Human Papillomavirus Testing at Beaumont Health

Dear healthcare provider,

The purpose of this memo is to provide a clear understanding of best practice HPV testing at Beaumont Laboratory. Beaumont Laboratory (all eight hospitals) has agreed to standardize to the Roche cobas 4800 HPV test. The Roche cobas 4800 HPV test has numerous advantages when compared to the Hologic Aptima mRNA and Qiagen/Digene hybrid capture II HPV tests. These are as follows:

<table>
<thead>
<tr>
<th>Category</th>
<th>Roche cobas 4800 HPV</th>
<th>Qiagen-Digene HCII HPV</th>
<th>Hologic Aptima mRNA HPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA-approved for Primary Screening</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>False Positives Results Due To Low-Risk</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Genotype Cross-Reactivity (1)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HPV 16/18 Genotyping (2)</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Direct Sample Testing (3)</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Cellularity Control (4)</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Sample Volume Required (5)</td>
<td>1 mL</td>
<td>4 mL</td>
<td>2 mL</td>
</tr>
</tbody>
</table>

(1) Qiagen (6,11,40,42,53-55,66); Hologic (26,67,70,82). False positive results will lead to unnecessary patient management.

(2) Hologic HPV 16/18 genotyping cannot distinguish genotypes 18 and 45. Patients infected with HPV 45 will therefore be managed as if HPV genotype 18 positive. Roche HPV 16/18 genotyping is automatically included at no additional charge.

(3) Direct testing from the liquid based cytology vial reduces specimen-to-specimen contamination and specimen labeling errors.

(4) A cellularity control ensures that sufficient clinical material was in the liquid based cytology vial. False negative test results due to poor sample collection cannot be excluded with the Qiagen and Hologic tests.

(5) Hologic requires 1ml of sample for initial testing and another 1ml of sample for high-risk genotype testing. This increases the chance that the patient will need repeat specimen collection due to insufficient sample volume.

Implementation of the Roche cobas 4800 HPV test at each affiliate is anticipated as follows:

- **Beaumont - Royal Oak, Grosse Pointe and Troy**: the Roche cobas 4800 HPV test has been in use for several years - no additional changes are anticipated.

- **Beaumont – Dearborn, Taylor, Trenton and Wayne**: the Roche cobas 4800 HPV test is anticipated to be in use by June 2016. Until that time, the Hologic Aptima mRNA HPV test will continue to be used.

- **Beaumont – Farmington Hills**: the Roche cobas 4800 HPV test is anticipated to be in use by 2018 once the existing Qiagen/Digene hybrid capture II HPV test contract expires.

As these implementation timelines draw closer, additional educational efforts will be provided to minimize disruption to your practice and daily routine.

We appreciate your effort in making this transition as smooth as possible.

Sincerely,

Mark Kolins, MD  Corporate Chair, Laboratory Services
David Grossman, MD  Chief, Laboratory Services, Beaumont Troy
Vaishali Pansare, MD  Chief, Laboratory Services, Beaumont Grosse Pointe
Michael Schaldenbrand, MD  Chief, Laboratory Services, Beaumont Oakwood
Gil Herman, MD  Chief, Laboratory Services, Beaumont Farmington Hills
Bobby Boyanton, MD  Medical Director, Microbiology; Associate Medical Director, Molecular Pathology, Beaumont Royal Oak

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References:


