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Laboratory Bulletin

Viral Load Testing (CMV, HBV, HCV, and HIV)

Effective Date: March 14, 2022

Beaumont Laboratory will be moving cytomegalovirus (CMV), hepatitis B and C virus (HBV and HCV), and HIV viral load testing to a new instrument, the cobas 6800 system. The new instrumentation uses less sample for for HIV-1 viral load assays, which will reduce the amount of patient recollections due to insufficient sample volume (QNS samples). Also, new lower limits of detection for HBV and CMV samples will quantify viral loads down to 10 IU/mL and 35 IU/mL, respectively. Method correlation studies between the old and new instrumentation yielded >95% concordance for viral load testing so no baseline change in previously tested patients will be required. Test names and orders will remain the same to provide a seamless transition. Details of the new test launch dates are listed below.

Viral Load Test Launch March 14th 2022:

HIV Viral Load (HIV 1 RNA Quantitation)

Synonyms	Human Immunodeficiency Virus 1 quantitation, HIV 1 RNA Quantitation By PCR
Specimen Collection Criteria	Plasma: Two Lavender-top EDTA tubes
Physician Office/Draw Site Specimen Preparation	Centrifuge to separate plasma from cells within 24 hours of collection
Specimen Preparation for Courier Transport	Plasma, refrigerated
Rejection Criteria	– Specimens not centrifuged within 24 hours of collection. – Specimens collected in Green-top heparin tubes or White-top PPT tubes. – Specimens not maintained refrigerated or frozen following separation. – Specimens exposed to repeated freeze/thaw cycles. – Specimens with less than 0.65 mL plasma/serum. – Unlabeled tubes.
Performed	Once per week
Reference Range	HIV-1 RNA “Not Detected”
Reportable Range	20 - 10,000,000 copies/mL. The analytical sensitivity is 13.2 copies/mL.
Test Methodology	Quantitative real-time polymerase chain reaction
Interpretation	A result reported as “Detected” indicates the presence of HIV-1 RNA
CPT Code	87536

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HCV RNA Quantitation By PCR

Synonyms	Hepatitis C RNA viral load
Specimen Collection Criteria	Plasma: One Lavender-top EDTA tube. Serum: One Gold-top SST or plain Red-top tube.
Physician Office/Draw Site Specimen Preparation	Centrifuge to separate plasma from cells within 24 hours of collection
Specimen Preparation for Courier Transport	Centrifuged/processed serum or plasma, refrigerated
Rejection Criteria	– Specimens not centrifuged within 24 hours of collection. – Specimens collected in Green-top heparin tubes or White-top PPT tubes. – Specimens not maintained refrigerated or frozen following separation. – Specimens exposed to repeated freeze/thaw cycles. – Specimens with less than 0.65 mL plasma/serum. – Unlabeled tubes.
Performed	Once per week
Reference Range	HCV RNA “Not Detected”
Reportable Range	15 - 100,000,000 IU/mL. The analytical sensitivity is 12.0 IU/mL (plasma) and 13.7 IU/mL (serum).
Test Methodology	Quantitative real-time polymerase chain reaction
Interpretation	A result reported as “Detected” indicates the presence of HCV RNA
CPT Code	87522

Viral Load Test Launch March 21st 2022:

HBV DNA Quantitation By PCR

Synonyms	Hepatitis B Virus viral load
Specimen Collection Criteria	Plasma: One Lavender-top EDTA tube. Serum: One Gold-top SST or plain Red-top tube.
Physician Office/Draw Site Specimen Preparation	Centrifuge to separate plasma from cells within 24 hours of collection
Specimen Preparation for Courier Transport	Centrifuged/processed serum or plasma, refrigerated
Rejection Criteria	– Specimens not centrifuged within 24 hours of collection. – Specimens collected in Green-top heparin tubes or White-top PPT tubes. – Specimens not maintained refrigerated or frozen following separation. – Specimens exposed to repeated freeze/thaw cycles. – Specimens with less than 0.65 mL plasma/serum. – Unlabeled tubes.
Performed	Once per week
Reference Range	HBV DNA “Not Detected”
Reportable Range	10-1,000,000,000 IU/mL. The analytical sensitivity is 6.6 IU/mL (plasma) and 3.5 IU/mL (serum).
Test Methodology	Quantitative real-time polymerase chain reaction
Interpretation	A result reported as “Detected” indicates the presence of HBV DNA
CPT Code	87517

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Cytomegalovirus (CMV) DNA Quantitation By PCR

Synonyms	Cytomegalovirus viral load
Specimen Collection Criteria	Plasma: One Lavender-top EDTA tube.
Physician Office/Draw Site Specimen Preparation	Centrifuge to separate plasma from cells within 24 hours of collection
Specimen Preparation for Courier Transport	Centrifuged/processed serum or plasma, refrigerated
Rejection Criteria	– Specimens not centrifuged within 24 hours of collection. – Specimens collected in Green-top heparin tubes or White-top PPT tubes. – Specimens not maintained refrigerated or frozen following separation. – Specimens exposed to repeated freeze/thaw cycles. – Specimens with less than 0.5 mL plasma/serum. – Unlabeled tubes.
Performed	Once per week
Reference Range	CMV DNA “Not Detected”
Reportable Range	35 - 10,000,000 IU/mL. The analytical sensitivity is 35 IU/mL (plasma).
Test Methodology	Quantitative real-time polymerase chain reaction
Interpretation	A result reported as “Detected” indicates the presence of CMV DNA
CPT Code	87497

Date submitted: **March 7, 2022**

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