MAYO CLINIC LABORATORIES

# Test Definition: HEVM

Hepatitis E Virus IgM Antibody Screen with Reflex to Confirmation, Serum

## Overview

### Useful For

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

### Reflex Tests

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

### Testing Algorithm

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

For more 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 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 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 acute hepatitis E infection with rising level of anti-hepatitis E virus (HEV) IgM, recent hepatitis E infection with declining level of anti-HEV IgM, or 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(13):1237-1244
3. Aggarwal R. Diagnosis of hepatitis E. Nat Rev Gastroenterol Hepatol. 2013;10(1):24-33

## Performance

### Method Description
This is a qualitative, in vitro test for the detection and identification of IgM antibodies specifically against 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 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.(Unpublished Mayo method)

### PDF Report
No

### Day(s) Performed
Tuesday, Thursday

### 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 |
|---|---|---|
| HEVM | HEV IgM Ab Screen, S | 14212-5 |

| Result ID | Test Result Name | Result LOINC® Value |
|---|---|---|
| 86212 | HEV IgM Ab Screen, S | 14212-5 |