

# Hepatitis B Quantitative Real-time DNA PCR

<b>Test ID</b>	<b>1100</b> Hepatitis B (HBV) Real-time qPCR
<b>Clinical Utility</b>	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.
<b>Procedure</b>	Extraction of DNA from plasma; amplification and detection of hepatitis B genotypes A through G using real-time, quantitative PCR. An internal control is added to ensure the extraction was performed correctly and the PCR reaction was not inhibited.
<b>Specimens</b>	<b>Whole Blood:</b> 7-10 ml submitted in EDTA, ACD Solution A, or PPT sterile tube. Minimum specimen requirement is 2 ml plasma. <ul style="list-style-type: none"><li>• Separate plasma from cells within 4 hours of collection by centrifuge at 1000 xg for 10-15 minutes. Do not clarify by filtration or further centrifugation.</li><li>• Ship ambient or frozen.</li></ul>
<b>Specificity</b>	<b>Detects all 7 HBV genotypes.</b> The primers and probes used in this assay are specific for HBV.
<b>Assay Range</b>	5 to 200,000,000 IU/ml plasma Reported in 4 formats: <ul style="list-style-type: none"><li>• IU/ml</li><li>• Log IU/ml</li><li>• copies/ml</li><li>• Log copies/ml</li></ul>
<b>Turnaround Time</b>	Within 24 hours of receiving specimen

PCR tests are performed pursuant to a license agreement with Roche Molecular Systems, Inc.

This assay was developed and the performance characteristics were determined at ViraCor Laboratories. This test is performed in a CLIA certified laboratory. FDA approval is not required for the performance of this test.

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