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Hepatitis B Virus (HBV) Quantitative Real-time PCR

Test Code: 1100

Clinical and Procedure

Clinical Utility

Hepatitis B quantitative DNA PCR can be used in conjunction with clinical presentation and other laboratory markers of disease status as an aid in managing individuals infected with HBV. Results from the assay can potentially be used to assess disease progression and to monitor the efficacy of antiviral therapy by measuring changes in HBV DNA levels during the course of therapy. Viral load tests should not be used to diagnose HBV infection.

Procedure

Extraction of DNA from specimen; amplification and detection of hepatitis B genotypes A through H using real-time, quantitative PCR. An internal control is added to ensure the extraction was performed correctly and the PCR reaction was not inhibited. RealTime HBV is a product of Abbott Laboratories. It is FDA approved for in vitro diagnostic use.

Specificity

Detects all 8 HBV genotypes. The primers and probes used in this assay are specific for HBV.

Turnaround Time

Same day (within 8 - 12 hours from receipt of specimen), Monday through Saturday.

Specimen Information

Specimen Type	Order Code	CPT Code	NY Approved	Volume	Assay Range
plasma	1101	87517	Yes	2 mL (min. 0.7 mL)	10 IU/mL to 1.0 x 10^{9} IU/mL, HBV DNA detected below 10 IU/mL will be reported as "<10 IU/mL". Reported in 2 formats: IU/mL and Log10 IU/mL.

Special Instructions
- Collect 4-5 mL whole blood in EDTA, ACD or PPT.
- Centrifuge within 6 hours of draw and transfer 2 mL plasma to a sterile, screw top tube.
- If the specimen was collected in PPT, the entire tube can be shipped frozen following centrifugation.
- If shipped ambient, separated plasma fraction must arrive within 24 hours of draw.

Specimen Type	Order Code	CPT Code	NY Approved	Volume	Assay Range
serum	1110	87517	Yes	2 mL (min. 0.7 mL)	10 IU/mL to 1.0 x 10^{9} IU/mL, HBV DNA detected below 10 IU/mL will be reported as "<10 IU/mL". Reported in 2 formats: IU/mL and Log10 IU/mL

Special Instructions
- Collect 4-5 mL whole blood in red-top or SST.
- Centrifuge within 6 hours of draw and transfer 2 mL serum to a sterile, screw top tube.
- If the specimen was collected in SST, the entire tube can be shipped frozen following centrifugation.
- If shipped ambient, separated serum fraction must arrive within 24 hours of draw.

Shipping

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Ship Monday through Friday. Friday shipments must be labeled for Saturday delivery. All specimens must be labeled with patient's name and collection date. A Viracor Eurofins test requisition form must accompany each specimen. Multiple tests can be run on one specimen. Ship specimens FedEx Priority Overnight® to: Viracor Eurofins, 1001 NW Technology Dr, Lee's Summit, MO 64086

Causes for Rejection

Specimens beyond their acceptable length of time from collection as listed in the specimen handling or specimen types other than those listed.

Disclaimer

Specimens are approved for testing in New York only when indicated in the Specimen Information field above.

The CPT codes provided are based on Viracor Eurofins' interpretation of the American Medical Association's Current Procedural Terminology (CPT) codes and are provided for general informational purposes only. CPT coding is the sole responsibility of the billing party. Questions regarding coding should be addressed to your local Medicare carrier. Viracor Eurofins assumes no responsibility for billing errors due to reliance on the CPT codes illustrated in this material.