

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

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum SST	Frozen (preferred)		
	Refrigerated	24 hours	

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 (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 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 (ie, 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

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 *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

86790

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
HEVG	HEV IgG Ab, S	49693-5

Result ID	Test Result Name	Result LOINC Value
86211	HEV IgG Ab, S	49693-5