MAYO CLINIC LABORATORIES

Test Definition: HEVM

HEV IgM Ab Screen, S

Overview

Useful For

Diagnosis of acute or recent (<6 months) hepatitis E infection

Testing Algorithm

If hepatitis E virus (HEV) IgM antibody screen is reactive or borderline, HEV IgM antibody confirmation will be performed.

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

Special Instructions

- Hepatitis E: Testing Algorithm for Diagnosis and Management

Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
HEVML	HEV IgM Ab Confirmation, S	Yes	No

Method Name

Enzyme Immunoassay (EIA)-Screening Procedure

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: 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.

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	Reject

Specimen Minimum Volume

0.1 mL

Specimen Stability Information

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

Clinical & Interpretive

Clinical Information

Hepatitis E virus (HEV) causes an acute, usually self-limited infection. This small, non-enveloped RNA virus is transmitted from animal reservoir (eg, 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 (eg, months) of viremia and virus shedding in the feces.

In immunocompetent patients, viremia and virus shedding in the feces 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, 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 IgM is the serologic marker of choice for diagnosis of acute HEV infection.

Reference Values

Negative

Interpretation

Positive results suggest 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. If clinical suspicion persists, submit new specimen for retesting in 1 to 2 weeks.

Borderline 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; or 3) cross-reactivity with nonspecific antibodies (ie, false-positive results).

Cautions

Despite having a high specificity rate, the positive predictive value of the hepatitis E virus (HEV) IgM antibody screening test may be low (ie, relatively high frequency of false-positive test results) due to low prevalence of acute hepatitis E in the patient population being screened. 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.

A negative test result does not exclude the presence of recent hepatitis E infection, especially in immunocompromised patients. Repeat testing of serum for anti-HEV IgM in 2 to 4 weeks may be necessary for diagnosis of acute in such patients.

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

1. Aggarwal R, Jameel S: Hepatitis E. Hepatology. 2011;54(6):2218-2226

2. Hoofnagle JH, Nelson KE, Purcell RH: Hepatitis E. New Engl J Med. 2012;367:1237-1244

3. Aggarwal R: Diagnosis of hepatitis E. Nat Rev Gastroenterol Hepatol. 2013;10:24-33

Performance

Method Description

The Mikrogen *recom*Well hepatitis E virus (HEV) is a qualitative, in vitro test for the detection and identification of IgM antibodies specifically 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 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 (IgM), 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 IgM antibodies present in the serum specimen.(Package insert: recomWell HEV IgG/IgM kit, MIKROGEN GmbH; rev 11/2019)

PDF Report

No

Specimen Retention Time

14 days

Performing Laboratory Location

Rochester

Fees & Codes

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 US Food and Drug Administration.

CPT Code Information

86790

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
HEVM	HEV IgM Ab Screen, S	14212-5

Result ID	Reporting Name	LOINC®
86212	HEV IgM Ab Screen, S	14212-5