



HCV

HCV RNA by RT-PCR - Qual/Quant

GA Test Code	219TQ <i>Note: It is recommended that all patients be genotyped prior to initiating therapy. For reflex to genotyping, use GA Test Code #8698.</i>
Method	Reverse Transcription-Polymerase Chain Reaction (RT-PCR) with Viral Load Monitoring
Specimens	Serum (recommended): 2.0 ml (1.0 ml), separated within 4 hours. Store refrigerated and ship on ice pack within 24 hours. If longer storage is required, freeze and ship on dry ice (stable up to 2 months). Plasma - EDTA or ACD: 2.0 ml (1.0 ml), separated and frozen. Freshly drawn whole blood may be held at room temp for up to 6 hours or refrigerated for up to 24 hours, prior to centrifugation. After centrifugation, remove plasma from cells. Plasma specimens may be stored at room temp for up to 24 hours or refrigerated for up to 5 days. If longer storage is required, plasma specimens must be stored frozen. Ship specimen frozen on dry ice. Plasma - PPT: 2.0 ml (1.0 ml), centrifuged, room temp or refrigerated (<i>do not freeze in PPT</i>). PPT can be stored at room temp up to 48 hours or refrigerated up to 72 hours. If longer storage is required, transfer plasma to separate tube before freezing (stable up to 2 months). <i>Note: If patient is monitored for therapy, subsequent specimens must be of the same specimen type.</i>
Causes for Rejection	Quantity not sufficient (QNS) for analysis; plasma frozen in PPT; time and/or temperature instructions not followed as specified; blood collected in heparin.
Reference Range	50 to 10,000,000 HCV RNA IU/mL
Turnaround Time	24-72 hours
CPT Code	87522

Description

HCV RNA is measured by means of target specific amplification using Reverse Transcription-Polymerase Chain Reaction (RT-PCR) to generate amplified product from the specific HCV RNA sequences.

Clinical Utility

The HCV RNA assay is an excellent confirmatory assay for initial laboratory diagnosis of infection or an adjunctive assay for an indeterminate RIBA result. HCV RNA, the only direct marker of HCV infection, can be detected in serum or plasma within 1-2 weeks of exposure to the virus and weeks before detectable anti-HCV antibodies or ALT increase. Chronic HCV infection is diagnosed by the presence of HCV RNA in the blood for at least 6 months. The quantification of HCV RNA provides important information, such as baseline viral levels, Early Viral Response (EVR), End of Treatment Response (ETR), and Sustained Virological Response (SVR). The best indicator of effective treatment is SVR, defined as the absence of detectable HCV RNA (< 50 IU/mL) at 24 weeks after the end of treatment.

Podzorski RP. Molecular Testing in the Diagnosis and Management of Hepatitis C Virus Infection. *Arch. Pathol. Lab. Med.*, Vol 126 March 2002.

EASL International Consensus Conference on Hepatitis C. Paris, Feb. 26-28, 1999, Consensus Statement. *Journal of Hepatology*. 30, 956-961.