Overview

Useful For
Diagnosis of recent or past hepatitis B infection

Determination of occult hepatitis B infection in otherwise healthy hepatitis B virus (HBV) carriers with negative test results for hepatitis B surface antigen, anti-hepatitis B surface, anti-hepatitis B core IgM, hepatitis Be antigen, and anti-HBe

This assay is **not useful** for differentiating among acute, chronic, and past or resolved hepatitis B infection

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

Special Instructions

- Viral Hepatitis Serologic Profiles

Method Name
Chemiluminescence Immunoassay (CIA)

NY State Available
Yes

Specimen

Specimen Type
Serum SST

Necessary Information
Date of collection is required.

Specimen Required
Collection Container/Tube: Serum gel

Submission Container/Tube: Plastic vial

Specimen Volume: 1 mL

Collection Instructions: Centrifuge and transfer serum from gel into a plastic vial within 24 hours of collection.

Forms
If not ordering electronically, complete, print, and send a Gastroenterology and Hepatology Client Test Request (T728) with the specimen.

Specimen Minimum Volume
0.4 mL

Reject Due To

<table>
<thead>
<tr>
<th>Gross hemolysis</th>
<th>Reject</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gross lipemia</td>
<td>Reject</td>
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</table>
Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
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<tbody>
<tr>
<td>Serum SST</td>
<td>Frozen (preferred)</td>
<td>30 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Refrigerated</td>
<td>7 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ambient</td>
<td>24 hours</td>
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Clinical and Interpretive

Clinical Information

Hepatitis B core antibodies (anti-HBc Ab) appear shortly after the onset of symptoms of hepatitis B infection and soon after the appearance of hepatitis B surface antigen (HBsAg). Initially, anti-HBc Ab consist almost entirely of the IgM class, followed by appearance of anti-HBc IgG, for which there is no commercial diagnostic assay.

The anti-HBc total antibodies test, which detects both IgM and IgG antibodies, and the test for anti-HBc IgM antibodies may be the only markers of a recent hepatitis B infection detectable in the "window period." The window period begins with the clearance of HBsAg and ends with the appearance of antibodies to hepatitis B surface antigen (anti-HBs Ab). Anti-HBc total Ab may be the only serologic marker remaining years after exposure to hepatitis B.

This assay is FDA-approved for in vitro diagnostic use and not for screening cell, tissue, and blood donors.

Reference Values

Negative

Interpretation depends on clinical setting.

See Viral Hepatitis Serologic Profiles in Special Instructions.

Interpretation

A positive result indicates acute, chronic, or past or resolved hepatitis B.

An inconclusive result suggests the presence of interfering substance in the patient’s serum specimen.

Positive anti-hepatitis B core (anti-HBc) total test results should be correlated with the presence of other hepatitis B virus serologic markers, elevated liver enzymes, clinical signs and symptoms, and a history of risk factors.

If clinically indicated, testing for HBIM / Hepatitis B Core Antibody, IgM, Serum is necessary to confirm an acute or recent infection.

Neonates (<1 month old) with positive anti-HBc total results from this assay should be tested for anti-HBc IgM (HBIM / Hepatitis B Core Antibody, IgM, Serum) to rule out possible maternal anti-HBc causing false-positive results. Repeat testing using this assay for anti-HBc total within 1 month is also recommended in these neonates.

Cautions

Performance characteristics have not been established for the following specimen characteristics:
Test Definition: HBC
 HBc Total Ab, S

- Grossly icteric (total bilirubin level of >20 mg/dL)
- Grossly lipemic (triolein level of >3,000 mg/dL)
- Grossly hemolyzed (hemoglobin level of >500 mg/dL)
- Containing particulate matter
- Cadaveric specimens
- Heat inactivated specimens

Clinical Reference

Performance

Method Description
The VITROS antihepatitis B core (anti-HBc) assay is a competitive immunoassay method based on the reaction of anti-HBc in the sample with hepatitis B core antigen (HBcAg)-coated wells. Unbound sample is removed by washing. Horseradish peroxidase (HRP)-labeled antibody conjugate (mouse monoclonal anti-HBc) is then allowed to react with the remaining exposed HBcAg on the well surface. Unbound conjugate is removed by washing.

The bound HRP conjugate is measured by a luminescent reaction. A reagent containing luminogenic substrates (a luminol derivative and a peracid salt) and an electron transfer agent are added to the wells. The HRP in the bound conjugate catalyzes the oxidation of the luminol derivative, producing light. The electron transfer agent increases the level and duration of the light produced. The light signals are read by the VITROS Immunodiagnostic System. The amount of HRP conjugate bound is indicative of the concentration of anti-HBc present in the sample. (Package insert: VITROS Anti-HBc Assay, Pub No GEM1211, version 13.1; Ortho-Clinical Diagnostics Inc, Rochester, NY 14626-5101, 09/2019)

PDF Report
No

Day(s) and Time(s) Test Performed
Monday through Saturday; Varies

Analytic Time
Same day/1 day

Maximum Laboratory Time
2 days

Specimen Retention Time
14 days
Performing Laboratory Location
Rochester

Fees and 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 or approved by the U.S. 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
86704

LOINC® Information

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<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
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<tbody>
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<td>Hbc Total Ab, S</td>
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<table>
<thead>
<tr>
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<tr>
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<td>Hbc Total Ab, S</td>
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