



DLS Laboratory Medicine Bulletin

Hepatitis B Virus DNA by Real-Time TaqMan Quantitative PCR— by Wesley J. Kim, MD

Hepatitis B virus (HBV) is a member of the Hepadnaviridae family having circular, partially double stranded DNA. The virus consists of a nucleocapsid center, containing the core antigen (HBc), surrounded by an envelope containing the surface antigen (HBsAg). Infected hepatocytes produce e antigen (HBeAg) when active viral replication is occurring. The virus is blood-borne and is transmitted by exposure to blood and/or body fluids. Perinatal transmission can also occur.

The laboratory diagnosis and monitoring of Hepatitis B infections involves a number of tests. Serologic testing for HBsAg, HBsAb, HBcAb (IgM and total), and in certain cases HBeAg, are the primary tests used to screen and diagnose Hepatitis B infection, and can help differentiate between an acute infection, past infection, chronic infection, or post immunization. The pattern of reactivity of these various tests is reflective of the natural course of the infection. Because of the potential for severe consequences in chronic HBV infection, once the diagnosis is made, monitoring of the disease's progression and response to treatment by means of quantitative Hepatitis B DNA testing is prudent.

Beginning on April 4th 2005, DLS will be introducing in-house, the new COBAS TaqMan HBV assay from Roche Diagnostics Corporation for the quantitative determination of HBV DNA in serum. This assay utilizes real-time TaqMan PCR amplification for the detection and quantitation of HBV DNA. The assay has an improved analytical sensitivity, with a reportable range from 6 HBV IU/mL (0.8 Log IU/mL; 35

copies/mL) to 110,000,000 HBV IU/mL (8.0 Log IU/mL; 640 million copies/mL). Patient results less than 6 HBV IU/mL do not negate the presence of Hepatitis B as viral levels may be below the detectable limit for this assay. As with all laboratory tests, results from the COBAS HBV TaqMan assay should be interpreted in conjunction with clinical and other laboratory findings.

* This assay is performed using a commercial kit designated as "Research Use Only" by the manufacturer. This test is not cleared or approved by the U.S. Food and Drug Administration. The performance characteristics have been determined by Diagnostic Laboratory Services.

Ordering Information

Test Code	Test Name	Price
5509	HBV-DNA Quant, TaqMan	\$160.02

Specimen Requirements:

1.5 ml serum, **separate from cells within 6 hours.**
Other acceptable specimen: EDTA plasma.

Storage and Specimen Stability:

Serum stable at room temperature for 24 hours.
Serum stable refrigerated for up to 5 days.
Serum stable frozen for up to 1 month.

CPT Code: 87517

3/2005