MAYO CLINIC LABORATORIES

Test Definition: HEVML

Hepatitis E Virus IgM Antibody Confirmation, Serum

Overview

Useful For

Confirmation of reactive hepatitis E virus IgM antibody screening test results for the diagnosis of acute or recent (<6 months) hepatitis E infection

Testing Algorithm

For information see Hepatitis E: Diagnostic Testing Algorithm.

Special Instructions

- Hepatitis E: Diagnostic Testing Algorithm

Method Name

Line Immunoassay (LIA)

NY State Available

Yes

Specimen

Specimen Type

Serum SST

Necessary Information

Date of collection is required.

Specimen Required

Supplies: Sarstedt Aliquot Tube, 5 mL (T914)
Collection Container/Tube: Serum gel
Submission Container/Tube: Plastic vial
Specimen Volume: 0.5 mL Serum
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.

Forms

If not ordering electronically, complete, print, and send 1 of the following:
-Gastroenterology and Hepatology Test Request (T728)
-Infectious Disease Serology Test Request (T916)

-Microbiology Test Request (T244)

Specimen Minimum Volume

Serum: 0.2 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)		
	Refrigerated	7 days	

Clinical & Interpretive

Clinical Information

Hepatitis E virus (HEV) causes an acute, usually self-limited, infection. This small, non-enveloped RNA virus is from animal reservoirs (eg, hogs) and is transmitted 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 individuals who have traveled to disease-endemic areas. Transmission of HEV may also occur rarely from direct person-to-person contact or transfusion of blood or blood products. Clinically severe cases occur in young to middle-aged adults. Unusually high mortality (approximately 20%) occurs in women infected during the third trimester of pregnancy. Although there is no carrier state associated with HEV, patients who are immunocompromised may have prolonged periods (eg, months) of viremia and virus shedding in the stool.

In immunocompetent individuals, viremia and virus shedding in the stool occur in the pre-icteric phase, lasting up to 10 days into the clinical phase. After an incubation period ranging from 15 to 60 days, patients infected with HEV 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 IgM is the serologic marker of choice for diagnosis of acute HEV infection.

The positive predictive value of a given diagnostic laboratory test is dependent on the prevalence rate of the disease for which the test is being used. Screening tests for detection of diseases with low prevalence rates, such as acute hepatitis E, will have low positive predictive values (ie, relatively high rates of false-positive test results), despite having high specificity rates for such tests. Therefore, an HEV IgM antibody confirmatory test is helpful and necessary to determine the true infection status of patients with reactive HEV IgM antibody screening test results.

Reference Values
Negative

Interpretation
Positive results confirm the presence of acute or recent (in the preceding 6 months) hepatitis E infection.

Negative results indicate absence of acute or recent hepatitis E infection.

Indeterminate results may be seen in:
1. Acute hepatitis E infection with rising level of anti-hepatitis E virus (HEV) IgM
2. Recent hepatitis E infection with declining level of anti-HEV IgM
3. Acute hepatitis E infection due to HEV genotype 2 strains
4. Cross-reactivity with nonspecific antibodies (ie, false-positive results)
Repeat testing of serum for anti-HEV IgM and anti-HEV IgG in 4 to 6 weeks is recommended to determine the definitive HEV infection status.

Unreadable results indicate the presence of unusually strong, nonspecific reactivity of the assay strip background that obscures proper reading of the bands. Such findings are usually due to nonspecific binding of non-hepatitis E IgM antibodies in the patient's serum to the HEVM antigens present on the assay strip. Repeat testing with anti-HEV IgM screen and anti-HEV IgG in 4 to 6 weeks is recommended.

Cautions
A negative test result does not exclude the presence of recent hepatitis E infection, especially in patients who are immunocompromised. Repeat testing of serum for anti-hepatitis E virus (HEV) IgM in 2 weeks may be necessary for diagnosis of acute or recent hepatitis E infection.

A positive result does not always indicate the presence of active disease.

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

Clinical Reference
1. Aggarwal R. Diagnosis of hepatitis E. Nat Rev Gastroenterol Hepatol. 2013;10(1):24-33
2. Pas SD, Streefkerk RH, Pronk M, et al. Diagnostic performance of selected commercial HEV IgM and IgG ELISAs for immunocompromised and immunocompetent patients. J Clin Virol. 2013;58(4):629-634. doi:10.1016/j.jcv.2013.10.010
3. Webb GW, Dalton HR. Hepatitis E: an underestimated emerging threat. Ther Adv Infect Dis. 2019;6:2049936119837162. doi:10.1177/2049936119837162

Performance

Method Description
Highly purified recombinant hepatitis E virus (HEV) antigens (O2N, O2C, and O3 from genotypes 1 and 3, and O2M from

genotype 1) are fixed to nitrocellulose membrane test strips. The test strips are incubated with the diluted patient serum sample, allowing virus-specific human IgM antibodies to bind to the antigens present on the test strips. Unbound human antibodies are then washed away. In the second step, the strips are incubated with anti-human IgM antibodies coupled with horseradish peroxidase enzyme. Unbound conjugate antibodies are then washed away. Specifically bound human IgM antibodies are detected with a staining reaction catalyzed by the peroxidase. A dark band will appear on the strip at the corresponding point if a reaction has taken place.(Package insert: recomLine HEV IgG/IgM kit. Mikrogen Diagnostik; rev 10/2014)

PDF Report
No

Day(s) Performed
Every other Friday

Report Available
1 to 21 days

Specimen Retention Time
14 days

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

CPT Code Information
86790

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
HEVML	HEV IgM Ab Confirmation, S	14212-5

Result ID	Test Result Name	Result LOINC® Value

61903	HEV IgM Ab Confirmation, S	14212-5