MAYO CLINIC LABORATORIES

Test Definition: HBVQN

Hepatitis B Virus (HBV) DNA Detection and Quantification by Real-Time PCR, Serum

Overview

Useful For

Detection and quantification of hepatitis B virus (HBV) DNA in serum of patients with chronic HBV infection (ie, hepatitis B surface antigen-positive)

Monitoring disease progression in chronic HBV infection

Monitoring response to anti-HBV therapy

Testing Algorithm

The following algorithms are available:
-Hepatitis B: Testing Algorithm for Screening, Diagnosis, and Management
-HBV Infection-Monitoring Before and After Liver Transplantation

Special Instructions

- HBV Infection-Monitoring Before and After Liver Transplantation
- Hepatitis B: Testing Algorithm for Screening, Diagnosis, and Management

Method Name

Real-Time Polymerase Chain Reaction (PCR)

NY State Available

Yes

Specimen

Specimen Type

Serum SST

Shipping Instructions

1. Ship specimen frozen on dry ice only.
2. If shipment will be delayed for more than 24 hours, freeze serum at -20 to -80 degrees C (up to 84 days) until shipment on dry ice.

Specimen Required

Supplies: Sarstedt Aliquot Tube, 5 mL (T914)
Collection Container/Tube: Serum gel
Submission Container/Tube: Plastic vial
Specimen Volume: 1.5 mL

Collection Instructions:
1. Centrifuge blood collection tube per collection tube manufacturer's instructions (eg, centrifuge within 2 hours of collection for BD Vacutainer tubes).
2. Aliquot serum into a plastic vial.

Forms
If not ordering electronically, complete, print, and send 1 of the following forms with the specimen:
-General Request (T239)
-Gastroenterology and Hepatology Test Request (T728)
-Microbiology Test Request (T244)
-Kidney Transplant Test Request

Specimen Minimum Volume
0.8 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	OK
Gross icterus	OK

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum SST	Frozen (preferred)	84 days	
	Refrigerated	6 days	

Clinical & Interpretive

Clinical Information
Diagnosis of acute or chronic hepatitis B virus (HBV) infection is based on the presence of HBV serologic markers such as hepatitis B surface antigen (HBsAg) and hepatitis B core IgM antibody (anti-HBc IgM), or the presence of HBV DNA detected by molecular assays. Although the diagnosis of acute and chronic HBV infection is usually made by serologic methods, the detection and quantification of HBV DNA in serum are useful to:
-Diagnose some cases of early acute HBV infection (before the appearance of HBsAg)
-Distinguish active from inactive HBV infection
-Monitor a patient's response to anti-HBV therapy

The presence of HBV DNA in serum is a reliable marker of active HBV replication. HBV DNA levels are detectable by 30 days following infection, generally reach a peak at the time of acute hepatitis, and gradually decrease and disappear when the infection resolves spontaneously. In cases of acute viral hepatitis with equivocal HBsAg test results, testing for HBV DNA in serum may be a useful adjunct in the diagnosis of acute HBV infection, since HBV DNA can be detected

approximately 21 days before HBsAg typically appears in the serum.

Patients with chronic HBV infection fail to clear the virus and remain HBsAg-positive. Such cases may be further classified as chronic active (replicative) HBV (high HBV levels, hepatitis Be antigen [HBeAg]-positive) or chronic inactive (nonreplicative) HBV (low or undetectable HBV DNA levels, HBeAg-negative). HBV DNA levels in serum are useful in determining the status of chronic HBV infection, by differentiating between active and inactive disease states. Patients with chronic active HBV are at greater risk for more serious liver disease and are more infectious than patients with inactive HBV infection. Reactivation of inactive chronic HBV infection (HBeAg-negative state) may occur with or without reappearance of HBeAg in serum. In patients with HBeAg-negative disease, detection of HBV DNA is the only reliable marker of active HBV replication.

The therapeutic goal of anti-HBV therapy in patients who are HBeAg-positive is to achieve long-term suppression of viral replication with undetectable HBV DNA, HBe seroconversion and loss of HBeAg. The therapeutic goal in patients with HBeAg-negative disease is typically long-term viral suppression. The emergence of drug-resistant HBV strains in response to treatment with nucleoside/nucleotide analogs (eg, lamivudine, adefovir, entecavir, tenofovir), is characterized by either the reappearance of HBV DNA in serum (after it had become undetectable) or an increase in HBV DNA levels (following an initial decline).

The following algorithms are available:
-Hepatitis B: Testing Algorithm for Screening, Diagnosis, and Management
-HBV Infection-Monitoring Before and After Liver Transplantation

Reference Values

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.

Cautions

This test is not licensed by the US Food and Drug Administration as a screening test for hepatitis B virus (HBV) infections.

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 antibody 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 and resolved HBV infection and chronic HBV infection with episodic viral replication.

Patient care providers are encouraged to use the same HBV DNA quantification assay for serial monitoring of HBV DNA levels in individual patient.

Clinical Reference

1. Bonino F, Piratvisuth T, Brunetto MR, Liaw YF. Diagnostic markers of chronic hepatitis B infection and disease. Antivir Ther. 2010;15 Supply 15:35-44
2. World Health Organization. Guidelines for the prevention, care and treatment of persons with chronic hepatitis B infection. World Health Organization; March 2015. Accessed January 29, 2025. Available at www.who.int/publications/i/item/9789241549059
3. Terrault NA, Bzowej NH, Chang KM, Hwang JP, Jonas MM, Murad MH. AASLD guidelines for treatment of chronic hepatitis B. Hepatology. 2016;63(1):261-283
4. World Health Organization: Guidelines on hepatitis B and C testing. World Health Organization; February 2017. Accessed January 29, 2025. Available at www.who.int/publications/i/item/9789241549981

Performance

Method Description

The cobas HBV is a US Food and Drug Administration-approved in vitro nucleic acid amplification test for the quantification of hepatitis B virus (HBV) DNA in human serum, using the using the cobas 5800/6800/8800 instruments for automated viral nucleic acid extraction (silica-based capture technique), purification, amplification, and detection of the viral nucleic acid target. This assay targets the highly conserved pre-Core/Core region of the HBV genome and generates amplification products that are detected real-time by a sequence-specific TaqMan probe during amplification. The probe contains a reporter fluorophore and a quencher dye that absorbs light emitted by the reporter. Cleavage of the probe physically separates the quencher from the reporter, enabling light emitted by the latter to be detected by a photomultiplier tube. Because amplification and detection are performed simultaneously, amplification products are measured during the exponential phase of DNA amplification regardless of the initial target concentration.(Package insert: cobas HBV-Quantitative nucleic acid test for use on the cobas 5800/6800/8800 Systems. Roche Molecular Systems, Inc.; Doc rev. 4.0, 02/2023)

PDF Report

No

Day(s) Performed
Monday through Saturday

Report Available
1 to 3 days

Specimen Retention Time
2 months

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Superior Drive

Fees & Codes

Fees
- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

Test Classification
This test has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information
87517

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
HBVQN	HBV DNA Detect/Quant, S	42595-9

Result ID	Test Result Name	Result LOINC® Value
65555	HBV DNA Detect/Quant, S	42595-9