TEST CHANGE

Hepatitis B Virus (HBV) by Quantitative NAAT

3000863, HBV QNT

Specimen Requirements:	
Patient Preparation:	
Collect:	Lavender (EDTA), pink (K2EDTA), ~~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 (ARUP supply #15824). Available online through eSupply using ARUP Connect(TM) or contact ARUP Client Services at 800-522-2787. (Min: 1.3 mL) ~~. (Min: 0.8 mL)~~
Transport Temperature:	Frozen
Unacceptable Conditions:	Heparinized specimens.
Remarks:	
Stability:	After separation from cells: Ambient: 24 hours (Critical: s~~S~~hip FROZEN); Refrigerated: 6~~5~~ days; Frozen: 3~~2~~ months
Methodology:	Quantitative Polymerase Chain Reaction (PCR~~Transcription-Mediated Amplification (TMA~~)
Performed:	Sun-Sat
Reported:	2-4 days
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 "Not Quantified, Detected". ~~"< 10 Detected." Specimens received with less than minimum volume for testing will automatically be run with a dilution. Specimens with 240-700 microL 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 Codes:	87517
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

~~Normal range for this assay is "Not Detected".~~
The quantitative range of this test~~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 test is intended for use as an aid in the management of patients with chronic HBV infection undergoing anti-viral therapy. The test can be used to measure HBV DNA levels at baseline and during treatment to aid in assessing response to treatment. Results must be interpreted within the context of all relevant clinical and laboratory findings.

This assay should not be used for blood donor screening, associated reentry protocols, or for screening human cell, tissues and cellular tissue-based products (HCT/P).

Reference Interval:

Not detected

HOTLINE NOTE: There is a numeric map change associated with this test. Refer to the Hotline Test Mix for interface build information.