

Overview

Useful For

Diagnosis of past exposure to hepatitis E virus

Testing Algorithm

For information see [Hepatitis E: Testing Algorithm for Diagnosis and Management](#).

Special Instructions

- [Hepatitis E: Testing Algorithm for Diagnosis and Management](#)

Method Name

Enzyme Immunoassay (EIA)

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

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 a 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

See Specimen Required

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 & Interpretive

Clinical Information

Hepatitis E virus (HEV) causes an acute, usually self-limited, infection. This small, nonenveloped RNA virus is transferred from an 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 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 acute or recent hepatitis E infection with rising level of anti-HEV IgG or 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: Diagnosis of hepatitis E. Nat Rev Gastroenterol Hepatol. 2013;10(1):24-33

2. Schemmerer M, Rauh C, Jilg W, Wenzel JJ. Time course of hepatitis E-specific antibodies in adults. J Viral Hepat. 2017;24(1):75-79. doi:10.1111/jvh.12621

3. European Association for the Study of the Liver. EASL Clinical Practice Guidelines on hepatitis E virus infection. J Hepatol. 2018;68(6):1256-1271. doi:10.1016/j.jhep.2018.03.005

4. Kar P, Karna R. A Review of the Diagnosis and Management of Hepatitis E. Curr Treat Options Infect Dis. 2020;12(3):310-320. doi:10.1007/s40506-020-00235-4

Performance

Method Description

This is a qualitative, in vitro test for the detection and identification of IgG antibodies specifically against to hepatitis E virus (HEV) in human serum. This assay is a screening test based on the principle of an indirect sandwich enzyme-linked immunosorbent assay.

Highly purified recombinant HEV-ORF2 viral antigens (specific for HEV genotypes 1 and 3) are fixed to microplate wells. Diluted patient serum samples 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.(Unpublished Mayo method)

PDF Report

No

Day(s) Performed

Wednesday, Friday

Report Available

1 to 7 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 |
|---------|-----------------|--------------------|
| HEVG | HEV IgG Ab, S | 49693-5 |

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