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.