (WBC) – TESTING UPDATE

Effective Date: November 6, 2012

Effective November 6, 2012, the Fecal Leukocyte (WBC) test will be offered on a limited basis. All orders for Fecal WBC testing will automatically be converted to Fecal Lactoferrin for patients greater than 18 months of age if the appropriate specimen is submitted.

Frequently Asked Questions:

What is the reason for primarily using the Fecal Lactoferrin test?

- Superior Test Results – the Fecal Lactoferrin test is a rapid immunoassay that provides highly accurate results. The Fecal Leukocyte (WBC) test is prone to false negative results due to a) WBC’s rapidly degrade after stool collection, and b) subjective identification of WBC’s by microscopy.

Why reserve the Fecal WBC test for patients less than 18 months of age?

- Lactoferrin is present in neutrophils and in human breast milk. Therefore patients that are actively breast feeding may yield a false positive Fecal Lactoferrin test.

What are the Specimen Collection and Handling Requirements?

- Test Order: Fecal Lactoferrin
- Collection: Fresh stool, in a clean, air-tight container without preservatives.
- Handling: Maintain at room or refrigeration temperature and send to the laboratory.

What if I order the Fecal WBC test and send the stool specimen to the laboratory?

- If unpreserved stool is received, the laboratory will automatically cancel the Fecal WBC test, then order, perform and report the Fecal Lactoferrin Test.

What if I want to add on the Fecal Lactoferrin Test to a previous test order?

- No problem, as long as the laboratory received unpreserved stool.
- The test can be added up to 2 weeks after stool collection in most cases.

For additional information, please utilize the following resources:

On-line Laboratory Test Directory:
Internal URL: http://beaunet.beaumont.edu/portal/pls/portal/lab.lab_pkg.lab_list
External URL: http://beaumonthospitals.com/labtestdirectory

Contact Client Services at 1-800-551-0488, option 5.
## Date Submitted
October 19, 2012

## Submitted by

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Location</th>
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<tbody>
<tr>
<td>Bobby L. Boyanton Jr., M.D.</td>
<td>Medical Director, Clinical Microbiology</td>
<td>Royal Oak</td>
</tr>
<tr>
<td></td>
<td>Associate Medical Director, Molecular Pathology</td>
<td>Royal Oak</td>
</tr>
<tr>
<td>Barbara Robinson-Dunn, Ph.D., D(ABMM)</td>
<td>Technical Director, Clinical Microbiology</td>
<td>Royal Oak</td>
</tr>
<tr>
<td>Vaishali Pansare M.D.</td>
<td>Laboratory Medical Director</td>
<td>Grosse Pointe</td>
</tr>
<tr>
<td></td>
<td>Medical Director of Microbiology, Grosse Pointe</td>
<td></td>
</tr>
<tr>
<td>Elizabeth Wey, M.D.</td>
<td>Medical Director, Microbiology</td>
<td>Troy</td>
</tr>
</tbody>
</table>

Continued from Front
Vancomycin-Resistant *Enterococcus* (VRE) Screening

TESTING UPDATE

Effective Date: November 6, 2012

Vancomycin-resistant *Enterococcus* (VRE) are multidrug-resistant organisms that can easily be spread throughout healthcare facilities. To limit the spread of VRE, the Beaumont Health System Infection Control Policy (BHS-ICP) states: “Precautions for vancomycin-resistant *Enterococcus* (VRE) remain in effect until the site of the VRE subsequently cultures negative x 3, from specimens taken at least 72 hours apart from a normally non-sterile body site (ex. sputum, wounds) and stools or rectal swabs for VRE are negative x 3, taken at least 72 hours apart (patient must be off antibiotics with action against VRE at the time of culture).

To comply with the BHS-ICP, patients previously positive for VRE from a urine culture, MUST have follow-up VRE screening cultures. This information will determine if the patient has cleared the organism and can be removed from transmission precautions. This change will become effective **November 6, 2012**.

Frequently Asked Questions:
1) Will the test name change? No. Order Culture, VRE (CXVRE).
2) Will there be a change in the specimen collection and handling requirements? No. Testing can be performed on any type of urine specimen.
3) When will the specimens be tested? 24 hours per day, 7 days per week.
4) Will there be a change in the turn-around time of test results? YES. Results will be available 1 to 2 days sooner than conventional urine culture.
5) Are there any other changes? YES. Susceptibility testing will not be performed.

For complete specimen collection instructions, please refer to the on-line Laboratory Test Directory:
- Internal URL: http://beaunet.beaumont.edu/portal/pls/portal/lab.lab_pkg.lab_list
- External URL: http://beaumonthospitals.com/labtestdirectory

If you need additional information, please contact Customer Services (1-800-551-0488, option 5).

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<td>Royal Oak: B. Robinson-Dunn, Ph.D., D(ABMM) Technical Director, Microbiology</td>
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<tr>
<td></td>
<td>Grosse Pointe: Vaishali Pansare, MD Laboratory Medical Director</td>
</tr>
<tr>
<td></td>
<td>Troy: Elizabeth Wey, M.D. Medical Director, Microbiology Medical Director of Microbiology</td>
</tr>
</tbody>
</table>
Culture, Abscess - TESTING UPDATE

CORRECTION – (Please see 5 a. below); A gram stain is included in superficial wound culture.

Effective Date: November 20, 2012

The Microbiology Laboratories of Beaumont Health System have agreed to discontinue the culture designated as Culture, Abscess because of the vagueness of the test designation. Tests to order in its place include Culture, Wound Superficial (CXWNS) or Culture, Wound Deep (CXWND). This change is effective immediately.

Frequently Asked Questions:
1) Will the test name change? Yes.
   a. In Epic OneChart, Culture Abscess will default to Culture, Wound Superficial or Culture, Wound Deep. When ordering the test, it will be necessary to select one of these.
   b. If ordering in Soft, you must pick either Culture, Wound Superficial or Culture, Wound Deep since Culture Abscess is no longer available.

2) Will there be a change in the specimen collection and handling requirements? No.

3) When will the specimens be tested? 24 hours per day, 7 days per week.

4) Will there be a change in the turn-around time of test results? No.

5) Are there any other changes? YES
   a. Final test results for Culture, Wound Superficial will be available in 2 days. A Gram stain is included in this type of culture.
   b. Final results for Culture, Wound Deep will be available in 4 days. A direct Gram stain is included in this type of culture.
   c. If an anaerobic infection is suspected, an anaerobic culture (Culture, Anaerobic) must be ordered. This test is not available on specimens from skin or mucous membranes.

For complete specimen collection instructions, please refer to the on-line Laboratory Test Directory:
Internal URL: http://beaunet.beaumont.edu/portal/pls/portal/lab.lab_pkg.lab_list
External URL: http://beaumonthospitals.com/labtestdirectory

If you need additional information, please contact Customer Services (1-800-551-0488, option 5).
Insulin – Reference Range Changes

Effective Date: November 30, 2012

The changes indicated below will be made to the reference ranges for insulin testing on November 30, 2012.

1. Test name: Insulin Level (fasting)

<table>
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<th>Reference Range</th>
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<tr>
<td>NEW</td>
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2. Test name: Insulin, 2 hours post 75g glucola

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<tr>
<td>NEW</td>
<td>29-93</td>
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3. Test name: Insulin Response, 5 hours (to GTT)

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<th>Reference Range</th>
<th>Normal (μIU/mL)</th>
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<tr>
<td></td>
<td>NEW</td>
<td>≤ 33</td>
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<tr>
<td>2hr. + 3 hr.</td>
<td>Old</td>
<td>&lt; 53</td>
</tr>
<tr>
<td></td>
<td>NEW</td>
<td>&lt; 64</td>
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Date Submitted: November 19, 2012

Submitted by: Gabriel Maine, PhD
Technical Director, Special Testing, Royal Oak
Elizabeth Sykes, MD
Medical Director, Special Testing, Royal Oak
Parvovirus B19 IgG and IgM

Effective Date: December 4, 2012

Beaumont Laboratory will commence offering Parvovirus B19-specific IgG and IgM testing on December 4th, 2012. Parvovirus B19 infection is normally acquired by direct contact with respiratory secretions, and is the causative agent of fifth disease (erythema infectiosum). Outbreaks typically occur during the winter and spring months, and are most notable in schools, daycare centers, hospitals and other environments that foster close contact between individuals. Infection during pregnancy presents the risk of transmission to the fetus, which may result in intrauterine death. Lastly, immunocompromised individuals are at risk for developing acute or chronic anemia following infection.

Clinical Indications for Parvovirus B19-specific IgG and IgM:
- Diagnosing a recent infection (IgM)
- Pregnant women that demonstrate clinical symptoms of a possible infection, such as the development of maculopapular facial rash.
- Development of aplastic anemia in immunocompromised patients

Ordering and Specimen Collection Criteria:
- Ordering options:
  1. Parvovirus B19 IgG
  2. Parvovirus B19 IgM
  3. Parvovirus B19 IgG and IgM
- Tube type: One 5 mL SST (gold-top, serum separator) is sufficient for any of the ordering options indicated above.

Test Methodology: Colorimetric ELISA
Reference Range: Same for IgG and IgM

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<tr>
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<th>Interpretation</th>
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<tr>
<td>≥ 1.11</td>
<td>Positive</td>
</tr>
</tbody>
</table>

Date Submitted: November 19, 2012

Submitted by: Gabriel Maine, PhD
Technical Director, Special Testing, Royal Oak
Elizabeth Sykes, MD
Medical Director, Special Testing, Royal Oak
Healthcare Worker Exposure to Patient Blood/Body Fluid
HIV 1/2 and Hepatitis (Source Patient Panel) - TESTING UPDATE

Effective Date: December 4, 2012

In order to provide optimal and timely test results for individuals exposed to blood-borne pathogens, Beaumont Laboratory, with endorsement from the Infection Prevention and Control Committee, will provide the following for healthcare worker exposure to patient blood/body fluid; this is known as source patient testing:

1) In an attempt to decrease the improper ordering of this test simply to obtain a rapid HIV test result, the following test instructions will display in Epic at the time of ordering:
   Test reserved for blood-borne pathogen exposures ONLY. Testing MUST be performed on the exposure SOURCE, NOT the exposed person. Exposed person MUST proceed immediately to OHS/EC with Employee Illness/Accident Form #553 for medical evaluation.

2) All negative HIV 1/2 rapid tests will automatically be reflexed to the current HIV testing algorithm, which detects both HIV 1/2 antibodies and HIV-1 p24 antigen.
   • Rapid HIV 1/2 test results will be available within 2 hours of blood collection.
   • HIV testing algorithm results will be available within 12 to 24 hours of blood collection.
   • Why is this change necessary?
     a) Enhanced detection of acute retroviral syndrome (ARS) in the source patient – this will lead to optimized therapy for the exposed individual.
     b) Note: patients with ARS will likely be negative for HIV 1/2 antibodies, but positive for HIV-1 p24 antigen.

3) All positive rapid HIV 1/2 test results will continue to be sent to the Send-Out laboratory for confirmation by Western Blot.

4) Hepatitis testing will remain the same.

5) No change in specimen collection. Continue to send two primary SST (gold-top) tubes.

For complete specimen collection instructions, please refer to the on-line Laboratory Test Directory:
Internal URL: http://beaunet.beaumont.edu/portal/pls/portal/lab.lab_pkg.lab_list
External URL: http://beaumonthospitals.com/labtestdirectory

If you need additional information, please contact Customer Services (1-800-551-0488, option 5).

Date submitted: December 5, 2012
Submitted by: Jeffrey Band, MD, Corporate Epidemiologist & Director, Dept of Epidemiology
            Bobby Boyanton, MD, Medical Director, Microbiology, Royal Oak
            Vaishali Pansare, MD, Medical Chief, Grosse Pointe Laboratories
            Yvonne Posey, MD, Associate Director, Chemistry, Royal Oak
            Elizabeth Sykes, MD, Medical Director, Chemistry/Special Testing, Royal Oak
            Elizabeth Wey, MD, Medical Director, Microbiology, Troy
GROSSE POINTE PROCESS CHANGE
FOR MICROBIOLOGY CULTURES

Effective Date: December 10, 2012

Beaumont Health System, Grosse Pointe Medical Staff:

- ALL GROSSE POINTE BLOOD CULTURES (including the associated gram stain): will continue to be performed at the Grosse Pointe Laboratory. If the blood culture is positive, the specimens will be promptly sent to Beaumont Laboratory, Royal Oak for final testing.

- ALL GROSSE POINTE STAT CULTURES: All gram stains and preliminary reports will be completed by the Grosse Pointe Laboratory. Final culture report will be completed by Beaumont Laboratory, Royal Oak.

- ALL GROSSE POINTE ROUTINE CULTURES (wound-deep and superficial, fluid cultures, ear cultures, eye cultures, tissue cultures, bone marrow cultures, tissue cultures and respiratory cultures): will be sent to Beaumont Laboratory, Royal Oak for testing. All sputum specimens will be screened for acceptability prior to being sent.

- For any questions, contact Beaumont Laboratory, Customer Service at 1-800-551-0488.

Date Submitted
November 29, 2012

Submitted by
Vaishali Pansare, M.D.
Medical Director, Beaumont Laboratory Grosse Pointe

Isabel Gauss, MT (ASCP)
Administrative Director, Beaumont Laboratory Grosse Pointe
Physicians Notice

In its compliance guidance for clinical laboratories the Office of the Inspector General (OIG) recommends that all clinical laboratories distribute a physician notice to its ordering clients at a minimum once per year. In an effort to comply with these recommendations, Beaumont Laboratory is providing this Physicians Notice delineating the guidelines used by Beaumont Laboratory for submitting claims to Medicare, Medicaid and other federally funded healthcare programs.

Clinical Laboratory Improvement Amendments (CLIA) Brochures

The Centers for Medicare and Medicaid Services (CMS) has several brochures to help explain the Clinical Laboratory Improvement Amendments (CLIA) regulation requirements including one on how to report concerns about a Laboratory's Operations to CMS. To access one or more of these brochures go to: CLIA Brochures Clinical Laboratory Improvement Amendments (CLIA). The CLIA Complaints brochure is also posted on the Laboratory’s web site under Laboratory Compliance Resources.

Medicare Medical Necessity

The Centers for Medicare and Medicaid Services (CMS) and the OIG recognize that physicians and other authorized individuals must be able to order any test that they believe are appropriate for the treatment or diagnosis of their patients. As the physician, you may order any test(s), including screening tests that you believe are appropriate for the treatment of your patients. Each test must be accompanied with a valid ICD-9 code or narrative (i.e., diagnosis, signs, symptoms or clinical complaint). Use of outdated terminology (e.g., SMAC, SMA21, Chem 12, etc.) or wording that is subject to multiple interpretations (e.g., Liver Function Test [LFT], Fasting Lipid Test [FLT], FLP, etc.) when ordering lab tests requires that our Customer Service staff contact your office for clarification. In an effort to reduce interruptions that these calls have on your practice, laboratory requisition forms are designed to assist you in communicating diagnostic information to the highest degree of accuracy and completeness at the time the test is ordered. However, Medicare will only pay for tests that are covered, reasonable, and necessary for the individual patient given his or her clinical condition.

For Beaumont Laboratory to bill Medicare, you must specify a valid, medically appropriate ICD-9 code (or provide a narrative diagnostic information), which is supported by the patient's medical record, for each test that you order, including all tests listed as part of organ or disease-oriented panels.

National Coverage Determinations (NCD), Local Coverage Determination (LCD), and Limited Coverage Tests

The Medicare Coverage Database (MCD) contains all 23 National Coverage Determinations (NCDs) outlined in the chart below as well as Local Coverage Determinations (LCDs), local policy articles, and proposed NCD decisions. The 23 National Coverage Determinations developed by the Centers for Medicare and Medicaid Services are updated on a quarterly basis and published in the NCD Coding Policy Manual. You can download the current NCD and LCD related information at: Medicare Coverage Database – Centers for Medicare & Medicaid Services.

<table>
<thead>
<tr>
<th>Alpha-fetoprotein</th>
<th>Blood Counts</th>
<th>Blood Glucose Testing</th>
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<tr>
<td>Carcinoembryonic Antigen</td>
<td>Collagen Crosslinks, Any Method</td>
<td>Digoxin Therapeutic Drug Assay</td>
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<td>Gamma Glutamyl Transferase</td>
<td>Glycated Hemoglobin/Glycated Protein</td>
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<td>HIV-1 or HIV-2 Quantification</td>
<td>Human Chorionic Gonadotropin</td>
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<td>Human Immunodeficiency Virus Testing (HIV Diagnosis)</td>
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<td>Tumor Antigen by Immunoassay CA-15-3/CA27.29</td>
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<td>Urine Culture, Bacterial</td>
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</table>

Advance Beneficiary Notice

The Medicare program will allow the laboratory to bill the patient for denied services only if an Advance Beneficiary Notice (ABN) is forwarded to the laboratory with the test requisition. The ABN must be completed by the ordering physician and signed by the patient; the ABN is intended to inform the patient that Medicare will not pay for the services that it determines to be not reasonable and necessary under Section 1862(a)(1) of the Medicare Lab. Medicare does not pay for:

1) tests that are limited coverage unless the ICD-9 code supports medical necessity;
2) tests that are considered noncovered;
3) tests that exceed frequency limits established by Medicare; or
4) tests that are for experimental or research use.

