SPECIALTY LABORATORIES
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HCV RNA DetectR™ PLUS by TMA
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.[1] Extremely small quantities of HCV RNA can be detected in clinical specimens.[1]

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%.[2,3] 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.[4] 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.[2]

Ordering Information and Specimen Requirements

Test Code	Test Name	Specimen Requirements
7516	**HCV RNA DetectR™ PLUS by TMA**	5 mL Plasma (EDTA or ACD). Freeze within 4 hours of collection; ship frozen on dry ice.
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

1. Germer JJ, Zein NN. Advances in the molecular diagnosis of hepatitis C and their clinical implications. Mayo Clin Proc 2001;76:911-20.
2. Sarrazin C, Teuber G, Kokka R, et al. Detection of residual HCV RNA by TMA in patients with complete virologic response according to PCR-based assays. Hepatology 2000;32:818-23.
3. McDonough SH, Giachetti C, Yang Y, et al. High throughput assay for the simultaneous detection of HIV and HCV. Infusion Ther Transf Med 1998;25:164-9.
4. Sarrazin C, Hendricks DA, Sedarati F, Zeuzem S. Assessment, by transcription-mediated amplification, of virologic response in patients with chronic hepatitis C treated with peginterferon α-2a. J Clin Microbiol 2001;39:2850-5.

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