
Lab Dept: Serology

Test Name: HEPATITIS B QUANTITATIVE (HBV-DNA) PCR

General Information

Lab Order Codes: HBDQN

Synonyms: HBV DNA Quantitative; HBV DNA Quantitation; HBV Viral Load; Hepatitis B Viral Load; HBV PCR

CPT Codes: 87517 – Hepatitis B virus, quantification

Test Includes: Quantitation of HBV virus measured in IU/mL.

Logistics

Test Indications: Confirmation of chronic hepatitis B virus (HBV) infection. Quantification of HBV DNA in serum of patients with chronic HBV infection (previously hepatitis B surface antigen-positive). Monitoring disease progression in chronic HBV infection and /or response to anti-HBV therapy.

Lab Testing Sections: Serology - Sendouts

Referred to: Mayo Medical Laboratories (Test: HBVQU)

Phone Numbers: MIN Lab: 612-813-6280

STP Lab: 651-220-6550

Test Availability: Daily, 24 hours

Turnaround Time: 2 – 4 days, test performed Monday - Friday.

Special Instructions: For optimal monitoring of viral response, serial specimens should be of the same type.

Specimen

Specimen Type: Blood

Container: Red top tube

Draw Volume: 4.5 mL (Minimum: 2.5 mL) blood

Processed Volume: 1.5 mL (Minimum: 0.8 mL) serum

Collection:	Routine venipuncture
Special Processing:	Lab Staff: Aseptically centrifuge specimen and separate serum from the clot within 6 hours. Serum aliquot should be placed in a screw-capped, round bottom plastic vial. Store and ship at frozen temperatures. Maintain sterility and forward promptly.
Patient Preparation:	None
Sample Rejection:	Specimens other than serum; warm specimens; lipemic specimens; icteric specimens; mislabeled or unlabeled specimens

Interpretive

Reference Range: Undetected

Interpretation:

The quantification range of this assay is 20 to 170,000,000 IU/mL (1.30-8.23 log IU/mL). An "Undetected" result indicates that hepatitis B virus (HBV) DNA was not detected in the specimen.

A "Detected" result with the comment, "HBV DNA level is <20 IU/mL (<1.30 log IU/mL). This assay cannot accurately quantify HBV DNA below this level" indicates that the HBV DNA level is below the lower limit of quantification for this assay. When clinically indicated, follow-up testing with this assay is recommended in 1 to 2 months.

A quantitative result expressed in IU/mL and log IU/mL indicates the degree of active HBV viral replication in the patient. Monitoring HBV DNA levels over time is important for assessing disease progression or monitoring a patient's response to anti-HBV therapy.

A "Detected" result with the comment, "HBV DNA level is >170,000,000 IU/mL (>8.23 log IU/mL). This assay cannot accurately quantify HBV DNA above this level" indicates that the HBV DNA level is above the upper limit of quantification for this assay.

An indeterminate result with the comment "Inconclusive Result: Submit a new specimen for testing if clinically indicated" indicates that inhibitory substances may be present in the specimen. When clinically indicated, collection and testing of a new specimen is recommended.

Critical Values: N/A

Limitations:

This test is not licensed by the FDA as a screening test for hepatitis B virus (HBV) infections or a diagnostic test to confirm the presence of HBV infection.

Laboratory evaluation of HBV infection status should begin with HBV serologic testing, including testing for the presence of hepatitis B surface antigen. A diagnosis of chronic HBV infection should not be based solely on the presence of detectable or quantifiable HBV DNA in a single serum specimen.

An "Undetected" HBV DNA test result in conjunction with a positive anti-HBV status does not exclude the possibility of a resolved HBV infection. When clinically indicated, patients should be retested for HBV DNA in 1 to 2 months, to distinguish between past/resolved HBV infection and chronic HBV infection with episodic viral replication.

Quantitative HBV DNA results generated by this assay may be more than 0.5 log IU/mL lower than those of the VERSANT HBV DNA 3.0 Assay (bDNA) among some clinical serum specimens.

Methodology:

Real-Time Polymerase Chain Reaction (PCR)

References:

[Mayo Medical Laboratories](#) December 2014

Updated:

4/29/2013: Method change, previously listed as bDNA, reference range change.