



HCV

Hepatitis C Virus by RT-PCR – Qualitative

GA Test Code	750
Method	Reverse Transcription-Polymerase Chain Reaction (RT-PCR) – Qualitative
Specimens	<p><u>Serum (recommended):</u> 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).</p> <p><u>Plasma - EDTA or ACD:</u> 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.</p> <p><u>Plasma - PPT:</u> 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).</p>
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	No HCV RNA Detected
Turnaround Time	24-72 hours
CPT Code	87521

Description

This assay uses real-time PCR detection of reverse transcribed HCV DNA amplicons using specific probes.

Clinical Utility

The HCV qualitative assay is useful in detecting the presence of HCV genomes prior to seroconversion or in the presence of indeterminate serologies and as a means of detecting chronic viral replication among seropositive individuals. 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. It is an excellent confirmatory assay for initial laboratory diagnosis of infection or an adjunctive assay for an indeterminate RIBA result. The qualitative HCV RNA assay should be performed to aid in confirming initial diagnosis and used to help monitor patients under treatment when the HCV RNA quantitative assay drops below 1000 IU per mL.

Alter HJ, Baine WB, Alter MJ, *et al.* Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-related Chronic Disease. CDC MMWR. Oct. 1998; 47(RR19):1-39.

Powell DW, *et al.* Consensus Statements: Management of Hepatitis C, National Institute of Health Consensus Development Conference Statement. 1997 March 24-26; 15(3):1-41.