Lab Dept: Microbiology/Virology

Test Name: HEPATITIS C (HCV) RNA QUANTITATIVE PCR

General Information

Lab Order Codes:	HCVRQ
Synonyms:	Hepatitis C Viral Load; Hepatitis C RNA Quantification; HCV (RT-PCR) Quantitative
CPT Codes:	87522 – Hepatitis C quantification
Test Includes:	Quantification of HCV RNA.

Logistics

Test Indications:	Detection of acute HCV infection before the appearance of HCV antibodies in serum (ie, <2 months from exposure). Detection and confirmation of chronic HCV infection. Quantification of HCV RNA in serum of patients with chronic HCV infection (HCV antibody-positive). Monitoring disease progression in chronic HCV infection and /or response to anti-HCV therapy.
Lab Testing Sections:	Microbiology/Virology - Sendouts
Referred to:	Mayo Medical Laboratories (MML Test: HCVQN)
Phone Numbers:	MIN Lab: 612-813-6280 STP Lab: 651-220-6550
Test Availability:	Daily, 24 hours
Turnaround Time:	1-3 days, test performed Monday-Saturday
Special Instructions:	This test is intended to be used to monitor known HCV-positive infections. It is not intended for primary detection of HCV infections.

Specimen

Specimen Type:	Blood
Container:	SST (Gold, marble or red) tube
Draw Volume:	4.5 mL (Minimum: 2.4 mL) blood
Processed Volume:	1.5 mL (Minimum: 0.8 mL) serum

Collection:	Routine blood collection
Special Processing:	Lab Staff: Aseptically centrifuge specimen within 2 hours of collection, remove serum aliquot into a screw-capped, round-bottom, plastic vial. Store and ship at frozen temperatures. Forward promptly.
Patient Preparation:	None
Sample Rejection:	Specimens other than serum; mislabeled or unlabeled specimens

Interpretive

Reference Range:	Undetected
	Interpretation: An “Undetected” result indicates that HCV is absent in the patient’s serum specimen.
	A result of <15 IU/mL (<1.18.log IU/mL) indicates that HCV RNA is detected, but the HCV RNA level present cannot be quantified accurately below this lower limit of quantification of this assay. When clinically indicated, follow-up testing with this assay is recommended in 1 to 2 months. To assess response-guided therapy eligibility, an “Undetected” result is required, and a result of “<15 IU/mL (<1.18 log IU/mL) should not be considered equivalent to an “Undetected” result.
	A quantitative result expressed in IU/mL and log IU/mL indicates the degree of active HCV viral replication in the patient. Monitoring HCV RNA levels over time is important to assess disease progression and /or monitoring a patient’s response to anti-HCV therapy.
	A result of “>100,000,000 IU/mL (>8.00 log IU/mL)” indicates the presence of active HCV viral replication, and the HCV RNA level present cannot be quantified accurately above this upper limit of quantification of this assay.
	An “Inconclusive” result. Submit a new specimen for testing if clinically indicated indicates that inhibitory substance(s) is/are present in the serum specimen tested. When clinically indicated, collection of a new serum specimen for retesting is recommended.
Critical Values:	None

Limitations:	The quantification range of this assay is 15 to 100,000,000 IU/mL (1.18 log to 8.00 log IU/mL) Except for immunocompromised patients or patients with suspected acute hepatitis, laboratory evaluation of hepatitis C (HCV) infection status should begin with HCV serologic testing, including testing for the presence of HCV antibodies. A diagnosis of chronic HCV infection should not be based solely on the presence of detectable or quantifiable HCV RNA in a single serum specimen. An “Undetected” HCV RNA test result with a “Reactive” HCV antibody screen result may be due to 1) a false-reactive HCV antibody screen result; 2) resolved or past HCV infection; or 3) transient low viremia (ie, episodic viral replication) of active HCV infection. To distinguish between the first 2 conditions, another HCV antibody test can be requested. To distinguish between the latter 2 conditions, patients should be retested for HCV RNA in 1 to 2 months, as clinically indicated.
Methodology:	Real-Time Reverse PCR (RT-PCR
References:	Mayo Medical Laboratories Web Page January 2018
Updates:	11/9/2009: Specimen volume increase due to assay change at MML. 11/4/2013: Method update to FDA approved version and lower detection limit, volume requirement decrease. 1/31/2018: Processing update.