Overview

Useful For
Diagnosis of past exposure to hepatitis E virus

Testing Algorithm
See Hepatitis E: Testing Algorithm for Diagnosis and Management in Special Instructions.

Special Instructions
- Hepatitis E: Testing Algorithm for Diagnosis and Management

Method Name
Enzyme Immunoassay (EIA)-Screening Procedure

NY State Available
Yes

Specimen

Specimen Type
Serum SST

Specimen Required
Collection Container/Tube: Serum gel

Submission Container/Tube: Plastic vial

Specimen Volume: 0.5 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 plastic vial.

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

Specimen Minimum Volume
0.1 mL

Reject Due To

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

<table>
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<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></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Refrigerated</td>
<td>24 hours</td>
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Clinical and Interpretive

Clinical Information
Hepatitis E virus (HEV) causes an acute, usually self-limited infection. This small, non-enveloped RNA virus is from animal reservoir (e.g., hogs) to humans via the fecal-oral route. HEV is endemic in Southeast and Central Asia, with several outbreaks observed in the Middle East, northern and western parts of Africa, and Mexico. In developed countries, HEV infection occurs mainly in persons who have traveled to disease-endemic areas. Transmission of HEV may also occur parenterally, and direct person-to-person transmission is rare. Clinically severe cases occur in young to middle-aged adults. Unusually high mortality (approximately 20%) occurs in patients infected during the third trimester of pregnancy. Although there is no carrier state associated with HEV, immunocompromised patients may have prolonged periods (e.g., months) of viremia and virus shedding in the feces.

In immunocompetent patients, viremia and virus shedding in the feces occur in the preicteric phase, lasting up to 10 days into the clinical phase. After an incubation period ranging from 15 to 60 days, HEV-infected patients develop symptoms of hepatitis with appearance of anti-HEV IgM antibody in serum, followed by detectable anti-HEV IgG within a few days. Anti-HEV IgM may remain detectable up to 6 months after onset of symptoms, while anti-HEV IgG usually persists for many years after infection. Anti-HEV IgG is the serologic test of choice to determine past exposure to HEV.

Reference Values
Negative

Interpretation
Positive results indicate past or resolved hepatitis E infection.

Negative results indicate absence of previous exposure to hepatitis E virus (HEV).

Borderline results may be seen in: 1) acute or recent hepatitis E infection with rising level of anti-HEV IgG, or 2) cross-reactivity with nonspecific antibodies (i.e., false-positive results). Repeat testing of serum for anti-HEV IgG in 4 to 6 weeks is recommended to determine the definitive HEV infection status.

Cautions
A negative test result does not exclude the presence of recent hepatitis E infection (<2 month duration), especially in immunocompromised patients. Repeat testing for anti-hepatitis E virus (HEV) IgM and anti-HEV IgG in 1 to 2 months is necessary for diagnosis of recent hepatitis E.

Performance characteristics of this assay have not been established for serum specimens that are heat inactivated, icteric, lipemic, hemolyzed, or contain particulate matter.

Clinical Reference

Document generated September 12, 2020 at 9:18am CDT
Performance

Method Description

The Mikrogen recomWell HEV is a qualitative, in vitro test for the detection and identification of IgG antibodies specific against HEV in human serum. This assay is a screening test based on the principle of an indirect sandwich enzyme-linked immunosorbent assay (ELISA).

Highly purified recombinant hepatitis E virus (HEV)-ORF2 viral antigens (specific for HEV genotypes 1 and 3) are fixed to microplate wells. Diluted patient serum specimens are incubated in the wells, in which antibodies bind specifically to the HEV recombinant antigens coating the surface of the wells. Unbound antibodies are then washed away. Anti-human immunoglobulin antibodies (IgG), which are coupled to horseradish peroxidase are then added to the wells and incubated. Unbound conjugate antibodies are then washed away. Specifically bound antibodies are detected by a peroxidase-catalyzed color reaction. Intensity of the color as measured with a photometric analyzer is proportionate to the quantity of bound HEV IgG antibodies present in the serum specimen. (Package insert: recomWell HEV IgG/IgM kit, catalog no. 5004/5005, Mikrogen GmbH, Foster, Neuried, Germany, rev.12/2017)

PDF Report

No

Day(s) and Time(s) Test Performed

Wednesday, Friday; Varies

Analytic Time

1 day

Maximum Laboratory Time

7 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 was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

CPT Code Information
### LOINC® Information

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<td>HEV IgG Ab, S</td>
<td>49693-5</td>
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