# Hepatitis C RNA

<table>
<thead>
<tr>
<th>Test Description</th>
<th>Assay for the detection and quantitation of Hepatitis C virus (HCV) RNA in human serum and plasma.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Use</td>
<td>To aid in the diagnosis of hepatitis C infection following a repeatedly reactive HCV antibody ELISA screening test result. Or to establish baseline viral load, as well as to measure on-treatment, and post-treatment responses.</td>
</tr>
<tr>
<td>Test Department</td>
<td>Virology</td>
</tr>
<tr>
<td>Phone</td>
<td>(860) 920-6662</td>
</tr>
<tr>
<td>FAX</td>
<td>(860) 920-6661</td>
</tr>
<tr>
<td>Methodology</td>
<td>Aptima HCV Quant Dx assay is a nucleic acid amplification test that detects and quantitates HCV RNA, genotypes 1, 2, 3, 4, 5, and 6, over the range of 10 to 100,000,000 IU/mL.</td>
</tr>
<tr>
<td>Availability</td>
<td>Test is performed on request.</td>
</tr>
<tr>
<td>Specimen Requirements</td>
<td>2.5 mL serum, collected in serum tubes or Serum Separator Tubes, or plasma, collected in tubes containing EDTA or ACD anticoagulants or in Plasma Preparation Tubes.</td>
</tr>
<tr>
<td>Collection kit/container</td>
<td>Category B shipping box with cold pack</td>
</tr>
<tr>
<td>To obtain collection kit, refer to Collection Kit Ordering Information, Ph (860) 920-6674</td>
<td></td>
</tr>
<tr>
<td>Collection Instructions</td>
<td>Standard venipuncture technique</td>
</tr>
<tr>
<td>Specimen Handling &amp; Transport</td>
<td>Whole blood can be stored at 2°C to 30°C and must be centrifuged within 6 hours of collection. Centrifuged specimen can be stored in the primary collection tube at 2°C to 8°C for up to 5 days. Serum or plasma transferred to a secondary tube can be stored at 2°C to 8°C for up to 5 days, or at -20°C for up to 60 days. Transport to the laboratory with an ice pack coolant. Avoid temperature extremes.</td>
</tr>
<tr>
<td>Unacceptable Conditions</td>
<td>Unlabeled specimens</td>
</tr>
<tr>
<td>Specimens that have leaked or containers that have broken in transit</td>
<td></td>
</tr>
<tr>
<td>Specimens not handled, stored, or transported as described above</td>
<td></td>
</tr>
<tr>
<td>Requisition Form</td>
<td>Clinical Test Requisition</td>
</tr>
<tr>
<td>For Hepatitis C screening select: <strong>Hepatitis C Testing</strong></td>
<td></td>
</tr>
<tr>
<td>Required Information</td>
<td>Name and address of submitter (and/or Horizon profile #)</td>
</tr>
<tr>
<td>Patient name or identifier, town of residence (city, state, zip), date of birth</td>
<td></td>
</tr>
<tr>
<td>Specimen type or source, date collected, test requested</td>
<td></td>
</tr>
<tr>
<td>Please ensure patient name on the requisition matches that on the specimen.</td>
<td></td>
</tr>
<tr>
<td>Limitations</td>
<td>• Though rare, mutations within the highly conserved regions of the viral genome covered by the primers and/or probes in the Aptima HCV Quant Dx assay may result in failure to detect the virus.</td>
</tr>
<tr>
<td>Additional Comments</td>
<td>• Repeatedly reactive HCV antibody specimens are reflexed to Hepatitis C RNA testing when specimen volume is sufficient and specimen stability requirements are met.</td>
</tr>
<tr>
<td></td>
<td>• Detection of hepatitis C viral RNA is evidence of active HCV infection but does not differentiate between acute and chronic states of infection.</td>
</tr>
</tbody>
</table>

Revision: 8/11/21