Medical Laboratory Fee Schedule:

CMS provides you with the Clinical Labs Center website to communicate information specific to Clinical Laboratories. To access the current laboratory fee schedule go to: Fee Schedule Clinical Laboratory Fee Schedule. Additionally, Medicaid reimbursement will be equal to, or less than Medicare reimbursement.
American Medical Association (AMA) Approved Organ or Disease Oriented Panels

The American Medical Association (AMA) has grouped certain tests into panels for coding purposes only. If one orders tests in addition to those specifically indicated for a particular panel, those tests are billed separately in addition to the panel code. A valid diagnosis code must be provided for each AMA-approved panel ordered. Individual components of these panels may be ordered separately.

1) Only order those tests that he or she believes are medically necessary for each patient.
2) Be aware that using a customized panel/profile may result in ordering tests for which Medicare or Medicaid will deny payment.
3) Order individual tests or a less inclusive panel/profile if all analytes in the panel/profile are not medically necessary.
4) Understand that the U.S. Department of Health and Human Services, Office of Inspector General takes the position that a physician who orders medically unnecessary tests may be subject to civil penalties.

### Reflex Testing

Reflex testing occurs when initial test results are positive or outside normal parameters and indicate that a second related test or further testing is medically appropriate. Mandated testing criteria set by government or accrediting agencies, relevant practices in laboratory medicine, and avoidance of performing unnecessary testing help dictate which tests are subject to reflexive testing. Upon results of an initial laboratory test, reflex tests will be performed as outlined based on "ALGORITHMS FOR REFLEX TESTS" located on Inside Beaumont on the Laboratory Services web page, under Reference Guides or on the internet at:
http://www.beaumonthospitals.com/laboratory-resources

Some reflex testing may result in additional charges. If you DO NOT want reflex testing, please clearly communicate this request on the laboratory test requisition form and contact Customer Services at 800-551-0488 or 248-551-1155.

### Screening Pap Tests

The College of American Pathologists, the accrediting organization for the Laboratory, requires that providers of cervicovaginal specimens be periodically notified that screening Pap tests are performed to primarily test for squamous cancers and its precursors and can have associated false negative or false positive results. Liquid based preparations may decrease but will not eliminate all false negative results. Regular sampling and follow-up of unexplained clinical signs and symptoms are recommended to minimize false negative results.

### Physician Clinical Consultants

Beaumont has a professional staff of over forty pathologists and Ph.D. scientists specializing in all areas of laboratory medicine. Our medical staff is available to discuss laboratory-testing questions including ordering and interpretation or contact Mark Kolins, M.D., System Chair, Pathology and Laboratory Medicine, directly at 248-551-8030.

Please feel free to contact Customer Service at 800-551-0488 or 248-551-1155 if you should have any further questions. Thank you.

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Please feel free to contact Customer Service at 800-551-0488 or 248-551-1155 if you should have any further questions. Thank you.
Rapid Influenza & RSV by PCR

Effective Date: January 2, 2013

Beaumont Laboratory (Grosse Pointe, Royal Oak, and Troy) will institute state-of-the-art real-time PCR technology to rapidly detect and differentiate influenza A, influenza B, and RSV from nasopharyngeal swab specimens. Rapid antigen tests for influenza and RSV will be available on a limited basis due to a national supply shortage. Rapid antigen tests are discouraged due to sub-optimal diagnostic sensitivity.

Frequently Asked Questions:

1) How do I order the new test?
   a. New test order code is FLRSV
   b. Until paper requisitions are updated, please write “FLRSV” at the bottom of the requisition.

2) When is testing performed? What is the expected turn-around-time (TAT) once the specimen is received in the testing laboratory?
   a. Monday – Sunday; TAT will be 90 minutes or less.
   b. This is only slightly longer than the 60 minute TAT for the rapid antigen tests.

3) What is the rationale for discouraging rapid antigen testing?
   a. Peer-reviewed literature (confirmed by Beaumont Laboratory) demonstrates the diagnostic sensitivity of rapid antigen tests to be between 50-70%; this means that 30-50% of patients will have a false negative test result. In contrast, the sensitivity of this PCR test is >97% (a false negative rate of about 3.0%).
   b. This unacceptably high false negative rate leads to improper patient care as follows:
      i. Inability to institute proper infection control measures (home, office, hospital, etc.).
      ii. Failure to institute antiviral therapy in the appropriate time frame.
      iii. Unnecessary use of antibiotics to treat an undiagnosed upper respiratory tract viral infection.

4) What if I order influenza A/B and/or RSV rapid antigen testing after January 2, 2013?
   a. As supplies are available, Beaumont Laboratory will perform the rapid antigen test(s). If supplies are unavailable, a client services representative will contact you to discuss alternative testing options.
   b. It is strongly recommended that all negative influenza and RSV rapid antigen test results be backed-up with a confirmatory test. (Refer to Respiratory Virus Testing Recommendations: 2012 – 2013.)

Continued on other side
5) Why is RSV testing included with influenza testing?
   a. It is well known that RSV causes severe disease in children less than two years of age.
   b. However, the epidemiology of RSV continues to evolve such that:
      i. Older adults infected with RSV tend to have a severe disease course complicated by pneumonia that may require hospitalization.
      ii. RSV is a frequent cause of upper respiratory tract illness and asthma exacerbation in both children and adults of all ages.

For complete specimen collection instructions, please refer to the on-line Laboratory Test Directory:
Internal URL:  http://beaunet.beaumont.edu/portal/pls/portal/lab.lab_pkg.lab_list
External URL:  http://beaumonthospitals.com/labtestdirectory

If you need additional information, please contact Customer Services (1-800-551-0488, option 5).

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<th>Date Submitted</th>
<th>January 3, 2013</th>
</tr>
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<tbody>
<tr>
<td>Submitted by</td>
<td></td>
</tr>
<tr>
<td>Royal Oak:</td>
<td>Royal Oak:</td>
</tr>
<tr>
<td>B. Robinson-Dunn, Ph.D., D(ABMM)</td>
<td>B. L. Boyanton, M.D.</td>
</tr>
<tr>
<td>Technical Director, Microbiology</td>
<td>Medical Director, Microbiology</td>
</tr>
<tr>
<td>Grosse Pointe:</td>
<td>Troy:</td>
</tr>
<tr>
<td>Vaishali Pansare, MD</td>
<td>Elizabeth Wey, M.D.</td>
</tr>
<tr>
<td>Medical Director, Cytology/Microbiology</td>
<td>Medical Director, Microbiology</td>
</tr>
</tbody>
</table>
Respiratory Virus Testing Recommendations: 2012 – 2013

Effective Date: January 2, 2013

The CDC reports that seasonal influenza A H3N2, seasonal influenza B and influenza A nH1N1 (2009) are the predominant influenza viruses circulating this viral respiratory season. These viruses remain susceptible to oseltamivir (TamiFlu) and zanamivir (Relenza). Therefore, molecular sub-typing is not needed at this time.

Specimen Collection: All swabs (rayon, Dacron, flocked) must be placed into viral transport medium (universal transport media [UTM], universal viral transport [UVT]) and refrigerated.

The following tests are available at Beaumont Laboratory:

1. Rapid Influenza & RSV by PCR. (Outreach order code: FLRSV)
   - Specimen: Nasopharyngeal (NP) only
   - Performed: Mon – Sun, results available within 90 minutes
   - Detects: Influenza A, influenza B, RSV.
   - Notes: 1) Testing for these common respiratory viruses by PCR has superior sensitivity (>97%, a false negative rate of about 3%). Rapid antigen testing for influenza A/B and RSV is highly discouraged.
   2) Despite the common belief that RSV only causes disease in patients less than 2 years of age, current epidemiologic evidence indicates that RSV causes severe disease in older adults, and is a frequent cause of upper respiratory tract illness and asthma exacerbation in children and adults of all ages.
   - When to Order: This should be the first-line test ordered for patients with influenza-like illness, due to superior diagnostic sensitivity and rapid turn-around-time.

2. Influenza A/B by EIA – Rapid Antigen Test (Outreach order code: AGFLU) - or - Respiratory Syncytial Virus by EIA – Rapid Antigen Test (Outreach order code: AGRSV)
   - Specimen: Nasopharyngeal (NP) only
   - Performed: Mon – Sun, results available within 60 minutes
   - Detects: Influenza A, influenza B, Respiratory Syncytial Virus
   - When to Order: These should be used as optional first-line tests for patients with influenza-like illness.
   - Note: Rapid antigen tests have sub-optimal diagnostic sensitivity (50-70%, a false negative rate of 30-50%). Therefore, negative test results should be confirmed by other PCR-based or culture tests.
3. **Respiratory Virus Panel (RVP) by PCR.** (Outreach order code: IRVPG)
   - **Specimen** Nasopharyngeal (NP) only
   - **Performed** Mon – Sat, results available in 24 – 48 hr.
   - **Detects** Influenza A with sub-typing, influenza B, RSV A/B, human metapneumovirus, adenovirus, rhinovirus/enterovirus, and parainfluenza viruses 1, 2, 3.
   - **Note** If the RVP by PCR result is “influenza A, unable to subtype as seasonal H1 or seasonal H3”, the specimen will be forwarded to MDCH for further testing.
   - **When to order** If you suspect the patient may be infected with respiratory viruses other than influenza A, or if you suspect co-infection with influenza A and other respiratory viruses.

4. **Culture, Virus** (Outreach Order Code: CXVIR)
   - **Specimen** Nasopharyngeal (NP) or Non-NP (BAL, bronchial wash, sputum, etc.)
   - **Performed** Mon – Sun, results available in 24 – 48 hr.
   - **Detects** Influenza A and B, RSV, adenovirus, and parainfluenza viruses 1, 2, 3.
   - **When to order** Non-NP specimens are preferred. NP specimens are acceptable, but should be performed by one of the PCR-based tests (above) due to improved test sensitivity.

5. **Influenza A nH1N1 (2009) by RT-PCR:** This test is no longer available.

### Influenza Antiviral Drug Susceptibility (2012-2013 Respiratory Virus Season)

<table>
<thead>
<tr>
<th>Antiviral Drug</th>
<th>Seasonal A H3N2</th>
<th>nH1N1 (2009) “Swine”</th>
<th>Seasonal B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oseltamivir (Tamiflu)</td>
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<tr>
<td>Zanamivir (Relenza)</td>
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<tr>
<td>Amantadine/Ramantadine</td>
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</table>

**Additional information:** [http://www.cdc.gov/flu](http://www.cdc.gov/flu)


**Reference 2:** Accuracy of Rapid Influenza Diagnostic Tests. *Ann Int Med* 2012;156(7):500-512


If you have questions, please contact Client Services (1-800-551-0488, option 5).

**Effective Date**: January 3, 2013

**Submitted by**

- **Royal Oak:**
  - B. Robinson-Dunn, Ph.D., D(ABMM)
  - Technical Director, Microbiology

- **Grosse Pointe:**
  - Vaishali Pansare, MD
  - Medical Director, Cytology/Microbiology

- **Troy:**
  - Elizabeth Wey, M.D.
  - Medical Director, Microbiology
**Algorithm 1: Start with Rapid Influenza & RSV by PCR**

1. **Testing Desired?**
   - **No**: No Further Action
   - **Yes**: Focused or Expanded Pathogen Detection Desired?

2. **Focused or Expanded Pathogen Detection Desired?**
   - **Yes**: Rapid Influenza & RSV by PCR
     - **Positive**: Is another test needed to exclude other viral respiratory pathogens?
       - **Yes**: Order:
         - Respiratory Viral Panel by PCR (NP Specimens)
         - OR
         - Culture, Virus (NP or Non-NP Specimens)
       - **No**: No Further Action
     - **Negative**: No Further Action
   - **No**: Expanded (Routine Only)

**SPECIAL NOTE:**

1. Rapid Antigen Tests for Influenza and RSV are highly discouraged due to sub-optimal diagnostic sensitivity.
2. The best first-line test for Influenza and RSV detection is the Rapid Influenza & RSV by PCR test.

**Effective: January 02, 2013**
Algorithm 2: Start with Influenza and/or RSV by EIA

1. No Further Action.
2. Molecular subtyping for influenza A NOT needed at this time.
3. Seasonal influenza A H3, seasonal influenza B, and influenza A nH1N1 (2009) are sensitive to oseltamivir (Tamiflu) and zanamivir (Relenza).

Expanded (Routine Only)

Focused (Routine or STAT)

Rapid Influenza A/B by EIA
-and/or –
Rapid RSV by EIA

Is another test needed to exclude other viral respiratory pathogens?
Is another test needed to detect co-infections?

Order:
Respiratory Viral Panel by PCR (NP Specimens)
OR
Culture, Virus (NP or Non-NP Specimens)

SPECIAL NOTE:
1. Rapid Antigen Tests for Influenza and RSV are highly discouraged due to sub-optimal diagnostic sensitivity.
2. The best first-line test for Influenza and RSV detection is the Rapid Influenza & RSV by PCR test.
PCA3 – Prostate Cancer Gene 3 Expression

Effective Date CORRECTION: January 8, 2013

The Molecular Pathology Laboratory in Beaumont’s Department of Pathology and Laboratory Medicine, Royal Oak will offer testing for PCA3 – Prostate Cancer Gene 3, a prostate specific gene that is highly expressed in >95% of prostate cancers.

<table>
<thead>
<tr>
<th>Synonyms</th>
<th>DD3 gene for prostate cancer; Progensa PCA3</th>
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<tr>
<td>Instructions</td>
<td>Collect urine: first-catch urine following digital rectal exam (DRE)</td>
</tr>
<tr>
<td>Physician Office/Draw Site Specimen Preparation</td>
<td>Follow instructions for DRE, urine collection and processing provided in the Physicians Instruction flyer.</td>
</tr>
<tr>
<td>Specimen Preparation for Courier Transport</td>
<td>Processed urine specimens transported at room temperature in the provided special transport tubes; frozen processed specimens also accepted.</td>
</tr>
<tr>
<td>Rejection Criteria</td>
<td>Unprocessed urine specimens, specimens received at room temperature later than 5 days, specimens with less than 2.5 mL volume.</td>
</tr>
<tr>
<td>Performed</td>
<td>Once a week. Results available within 7-10 days.</td>
</tr>
<tr>
<td>Reference Range</td>
<td>Negative: PCA3 score &lt; 25</td>
</tr>
<tr>
<td>Test Methodology</td>
<td>Quantitation of urine PCA3 mRNA transcripts normalized to PSA mRNA transcripts, based on transcription mediated amplification (TMA), with calculated PCA3/PSA score.</td>
</tr>
<tr>
<td>Interpretation</td>
<td>PCA3 is a prostate specific gene that is highly overexpressed in over 95% of prostate cancers: prostate cancer cells express 60-100 times more PCA3 mRNA than normal cells. The specific information provided by the test is the PCA3 score in the patient’s urine sample, collected after digital rectal exam. PCA3 is specific for prostate cancer and is not affected by prostate enlargement or other non-malignant prostate conditions, unlike PSA. The PCA3 score provides useful information to help decide if a biopsy is needed or can be delayed, and may give an indication about aggressiveness of diagnosed prostate cancer. The higher the PCA3 score above the cut off value of 25, the more likely the biopsy will be positive. PCA3 scores below the cut off value are associated with decreased likelihood of a positive biopsy. Specimens with PCA3 scores near the cut off value, in the 18-31 range, should be interpreted with caution, and repeated assay is suggested. Reliable results are dependent on accurate urine specimen collection and processing.</td>
</tr>
</tbody>
</table>

| CPT Codes                                    | 83891, 83892, 83896, 83898, 83902, 83907 |
| Date Submitted                               | November 14, 2012 |
| Submitted by                                 | Domnita Crisan, MD, PhD |
|                                              | Medical Director, Molecular Pathology Laboratory |
Blood Cultures for Viruses and Mycobacteria

Effective Date: January 8, 2013

Effective January 8, 2013, these tests will be orderable in both Epic OneChart and Soft.

