



# HCV

## HCV RNA by RT-PCR - Qual/Quant

<b>GA Test Code</b>	<b>219TQ</b> <i>Note: It is recommended that all patients be genotyped prior to initiating therapy. For reflex to genotyping, use GA Test Code #8698.</i>
<b>Method</b>	<b>FDA-Cleared</b> , Reverse Transcription-Polymerase Chain Reaction (RT-PCR) with Viral Load Monitoring
<b>Specimens</b>	<b>Serum (recommended):</b> 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). <b>Plasma - EDTA or ACD:</b> 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. <b>Plasma - PPT:</b> 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>
<b>Causes for Rejection</b>	Quantity not sufficient (QNS) for analysis; plasma frozen in PPT; time and/or temperature instructions not followed as specified; blood collected in heparin.
<b>Reference Range</b>	No HCV RNA Detected
<b>Limit of Detection</b>	12 HCV RNA IU/mL
<b>Limit of Quantitation</b>	12 to 100,000,000 HCV RNA IU/mL
<b>Turnaround Time</b>	24-72 hours
<b>CPT Code</b>	87522

### **Description**

The **FDA-cleared** Abbott RealTime HCV assay is an in vitro reverse transcription-polymerase chain reaction (RT-PCR) assay for the quantitation of hepatitis C viral ribonucleic acid (HCV RNA) in human serum and plasma from HCV-infected individuals. The detection limit and the linear range of this assay is 12 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.

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.

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