MAYO CLINIC LABORATORIES

# Test Definition: HBNTP

Hepatitis B Surface Antigen Confirmation, Prenatal, Serum

## Overview

### Useful For

Diagnosis of acute, recent, or chronic hepatitis B infection in prenatal patients

This test is **not useful** during the "window period" of acute hepatitis B virus (HBV) infection (ie, after disappearance of HBsAg and prior to appearance of hepatitis B surface antibody).

This test is **not suitable** as stand-alone prenatal screening test of HBsAg status in pregnant women.

This test is **not offered** as a HBsAg screening or confirmatory test for blood donor specimens.

### Testing Algorithm

For information see Hepatitis B: Testing Algorithm for Screening, Diagnosis, and Management

### Special Instructions

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

### Method Name

Only orderable as a reflex. For more information see HBAGP / Hepatitis B Surface Antigen Prenatal, Serum.

Chemiluminescence Immunoassay (CIA)

### NY State Available

Yes

## Specimen

### Specimen Type

Serum SST

### Ordering Guidance

Postmortem, cadaver, and hemolyzed serum specimens should be tested only by assays that are US Food and Drug Administration-licensed for testing on such specimen sources. Order HBGCD / Hepatitis B Surface Antigen for Cadaveric or Hemolyzed Specimens, Serum.

Testing for acute HBV infection should also include HBIM / Hepatitis B Core Antibody, IgM, Serum.

## Specimen Required

Only orderable as a reflex. For more information see HBAGP / Hepatitis B Surface Antigen Prenatal, Serum.

**Collection Container/Tube:** Serum gel
**Submission Container/Tube:** Plastic vial
**Specimen Volume:** 2 mL
**Collection Instructions:**
1. Centrifuge blood collection tube per collection tube manufacturer's instructions (eg, centrifuge and aliquot within 2 hours of collection for BD Vacutainer tubes).
2. Aliquot serum into plastic vial.

## Specimen Minimum Volume

1.5 mL

## Reject Due To

| | |
|---|---|
| Gross hemolysis | Reject |
| Gross lipemia | Reject |
| Gross icterus | Reject |

## Specimen Stability Information

| Specimen Type | Temperature | Time | Special Container |
|---|---|---|---|
| Serum SST | Frozen (preferred) | 28 days | |
| | Refrigerated | 7 days | |
| | Ambient | 24 hours | |

## Clinical & Interpretive

### Clinical Information

Hepatitis B virus (HBV) is endemic throughout the world. The infection is spread primarily through percutaneous contact with infected blood products (eg, blood transfusion, sharing of needles by intravenous drug addicts). The virus is also found in various human body fluids, and it is known to be spread through oral and genital contact. HBV can be transmitted from mother to child during delivery through contact with blood and vaginal secretions, but it is not commonly transmitted transplacentally.

Hepatitis B surface antigen (HBsAg) is the first serologic marker appearing in the serum at 6 to 16 weeks following exposure to HBV. In acute infection, HBsAg usually disappears in 1 to 2 months after the onset of symptoms. Persistence of HBsAg for more than 6 months in duration indicates development of either a chronic carrier state or chronic HBV infection.

For information, see the following:
-Hepatitis B: Testing Algorithm for Screening, Diagnosis, and Management

-HBV Infection-Monitoring Before and After Liver Transplantation
-Viral Hepatitis Serologic Profiles

## Reference Values

Only orderable as a reflex. For more information see HBAGP / Hepatitis B Surface Antigen Prenatal, Serum.

Negative

## Interpretation

A reactive screen result (signal-to-cutoff ratio > or =1.00 but < or =100.0) confirmed as positive by a hepatitis B surface antigen (HBsAg) confirmatory test is indicative of acute or chronic hepatitis B virus (HBV) infection or chronic HBV carrier state.

Specimens with reactive screen results but negative (ie, not confirmed) HBsAg confirmatory test results are likely to contain cross-reactive antibodies from other infectious or immunologic disorders. Repeat testing at a later date is recommended if clinically indicated.

Confirmed presence of HBsAg is frequently associated with HBV replication and infectivity, especially when accompanied by presence of hepatitis B envelope (HBe) antigen and/or detectable HBV DNA.