Frequently Asked Questions

1) How do I order the new test?
   a. The new test order code for Culture, Blood Virus is CXVBL
   b. The new test order code for Culture, Blood AFB is CXABL

2) When is testing performed? What is the expected turn-around-time (TAT)?
   a. Both Virology and Mycobacteriology are performed Monday – Sunday in the Royal Oak Microbiology Laboratory;
   b. Final results can be expected in less than one week for a negative viral culture and 8 weeks for a negative AFB culture.

3) What kind of container should be used to transport the specimen to the laboratory?
   a. For virus culture, 8-10 mL of blood should be placed in an EDTA tube and transported refrigerated (2°-8° C or 36°-46° F).
   b. For AFB culture, blood should be drawn into a large (10 mL) Isolator tube and transported to the laboratory at room temperature (20°-25° C or 68°-77° F).

For complete specimen collection instructions, please refer to the on-line Laboratory Test Directory:
Internal URL: http://beaunet.beaumont.edu/portal/pls/portal/lab.lab_pkg.lab_list
External URL: http://beaumonthospitals.com/labtestdirectory

If you need additional information, please contact Customer Services (1-800-551-0488, option 5).

<table>
<thead>
<tr>
<th>Date Submitted</th>
<th>Royal Oak: B. Robinson-Dunn, Ph.D., D(ABMM) Technical Director, Microbiology</th>
<th>Royal Oak: B. L. Boyanton, M.D. Medical Director, Microbiology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submitted by</td>
<td>Grosse Pointe: Vaishali Pansare, MD Medical Director, Cytology/Microbiology</td>
<td>Troy: Elizabeth Wey, M.D. Medical Director, Microbiology</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
PRENATAL SNP ARRAY KARYOTYPING,
PRENATAL CHROMOSOME MICROARRAY ANALYSIS (CMA)

Effective Date: February 5, 2013

Conventional cytogenetic analysis (karyotyping) permits an analysis of the entire human genome, but does so at a relatively low-level of resolution (5-10 Mb). While this is more than adequate to diagnosis many constitutional cytogenetic disorders, such as trisomy 21 (Down syndrome), it will fail to identify smaller abnormalities which may be associated with significant genetic morbidity. Fluorescence in situ hybridization (FISH) provides a much higher level of resolution (150kb), but interrogates only a specific region of the genome. Chromosome microarray analysis (CMA) provides a genome-wide assessment of copy number changes (deletions and duplications) at a resolution far greater than what is achievable with other cytogenetic methodologies such as karyotyping and FISH. CMA is now considered a first-line test, replacing the karyotype, in children with developmental delay/intellectual disability, multiple congenital anomalies, dysmorphic features, and autism/autism spectrum disorder. Several recent multicenter studies have demonstrated the utility of prenatal CMA. In one study which compared karyotyping with CMA in 4406 women (Wappner et al, 2012), clinically significant deletions and duplications were identified in 1.7% of cases with a normal karyotype referred for advanced maternal age or a positive screening result. If a structural fetal anomaly was identified by ultrasound, a clinically significant copy number change was observed in 6.0% of cases. In another study (Shaffer et al, 2012), the overall detection rate of clinically significant deletions or duplications was 5.3% for any indication for study and 6.5% for pregnancies with one or more fetal ultrasound anomalies. As in the previous study, many of the genomic changes identified by CMA were below the level of resolution achievable by karyotyping. At Beaumont, the CMA test utilizes the Affymetrix CytoScan HD single nucleotide polymorphism (SNP) array which can reliably detect 25–50 kb copy number changes across the genome. With more than two million copy number markers, including 750,000 SNPs, the Beaumont CytoScan Array offers high-density resolution of the entire genome. The Beaumont SNP array can also provide genotype information that allows for detection of uniparental disomy and consanguinity. Prenatal CMA should be considered in any pregnancy with one or more fetal ultrasound anomalies and a normal karyotype.

Results reported for:
- Deletions or duplications larger than 500kb across the genome; Deletions greater than 50kb and duplications greater than 100kb in known syndromic regions
- No susceptibility genes are reported unless they are associated with an unambiguous outcome
- Uniparental disomy or clear consanguinity

<table>
<thead>
<tr>
<th>Specimen</th>
<th>20-30 ml of amniotic fluid or 15-20mg chorionic villi or two confluent T-25 flasks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference Range</td>
<td>Positive or negative for chromosome abnormality. A comprehensive interpretative report will be provided</td>
</tr>
<tr>
<td>Test Limitations</td>
<td>CMA cannot detect 1) balanced chromosome rearrangements such as translocations, balanced insertions, or inversions, 2) low-level mosaicism, 3) polyploidy, and 4) an abnormality in a region not represented on the array.</td>
</tr>
<tr>
<td>CPT Code</td>
<td>81229 Note: This test requires insurance preauthorization. The laboratory will not accept the specimen without preauthorization. Also note that CMA is generally performed in the outpatient setting.</td>
</tr>
<tr>
<td>Date Submitted</td>
<td>January 22, 2013</td>
</tr>
<tr>
<td>Submitted by</td>
<td>Dr. Mark Micale, Clinical Cytogenomics Laboratory Medical Director</td>
</tr>
</tbody>
</table>

Clinical References:
ONCOLOGY SNP ARRAY KARYOTYPING, ONCOLOGY MOLECULAR KARYOTYPING

Effective Date: February 5, 2013

The importance of identifying chromosome abnormalities in cancer, especially in hematolymphoid disorders, has long been well established as they provide diagnostic, prognostic, and therapeutic information critical to proper patient management. Furthermore, the identification by both conventional karyotyping and FISH of recurrent balanced or unbalanced chromosome changes in specific disorders has permitted the elucidation of the genetic mechanisms that underlie their malignant origins, thus providing the basis for the development of specific treatments. FISH panels are now routinely utilized in evaluation of hematological disorders including myelodysplastic syndrome, acute myeloid leukemia, chronic lymphocytic leukemia, pediatric acute lymphoblastic leukemia, and plasma cell myeloma. Recent advances in chromosome array technology have provided an opportunity to examine the whole genome of cancer cells at a level of resolution far greater than what is achievable by previous methods including FISH. A single nucleotide polymorphism (SNP) DNA array can detect genomic gain or loss at a very high level of resolution and can also provide genotype information which permits detection of copy number neutral loss of heterogeneity (acquired uniparental disomy or aUPD). The Beaumont SNP Oncology array test utilizes the Affymetrix CytoScan HD SNP array which provides the broadest coverage and highest performance for detecting both copy number altering and copy number neutral aberrations. In the last several years, a number of different neoplastic conditions have been studied using SNP array analysis. These conditions include chronic lymphocytic leukemia, myelodysplastic syndromes, acute myeloid leukemia (especially with a normal karyotype), plasma cell myeloma, B-cell lymphomas, and solid tumors. These studies have demonstrated a greater sensitivity compared with traditional FISH studies for identifying unbalanced chromosome abnormalities. SNP array can detect complex genomic changes not apparent by either karyotype or FISH, changes which have been correlated with a poorer prognosis in most cases. As a demonstration of the clinical importance of SNP analysis in patients with hematological malignancies, Dougherty et al. (2011) performed array analysis on 180 samples from children with a suspected or confirmed hematological malignancy. Of these 180 bone marrow or lymph node biopsies, 130 (72%) revealed aberrations not seen by karyotype. SNP array analysis has also provided valuable, and previously unattainable in a high throughput fashion, information in renal cell carcinoma, neuroblastoma, and glial tumors. At the present time, there is strong supporting data to recommend the use of SNP-array karyotyping in all newly diagnosed cases of CLL, MDS, AML negative for karyotype abnormalities as well as for FLT3 and NPM1 mutations, renal cell carcinomas with equivocal histology, and neuroblastoma.

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Bone marrow or peripheral blood (for CLL cases if appropriate)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference Range</td>
<td>Positive or negative for chromosome abnormality. A comprehensive interpretative report will be provided</td>
</tr>
<tr>
<td>Test Limitations</td>
<td>CMA cannot detect 1) balanced chromosome rearrangements such as translocations, balanced insertions, or inversions, 2) low-level mosaicism, 3) polyploidy, and 4) an abnormality in a region not represented on the array.</td>
</tr>
<tr>
<td>CPT Code</td>
<td>81229 Note: This test requires insurance preauthorization. The laboratory will not accept the specimen without preauthorization. Also note that CMA is generally performed in the outpatient setting.</td>
</tr>
<tr>
<td>Date Submitted</td>
<td>January 22, 2013</td>
</tr>
<tr>
<td>Submitted by</td>
<td>Dr. Mark Micale, Clinical Cytogenomics Laboratory Medical Director</td>
</tr>
</tbody>
</table>

The importance of identifying chromosome abnormalities in cancer, especially in hematolymphoid disorders, has long been well established as they provide diagnostic, prognostic, and therapeutic information critical to proper patient management. Furthermore, the identification by both conventional karyotyping and FISH of recurrent balanced or unbalanced chromosome changes in specific disorders has permitted the elucidation of the genetic mechanisms that underlie their malignant origins, thus providing the basis for the development of specific treatments. FISH panels are now routinely utilized in evaluation of hematological disorders including myelodysplastic syndrome, acute myeloid leukemia, chronic lymphocytic leukemia, pediatric acute lymphoblastic leukemia, and plasma cell myeloma. Recent advances in chromosome array technology have provided an opportunity to examine the whole genome of cancer cells at a level of resolution far greater than what is achievable by previous methods including FISH. A single nucleotide polymorphism (SNP) DNA array can detect genomic gain or loss at a very high level of resolution and can also provide genotype information which permits detection of copy number neutral loss of heterogeneity (acquired uniparental disomy or aUPD). The Beaumont SNP Oncology array test utilizes the Affymetrix CytoScan HD SNP array which provides the broadest coverage and highest performance for detecting both copy number altering and copy number neutral aberrations. In the last several years, a number of different neoplastic conditions have been studied using SNP array analysis. These conditions include chronic lymphocytic leukemia, myelodysplastic syndromes, acute myeloid leukemia (especially with a normal karyotype), plasma cell myeloma, B-cell lymphomas, and solid tumors. These studies have demonstrated a greater sensitivity compared with traditional FISH studies for identifying unbalanced chromosome abnormalities. SNP array can detect complex genomic changes not apparent by either karyotype or FISH, changes which have been correlated with a poorer prognosis in most cases. As a demonstration of the clinical importance of SNP analysis in patients with hematological malignancies, Dougherty et al (2011) performed array analysis on 180 samples from children with a suspected or confirmed hematological malignancy. Of these 180 bone marrow or lymph node biopsies, 130 (72%) revealed aberrations not seen by karyotype. SNP array analysis has also provided valuable, and previously unattainable in a high throughput fashion, information in renal cell carcinoma, neuroblastoma, and glial tumors. At the present time, there is strong supporting data to recommend the use of SNP-array karyotyping in all newly diagnosed cases of CLL, MDS, AML negative for karyotype abnormalities as well as for FLT3 and NPM1 mutations, renal cell carcinomas with equivocal histology, and neuroblastoma.

**Specimen**
Bone marrow or peripheral blood (for CLL cases if appropriate)

**Reference Range**
Positive or negative for chromosome abnormality. A comprehensive interpretative report will be provided

**Test Limitations**
- SNP array cannot detect 1) balanced chromosome rearrangements such as translocations, balanced insertions, or inversions, 2) low-level mosaicism, 3) polyploidy, and 4) an abnormality in a region not represented on the array.

**CPT Code**
81406  **Note:** SNP arrays are generally performed in the outpatient setting.

**Date Submitted:** May 31, 2013

**Submitted by:** Dr. Mark Micale, Clinical Cytogenomics Laboratory Medical Director

**Clinical References:**
Moderate to severe mental retardation occurs in ~1% of the population and has many causes, with one third to one-half of cases being idiopathic. Unbalanced chromosome abnormalities are the most common cause of mental retardation, accounting for approximately 10% of cases; however, the ability of traditional karyotype analysis and fluorescence in situ hybridization (FISH) to identify a pathogenetic chromosome abnormality is limited by the band resolution achieved in the study and by the need for some clinical information to choose the proper FISH probes to utilize. Since the resolution of conventional cytogenetic analysis is 5-10Mb (5-10 million base pairs), any rearrangement smaller than this would be missed. In addition to mental retardation and developmental delay, unbalanced chromosome abnormalities and aneuploidy are also identified in patients with autism/autism spectrum disorder, dysmorphic features, and multiple congenital anomalies. Chromosome microarray analysis (CMA) utilizes a “DNA chip” that provides a genome-wide assessment of copy number changes (deletions and duplications) at a resolution far greater than what is achievable with other cytogenetic methodologies. At Beaumont, this test utilizes the Affymetrix CytoScan HD single nucleotide polymorphism (SNP) array that provides the broadest coverage and highest performance for detecting constitutional chromosome abnormalities. CytoScan HD Array has greater than 99 percent sensitivity and can reliably detect 25–50 kb copy number changes across the genome. With more than two million copy number markers (akin to performing over two million simultaneous FISH experiments), including 750,000 SNPs, the Beaumont CytoScan Array offers high-density resolution of the entire genome, extending throughout promoter and miRNA regions for relevant aberration detection and reporting. The Beaumont SNP array can also provide genotype information that allows for detection of copy number neutral aberrations such as uniparental disomy and consanguinity which can provide evidence for candidate recessive disorders. SNP array analysis is similar to the previously offered oligonucleotide array; however, it has comparatively superior sensitivity with resolution as good as 880 base pairs between each marker. The Beaumont experience with CMA has demonstrated a pathogenetic copy number in over 20% of the nearly 400 children tested since 2008, many of whom had a previously “normal” karyotype. In addition to intellectual disability, CMA has been shown to detect a submicroscopic rearrangement in 7% of children with nonsyndromic autism, 27% of children with syndromic autism spectrum disorder, and 17% of neonates with birth defects. Thus, SNP chromosome microarray analysis should be considered as a front-line test to evaluate patients with a suspected genetic disorder.

Specimen | Whole blood sodium heparin tube
---|---
Reference Range | Positive or negative for chromosome abnormality. A comprehensive interpretative report will be provided
Test Limitations | CMA cannot detect 1) balanced chromosome rearrangements such as translocations, balanced insertions, or inversions, 2) low-level mosaicism, 3) polyploidy, and 4) an abnormality in a region not represented on the array.
CPT Code | 81229  Note: This test requires insurance preauthorization. The laboratory will not accept the specimen without preauthorization. Also note that CMA is generally performed in the outpatient setting.
Date Submitted | January 22, 2013
Submitted by | Dr. Mark Micale, Clinical Cytogenomics Laboratory Medical Director

Clinical References:
Ethanol and Glucose Critical Value/Call Changes

TSH Unit Change

Effective Date: February 14, 2013

Ethanol critical value changes

Effective February 14th, 2013, the critical values for adults aged 21 years and older will be changed. Critical values will be as follows:

- 0 – 12 years: > 50 mg/dL
- 13 – 20 years: > 250 mg/dL
- 21 years +: > 400 mg/dL

Glucose critical calls

The high critical for glucose is > 500 mg/dL. If such a result is encountered on an outpatient, it will be called to the physician 24 hours/7 days a week.

TSH units

With implementation of Soft (Lab Information System) in September 2011, TSH units were unfortunately reported incorrectly as mcIU/L instead of mcIU/mL. However, the patient’s numerical result was appropriate for mcIU/mL units. Effective February 14th, 2013 TSH units will be corrected to read mcIU/mL instead of mcIU/L.

Therefore between September 9, 2011 and February 13, 2013, if you received a TSH result of 3.0 mcIU/L, this was actually 3.0 mcIU/mL.

Date Submitted
01/30/2013

Submitted by
Elizabeth Sykes MD, Medical Director of Chemistry Royal Oak
Ralph Zade MD, Medical Director of Chemistry Troy
Beatrice Muglia MD, Medical Director of Chemistry Grosse Pointe
Reporting Format Change for Drug Screens

Effective Date: February 14, 2013

The language for reporting drug screens and confirmation results on the Drugs of Abuse Panel (DAUPN) and EC, Drugs of Abuse Panel (ECDAU) has been updated.

Previously, positive drug screens that did not confirm were reported as negative. Effective February 14, 2013, the following changes will be made:

- Initial negative drug screens will continue to be reported as “Negative”.
- Initial positive drug screens will be reported as “Unconf Pos” (Unconfirmed Positive).
- Final drug confirmations will be reported as “Confirmed Pos” or “Negative”.

When appropriate, the specific drug(s) that are confirmed will be reported with the confirmation result. A negative drug confirmation following a positive screen is usually due to a cross-reacting substance. As before, drug testing results should not be used for non-medical decision purposes.

