Hepatitis E Virus (HEV) Quantitative Real-time RT-PCR
Test Code: 3800

Clinical and Procedure

Clinical Utility
Diagnostic testing for Hepatitis E Virus (HEV) is important in patients for which other causes of acute hepatitis have been excluded, since HEV infection is clinically indistinguishable from other types of acute viral hepatitis. Diagnosis is based upon the detection of anti-HEV antibodies or detection of HEV nucleic acid; a combination of these two approaches is preferred particularly in acute cases of HEV infection. Detection of multiple HEV genotypes is clinically relevant since HEV genotypes 1, 2, 3 and 4 have all been implicated in human disease, and viral quantitation has a role in monitoring response to therapy.


Procedure
Extraction of nucleic acid from specimen, followed by reverse transcription of viral RNA, then amplification and detection of cDNA using real-time, quantitative PCR. An internal control is added to ensure the extraction was performed correctly and the PCR reaction was not inhibited. This test has not been cleared or approved for diagnostic use by the U.S. Food and Drug Administration.

Specificity
Detects all known genotypes (1 to 4) in one assay. The primers and probes used in this assay are specific and inclusive for all 4 known HEV genotype strains based on similarity search algorithms. Additionally, potential cross-reactivity was evaluated with various pathogens that could cause similar symptoms or pathogens related to HEV due to sequence identity.

Turnaround Time
Same day (within 8 - 12 hours from receipt of specimen), Monday through Saturday.

Specimen Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Order Code</th>
<th>CPT Code</th>
<th>NY Approved</th>
<th>Volume</th>
<th>Assay Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>fecal</td>
<td>3808</td>
<td>87798</td>
<td>Yes</td>
<td>Size of pea, or 2 mL liquid stool</td>
<td>Detected/Not Detected</td>
</tr>
<tr>
<td>plasma</td>
<td>3801</td>
<td>87799</td>
<td>Yes</td>
<td>2 mL (min. 0.5 mL)</td>
<td>430 IU/mL to 4.3x10e8 IU/mL</td>
</tr>
</tbody>
</table>

Special Instructions
- Collect and place in a sterile, screw top tube.
- Store frozen and ship on dry ice for overnight delivery.

- Collect 4-5 mL whole blood in EDTA or ACD tube.
- Avoid using gel separator tubes; samples collected in gel separator tubes have increased rate of PCR inhibition.
<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Order Code</th>
<th>CPT Code</th>
<th>NY Approved</th>
<th>Volume</th>
<th>Assay Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>serum</td>
<td>3810</td>
<td>87799</td>
<td>Yes</td>
<td>2 mL (min. 0.5 mL)</td>
<td>430 IU/mL to 4.3x10e8 IU/mL</td>
</tr>
</tbody>
</table>

**Specimen Information**

- Centrifuge and transfer 2 mL plasma to sterile, screw top tube.
- Can be shipped at ambient or frozen temperature Monday through Friday.
- Specimens shipped at ambient temperature must be received within 96 hrs. of collection.

**Special Instructions**

- Collect 4-5 mL whole blood in red top tube.
- Avoid using gel separator tubes; samples collected in gel separator tubes have increased rate of PCR inhibition.
- Centrifuge and transfer 2 mL serum to sterile, screw top tube.
- Can be shipped at ambient or frozen temperature Monday through Friday.
- Specimens shipped at ambient temperature must be received within 96 hrs. of collection.

430 IU/mL to 4.3x10e8 IU/mL

**Shipping**

Ship Monday through Friday. Friday shipments must be labeled for Saturday delivery. All specimens must be labeled with patient's name and collection date. A Viracor Eurofins test requisition form must accompany each specimen. Multiple tests can be run on one specimen. Ship specimens FedEx Priority Overnight® to: Viracor Eurofins, 1001 NW Technology Dr, Lee's Summit, MO 64086.

**Causes for Rejection**

Specimens beyond their acceptable length of time from collection as listed in the specimen handling, or specimen types other than those listed.

**Disclaimer**

Specimens are approved for testing in New York only when indicated in the Specimen Information field above. The CPT codes provided are based on Viracor Eurofins’ interpretation of the American Medical Association's Current Procedural Terminology (CPT) codes and are provided for informational purposes only. CPT coding is the sole responsibility of the billing party. Questions regarding coding should be addressed to your local Medicare carrier. Viracor Eurofins assumes no responsibility for billing errors due to reliance on the CPT codes illustrated in this material.

**References**


