

# TEST UPDATE: Hepatitis B Virus (HBV) by Quantitative PCR, with or without Reflex to Genotype

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Effective **March 29, 2018**, PathGroup will perform testing for Hepatitis B Virus via Quantitative Real-Time PCR.

Hepatitis B virus (HBV), one of several viruses that cause viral hepatitis, is a major contributor of liver disease in the US. Over 2 billion people throughout the world have been infected with HBV and over 350 million of them are chronically infected carriers. The overall prevalence of HBV infection in the U.S. has been estimated to be 0.3% to 0.5%, with 47% to 70% of cases attributed to people born outside the U.S. Patients with chronic HBV infection are at high risk of long-term complications of infection, including chronic hepatitis, cirrhosis, and hepatocellular carcinoma.

Serologic markers are commonly used as diagnostic and/or prognostic indicators of acute or chronic HBV infection. HBV DNA in plasma can be quantitated by nucleic acid amplification technologies, such as PCR. Several key guidelines have recommended the use of real-time PCR methodology for HBV DNA quantitation primarily due to increased sensitivity and a broader linear range.<sup>3</sup>

PCR testing is intended primarily for the management of patients with chronic HBV infection undergoing antiviral therapy. The test can be used to measure HBV DNA levels at baseline and during treatment to aid in assessing response to treatment.

**PLEASE NOTE**: PathGroup test codes, test specifications and pricing will remain the same. **No action is** required of PathGroup accounts or providers.

## **PATHGROUP TEST METHODOLOGY:**

**HBV Viral Load:** COBAS® AmpliPrep/COBAS® TagMan® HBV Test, version 2.0

The viral load test can quantitate HBV DNA over the range of 20 to 1.70E+08 IU/mL.

**HBV Genotyping:** Polymerase Chain Reaction/Sequencing.



### **ORDERING:**

| PATHGROUP<br>TEST CODE | PATHGROUP TEST NAME                              | СРТ          |
|------------------------|--|--------------|
| HEPBP                  | HBV DNA, Quantitative PCR                        | 87517        |
| HBVQRG                 | HBV DNA Quantitative PCR with Reflex to Genotype | 87517, 87912 |
| HBVG                   | HBV, Genotype                                    | 87912        |

**NOTE:** If automatic reflex to HBV genotype is desired based on the viral load results, **Test Code HBVQRG** must be ordered, and **two (2)** specimen collection tubes must be submitted at the time of order. One tube will be used to perform HBV DNA, Quantitative PCR, while the other tube will be used to perform HBV, Genotype. If HBV, Genotype is ordered at a separate time, an additional collection tube will be needed at that time.

### **SPECIMEN COLLECTION AND STORAGE:**

**SPECIMEN TYPE:** Plasma or Serum

**SPECIMEN VOLUME:** 3 mL plasma or serum (Min: 2.0 mL)

**SPECIMEN CONTAINER:** One 5 mL EDTA (Lavender) or K2EDTA (Pink) or SST (Gold) Tube.

Separating serum or plasma from cells within 24 hours of collection.

**SPECIMEN TRANSPORT:** Frozen

**TEST PERFORMED:** Monday and Thursday

**TURNAROUND TIME:** 72 hours

For further questions, please contact Client Services at 615-562-9300 or 1-888-474-5227.

### References

- 1. Custer B, Sullivan SD, Hazlet TK, et al. Global epidemiology of hepatitis B virus J Clin Gastroenterol. 2004 Nov-Dec;38(10 Suppl 3):S158-168.
- 2. Weinbaum CM, Williams I, Mast EE, Wang SA, Finelli L, Wasley A, Neitzel SM, Ward JW; Centers for Disease Control and Prevention (CDC). Recommendations for identification and public health management of persons with chronic hepatitis B virus infection. MMWR Recomm Rep. 2008 Sep 19;57(RR-8):1-20.
- 3. Pawlotsky JM, Dusheiko G, Hatzakis A, et al. Virologic monitoring of hepatitis B virus therapy in dinical trials and practice: recommendations for a standardized approach. Gastroenterology. 2008;134 (2):405-415.