Date Submitted: February 12, 2013

Submitted by:
Michael Smith, Ph.D., Clinical Chemist, Royal Oak
Yvonne Posey MD, Assoc. Medical Director, Clinical Chemistry, Royal Oak
Elizabeth Sykes MD, Medical Director of Chemistry Royal Oak
Beatrice Muglia MD, Medical Director of Chemistry, Grosse Pointe
Ralph Zade MD, Medical Director of Chemistry, Troy
NEW REFERENCE RANGES FOR THROMBIN TIME AND FIBRINOGEN

Effective Date: 2/25/2013 after 12:00 p.m.

The changes indicated below will be made to the reference ranges for Thrombin time and Fibrinogen on February 25, 2013.

<table>
<thead>
<tr>
<th>Test</th>
<th>Old Reference Range</th>
<th>New Reference Range</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Thrombin Time</strong> – Royal Oak only</td>
<td>15-19 seconds</td>
<td>16-20 seconds</td>
</tr>
<tr>
<td>Not performed at Grosse Pointe or Troy</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Fibrinogen</strong></td>
<td>175-400 mg/dL</td>
<td>175-375 mg/dL</td>
</tr>
<tr>
<td>All campuses – Grosse Pointe, Royal Oak &amp; Troy</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Date Submitted: February 5, 2013
Submitted by: Marc Smith, MD, Medical Director, Coagulation Lab, Royal Oak
            Ming Xie, MD, Medical Director, Coagulation, Troy
            LeiLei Chen, MD Medical Director, Hematology, Grosse Pointe
CYTOMEGALOVIRUS (CMV) DNA VIRAL LOAD TESTING

Effective Date: February 26, 2013

On February 26, 2013, the Molecular Laboratory will offer viral load testing for the quantitative measurement of CMV DNA in human plasma. The primary use of this test is for solid-organ transplant patients undergoing anti-CMV therapy. This test is calibrated to the 1st WHO International Standard.

For complete specimen collection and handling instructions, please refer to the “on-line” Laboratory Test Directory:

<table>
<thead>
<tr>
<th>Synonyms</th>
<th>CMV, human CMV, hCMV, herpesvirus, viral load, quantitation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specimen Collection</td>
<td>4 mL lavender-top EDTA tube. Minimum plasma volume (0.5 mL).</td>
</tr>
<tr>
<td>Physician Office/Draw Site Specimen Preparation</td>
<td>Plasma must be separated (centrifuged) within 6 hours of collection. Transfer plasma into a plastic transport tube. Refrigerate (2-8oC) or freeze (≤-20oC).</td>
</tr>
<tr>
<td>Specimen Preparation for Courier Transport</td>
<td>Transport refrigerated (2-8oC) or frozen (≤-20oC).</td>
</tr>
<tr>
<td>Rejection Criteria</td>
<td>Specimens not collected in an EDTA lavender-top tube. Specimens not centrifuged within 6 hours of collection.</td>
</tr>
<tr>
<td>Performed</td>
<td>Twice per week. Results available in 3 to 4 days.</td>
</tr>
<tr>
<td>Reference Range</td>
<td>Limit of Detection: 91 IU/mL Reportable Range: 137 to 9,100,000 IU/mL</td>
</tr>
<tr>
<td>Test Methodology</td>
<td>Real-time PCR (FDA-approved, Roche COBAS Ampliprep / COBAS TaqMan CMV Test)</td>
</tr>
<tr>
<td>Interpretation</td>
<td>Serial CMV DNA viral load measurements within human plasma are important determinants in assessing risk for CMV disease and/or the effectiveness of anti-CMV therapy.</td>
</tr>
<tr>
<td>CPT Code</td>
<td>87497</td>
</tr>
</tbody>
</table>

For complete specimen collection instructions, please refer to the on-line Laboratory Test Directory:

Internal URL:  http://beaunet.beaumont.edu/portal/pls/portal/lab.lab_pkg.lab_list
External URL:  http://beaumonthospitals.com/labtestdirectory

If you need additional information, please contact Customer Services (1-800-551-0488, option 5).

<table>
<thead>
<tr>
<th>Date Submitted</th>
<th>February 5, 2013</th>
</tr>
</thead>
</table>
| Submitted by   | B. L. Boyanton, M.D.  
Medical Director, Microbiology  
Associate Medical Director, Molecular Pathology  

Domnita Crisan, MD, PhD  
Medical Director, Molecular Pathology Laboratory |
Calprotectin no longer offered

Effective Date: March 5, 2013

Effective March 5, 2013 the Calprotectin will no longer be offered through Beaumont Laboratories.

Beaumont Laboratory does not perform the Calprotectin assay and will no longer forward specimens to an external reference lab. Physicians wanting access to testing may make arrangements directly with a laboratory that performs this assay.

<table>
<thead>
<tr>
<th>Synonym</th>
<th>XCALP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Submitted</td>
<td>February 25, 2013</td>
</tr>
</tbody>
</table>
| Submitted by | Joel Waddington, MT Sendout Coordinator  
               Yvonne Posey, MD Medical Director, Sendout |
INSULIN LIKE GROWTH FACTOR 1 (IGF-1)

Effective Date: 03/29/2013

Insulin like growth factor 1 (IGF-1) testing will be sent out to Esoterix Lab. This change is necessary because the manufacturer of our current reagent system (Siemens Immulite) is no longer able to supply reagents. Siemens hopes to have new reagent available in June. There is no change in sample requirements.

Esoterix reports pediatric ranges according to Tanner stage. Below are ranges for adults.

<table>
<thead>
<tr>
<th>Age</th>
<th>Male (ng/mL)</th>
<th>Female (ng/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>19 – 20 years</td>
<td>281 – 510</td>
<td>217 – 475</td>
</tr>
<tr>
<td>21 – 30 years</td>
<td>155 – 432</td>
<td>87 – 368</td>
</tr>
<tr>
<td>31 – 40 years</td>
<td>132 – 333</td>
<td>106 – 368</td>
</tr>
<tr>
<td>41 – 50 years</td>
<td>121 – 237</td>
<td>118 – 298</td>
</tr>
<tr>
<td>51 – 60 years</td>
<td>68 – 245</td>
<td>53 – 287</td>
</tr>
<tr>
<td>61 – 70 years</td>
<td>60 – 220</td>
<td>75 – 263</td>
</tr>
<tr>
<td>71 – 80 years</td>
<td>36 – 215</td>
<td>54 – 205</td>
</tr>
</tbody>
</table>

Beaumont adult ranges are as follows:

<table>
<thead>
<tr>
<th>Age</th>
<th>WBH Male ng/mL</th>
<th>WBH Female ng/mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>16 – 24 years</td>
<td>182 – 780</td>
<td>182 – 780</td>
</tr>
<tr>
<td>25 – 39 years</td>
<td>114 – 492</td>
<td>114 – 492</td>
</tr>
<tr>
<td>40 – 54 years</td>
<td>90 – 360</td>
<td>90 – 360</td>
</tr>
<tr>
<td>55 yr and over</td>
<td>71 – 290</td>
<td>71 – 290</td>
</tr>
</tbody>
</table>

Date Submitted: 04/01/2013

Submitted by: Elizabeth Sykes MD, Medical Director of Automated Chemistry and Special Testing Royal Oak
INSULIN LIKE GROWTH FACTOR 1 (IGF-1) UPDATE

Effective Date: September 10, 2013

Effective September 10, 2013, Beaumont Laboratory will re-commence performing IGF-1 testing on the Siemens Immulite. There is no change in specimen requirements. As indicated in a previous bulletin, Insulin like growth factor 1 (IGF-1) test orders have been sent to Esoterix Lab since March 29, 2013. This change was necessary because the manufacturer of our in-house test system (Siemens Immulite) temporarily discontinued distributing reagents.

Beaumont adult reference ranges:

<table>
<thead>
<tr>
<th>Age</th>
<th>WBH Male (ng/mL)</th>
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</tr>
<tr>
<td>40 – 54 years</td>
<td>90 – 360</td>
<td>90 – 360</td>
</tr>
<tr>
<td>55 years &amp; over</td>
<td>71 – 290</td>
<td>71 – 290</td>
</tr>
</tbody>
</table>

Esoterix adult reference ranges (Testing performed 03/29/2013 – 09/09/2013):

<table>
<thead>
<tr>
<th>Age</th>
<th>Male (ng/mL)</th>
<th>Female (ng/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>19 – 20 years</td>
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<td>60 – 220</td>
<td>75 – 263</td>
</tr>
<tr>
<td>71 – 80 years</td>
<td>36 – 215</td>
<td>54 – 205</td>
</tr>
</tbody>
</table>

Date Submitted: August 20, 2013
Submitted By: Gabriel Maine, PhD
Technical Director, Special Testing, Royal Oak
Elizabeth Sykes, MD
Medical Director, Special Testing, Royal Oak
BCL-2 GENE REARRANGEMENT TESTING UPDATE

Effective Date: April 1, 2013

BCL-2 gene rearrangement testing by fluorescent in-situ hybridization (FISH) is offered by the Cytogenomics Laboratory. In all comparative studies to date, FISH has been shown to be the most reliable BCL-2 gene rearrangement detection method. FISH provides rapid turn-around-time and can be performed on fresh or formalin fixed paraffin-embedded tissue specimens.

Because of the numerous advantages that FISH testing offers, BCL-2 gene rearrangement testing by PCR will no longer be offered by the Advanced Diagnostics Laboratory. This change will be effective April 1, 2013.

If you need additional information, please contact Customer Services (1-800-551-0488, option 5) and ask for the Cytogenomics Laboratory.

Date Submitted | April 2, 2013
Submitted by

| Mitual B. Amin, M.D. |
| Medical Director, Advanced Diagnostics Laboratory |

| Bobby L. Boyanton Jr., M.D. |
| Associate Medical Director, Molecular Pathology |

| Mark A. Micale, Ph.D. |
| Medical Director, Cytogenomics Laboratory |
Culture of normally sterile body fluids will be automated using the same system currently used for blood cultures. After extensive evaluation, we expect to recover significantly more organisms by this method. Please note that cerebrospinal fluid will not be handled in this manner because quantities of these specimens sufficient for automated cultures are not usually submitted to the laboratory.

**Frequently Asked Questions:**

1) How do I order the new test?
   a. Order code for Culture, Fluid is CXFLD.

2) When is testing performed? What is the expected turn-around-time?
   a. This test is performed Sunday through Saturday.
   b. If the culture result is negative, final results will be available in 5 days.

3) How should specimens be submitted to the laboratory?
   a. Ideally 30 mL of fluid should be submitted to the Microbiology Laboratory in a sterile, screw-cap container. Fluid specimens will routinely be inoculated into aerobic and anaerobic blood culture bottles by Microbiology staff using sterile technique.
      i. NOTE: If smaller fluid volumes are submitted, the requesting physician will be contacted to prioritize the microbiological tests requested.
   b. Do NOT send a swab specimen dipped into the fluid as it does not capture sufficient specimen for all of the required microbiological tests.

4) Can I inoculate the blood culture bottles before sending them to the laboratory?
   a. Yes. You must use the same sterile technique as for blood culture collection.
   b. Along with the inoculated bottles, additional fluid must be sent for Gram stain and additional cultures as necessary.
   c. Instructions on inoculating blood culture bottles are available on Beaumont’s internal web site at: [http://employee.beaumont.edu/portal/pls/portal/docs/1181822.PDF](http://employee.beaumont.edu/portal/pls/portal/docs/1181822.PDF)

For complete specimen collection instructions, please refer to the on-line Laboratory Test Directory:
- Internal URL: [http://beaunet.beaumont.edu/portal/pls/portal/lab.lab_pkg.lab_list](http://beaunet.beaumont.edu/portal/pls/portal/lab.lab_pkg.lab_list)
- External URL: [http://beaumonthospitals.com/labtestdirectory](http://beaumonthospitals.com/labtestdirectory)

If you need additional information, please contact Customer Services (1-800-551-0488, option 5).

<table>
<thead>
<tr>
<th>Date Submitted</th>
<th>March 20, 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submitted by</td>
<td></td>
</tr>
<tr>
<td>Royal Oak:</td>
<td></td>
</tr>
<tr>
<td>B. Robinson-Dunn, Ph.D., D(ABMM)</td>
<td>Royal Oak:</td>
</tr>
<tr>
<td>Technical Director, Microbiology</td>
<td>B. L. Boyanton, M.D.</td>
</tr>
<tr>
<td>Grosse Pointe:</td>
<td></td>
</tr>
<tr>
<td>Vaishali Pansare, MD</td>
<td>Troy:</td>
</tr>
<tr>
<td>Medical Director, Cytology/Microbiology</td>
<td>Elizabeth Wey, M.D.</td>
</tr>
<tr>
<td>Troy:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Medical Director, Microbiology</td>
</tr>
</tbody>
</table>
24-HOUR URINE JUGS

Effective Date: April 15, 2013

Beaumont Laboratory has improved the 24 hour urine jugs and will begin distribution on April 15, 2013. The new standardized 24 hour jug is safer and easier for patients to use.

The jug has:
- A more accessible opening for urine collection.
- A safer closing mechanism effectively preventing acid preservatives from leaking or spilling.

How to order:
If you obtain 24 hour urine jugs from Oracle/Beaumont ordering:

<table>
<thead>
<tr>
<th>Standardized Product</th>
<th>Old – DO NOT ORDER</th>
<th>Old – DO NOT ORDER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oracle #0012-0899</td>
<td>Fisher #14375116</td>
<td>Oracle 0010-4872</td>
</tr>
</tbody>
</table>

If you obtain 24 hour urine jugs from Beaumont Laboratory, the standardized product will be sent to you automatically.

Please contact either a Beaumont Laboratory Sales Representative or Customer Services 1-800-551-0488 if you have any questions.

Date Submitted             | March 25, 2013
Submitted by               | Keith Reynolds
                           | Assistant Administrative Director, Beaumont Laboratory
                           | Royal Oak
NEW CBC PARAMETERS: IMMATURE GRANULOCYTE AND IMMATURE RETICULOCYTE FRACTION BEAUMONT GROSSE POINTE ONLY

Effective Date: 04-16-2013

Beginning 4/16/13 the Hematology laboratory at Beaumont Grosse Pointe will implement the new Sysmex XN-3000 Automated Hematology analyzer. Due to this new instrumentation, we will be able to report Immature Granulocyte (IG) and Immature Reticulocyte Fraction (IRF) as part of the automated WBC differential and CBC (Complete Blood Count).

IG includes an automated count of Neutrophilic metamyelocytes, Myelocytes and Promyelocytes. Presence of these cells indicates granulocytic left shift in the blood and may be an early indicator of acute infection, inflammatory response or myeloproliferative disorder. The ability to report immature granulocytes without performing a manual differential provides faster turn around time. Manual differential will still be provided when it meets certain laboratory criteria.

IRF is a ratio of the immature reticulocytes to the total number of reticulocytes and is a direct cellular measurement of erythropoiesis. If the reticulocyte count is low and the IRF is high, the bone marrow is being stimulated and actively producing reticulocytes. If the reticulocyte count is low and the IRF is low, the bone marrow is not producing reticulocytes. It is a useful parameter to evaluate erythropoietic activity in anemia.

Results of both IG and IRF are obtained rapidly with no additional blood draw and at no extra cost.

Reference ranges:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Female Range</th>
<th>Male Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>IG (bill/L)</td>
<td>0.0-0.03</td>
<td>0-0.04</td>
</tr>
<tr>
<td>IRF</td>
<td>0.02-0.14</td>
<td>0.01-0.16</td>
</tr>
</tbody>
</table>

Date Submitted: 04/01/2013
Submitted by: Vaishali Pansare, M.D., Medical Director, Beaumont Lab GP
LeiLei Chen, M.D., Hematology Medical Director, Beaumont Lab GP
Cynthia Kopenski, MT(ASCP), Hematology Supervisor, Beaumont Lab GP
Platelet Aggregation New Normal Ranges

Effective Date: May 7, 2013

The changes below will be made to the following Normal ranges for Routine Platelet Aggregation and Hyper Aggregation

<table>
<thead>
<tr>
<th>Routine Aggregation</th>
<th>Old Ranges</th>
<th>New Ranges</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ristocetin 1.5 mg/mL</td>
<td>≥60% (Max &amp; Rate)</td>
<td>≥70% (Max &amp; Rate)</td>
</tr>
<tr>
<td>Ristocetin 1.0 mg/mL</td>
<td>≥60% (Max &amp; Rate)</td>
<td>≥65% (Max &amp; Rate)</td>
</tr>
<tr>
<td>Ristocetin 0.5 mg/mL</td>
<td>≤20% (Max &amp; Rate)</td>
<td>≤15% (Max)</td>
</tr>
<tr>
<td>Collagen Lag Phase</td>
<td></td>
<td>≤70 second</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hyper Aggregation</th>
<th>Old Ranges</th>
<th>New Ranges</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADP 2.0 mcM</td>
<td>8 – 55 % (Max)</td>
<td>13 – 82 % (Max)</td>
</tr>
<tr>
<td>ADP 1.0 mcM</td>
<td>2 – 36 % (Max)</td>
<td>4 – 35 % (Max)</td>
</tr>
<tr>
<td>ADP 0.5 mcM</td>
<td>0 – 20 % (Max)</td>
<td>0- 30 % (Max)</td>
</tr>
<tr>
<td>Epinephrine 10 mcM</td>
<td>54-95% (Max)</td>
<td>70 – 95 % (Max)</td>
</tr>
<tr>
<td>Epinephrine 1.0 mcM</td>
<td>15 – 60% (Max)</td>
<td>7 – 85 % (Max)</td>
</tr>
<tr>
<td>Epinephrine 0.5 mcM</td>
<td>9 – 55 % (Max)</td>
<td>5 – 84 % (Max)</td>
</tr>
</tbody>
</table>

Date Submitted 04/09/2013
Submitted by Marc Smith MD, Medical Director Coagulation Laboratory
Effective May 7th, 2013, samples for CA 27.29 testing will be sent out to ARUP (Associated Regional University Pathologists). ARUP uses the same method as Beaumont Labs – this is the Siemens’ Centaur chemiluminescent immunoassay.

