Questions & Answers

Q. What is the Hepatitis C Virus RNA DetectR™ PLUS by TMA?
A. This is a qualitative (detected/not detected) assay by Transcription Mediated Amplification (TMA). TMA is a nucleic acid amplification method that relies on the enzymes reverse transcriptase and T7 RNA polymerase to make multiple RNA copies of an RNA or DNA template. Extremely small quantities of HCV RNA can be detected in clinical specimens.

Q. What is the sensitivity and specificity of this method?
A. The HCV RNA assay by TMA has an analytical sensitivity of >95% at 50 HCV genome copies/mL or 10 IU/ml, and a specificity of >99%. HCV RNA by TMA is intended for use in monitoring of hepatitis C virus infection. This test has not been cleared or evaluated by the FDA.

Q. What is the Clinical Utility?
A. After discontinuation of antiviral treatment a number of patients relapse. TMA monitoring of patients who receive antiviral therapy can improve end-of-treatment management and identify those with residual HCV RNA viremia who have the potential to relapse after therapy cessation. In a recent study, HCV RNA was detectable by TMA in end-of-treatment serum samples from 16 of 25 (64%) patients negative by RT-PCR, who later relapsed.

Ordering Information and Specimen Requirements

<table>
<thead>
<tr>
<th>Test Code</th>
<th>Test Name</th>
<th>Specimen Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>7516</td>
<td>HCV RNA DetectR™ PLUS by TMA</td>
<td>5 mL Plasma (EDTA or ACD). Freeze within 4 hours of collection; ship frozen on dry ice.</td>
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Specify “Send HCV RNA DetectR™ PLUS by TMA to Specialty Laboratories”
For immediate attention and sample pick-up, call 800-421-4449.

Related Tests

- 7486  Hepatitis C Virus RNA AccuQuant®
- 7576  Hepatitis C Virus RNA UltraQuant®
- 7473  Hepatitis C Virus SubtypR™
- 7518  Hepatitis C Virus RNA DetectR™ reflex to UltraQuant®
- 7578  Hepatitis C Virus RNA UltraQuant® reflex to SubtypR™

References


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