Quarterly HOTLINE: Effective November 12, 2018

New Test **3000863** **Hepatitis B Virus (HBV) by Quantitative NAAT** **HBV QNT**

Methodology: Quantitative Transcription-Mediated Amplification
Performed: Sun-Sat
Reported: 2-4 days

Specimen Required: Collect: Lavender (EDTA), Pink (K_2EDTA), Yellow (ACD), Plasma Preparation Tube (PPT), or Serum Separator Tube (SST).
Specimen Preparation: Separate from cells within 24 hours. Transfer 2 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.8 mL)
Storage/Transport Temperature: Frozen.
Unacceptable Conditions: Heparinized specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: Unacceptable; Refrigerated: 5 days; Frozen: 2 months

Reference Interval: Not detected

Interpretive Data: Normal range for this assay is "Not Detected".
The quantitative range of this assay is 1.00-9.00 log IU/mL (10-1,000,000,000 IU/mL).

An interpretation of "Not Detected" does not rule out the presence of inhibitors in the patient specimen or HBV DNA concentration below the level of detection of the test. Care should be taken when interpreting any single viral load determination.

This assay should not be used for blood donor screening, associated re-entry protocols, or for screening Human Cell, Tissues and Cellular Tissue-Based Products (HCT/P).

Note: The limit of quantification for this DNA assay is 1.00 log IU/mL (10 IU/mL). If the assay DID NOT DETECT the virus, the test result will be reported as "Not Detected". If the assay DETECTED the presence of the virus but was not able to accurately quantify the viral load, the test result will be reported as "< 10 Detected".

Specimens received with less than minimum volume for testing will automatically be run with a dilution.
-Specimens with 240-700 µL will be diluted resulting in a modification of the quantitative range of the assay to 1.48-9.48 log IU/mL (30-3,000,000,000 IU/mL).

This test is intended for use in conjunction with clinical presentation and other laboratory markers as an indicator of disease prognosis. This test is also used as an aid in assessing viral response to treatment as measured by changes in HBV DNA concentration.

CPT Code(s): 87517

New York DOH Approved.

HOTLINE NOTE: Refer to the Test Mix Addendum for interface build information.