Comparison of Beaumont Lab results with those from ARUP shows excellent correlation ($r = 0.99$). Therefore there should be no problems with following patients and test interpretation when this change occurs. Beaumont Lab has used a reference range of $< 38.7$ U/mL, however the new range is:

ARUP reference range: $0 – 40$ U/mL

Date Submitted: 04/10/2013
Submitted by: Elizabeth Sykes MD, Medical Director of Automated Chemistry and Special Testing, Royal Oak
Yvonne Posey MD, Medical Director, Send Out Lab, Royal Oak
Adrenal Mass Panel - UPDATE

Effective Date: 05/07/2013

Effective May 7th an “Adrenal Mass Panel’ will be available for ordering from Beaumont Labs. The panel is intended as an initial screen for a patient who is found to have an incidental adrenal mass on radiological investigation. The panel, requiring both blood and urine collections, includes the tests listed below. Each test is also available individually.

- Plasma metanephrines 1 lavender-top EDTA tube to be placed on ice and processed immediately (send-out test)
- Urinary free cortisol 24 hour urine with boric acid as preservative (send-out test)
- DHEA sulfate 1 gold top SST
- Potassium 1 gold top SST

Interpretation of results is suggested below. However use of this panel does not preclude a complete endocrine evaluation and consultation with an endocrinologist is recommended prior to biopsy or surgery.

- Plasma free metanephrine and normetanephrine – elevations are suggestive of a phaeochromocytoma.
- Urinary free cortisol – elevation suggests a cortisol secreting tumor
- DHEA sulfate – elevation may occur with an androgen-producing tumor
- Potassium – decreased level may be seen with an aldosterone secreting tumor

Date Submitted 04/30/2013
Submitted by Elizabeth Sykes MD, Medical Director of Automated Chemistry and Special Testing, Royal Oak

Bindu Niravel DO, Chemical Pathology Fellow, Royal Oak

Luis Ospina, MD, Section Head, Endocrinology and Metabolism, Royal Oak
Adrenal Mass Panel – Date Postponed

Effective Date: 05/07/2013

Technical bulletins last week indicated that an “Adrenal mass panel” would be available on May 7th. Implementation has been delayed. We hope to have additional information concerning initial investigation of an incidental adrenal mass in the next few weeks.

Date Submitted 05/06/2013

Submitted by Elizabeth Sykes MD, Medical Director of Automated Chemistry and Special Testing, Royal Oak
ERYTHROCYTE SEDIMENTATION RATE (ESR)

Effective Date: 5/10/2013

Beginning 5/10/13, the Hematology laboratory at Beaumont Royal Oak, will implement a new analyzer, the iSED™ for ESR analysis. The iSED™ utilizes photometric rheoscope as its methodology and has been found to have greater than 95% correlation with the Westergren method. The iSED™ advanced automation assures repeatability by removing external variables such as mixing, vibration, temperature, timing and other factors that introduce imprecision in other manual and semi-automated Westergren methods.

This technology may not be affected by low hemoglobin/hematocrit levels as the other methodologies and thus is less likely to cause false elevations in the ESR. Thus, if the ESR is being used to follow the progress of a patient’s inflammatory disease, during treatment, there may be some variation from prior evaluations, and the patient may need to have a new baseline established.

Specimen collection criteria remain unchanged; however, it has been determined that specimens are stable up to 48 hrs.

<table>
<thead>
<tr>
<th>Date submitted</th>
<th>5/3/13</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submitted by</td>
<td>Ann Marie Blenc, MD  Medical Director Hematology, Beaumont Lab RO Noelle Procopio, MT (ASCP), Hematology Supervisor, Beaumont Lab RO</td>
</tr>
</tbody>
</table>
Stability of Folate in Serum  
Change in Effective Date

Effective Date: May 20, 2013

After review of literature/guidelines from our manufacturer, we have determined that folate is only stable in refrigerated serum for 2 days. Therefore, Beaumont will no longer be able to add-on serum folate testing to an original sample after 2 days. We apologize for any inconvenience this may cause.

**Folate (and Vitamin B12) stability**

**Folate, serum**

Sample: 5 mL serum separator tube  
Serum stability: 2 days refrigerated  
**Cannot add-on to an original sample after 2 days**

**Vitamin B12, serum**

Sample: 5 mL serum separator tube  
Serum stability: 7 days refrigerated

**Date Submitted:** May 2, 2013  
**Submitted by:** Elizabeth Sykes MD, Medical Director of Automated Chemistry and Special Testing, Royal Oak
Cystatin C

Effective Date: May 28, 2013

Effective May 28, 2013, the Cystatin C now includes the estimated GFR (eGFR). In addition, the reference range has changed. Specimen collection and processing remain unchanged.

<table>
<thead>
<tr>
<th>Specimen Collection Criteria</th>
<th>Collect one 5 mL Red top or Gold SST</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician Office/Draw Site Specimen Preparation</td>
<td>Separate serum from cells. Transfer 1 mL serum to a standard transport tube. (Min: 0.5 mL)</td>
</tr>
<tr>
<td>Specimen Preparation for Courier Transport</td>
<td>Storage/Transport temperature: Refrigerated</td>
</tr>
<tr>
<td>Rejection Criteria</td>
<td>Any sample other than serum</td>
</tr>
<tr>
<td>Performed</td>
<td>Mayo Medical Laboratories</td>
</tr>
</tbody>
</table>

### Reference Range

<table>
<thead>
<tr>
<th>Reference Range</th>
<th>Old Reference Range</th>
<th>New Reference Range Male</th>
<th>New Reference Range Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;23 years of age</td>
<td>No reference values established</td>
<td>0.57-1.29 mg/L</td>
<td></td>
</tr>
<tr>
<td>≥23 years</td>
<td>No reference values established</td>
<td>0.60-1.03 mg/dL</td>
<td>0.57-0.90 mg/dL</td>
</tr>
<tr>
<td>23-29 years</td>
<td>0.64-1.12 mg/dL</td>
<td>0.59-0.98 mg/dL</td>
<td></td>
</tr>
<tr>
<td>30-39 years</td>
<td>0.68-1.22 mg/dL</td>
<td>0.62-1.07 mg/dL</td>
<td></td>
</tr>
<tr>
<td>40-49 years</td>
<td>0.72-1.32 mg/dL</td>
<td>0.64-1.17 mg/dL</td>
<td></td>
</tr>
<tr>
<td>50-59 years</td>
<td>0.77-1.42 mg/dL</td>
<td>0.66-1.26 mg/dL</td>
<td></td>
</tr>
<tr>
<td>60-69 years</td>
<td>0.82-1.52 mg/dL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male 70-79 years</td>
<td>No reference values established</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female 70-80 years</td>
<td></td>
<td>0.68-1.36 mg/dL</td>
<td></td>
</tr>
<tr>
<td>Male &gt;79 years</td>
<td>No reference values established</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female 81-86 years</td>
<td></td>
<td>0.70-1.45 mg/dL</td>
<td></td>
</tr>
<tr>
<td>Female &gt;86 years</td>
<td>No reference values established</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### eGFR

- >60 mL/min/BSA: eGFR will not be calculated for patients under 18 years of age.

### Test Methodology

- Immunoturbidimetric

### CPT Code

- 86210

### Date Submitted

- May 15, 2013

### Submitted by

- Yvonne Posey, MD, Medical Director, Sendouts
Discontinuation of Allergen-Specific IgA & IgG Testing

Effective Date: May 28, 2013

Beaumont Laboratory will no longer offer allergen-specific IgA and IgG testing for the following allergens:

Allergen
- Aspergillus fumigatus
- Aspergillus niger
- Aspergillus versicolor
- Chaetomium globosum
- Cladosporium herbarum
- Fusarium proliferatum
- Penicillium chrysogenum
- Stachybotrys atra

To assess sensitization in the context of allergic hypersensitivity, allergen-specific IgE testing is recommended.

Date Submitted: May 23, 2013
Submitted by: Gabriel Maine, PhD
Technical Director, Special Testing, Royal Oak
Elizabeth Sykes, MD
Medical Director, Special Testing, Royal Oak
Motor and Sensory Neuropathy Evaluation

Effective Date: May 28, 2013

The Motor & Sensory Neuropathy Evaluation will include tests for an additional two antibodies - the Purkinje and Amphiphysin antibodies. If the screen is positive at 1:10 or greater, then a titer and immunoblot will be added. Specimen collection and processing remain unchanged.

<table>
<thead>
<tr>
<th>Specimen Collection Criteria</th>
<th>Collect one 5 mL Red top or Gold SST</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician Office/Draw Site Specimen Preparation</td>
<td>Separate serum from cells within 2 hours of collection. Transfer 2 mL serum to a standard transport tube. (Min: 1 mL)</td>
</tr>
<tr>
<td>Specimen Preparation for Courier Transport</td>
<td>Storage/Transport temperature: Refrigerated</td>
</tr>
<tr>
<td>Rejection Criteria</td>
<td>Any sample other than serum</td>
</tr>
</tbody>
</table>
| Performed | ARUP Laboratories
Test Code - 2007966 |
| Reference Range | See Chart on next page |
| Test Methodology | Semi-Quantitative Enzyme-Linked Immunosorbent Assay |
| CPT Code | 83516X7
86255, 86256 and 83516 if reflexed |
| Date Submitted | May 15, 2013 |
| Submitted by | Yvonne Posey, MD, Medical Director, Sendouts |

Continued on next page
<table>
<thead>
<tr>
<th>Components</th>
<th>Reference Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neuronal Nuclear Antibodies Screen</td>
<td>None detected</td>
</tr>
<tr>
<td>Neuronal Nuclear Antibody (ANNA) titer (if indicated)</td>
<td>Less than 1:10</td>
</tr>
<tr>
<td>Purkinje Cell Antibody titer (if indicated)</td>
<td>Less than 1:10</td>
</tr>
<tr>
<td>Asialo-GM1 Antibodies, IgG/IgM</td>
<td>29 IV or less: Negative 30-50 IV: Equivocal 51-100 IV: Positive 101 IV or greater: Strong Positive</td>
</tr>
<tr>
<td>GM1 Antibodies, IgG/IgM</td>
<td>29 IV or less: Negative 30-50 IV: Equivocal 51-100 IV: Positive 101 IV or greater: Strong Positive</td>
</tr>
<tr>
<td>GM2 Antibodies, IgG/IgM</td>
<td>29 IV or less: Negative 30-50 IV: Equivocal 51-100 IV: Positive 101 IV or greater: Strong Positive</td>
</tr>
<tr>
<td>GD1a Antibodies, IgG/IgM</td>
<td>29 IV or less: Negative 30-50 IV: Equivocal 51-100 IV: Positive 101 IV or greater: Strong Positive</td>
</tr>
<tr>
<td>GD1b Antibodies, IgG/IgM</td>
<td>29 IV or less: Negative 30-50 IV: Equivocal 51-100 IV: Positive 101 IV or greater: Strong Positive</td>
</tr>
<tr>
<td>GQ1b Antibodies, IgG/IgM</td>
<td>29 IV or less: Negative 30-50 IV: Equivocal 51-100 IV: Positive 101 IV or greater: Strong Positive</td>
</tr>
<tr>
<td>Myelin Associated Glycoprotein (MAG) Antibody, IgM</td>
<td>Less than 1000 TU</td>
</tr>
<tr>
<td>Sulfate-3-Glucuronyl Paragloboside (SGPG) Antibody, IgM</td>
<td>Less than 1.00 IV</td>
</tr>
</tbody>
</table>
Pneumococcal Antibodies, IgG

Effective Date:  May 28, 2013

Currently the Pneumococcal Antibodies, IgG test includes 14 serotypes: 1, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 12F, 14, 18C, 19F, and 23F. Effective May 28, 2013, we now test for 23 serotypes to match the current vaccine (2, 10A, 11A, 15B, 17F, 19A, 20, 22F, and 33F). Specimen collection and processing remain unchanged.

<table>
<thead>
<tr>
<th>Specimen Collection Criteria</th>
<th>Collect one 5 mL Red top or Gold SST</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician Office/Draw Site Specimen Preparation</td>
<td>Separate serum from cells within 2 hours of collection. Transfer 2 mL serum to a Standard Transport Tube. (Min: 1 mL)</td>
</tr>
<tr>
<td>Specimen Preparation for Courier Transport</td>
<td>Storage/Transport Temperature: Refrigerated</td>
</tr>
<tr>
<td>Rejection Criteria</td>
<td>Any sample other than serum</td>
</tr>
<tr>
<td>Performed</td>
<td>ARUP Laboratories</td>
</tr>
<tr>
<td>Interpretive Data</td>
<td>A post-immunization antibody concentration of 1.30 mcg/mL or greater indicates adequate immune response. When comparing to pre-immunization concentrations that are 1.30 mcg/mL or greater, a fourfold or greater increase in post-immunization concentration indicates adequate response; however, a high pre-immunization antibody concentration may preclude a fourfold increase.</td>
</tr>
<tr>
<td>Note</td>
<td>Indication of immune system competence is demonstrated by an adequate immune response to at least 50 percent of the serotypes included in the vaccine challenge.</td>
</tr>
<tr>
<td>Test Methodology</td>
<td>Quantitative Multiplex Bead Assay</td>
</tr>
<tr>
<td>CPT Code</td>
<td>83617 x 23</td>
</tr>
<tr>
<td>Date Submitted</td>
<td>May 15, 2013</td>
</tr>
<tr>
<td>Submitted by</td>
<td>Yvonne Posey, MD, Medical Director Sendouts</td>
</tr>
</tbody>
</table>
### Warfarin Sensitivity Genotyping

**Effective Date:** June 4, 2013

The Molecular Pathology Laboratory in Beaumont’s Department of Pathology and Laboratory Medicine will offer a Pharmacogenomics assay for patients treated with warfarin, including genotyping for VKORC1 (Vitamin K Epoxide Reductase Complex subunit 1) in addition to the previously available cytochrome P450 CYP2C9 genotyping. The new test is FDA approved.

<table>
<thead>
<tr>
<th>Synonyms</th>
<th>CYP2C9/VKORC1 genotyping for warfarin/Coumadin hyper-responsiveness.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Instructions</td>
<td>Collect 5-6 mL whole blood in EDTA (lavender top) or ACD (yellow top) tubes.</td>
</tr>
<tr>
<td>Physician Office/Draw Site Specimen Preparation</td>
<td>Specimens are stable at room temperature for up to 72 hours. Specimens may be refrigerated (2-8°C or 36-46°F) <strong>DO NOT FREEZE SPECIMENS.</strong></td>
</tr>
<tr>
<td>Specimen Preparation for Courier Transport</td>
<td>Transport at room temperature (20-25°C or 68-77°F)</td>
</tr>
<tr>
<td>Rejection Criteria</td>
<td>Specimens collected in heparin (green top), clot tubes, SST tubes, unlabeled tubes or frozen specimens will not be tested.</td>
</tr>
<tr>
<td>Performed</td>
<td>Once a week Results available in 7-10 days.</td>
</tr>
<tr>
<td>Reference Range</td>
<td>Wild Type CYP2C9 <em>1</em>1 genotype Wild Type VKORC1 G/G genotype</td>
</tr>
<tr>
<td>Test Methodology</td>
<td>PCR (Polymerase chain reaction) amplification followed by multiplexed hybridization detection.</td>
</tr>
<tr>
<td>Interpretation</td>
<td>This test detects the wild type alleles of the CYP2C9 and VKORC1 genes and the mutant alleles *2 and *3 of CYP2C9 and the VKORC1 mutation -1639G&gt;A. The CYP2C9 enzyme metabolizes warfarin and the Vitamin K Epoxide Reductase Complex subunit 1 (VKORC1) is the target of warfarin therapy. The combined CYP2C9/VKORC1 genotype can be used to predict a patient’s response to warfarin therapy and individualize warfarin dose.</td>
</tr>
<tr>
<td>CPT Code</td>
<td>81227, 81355</td>
</tr>
<tr>
<td>Date Submitted</td>
<td>April 10, 2013</td>
</tr>
<tr>
<td>Submitted by</td>
<td>Domnita Crisan, MD, PhD Medical Director, Molecular Pathology Laboratory</td>
</tr>
</tbody>
</table>
Adult Reticulocyte Reference Range Change

Effective Date: June 25, 2013

The changes indicated below will be made to the reference ranges for Adult Reticulocyte Count on June 25, 2013.

