Hepatitis C Virus (HCV) Quantitative Real-time RT-PCR
Test Code: 1200

Clinical and Procedure

Clinical Utility
Assessment of HCV-RNA levels in patients undergoing antiviral therapy provides important information for measuring treatment response, which may aid in response guided treatment. The package inserts for the FDA-approved protease inhibitor drugs, Incivek™ (telaprevir) and Victrelis™ (boceprevir), for the treatment of chronic HCV Genotype 1, recommend patients be monitored utilizing a quantitative Real-time RT-PCR assay with a limit of quantification (LOQ) of 25 IU/mL and a limit of detection (LOD) of 10-15 IU/mL.1,2 The HCV Quantitative, Real-time RT-PCR assay meets these HCV-RNA testing requirements with an LOQ of 12 IU/mL and a LOD of 12 IU/mL.

Procedure
Extraction of nucleic acid from specimen; reverse transcription of the target RNA to generate complementary DNA, and amplification of target complementary DNA. Detection of hepatitis C genotypes 1 through 6 using Real-time, quantitative PCR. An internal control is added to ensure the extraction was performed correctly and the PCR reaction was not inhibited. RealTime HCV is a product of Abbott Laboratories. It is FDA approved for in vitro diagnostic use.

Specificity
Detects all 6 HCV genotypes. The primers and probes used in this assay are specific for HCV.

Turnaround Time
Same day (within 8 - 12 hours from receipt of specimen), Tuesday 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>plasma</td>
<td>1201</td>
<td>87522</td>
<td>Yes</td>
<td>2 mL (min. 0.7 mL)</td>
<td>12 IU/mL to 1.0 x 10^8 IU/mL. HCV DNA detected below 10 IU/mL will be reported as &quot;&lt;10 IU/mL&quot;. Reported in 2 formats: IU/mL and Log10 IU/mL.</td>
</tr>
<tr>
<td>serum</td>
<td>1210</td>
<td>87522</td>
<td>Yes</td>
<td>2 mL (min. 0.7 mL)</td>
<td>12 IU/mL to 1.0 x 10^8 IU/mL. HCV DNA detected below 10 IU/mL will be reported as &quot;&lt;10 IU/mL&quot;. Reported in 2 formats: IU/mL and Log10 IU/mL.</td>
</tr>
</tbody>
</table>

Special Instructions
- Collect 4-5 mL whole blood in EDTA.
- Centrifuge within 6 hours of draw and transfer 2 mL plasma to a sterile, screw top tube.
- If the specimen was collected in PPT, the entire tube can be shipped frozen following centrifugation.
- If shipped ambient, separated plasma fraction must arrive within 24 hours of draw.

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Special Instructions
- Collect 4-5 mL whole blood in red-top.
- Centrifuge within 6 hours of draw and transfer 2 mL serum to a sterile, screw top tube.
- If the specimen was collected in SST, the entire tube can be shipped frozen following centrifugation.
- If shipped ambient, separated serum fraction must arrive within 24 hours of draw.
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.

PCR tests are performed pursuant to a license agreement with Roche Molecular Systems, Inc.

References
1. Incivek™ package insert. Cambridge, MA: Vertex Pharmaceuticals Incorporated; 2011
3. CDC: Division of Viral Hepatitis and National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention. [link]