New Molecular Test for Hepatitis B Virus DNA Quantitation by PCR

WHAT’S NEW?
Effective Wednesday, September 19, 2012, PeaceHealth Laboratories will implement a new molecular test to detect and quantify hepatitis B virus DNA in serum or plasma using PCR amplification with the Roche COBAS AmpliPrep/COBAS TaqMan HBV Test v2.0.

Hepatitis B virus DNA by PCR is indicated to:
- Quantify HBV DNA in serum or plasma in patients with chronic HBV infection (previously hepatitis B surface antigen-positive)
- Monitor disease progression in chronic HBV infection and/or response to anti-HBV therapy

BACKGROUND
Serology screening
In the U.S., there are an estimated 1.25 million hepatitis B carriers. The tests used to screen for HBV should include Hepatitis B Surface Antigen (HBsAg) (42120) and Hepatitis B Surface Antibody (anti-HBs) (40770). Alternatively, Hepatitis B Core Antibody (Anti-HBc) (42130) can be used with a reflex of positive tests to both HBsAg and anti-HBc to differentiate infection from immunity.1

HBV DNA quantification in HBV infections
The quantitative detection of HBV DNA in serum or plasma is useful to help differentiate between active (infectious) and inactive (carrier) HBV infection and to monitor a patient’s response to anti-HBV therapy.1

HBV DNA serum levels, rather than hepatitis Be-antigen (HBeAg) status, is now recommended by the Centers for Disease Control and Prevention to monitor the infectivity of HBV-infected health care providers and students.2

Interpretation and serial monitoring
HBV DNA in serum or plasma is a reliable marker of active HBV replication. Although longitudinal data is limited, liver disease is generally present in people with high HBV DNA levels.

However, it is also recognized that lower HBV DNA levels (3-5 log10 IU/mL) may be associated with progressive liver disease and may warrant treatment, particularly in people who are HBeAg-negative or who have already developed cirrhosis.

Interpreting serum HBV DNA levels is complicated by the uncertainty in cutoff values used to define treatment indications and response. Although HBV DNA levels may gradually decrease and disappear when the infection resolves spontaneously, HBV DNA can also persist even in those who have serological recovery from acute HBV infection, and low levels of HBV DNA may not be associated with progressive liver disease.

Serial monitoring of HBV DNA levels is more important than any single arbitrary cutoff value to predict or determine the need for treatment.

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QUANTIFICATION RANGE
The quantification range of this assay is 20 IU/mL to 170,000,000 IU/mL (1.30 log IU/mL to 8.23 log IU/mL).

QUESTIONS?
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ORDERING INFORMATION
58126 Hepatitis B Virus (HBV) Quantitative PCR
Methodology: Real-Time Polymerase Chain Reaction (RT-PCR)
Performed: Thursday
Released: Same day as tested
CPT Codes: 87517
Comments: The quantitative range of this assay is 20-170,000,000 IU/mL (1.30-8.23 log IU/mL). 1 IU/mL of HBV DNA is approximately 5.82 copies/mL.

SPECIMEN REQUIREMENTS
Collect: One 7.5 mL serum separator tube (SST). Also acceptable: One 4 mL lavender top tube (EDTA).
Handling: Centrifuge and separate serum or plasma from the cells within 24 hours of collection.
Standard Volume: 2 mL serum or plasma
Minimum Volume: 1 mL serum or plasma
Stability: On cells (uncentrifuged):
Ambient: 24 hours
Refrigerated: 24 hours
After centrifugation (after separation from the cells):
Ambient: 72 hours
Refrigerated: 7 days
Frozen: 6 weeks
Serum or plasma may be frozen and thawed up to 5 times without a loss of HBV DNA.
Transport: On cells (uncentrifuged): Ambient or refrigerated. Uncentrifuged specimens must be centrifuged within 24 hours of collection. Serum or plasma: Refrigerated or frozen.
Rejection Criteria: Specimen not centrifuged within 24 hours of collection; specimen frozen and thawed more than 5 times; heparinized specimen.

REFERENCES