<table>
<thead>
<tr>
<th>Current Range</th>
<th>New Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male / Female</td>
<td>Male / Female</td>
</tr>
<tr>
<td>25-85 bill/L</td>
<td>21-100 bill/L</td>
</tr>
</tbody>
</table>

Current ranges for Immature Retic Fraction (IRF) will not change:

IRF: 0.02-0.14 (female) 0.01-0.16 (male)

Date Submitted: June 25, 2013

Submitted by: Ann Marie Blenc, MD, Medical Director, Hematology Lab, Royal Oak
Hongwei Ma, MD, Medical Director, Hematology, Troy
LeiLei Chen, MD Medical Director, Hematology, Grosse Pointe
Fecal Occult Blood Testing Changes

Effective Date: June 26, 2013

Effective June 26th Beaumont Health System is standardizing fecal occult blood testing. At this time testing for both inpatients and outpatients will be performed using Hemoccult SENSA cards (blue stripe and developer top). Standard Hemoccult cards (yellow stripe and developer top) will no longer be available from stores or the outreach supply. Areas of the hospital, draw-sites or physician offices that currently use standard cards are being informed of the new ordering information.

Hemoccult SENSA cards are very similar, but more sensitive and easier to read than the standard Hemoccult card. They are guaiac-based and still subject to the same false positives and false negatives as the standard cards.

Important note:
- Hemoccult SENSA test should not be used for gastric specimens.
- Dietary iron supplements will not produce false-positive test results.
- Developing solutions should not be used interchangeably between the Hemoccult SENSA (blue top) and standard Hemoccult (yellow top).

UPCOMING change to Immunochemical Method
Later this year, Beaumont Laboratory will introduce the Polymedco Immunochemical Method for colorectal cancer screening. At that time the Hemoccult SENSA card will be used primarily by physicians and mid-level providers as a point-of-care method for immediate patient assessment.

Date Submitted: June 5, 2013
Submitted by: Elizabeth Sykes, MD, Medical Director, Automated Chemistry and Special Testing, Royal Oak
Ralph Zade, MD, Medical Director, Chemistry, Troy
Vaishali Pansare, MD, Medical Director, Beaumont Lab, Grosse Pointe
Anti-Striated Muscle IgG

Effective Date: July 9, 2013

Testing for IgG antibodies to anti-striated muscle can be used to support a diagnosis of Myasthenia Gravis, particularly in those with thymoma. The test will be moved from an in-house to a send-out test due to low volumes.

<table>
<thead>
<tr>
<th>Specimen Collection Criteria</th>
<th>Collect one 5 mL gold Serum-Separator tube (SST)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician Office/Draw Site Specimen Preparation</td>
<td>Separate serum from cells within 2 hours of collection. Transfer 1 mL serum to a Standard Transport Tube (Minimum: 0.15 mL)</td>
</tr>
<tr>
<td>Specimen Preparation for Courier Transport</td>
<td>Storage/Transport Temperature: Refrigerated</td>
</tr>
<tr>
<td>Rejection Criteria</td>
<td>Any sample other than serum</td>
</tr>
<tr>
<td>Performed</td>
<td>ARUP Laboratories</td>
</tr>
<tr>
<td>Test Methodology</td>
<td>Semi-Quantitative Indirect Fluorescent Antibody (IFA)</td>
</tr>
<tr>
<td>Reference Interval</td>
<td>&lt; 1:40 (No antibody detected)</td>
</tr>
<tr>
<td>Interpretation</td>
<td>Titers greater than or equal to 1:80 are suggestive of Myasthenia Gravis. However, striated muscle can be found in rheumatic fever, myocardial infarction, and a variety of post-cardiotomy states.</td>
</tr>
<tr>
<td>Note</td>
<td>All positives will be titered to endpoint. If striated muscle antibody is &gt;1:40, then a titer will be added.</td>
</tr>
<tr>
<td>CPT Code</td>
<td>86255; If reflexed to titer, add 86256</td>
</tr>
<tr>
<td>Date Submitted</td>
<td>June 19, 2013</td>
</tr>
</tbody>
</table>
| Submitted by | Gabriel Maine, PhD  
Technical Director, Special Testing  
Yvonne Posey, MD  
Medical Director, Send-Out Laboratory |
Herpes Simplex Virus Testing

Effective Date: July 9, 2013

The objectives of this bulletin are to provide test options for herpes simplex virus (HSV) diagnosis and their appropriate use.

I. HSV Test Options

Refer to Beaumont Laboratory Test Directory for specimen collection requirements.

A. Direct HSV diagnostics
   - HSV-1 and HSV-2 by PCR
   - HSV-1 and HSV-2 by culture

B. Indirect HSV diagnostics (IgG serology)
   - HSV-1 IgG
   - HSV-2 IgG
   - HSV Antibody Panel: 2 results reported – HSV-1 IgG & HSV-2 IgG

Guidelines published by the Centers for Disease Control indicate that HSV IgM testing is not clinically useful for the diagnosis of an HSV infection. Beaumont Laboratory has independently confirmed that claim and will no longer perform HSV IgM testing in-house, due to sub-optimal specificity and better test alternatives (see below). An HSV IgM send-out option is available, but will require pre-approval by a Laboratory medical staff member for clinical appropriateness.

II. HSV Test Utilization

An adequate clinical history consistent with a heightened risk for HSV infection (e.g. patients who report having a partner with genital herpes, patients presenting for an STD evaluation) warrants laboratory testing. These patients can fall into 1 of 2 categories:

A. Symptoms Present
   - Clinical Hallmark: Presence of vesicular or ulcerative lesion
   - Appropriate Laboratory Orders:
     a. HSV-1 & HSV-2 PCR or culture
        Note: PCR is substantially more sensitive than culture and is the method of choice for direct viral detection.
     b. HSV Antibody Panel

B. No Symptoms Present
   - No vesicular or ulcerative lesion observed at the time of clinical examination, but present with a history of a possible exposure to genital herpes.
   - Appropriate Laboratory Order:
     - HSV Antibody Panel

Continued on other side
Continued

III. HSV Test Interpretations

A. Symptoms Present

<table>
<thead>
<tr>
<th>PCR/Culture</th>
<th>Serology</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>HSV-1</td>
<td>HSV-2</td>
<td>HSV-1 IgG</td>
</tr>
<tr>
<td>Pos</td>
<td>Neg</td>
<td>Neg</td>
</tr>
<tr>
<td>Neg</td>
<td>Pos</td>
<td>Neg</td>
</tr>
<tr>
<td>Pos</td>
<td>Neg</td>
<td>Pos</td>
</tr>
<tr>
<td>Neg</td>
<td>Pos</td>
<td>Neg</td>
</tr>
<tr>
<td>Neg</td>
<td>Pos</td>
<td>Pos</td>
</tr>
<tr>
<td>Pos</td>
<td>Neg</td>
<td>Neg</td>
</tr>
<tr>
<td>Neg</td>
<td>Pos</td>
<td>Pos</td>
</tr>
</tbody>
</table>

*If HSV-1 and HSV-2 PCR results are negative, the lesion is unlikely due to a primary or recurrent herpes infection; consider alternative diagnoses.

B. No Symptoms Present

<table>
<thead>
<tr>
<th>Serology</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>HSV-1 IgG</td>
<td>HSV-2 IgG</td>
</tr>
<tr>
<td>Neg</td>
<td>Neg</td>
</tr>
<tr>
<td>Pos</td>
<td>Neg</td>
</tr>
<tr>
<td>Neg</td>
<td>Pos</td>
</tr>
<tr>
<td>Pos</td>
<td>Pos</td>
</tr>
</tbody>
</table>

<sup>a</sup> If an acute infection is still suspected in patients that test negative for HSV-1 and HSV-2 IgG, re-assess serological status in 3-4 weeks.

<sup>b</sup> A positive HSV-1 IgG or HSV-2 IgG test result does not provide information regarding timing of acquisition of herpes infection.

Reference:

Date Submitted: June 19, 2013
Submitted by: Gabriel Maine, PhD
Elizabeth Sykes, MD
Bobby Boyanton, MD
Barbara Robinson-Dunn, PhD
Christopher Carpenter, MD
Infectious Diseases, Royal Oak
Clinical Pathology, Royal Oak

http://www.beaumont.edu/labs
**Y CHROMOSOME MICRODELETION MOLECULAR ANALYSIS FOR MALE INFERTILITY**

**Effective Date: July 9, 2013**

Infertility affects 10% of couples of reproductive age. Male factor infertility accounts for half of these cases. Microdeletions of the Y chromosome are identified in 1/2000-3000 males, and are suspected in otherwise healthy males with azoospermia or oligozoospermia and/or abnormal sperm morphology/motility for whom other causes of infertility have been eliminated. Cytogenetic testing reveals chromosome abnormalities (such as Klinefelter syndrome) in 5%-10% of these men. Molecular testing reveals microdeletions involving the long arm of the Y chromosome in another 5%-13% of these males. Microdeletions of the Y chromosome are found in approximately 35% of men with idiopathic azoospermia, 20-25% of men with severe oligospermia, and overall in approximately 7% of all infertile men. Y chromosome microdeletions are detected utilizing a multiplex PCR format that utilizes 20 primer pairs that amplify nonpolymorphic sequence-tagged sites (STS) along the long arm of the Y chromosome (designated as regions AZFa, AZFb, and AZFc). Y chromosome deletions in these regions that are amplified by these primer sets have been associated with male infertility. In addition, one primer pair amplifies a region of the SRY gene on the short arm of the Y chromosome that permits identification of XX males arising from a translocation involving the X and Y chromosomes. Amplification of a unique DNA locus in both male and female genomes (ZFX/ZFY) serves as a control in this assay. This test should detect over 90% of all deletions in the AZF regions analyzed. Identification of Y chromosome microdeletions is important for medical management utilizing assisted reproductive technologies in couples experiencing infertility.

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Peripheral blood</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference Range</td>
<td>Positive or negative for Y chromosome microdeletion with identification of specific region(s) deleted. An interpretative report will be provided.</td>
</tr>
<tr>
<td>Interpretation</td>
<td>The analytical sensitivity/specificity of this test is ~99%. A positive result identifies the cause of azoospermia/oligospermia. A negative result greatly reduces the possibility of Y chromosome microdeletion as the cause of azoospermia or oligospermia. Limitations of the test include an inability to molecularly delineate breakpoints in positive cases, failure to identify mutations in specific genes within the interrogated regions, a rare diagnostic errors caused by primer site mutations, and the inability to detect other genetic causes of infertility.</td>
</tr>
<tr>
<td>CPT Code</td>
<td>81403</td>
</tr>
<tr>
<td>Date Submitted</td>
<td>June 20, 2013</td>
</tr>
<tr>
<td>Submitted By</td>
<td>Dr. Mark Micale, Clinical Cytogenomics Laboratory Medical Director</td>
</tr>
</tbody>
</table>
PTH (PARATHYROID HORMONE) TEMPORARY METHOD CHANGE ROYAL OAK/TROY (Not applicable to Grosse Pointe Testing)

Effective Date: July 10, 2013

Due to a national backorder of Siemens reagent used at Royal Oak, PTH samples collected after July 4th will be tested using the Siemens Centaur instead of the Immulite analyzer. All samples collected since July 4th have been stored frozen and therefore the PTH should have remained stable.

Because the new method generates results that differ from the prior method, correction factors will permit results from the current method and the new method to be comparable.

We anticipate that the reagent shortage will be relatively short and you will be informed when testing resumes on the Immulite.

Please contact Customer Service at 1-800-551-0488 with any questions.

<table>
<thead>
<tr>
<th>Date Submitted</th>
<th>July 9, 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submitted by</td>
<td>Elizabeth Sykes, MD</td>
</tr>
<tr>
<td></td>
<td>Medical Director of Automated Chemistry and Special Testing</td>
</tr>
<tr>
<td></td>
<td>Royal Oak</td>
</tr>
</tbody>
</table>
PTH (PARATHYROID HORMONE)
TEMPORARY METHOD CHANGE - UPDATE
Royal Oak & Troy
(Not applicable to Grosse Pointe Testing)

Effective Date: July 19, 2013

As indicated in a previous bulletin distributed on July 10, 2013, testing for orders placed for PTH from July 5 - 18, 2013 was performed on the Siemens Centaur instead of the Immulite analyzer due to a national backorder of Siemens reagent used at Royal Oak. Testing will resume on the Immulite analyzer commencing on July 19, 2013.

Test results from the Centaur are comparable to results from the Immulite due to the use of correction factors.

Please contact Customer Service at 1-800-551-0488 with any questions.

<table>
<thead>
<tr>
<th>Date Submitted</th>
<th>July 19, 2013</th>
</tr>
</thead>
</table>
| Submitted by   | Gabriel Maine, PhD  
                 Technical Director, Special Testing, Royal Oak  
                 Elizabeth Sykes, MD  
                 Medical Director, Automated Chemistry & Special Testing, Royal Oak |
For Beaumont Laboratory Outreach Clients
REGISTRATION OF PATIENTS WITH
PATIENT IDENTIFIERS

Effective Date: July 11, 2013

To ensure that Beaumont Laboratory can accurately verify all patient identification, report results, and be consistent with Beaumont Health System registration requirements, all Beaumont Laboratory paperwork must be submitted with a minimum of three legible patient identifiers (two required and one permissible).

Required patient identifiers:
- Patient’s full legal name, First name, Last name and Middle Initial
- Patient’s Date of Birth

Permissible patient identifiers include:
- Patient’s Beaumont Health System Medical Record Number
- Patient’s current address
- Patient’s phone number
- Patient’s full Social Security number (last 4 digits are acceptable only if the Beaumont Health System’s computer system already has full Social Security number entered)

Without three patient identifiers, there is high potential to create duplicate patient records in the Beaumont Health System. This impacts you by no longer having the patient’s result in the same patient file (e.g., loss of trending). In addition, the Laboratory’s ability to properly route electronic patient results to your EMR system may be compromised.

Failure to provide three patient identifiers will result in non-processing of specimens and delayed test resulting.

If you have any questions or concerns, please contact Beaumont Laboratory Customer Service at 1-800-551-0488.

Date Submitted: July 10, 2013
Submitted by:
- Mark Kolins, MD
  Beaumont Laboratory Medical Director
- Don Henderson
  Beaumont Laboratory Executive Director
HCV VIRAL LOAD TESTING – UPDATE

Effective Date: August 6, 2013

On August 6, 2013, the Molecular Pathology Laboratory will upgrade from version 1.0 to version 2.0 of the Roche COBAS Ampliprep / COBAS Taqman HCV Test.

Version 2.0 of this test offers the following advantages over the previous version:
- Greater dynamic range for quantitation (15 to 100,000,000 IU/mL)
- Improved analytical sensitivity / limit of detection (15 IU/mL)
- **Note:** The performance of this test is compatible with all treatment guidelines for the management of patients with HCV infection undergoing antiviral therapy, including the new direct acting antivirals (Boceprevir [Victrelis] and Telaprevir [Incivek]).

Specimen Collection and Ordering Summary:
- Acceptable specimens: serum or plasma
- Sample volume: 1.1 mL [minimum = 650 µL (0.650 mL)]
- Separate (centrifuge) serum or plasma within 6 hours of collection
- No change in the way you order the test: SOFT Order Code (IQHCG).

Special Notes:
- This will be a seamless transition. There is **NO need to re-baseline your patients**, as correlation studies performed by our laboratory have demonstrated exceptional agreement between the new and previous versions of this test.
- **This test should be used to monitor patients undergoing HCV antiviral therapy.**

For complete specimen collection and handling instructions, please refer to the “on-line” Laboratory Test Directory:
- Internal URL: [http://beaunet.beaumont.edu/portal/pls/portal/lab.lab_pkg.lab_list](http://beaunet.beaumont.edu/portal/pls/portal/lab.lab_pkg.lab_list)
- External URL: [http://beaumonthospitals.com/labtestdirectory](http://beaumonthospitals.com/labtestdirectory)

If you need additional information, please contact Client Services at 1-800-551-0488, option 5.

