GENETIC ASSAYS
A Molecular Diagnostics Laboratory

HCV HCV RNA by TMA - Quantitative

GA Test Code	**219TQ** *Note: It is recommended that all patients be genotyped prior to initiating therapy. For reflex to genotyping, use GA Test Code* ***#8698****.*
Method	***FDA-approved*** Hologic Aptima® HCV Quant Dx assay, using real-time transcription-mediated amplification (TMA)
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 *(do not freeze in PPT)*. 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). *Note: If patient is monitored for therapy, subsequent specimens must be of the same specimen type.*
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	Not Detected (< 4 IU/mL)
Quantitative Range	10 to 100,000,000 HCV RNA IU/mL
Turnaround Time	24-72 hours
CPT Code	87522

Description

The ***FDA-approved*** Hologic Aptima® HCV Quant Dx assay is a real-time transcription-mediated amplification (TMA) test used for both detection and quantitation of hepatitis C virus (HCV) RNA in fresh and frozen human serum and plasma from HCV-infected individuals. Specimens containing HCV genotypes 1 to 6 are validated for detection and quantitation in the assay.
The detection limit and linear range of this assay is 10 to 100,000,000 International Units per mL (IU/mL). A "No HCV RNA Detected" result indicates that a detectable amount of HCV was not present in the submitted sample and does not rule out HCV infection.

Clinical Utility

This test is used together with other laboratory results and clinical information to evaluate the treatment of an individual infected with the hepatitis C virus. Test results help predict an individual's response to treatment and aid in the management of patients with HCV infection undergoing anti-viral therapy.