For more information, see the following:
-Hepatitis B: Testing Algorithm for Screening, Diagnosis, and Management
-HBV Infection-Monitoring Before and After Liver Transplantation
-Viral Hepatitis Serologic Profiles

## Cautions

Positive hepatitis B surface antigen (HBsAg) test results should be reported by the healthcare provider to the State Department of Health, as required by law in some states.

Individuals, especially neonates and children, who recently received hepatitis B vaccination may have transient positive HBsAg test results because of the large dose of HBsAg used in the vaccine relative to the individual's body mass.

Performance characteristics have not been established for the following specimen characteristics:
-Grossly icteric (total bilirubin level of >20 mg/dL)
-Grossly lipemic (triolein level of >3000 mg/dL)
-Grossly hemolyzed (hemoglobin level of >500 mg/dL)
-Containing particulate matter
-Cadaveric specimens

## Clinical Reference

1. Bonino F, Piratvisuth T, Brunetto MR, Liaw YF: Diagnostic markers of chronic hepatitis B infection and disease. Antiviral Therapy. 2010;15(3):35-44. doi: 10.3851/IMP1622
2. Servoss JC, Friedman LS: Serologic and molecular diagnosis of hepatitis B virus. Clin Liver Dis. 2004 May;8(2):267-281. doi: 10.1016/j.cld.2004.02.001
3. Badur S, Akgun A: Diagnosis of hepatitis B infections and monitoring of treatment. J Clin Virol. 2001 Jun;21(3):229-237.

doi: 10.1016/s1386-6532(01)00147-0
4. LeFebre ML, U.S. Preventive Services Task Force: Screening for hepatitis B virus infection in nonpregnant adolescents and adults: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med. 2014 Jul 1;161(1):58-66. doi: 10.7326/M14-1018
5. Jackson K, Locarnini S, Gish R: Diagnostics of hepatitis B virus: Standard of care and investigational. Clin Liver Dis. 2018 Aug 22;12(1):5-11. doi: 10.1002/cld.729
6. Coffin CS, Zhou K, Terrault NA: New and old biomarkers for diagnosis and management of chronic hepatitis B virus infection. Gastroenterology. 2019 Jan;156(2):355-368. doi: 10.1053/j.gastro.2018.11.037
7. WHO Guidelines Development Group: WHO guidelines on hepatitis B and C testing. World Health Organization; 2017. Accessed September 9, 2022. Available at www.who.int/publications/i/item/9789241549981
8. Centers for Disease Control and Prevention: Testing and public health management of persons with chronic hepatitis B virus infection. CDC; Updated March 28, 2022. Accessed September 9, 2022. Available at www.cdc.gov/hepatitis/hbv/testingchronic.htm

## Performance

### Method Description

The VITROS hepatitis B surface antigen (HBsAg) confirmatory kit uses the principle of specific antibody neutralization to confirm the presence of HBsAg. The sample is tested twice: one aliquot is incubated with a neutralizing reagent containing high-titer anti-HBs (the confirmatory antibody); the second aliquot is incubated with a non-neutralizing control reagent (the sample diluent). The confirmatory antibody binds to HBsAg in the sample inhibiting its reaction in the VITROS HBsAg assay. This leads to a reduced result compared to that for the non-neutralized control sample.(Package insert: VITROS HBsAg Confirmation assay, Pub. No. GEM4201. Ortho-Clinical Diagnostics Inc; Version 13.1, 09/06/2019)

### PDF Report

No

### Day(s) Performed

Monday, Wednesday, Friday

### Report Available

2 to 4 days

### Specimen Retention Time

14 days

### Performing Laboratory Location

Rochester

## 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 Regional Manager. 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

87341

## LOINC® Information

| Test ID | Test Order Name | Order LOINC® Value |
|---|---|---|
| HBNTP | HBs Ag Confirmation Prenatal, S | 7905-3 |

| Result ID | Test Result Name | Result LOINC® Value |
|---|---|---|
| HBNTP | HBs Ag Confirmation Prenatal, S | 7905-3 |