Date Submitted: July 15, 2013

Submitted By: Bobby L. Boyanton Jr., M.D.
Medical Director, Microbiology
Associate Medical Director, Molecular Pathology

Domnita Crisan, M.D., Ph.D.
Medical Director, Molecular Pathology
**Clostridium difficile TESTING UPDATE**

Effective Date: August 15, 2013

Beaumont Laboratory (Royal Oak) will switch to an automated **real-time PCR** testing platform for **toxigenic Clostridium difficile** detection on August 15, 2013, replacing the current BD GeneOhm (manual method).

This will be a **seamless transition**. There is **NO change** in test ordering or specimen collection and handling requirements.

**Improvements to turn-around-time** will gradually occur over the next few months for specimens originating at Royal Oak and Grosse Pointe. We are restructuring laboratory staffing at Royal Oak to accommodate more frequent testing intervals as follows:

- Monday – Friday (every 8 hours will move to every 6 hours.)
- Weekends (every 12 hours will move to every 8 hours).

*There will be no change in turn-around-time for specimens being tested at Troy.*

**Circumstances where testing will NOT be performed:**

- Stool specimens that do NOT conform to the shape of the collection container.
- Stool specimens submitted on a swab.
- Repeat stool specimens if the patient had a previous real-time PCR test within 7 days.

*Remember - “Serial testing” is no longer needed with real-time PCR testing.*

Exceptions to the above require approval by the Medical Director or Technical Director of the Microbiology Laboratory.

For complete specimen collection and handling instructions, please refer to the on-line Laboratory Test Directory:

**Internal URL:** [http://beaunet.beaumont.edu/portal/pls/portal/lab.lab_pkg.lab_list](http://beaunet.beaumont.edu/portal/pls/portal/lab.lab_pkg.lab_list)

**External URL:** [http://beaumonthospitals.com/labtestdirectory](http://beaumonthospitals.com/labtestdirectory)

If you need additional information, please contact Customer Services (1-800-551-0488, option 5).

**Date Submitted:** July 29, 2013

**Submitted By:**

- **Bobby L. Boyanton Jr., M.D.**
  Medical Director, Microbiology
  Associate Medical Director, Molecular Pathology

- **Barbara Robinson-Dunn, Ph.D., D(ABMM)**
  Technical Director, Microbiology
Trypsin, Fecal
No Longer Offered

Effective Date: August 19, 2013

Effective August 19, 2013 the Trypsin, Fecal will no longer be offered through ARUP Laboratories. Suggested alternate testing is the Pancreatic Elastase (XPE1F).

<table>
<thead>
<tr>
<th>No Longer Offered</th>
<th>Alternative Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trypsin, Fecal</td>
<td>Fecal Elastase, E1</td>
</tr>
<tr>
<td>Code</td>
<td>XTRPS</td>
</tr>
<tr>
<td>Performed</td>
<td>XPE1F</td>
</tr>
<tr>
<td></td>
<td>ARUP Laboratories</td>
</tr>
<tr>
<td></td>
<td>Salt Lake City, UT</td>
</tr>
<tr>
<td></td>
<td>JOLI Diagnostics, Inc.</td>
</tr>
<tr>
<td></td>
<td>Williamsville, NY</td>
</tr>
</tbody>
</table>

Date Submitted: August 7, 2013
Submitted by: Joel Waddington, MT Sendout Coordinator
Yvonne Posey, MD Medical Director, Sendout
Detection of Antibodies to Arboviruses, Serum

Effective Date: August 26, 2013

The best evidence for infection with Arbovirus is a significant change on two appropriately timed specimens, where both tests are done in the same laboratory at the same time. By the 8th day of illness, most people will have detectable serum IgM antibody to West Nile virus. This antibody will remain detectable for at least 1-2 months after onset of illness. In some cases, it may be detectable for 1-2 years or longer. Therefore, in order to accurately interpret results, Arbovirus IgM, serum testing will only be run on paired samples (acute and convalescent). The convalescent specimens must be received within 30 days from receipt of acute specimens. **Mark specimens plainly as “acute” or “convalescent.”** Acute samples will be stored until the convalescent specimen is received. Seroconversion between acute and convalescent sera is considered strong evidence of current or recent infection. Arbovirus IgG, serum testing will only be performed when IgM testing is ordered at the same time.

<table>
<thead>
<tr>
<th>Specimen Collection Criteria</th>
<th>One 6 mL SST. (Min: 4 mL SST) or one 6 mL Red top tube</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specimen Preparation for Courier Transport</td>
<td>Centrifuge to separate serum from cells within 2 hours of collection. Transfer 1mL (Min: 0.15 mL) serum to aliquot tube and refrigerate.</td>
</tr>
<tr>
<td>Rejection Criteria</td>
<td>Plasma, hemolyzed, or severely lipemic specimens.</td>
</tr>
<tr>
<td>Performed</td>
<td>ARUP Laboratories</td>
</tr>
<tr>
<td>Reference Range</td>
<td>See Table on next page</td>
</tr>
<tr>
<td>Test Methodology</td>
<td>Semi-Quantitative Indirect Fluorescent Antibody/Semi-Quantitative Enzyme-Linked Immunosorbent Assay</td>
</tr>
<tr>
<td>Interpretation</td>
<td>This test is intended to be used as a semi-quantitative means of detecting West Nile virus-specific IgM in serum specimens in which there is a clinical suspicion of West Nile virus infection. This test should not be used solely for quantitative purposes, nor should the results be used without correlation to clinical history or other data. Because other members of the Flaviviridae family, such as St. Louis encephalitis virus, show extensive cross-reactivity with West Nile virus, serologic testing specific for these viruses is included in this test.</td>
</tr>
<tr>
<td>CPT Code</td>
<td>86651; 86652; 86653; 86654; 86788</td>
</tr>
<tr>
<td>Date Submitted</td>
<td>August 21, 2013</td>
</tr>
<tr>
<td>Submitted by</td>
<td>Yvonne Posey, MD, Medical Director, Sendouts Barbara Robinson-Dunn, PhD, Technical Director, Microbiology</td>
</tr>
</tbody>
</table>

Continued on other side
Arbovirus IgM Reference Interval:

<table>
<thead>
<tr>
<th>ARUP Test Number</th>
<th>Components</th>
<th>Reference Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>0098732</td>
<td>St. Louis Encephalitis Antibody, IgM by IFA, Serum</td>
<td>Less than 1:16</td>
</tr>
<tr>
<td>0098731</td>
<td>California Encephalitis Antibody, IgM by IFA, Serum</td>
<td>Less than 1:16</td>
</tr>
<tr>
<td>0098733</td>
<td>Eastern Equine Encephalitis Antibody, IgM by IFA, Serum</td>
<td>Less than 1:16</td>
</tr>
<tr>
<td>0098734</td>
<td>Western Equine Encephalitis Antibody, IgM by IFA, Serum</td>
<td>Less than 1:16</td>
</tr>
</tbody>
</table>
| 0050236          | West Nile Virus Antibody, IgM by ELISA, Serum      | 0.89 or less: Negative - No significant level of West Nile virus IgM antibody detected.  
|                  |                                                    | 0.90-1.10: Equivocal - Questionable presence of West Nile virus IgM antibody detected. Repeat testing in 10-14 days may be helpful.  
|                  |                                                    | 1.11 or greater: Positive - Presence of IgM antibody to West Nile virus detected, suggestive of current or recent infection.  |

Arbovirus IgG Reference Interval:

<table>
<thead>
<tr>
<th>ARUP Test Number</th>
<th>Components</th>
<th>Reference Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>0050507</td>
<td>St. Louis Encephalitis Antibody, IgG by IFA, Serum</td>
<td>Less than 1:16</td>
</tr>
<tr>
<td>0050508</td>
<td>California Encephalitis Antibody, IgG by IFA, Serum</td>
<td>Less than 1:16</td>
</tr>
<tr>
<td>0050509</td>
<td>Eastern Equine Encephalitis Antibody, IgG by IFA, Serum</td>
<td>Less than 1:16</td>
</tr>
<tr>
<td>0050514</td>
<td>Western Equine Encephalitis Antibody, IgG by IFA, Serum</td>
<td>Less than 1:16</td>
</tr>
</tbody>
</table>
| 0050234          | West Nile Virus Antibody, IgG by ELISA, Serum      | 1.29 or less: Negative - No significant level of West Nile virus IgG antibody detected.  
|                  |                                                    | 1.30-1.49: Equivocal - Questionable presence of West Nile virus IgG antibody detected. Repeat testing in 10-14 days may be helpful.  
|                  |                                                    | 1.50 or greater: Positive - Presence of IgG antibody to West Nile virus detected, suggestive of current or past infection.  |
HCV GENOTYPE TESTING – UPDATE

Effective Date: September 1, 2013

On September 1, 2013, the Molecular Laboratory will switch HCV genotyping methods.

This transition will be seamless. There will be no change in specimen collection and handling requirements or test ordering (paper or electronic).

Advantages of the new test:
- In addition to reporting HCV genotypes 1-6, the new test will be able to accurately determine and report the subtypes of genotype 1 HCV infections, which may have implications for selecting appropriate direct acting antiviral therapy.

Specimen Collection and Ordering Summary:
- Acceptable specimens: serum or plasma
- Sample volume: 1.1 mL [minimum = 650 µL (0.650 mL)]
- Separate (centrifuge) serum or plasma within 6 hours of collection
- SOFT Order Code (IHCVG).
- The minimum HCV RNA viral load required to obtain an accurate HCV genotype is 1,000 IU/mL

For complete specimen collection and handling instructions, please refer to the “on-line” Laboratory Test Directory:
- Internal URL: http://beaunet.beaumont.edu/portal/pls/portal/lab.lab_pkg.lab_list
- External URL: http://beaumonthospitals.com/labtestdirectory

If you need additional information, please contact client services (1-800-551-0488, option 5).

<table>
<thead>
<tr>
<th>Date Submitted</th>
<th>August 26, 2013</th>
</tr>
</thead>
</table>
| Submitted by   | B.L. Boyanton, M.D.  
                Medical Director, Microbiology  
                Associate Medical Director, Molecular Pathology  
                Donnita Crisan, M.D., Ph.D.  
                Medical Director, Molecular Pathology |
SERUM IRON

Effective Date: October 1, 2013

A serum iron by itself may be misleading in the assessment of a patient's iron status. It is possible for iron concentration to be within the reference range, but when seen with the total iron binding capacity and calculated percent saturation, have results consistent with iron deficiency or iron overload. For example:

<table>
<thead>
<tr>
<th></th>
<th>Iron Deficiency</th>
<th>Iron Overload</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iron</td>
<td>53 mcg/dL (45 – 160)</td>
<td>135 mcg/dL (45 – 160)</td>
</tr>
<tr>
<td>TIBC</td>
<td>462 mcg/dL (228 – 417)</td>
<td>213 mcg/dL (228 – 417)</td>
</tr>
<tr>
<td>% Saturation</td>
<td>11 % (15 – 55)</td>
<td>63 % (15 – 55)</td>
</tr>
<tr>
<td>Ferritin</td>
<td>10 ng/dL (12 – 207)</td>
<td>1493 ng/dL (14 – 338)</td>
</tr>
</tbody>
</table>

Therefore, starting Tuesday October 1st, 2013, physician offices will be contacted to change orders for a serum iron alone to one for iron, total iron binding capacity and percent saturation (transferrin saturation). This change has been approved by the Medical Executive Committees at Grosse Pointe, Royal Oak and Troy.

Timing of blood draws for assessment of iron status:

- Ideally, iron-containing supplements should be avoided for 24 hours prior to draw. If this is not possible, suggest blood draw shortly before the next iron supplement.
- Wait at least 48 hours after parenteral administration.

If the blood is drawn too soon after iron administration, the results will show a falsely elevated percent saturation, in some cases > 100%.

Date Submitted: September 20, 2013

Submitted by: Elizabeth Sykes, MD, Medical Director, Chemistry, Royal Oak
Yvonne Posey, MD, Associate Medical Director, Chemistry, Royal Oak
Beatrice Muglia, MD, Medical Director, Chemistry, Grosse Pointe
Ralph Zade, MD, Medical Director, Chemistry, Troy
Myelin Basic Protein

Effective Date: October 16, 2014

Due to a change at the reference lab, the methodology and reference range have changed for the Myelin Basic Protein.

<table>
<thead>
<tr>
<th>Synonym</th>
<th>XMBP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specimen Collection Criteria</td>
<td>CSF</td>
</tr>
<tr>
<td>Specimen Preparation for Courier Transport</td>
<td>If CSF is bloody, centrifuge the sample and separate supernatant from cells prior to freezing the sample.</td>
</tr>
<tr>
<td>Rejection Criteria</td>
<td>Hemolysis can produce falsely elevated levels of MBP in the CSF. CSF should be free from contamination with blood,</td>
</tr>
<tr>
<td>Performed</td>
<td>ARUP Laboratories (Test Code 51224)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reference Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Old: 0.00-1.10 ng/mL</td>
</tr>
<tr>
<td>New: 0.00-5.50 ng/mL</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Methodology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Old: Quantitative Enzyme-Linked Immunosorbent Assay (ELISA)</td>
</tr>
<tr>
<td>New: Chemiluminescent Immunoassay (CIA)</td>
</tr>
</tbody>
</table>

| CPT Code | 83873 |
|------------------|
| Date Submitted   | October 9, 2013 |
| Submitted by     | Joel Waddington – Sendout Coordinator, Yvonne Posey, MD – Medical Director Sendouts |
Laboratory Reports for Urinalysis Microscopic Examinations

Effective Date: October 16, 2013

On September 15, 2013, Beaumont Health System Laboratory installed a manufacturer’s update to our Laboratory Information System. The update caused an unforeseen issue in the laboratory reports generated for Urinalysis Microscopic Examinations.

Although all urinalysis microscopic results were reported correctly, abnormal results do not consistently trigger a flag for abnormal on the final report. To rectify the situation, the laboratory staff will begin manually flagging abnormal results and reissuing electronic reports with flags from September 15th to present.

Depending on your laboratory report method, you may see one of the following:

- **Epic oC**: Results that have been completed without flags will appear with flags once they have been repaired. They will also appear in your abnormal results inbox.

- **Printed Reports**: Reports may have been received without the abnormal flagging. Clients will not automatically receive a reprinted paper report.

- **Electronic Medical Record reports**: Result originally delivered without flags, will be resent to include abnormal flags.

We will continue this process until we resolve this high priority issue with the laboratory information system vendor.

We apologize for the inconvenience.

Date Submitted: October 14, 2013

Submitted by: Mark Kolins, MD
Medical Director, Beaumont Laboratory

Don Henderson
Administrative Director, Beaumont Laboratory
NEWBORN DIRECT ANTIGLOBULIN TESTING BY GEL

Effective Date: November 11, 2013

To enhance the sensitivity of the Direct Antiglobulin Tests for newborns (< 4 months old), the Grosse Pointe and Troy Blood Banks will utilize the MTS Gel methodology instead of the current Tube method. Gel technology is more sensitive than Tube in detecting in-vivo IgG coating of red cells, and is currently in use at Royal Oak. The Tube method will be discontinued and will no longer be available for this patient population.

<table>
<thead>
<tr>
<th>Synonyms</th>
<th>DAT, Direct Coombs test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specimen Collection Criteria</td>
<td>Cord blood or heel stick collected in an EDTA tube</td>
</tr>
<tr>
<td>Specimen Preparation for Courier Transport</td>
<td>Transport at room temperature. Do not refrigerate.</td>
</tr>
<tr>
<td>Rejection Criteria</td>
<td>Improperly labeled samples. See LTD for labeling requirements.</td>
</tr>
<tr>
<td>Performed</td>
<td>Sunday - Saturday</td>
</tr>
<tr>
<td>Reference Range</td>
<td>Negative</td>
</tr>
<tr>
<td>Test Methodology</td>
<td>Ortho MTS System</td>
</tr>
<tr>
<td>Interpretation</td>
<td>The gel DAT detects the presence or absence of IgG on human red blood cells. It does not detect complement components bound to red blood cells.</td>
</tr>
<tr>
<td>Date Submitted</td>
<td></td>
</tr>
<tr>
<td>Submitted by</td>
<td>James Liu, M.D.</td>
</tr>
<tr>
<td></td>
<td>Blood Bank Medical Director</td>
</tr>
<tr>
<td></td>
<td>Grosse Pointe</td>
</tr>
<tr>
<td></td>
<td>Xia Chen, M.D.</td>
</tr>
<tr>
<td></td>
<td>Blood Bank Medical Director</td>
</tr>
<tr>
<td></td>
<td>Troy</td>
</tr>
</tbody>
</table>
**Blood Cultures-Testing Update**

**Effective Date: November 18, 2013**

Effective immediately, Beaumont Laboratory will begin distributing plastic aerobic and anaerobic blood culture bottles in place of the glass aerobic and anaerobic bottles. These bottles have been verified for use in the Microbiology Laboratory at Grosse Pointe, Royal Oak and Troy and will provide the same rapid detection of growth and *in vitro* performance that is expected from our state-of-the-art blood culture equipment, the Bactec FX system. The plastic bottles should be handled in exactly the same manner as the glass bottles.

