Lab Dept: Serology

Test Name: HEPATITIS B VIRUS DNA DETECTION AND QUANTIFICATION 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:	Detection and quantification of hepatitis B virus (HBV) DNA in serum of patients with chronic HBV infection (i.e., hepatitis B surface antigen-positive) Monitoring disease progression in chronic HBV infection Monitoring response to anti-HBV therapy
Lab Testing Sections:	Serology - Sendouts
Referred to:	Mayo Clinic Laboratories (Test: HBVQN)
Phone Numbers:	MIN Lab: 612-813-6280 STP Lab: 651-220-6550
Test Availability:	Daily, 24 hours
Turnaround Time:	1-3 days
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: Centrifuge specimen and separate serum from the clot within 2 hours. Serum aliquot should be placed in a screw-capped, round bottom plastic vial. Store and ship at frozen temperatures. Forward promptly. Specimen stable frozen (preferred) for 84 days, refrigerated for 6 days.
Patient Preparation:	None
Sample Rejection:	Specimens other than serum; hemolyzed specimens; mislabeled or unlabeled specimens

Interpretive

Reference Range:	Undetected Interpretation: The quantification range of this assay is 10 to 1,000,000,000 IU/mL (1.00 log to 9.00 log IU/mL). An "Undetected" result indicates that hepatitis B virus (HBV) DNA was not detected in the serum specimen. A result of "<10 IU/mL (<1.00 log IU/mL)" indicates that HBV DNA is detected, but the HBV DNA level present cannot be quantified accurately below this lower limit of quantification of 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 result of ">1,000,000,000 IU/mL (>9.00 log IU/mL)" indicates the presence of active HBV viral replication, and the HBV DNA level present cannot be quantified accurately above this upper limit of quantification of this assay. An “Inconclusive” result with the comment "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 Clinic Laboratories December 2024

Updated:

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

12/27/2024: Updated display name, Mayo test code, turnaround time, and interpretation. Added specimen stability.