**Frequently asked questions:**

1. **What if we still have glass aerobic and anaerobic bottles left over at our station/site?**
   The supply of glass bottles should be depleted before changing to plastic bottles.

2. **Are the pediatric bottles changing to plastic also?**
   Becton-Dickinson will not have plastic pediatric bottles available until mid-2014. When these become available, the Laboratory will perform verification studies to assure their efficacy.

3. **What should we do with fluid samples that are submitted in glass blood culture bottles?**
   a. The Laboratory will maintain a supply of glass bottles for culture of fluid samples. Please continue to submit fluid specimens to the Microbiology Laboratory in sterile containers and they will be placed into the appropriate bottles for culture.
   b. The Microbiology Laboratory will verify the use of plastic bottles for fluid specimens in the near future.

4. **Has the volume of blood to be placed in the bottles changed?**
   No. The optimal amount of blood is 8-10 mL per bottle with a minimum of 5 mL per bottle.

If you need additional information, please contact Customer Service (1-800-551-0488, option 5).

**Date Submitted:** November 14, 2013  
**Submitted By:**
- Royal Oak: B. Robinson-Dunn, Ph.D., D(ABMM)  
  Technical Director, Microbiology  
- Troy: Elizabeth Wey, M.D.  
  Medical Director, Microbiology

- B.L. Boyanton, M.D.  
  Medical Director, Microbiology  
  Associate Medical Director, Molecular Pathology  
- Grosse Pointe: Vaishali Pansare, M.D.  
  Chief, Grosse Pointe Laboratory
Mycoplasma pneumoniae by Nucleic Acid Amplification

Effective Date: December 03, 2013

M. pneumoniae is a common cause of upper and lower respiratory infections, including atypical pneumonia - associated symptoms are headache, malaise, fever, sore throat, and a dry paroxysmal cough. It is transmitted by coughing and can lead to outbreaks in close personal contact settings, including healthcare facilities. Nucleic acid amplification is the preferred testing modality since culture and serologic methods can not provide useful information in a timely manner.

On December 03, 2013, the Molecular Pathology Laboratory will begin offering nucleic acid amplification testing for M. pneumoniae; send-out testing will no longer be required.

High Yield Facts:
1) SOFT test order code: IMYCG
2) Testing Schedule: Monday, Wednesday, Friday
3) Specimen Sources:
   a. Swabs (preferred): throat, nasopharyngeal
   b. Fluids (alternative): bronchialveolar lavage (BAL), bronchial washing (BW), pleural fluid, sputum
4) Specimen transportation to the laboratory
   a. Swabs: place into viral transport medium (M4-RT, universal transport media [UTM], or universal viral transport [UVT]), maintain refrigerated.
   b. Fluids: place into a sterile screw capped container, maintain refrigerated.

For complete specimen collection instructions, please refer to the on-line Laboratory Test Directory:
Internal URL: http://beaunet.beaumont.edu/portal/pls/portal/lab.lab_PKG.lab_list
External URL: http://beaumonthospitals.com/labtestdirectory

For additional information, please contact Customer Services (1-800-551-0488, option 5).

<table>
<thead>
<tr>
<th>Date Submitted</th>
<th>October 23, 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submitted by</td>
<td>Bobby L. Boyanton Jr., M.D.</td>
</tr>
<tr>
<td></td>
<td>Medical Director, Microbiology</td>
</tr>
<tr>
<td></td>
<td>Associate Medical Director, Molecular Pathology</td>
</tr>
<tr>
<td></td>
<td>Domnita Crisan, M.D., Ph.D.</td>
</tr>
<tr>
<td></td>
<td>Medical Director, Molecular Pathology</td>
</tr>
</tbody>
</table>
Respiratory Virus Panel by PCR (RVP by PCR) - Testing Update

Effective Date: December 03, 2013

On December 03, 2013, the Molecular Laboratory will switch to an improved nucleic acid amplification test for the detection of respiratory viruses.

This transition will be seamless:
- No change in test name or ordering (paper or electronic).
  - SOFT Order Code: IRVPG
- No change in specimen collection and handling requirements.
  - Specimen: Nasopharyngeal swab
  - Handling: Place NP swab in viral transport media, maintain refrigerated

Advantages of the new test:
- Overall increased sensitivity and detection of co-infections
- Enhanced detection and sub-typing of influenza A viruses
  - Specific reporting of influenza A H1 and influenza H3. In addition, specific reporting of influenza A/H1N1 2009 (no need to use a separate test)
- Enhanced detection of respiratory syncytial viruses A and B
- Enhanced detection and sub-typing of adenovirus
  - Specific reporting of adenovirus B/E and adenovirus C
- Specific detection of rhinovirus
  - The new version of the RVP by PCR test has no known cross reactivity with enterovirus, thereby avoiding false positive test results.

For complete specimen collection and handling instructions, please refer to the “on-line” Laboratory Test Directory:
- Internal URL: http://beaunet.beaumont.edu/portal/pls/portal/lab.lab_pkg.lab_list
- External URL: http://beaumonthospitals.com/labtestdirectory

If you need additional information, please contact Client Services (1-800-551-0488, option 5).

<table>
<thead>
<tr>
<th>Date Submitted</th>
<th>November 04, 2013</th>
</tr>
</thead>
</table>
| Submitted by   | Bobby L. Boyanton, Jr., M.D.  
Medical Director, Microbiology  
Associate Medical Director, Molecular Pathology  
Domnita Crisan, M.D., Ph.D.  
Director, Molecular Pathology |
Effective Date: December 03, 2013

Effective December 03, 2013, Beaumont Laboratory will no longer accept nasopharyngeal specimens (i.e. aspirate, swab, wash) for Virus Culture. If testing of NP specimens is clinically indicated, order the Respiratory Virus Panel (RVP) by PCR test to detect those viruses normally identified by culture.

The RVP by PCR test offers the following advantages over virus culture:

1. Superior test performance
   a. molecular amplification and reporting of each viral target
   b. not adversely affected by unpredictable conditions pertaining to specimen handling and transportation (i.e. temperature extremes, delays in specimen transportation, etc.) that can damage viruses and prevent them from being cultivated.
2. Expanded list of potential pathogens that can be detected
3. Faster turn-around-time (1 day versus 2-4 days for culture)

### Target | Culture, Virus | RVP by PCR
--- | --- | ---
Influenza A (generic) | X | X
Influenza A H1 | | X
Influenza A H3 | | X
Influenza A/H1N1 2009 | | X
Influenza B | X | X
RSV (generic) | | X
RSV A | | X
RSV B | | X
Parainfluenza 1 | X | X
Parainfluenza 2 | X | X
Parainfluenza 3 | X | X
Human Metapneumovirus | | X
Adenovirus (generic) | | X
Adenovirus B/E | | X
Adenovirus C | | X
Human Rhinovirus | | X

**Note:** If enterovirus is clinically suspected as the infectious agent:

- Order Culture, Virus and indicate “enterovirus” on the requisition (paper or electronic)
- The laboratory will set-up specific cell lines to cultivate and identify enterovirus.
- The laboratory is developing an enterovirus-specific PCR test; this is likely to be available for clinical use in the next 45 days.
If you have questions, please contact Client Services (1-800-551-0488, option 5).

<table>
<thead>
<tr>
<th>Date Submitted</th>
<th>Submitted by</th>
</tr>
</thead>
<tbody>
<tr>
<td>November 8, 2013</td>
<td><strong>Royal Oak:</strong> B. Robinson-Dunn, Ph.D., D(ABMM) Technical Director, Microbiology</td>
</tr>
<tr>
<td></td>
<td><strong>Royal Oak:</strong> B. L. Boyanton, M.D. Medical Director, Microbiology Associate Medical Director, Molecular Pathology</td>
</tr>
<tr>
<td></td>
<td><strong>Grosse Pointe:</strong> Vaishali Pansare, MD Medical Director, Cytology/Microbiology</td>
</tr>
<tr>
<td></td>
<td><strong>Troy:</strong> Elizabeth Wey, M.D. Medical Director, Microbiology</td>
</tr>
</tbody>
</table>
The CDC predicts that seasonal influenza A H3, influenza A H1N1 2009 and seasonal influenza B will be the predominant influenza viruses circulating this viral respiratory season. These viruses are predicted to remain susceptible to oseltamirvir (Tamiflu) and zanamivir (Relenza). Therefore, molecular sub-typing for influenza A will not be needed at this time. For additional information: [http://www.cdc.gov/flu](http://www.cdc.gov/flu)

**Important:** *Intranasal influenza vaccine (i.e. FluMist):* recipients (esp. children) of the intranasal vaccine can shed vaccine-related viruses up to 14 days after vaccination; these will be detected by our testing methods and are indistinguishable from wild-type influenza viruses.

**Rapid Antigen Testing:** No longer available due to unacceptable test performance.

**Billing obstacle:** Insurance will NOT pay for a) more than one of the tests listed below on the same date of service, or b) reflex testing since influenza A, influenza B and RSV would be repeated on the same sample. If a specimen tested with the Rapid Influenza & RSV by PCR test is negative and the RVP by PCR test is desired, another specimen (different day of service) MUST be collected.

**Tests Available at Beaumont Laboratory:**

**Rapid Influenza & RSV by PCR. (Outreach order code: FLRSV)**
- **Specimen** Nasopharyngeal (NP) only
- **Performed** Mon – Sun, results available within 90 minutes
- **Detects** Influenza A, influenza B, RSV.
- **Notes**
  1) This test has exceptional sensitivity (>97%) -a false negative rate of about 3%.
  2) This test detects all sub-types of influenza A but can not provide individual sub-typing results.
- **When to order** This should be the first-line test ordered for patients with influenza-like illness, due to superior diagnostic sensitivity and rapid turn-around time.

**Respiratory Virus Panel (RVP by PCR. (Outreach order code: IRVPG)**
- **Specimen** Nasopharyngeal (NP) only
- **Performed** Mon – Sat, results available in 24 – 48 hr.
- **Detects** Influenza A with sub-typing (H1, H3, H1N1 2009), influenza B, RSV A, RSV B, human metapneumovirus, adenovirus B/E, adenovirus C, rhinovirus and parainfluenza viruses 1, 2, 3.
- **Note** If test results demonstrate the presence of a non-typeable strain of influenza A, the specimen will be forwarded to MDCH for further testing.
- **When to order** This should be used as a comprehensive test (non-urgent) if you suspect the patient may be infected with respiratory viruses other than influenza A/B or RSV.
Culture, Virus (Outreach Order Code: CXVIR)

- **Specimen** Non-NP (BAL, bronchial wash, sputum, etc.)
- **Perform** Mon – Sun, results available in 24 – 48 hr.
- **Detect** Influenza A and B, RSV, adenovirus and parainfluenza viruses 1, 2, 3.
  This test detects all sub-types of influenza A but can not provide individual sub-typing results.

**When to order**
- Preferred test for Non-NP specimens. NP specimens MUST be analyzed by the RVP by PCR test due to improved test sensitivity and an expanded panel of pathogens that can be detected.

**REFERENCES:**

If you have questions, please contact Client Services (1-800-551-0488, option 5).

**Date Submitted** November 8, 2013
**Submitted by**
- **Royal Oak:**
  - B. Robinson-Dunn, Ph.D., D(ABMM)
    - Technical Director, Microbiology
- **Grosse Pointe:**
  - Vaishali Pansare, MD
    - Medical Director, Cytology/Microbiology

**Royal Oak:**
- B. L. Boyanton, M.D.
  - Medical Director, Microbiology
  - Associate Medical Director, Molecular Pathology

**Troy:**
- Elizabeth Wey, M.D.
  - Medical Director, Microbiology
IN-PATIENT
Respiratory Virus Testing Algorithm (2013-2014)

Testing Desired on an *In-Patient*?  
Yes  

Focused or Expanded Pathogen Detection Desired?  

Focused (Routine or STAT)  
Rapid Influenza & RSV by PCR¹  
(NP SWAB SPECIMENS ONLY)  

Positive  
Negative  

No Further Action  

Expanded (Routine Only)  
Respiratory Virus Panel by PCR  
(NP SWAB SPECIMENS ONLY)  

Is another test needed to exclude other viral respiratory pathogens?  
Yes  

Expanded (Routine Only)  
Culture, Virus²  
(NON-NP SPECIMENS ONLY)  

No Further Action

---

1. **Rapid Antigen Tests**: No longer available for Influenza or RSV due to unacceptable test performance. Rapid Influenza & RSV by PCR is the preferred replacement test.

2. **Virus Culture**: Nasopharyngeal swab (NP) specimens will no longer be accepted for Virus Culture without the approval of the Medical or Technical Director of Microbiology. Please order the Respiratory Virus Panel by PCR test as it provides enhanced test sensitivity and an expanded panel of pathogens that can be detected.

Effective: December 03, 2013
**OUT-PATIENT**

Respiratory Virus Testing Algorithm (2013-2014)

---

**Testing Desired on an Out-Patient?**

- **No** → **No Further Action**

---

**Focused or Expanded Pathogen Detection Desired?**

- **Yes** → **Focused (Routine or STAT)**

---

**Rapid Influenza & RSV by PCR (NP Specimens)\(^1\)**

- **Positive** → **No Further Action**
- **Negative** → **Is another test needed to exclude other viral respiratory pathogens?**

---

**Order:**

- Respiratory Virus Panel by PCR (NP Specimens)
- OR
- Culture, Virus (Non-NP Specimens)\(^3\)

---

1. **Rapid Antigen Tests:** No longer available for Influenza or RSV due to unacceptable test performance. Rapid Influenza & RSV by PCR is the preferred replacement test.

2. **Billing Obstacle:** Insurance will NOT pay for more than one of the three tests listed above on the same date of service. If you obtain negative test results for the Rapid Influenza & RSV by PCR test, reflex testing to the RVP by PCR or Virus Culture is not covered by insurance. If additional testing is desired, another specimen MUST be collected (different day of service) and sent to the laboratory for the appropriate requested test.

3. **Virus Culture:** Nasopharyngeal swab (NP) specimens are no longer acceptable for this test. Please order the Respiratory Virus Panel by PCR test as it provides enhanced test sensitivity and an expanded panel of pathogens that can be detected.

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*Effective: December 01, 2013*
Allergen-Specific IgE Testing

Effective Date: December 3, 2013

The allergens indicated below will be added to the allergen-specific IgE test menu. The performance of these assays on the ImmunoCAP allergen-specific IgE test system has been independently verified by Beaumont Laboratory.

New Allergens
1. Catfish
2. Grape
3. Linseed
4. Poppy Seed
5. Whey

Specimen Collection Criteria
- Tube type: 5 mL SST (gold-top, serum separator)
- One filled 5 mL SST tube is sufficient to test up to 20 individual allergens.

Date Submitted: November 11th, 2013

Submitted by: Gabriel Maine, PhD
Technical Director, Special Testing, Royal Oak
Elizabeth Sykes, MD
Medical Director, Special Testing, Royal Oak
Erythropoietin Reference Range Change

Effective Date: December 19, 2013

Erythropoietin testing will be moved from the Siemens Immulite 2000 platform to the Beckman Coulter DxI immunoassay test system. Test performance was verified independently by Beaumont Laboratory. The reference range for the test will be changed as indicated below.

Old Reference Range: 3.7 – 29.5 mU/mL
New Reference Range: 4.5 – 29.0 mU/mL

Specimen collection requirements will not change. Please refer to the Beaumont Lab Test Directory for further details.

Internal URL:
http://beaunet.beaumont.edu/portal/pls/portal/lab.lab_pkg.lab_test_info_content?xid=756

External URL:
http://www.beaumontlaboratory.com/test-lab-directory/lab-test-details/?testid=756

Date Submitted: December 17, 2013
Submitted by: Gabriel Maine, PhD
Technical Director, Special Testing, Royal Oak
Elizabeth Sykes, MD
Medical Director, Special Testing, Royal Oak