

Test Menu

TOPIC	DESCRIPTION
Test Name	HCV RNA NAAT
Other Name (s)	Hepatitis C RNA NAAT
Analyte(s)	Hepatitis C RNA
Test Code	0390
Lab location	Jacksonville and Miami location
Department	Serology
Pre-Approval Required	None
Additional Required Forms	None
Specimen Source	Serum or plasma
Special Specimen Preparation	Whole blood can be stored at 2°C to 30°C and must be centrifuged within 6 hours of specimen collection. Separate the plasma or serum from the pelleted red blood cells following the manufacturer's instructions for the tube used.
Minimum Volume	2 ml serum or plasma
Storage Conditions	Serum may be stored in primary collection tube or secondary at 2-8C up to 5 days or at -20C for up to 60 days from collection date. Whole blood can be stored at 2°C to 30°C and must be centrifuged within 6 hours of specimen collection. Storage: RT 1 day, 2-8 ≤5 days, -20C or colder ≤60 days
Collection Media	Serum (tiger or yellow top SST) preferred
Specimen Labeling	Specimen must be labeled with at least two unique patient identifiers, Ex: Name and DOB. Electronic lab order preferred, HMS, Etc. Information on the specimen must match the requisition.
Packaging and Shipping Instructions and Handling	Ship in a cooler with ice packs at 2-8C to be received no more than 6 days from collection date. If it will be more than 4 days before the specimen reaches the laboratory, ship on dry ice at -20C or less.
Test Methodology	Real-time transcription-mediated amplification (TMA)
Turnaround Time	N/A
Result Indicator	Qualitative: Positive or Negative. Viral load: If positive, reported in Log10 IU/mL and IU/mL. If negative, reported as Not Detected. Invalid result if error in generation of the result. Submit new specimen and order Test 0390.
Unsatisfactory Specimen	Specimens not shipped or stored within specifications
Interferences and Limitations	<ol style="list-style-type: none"> 1. Avoid cross-contamination during sample handling steps. 2. <i>Low volume specimens that are diluted with Sample Diluent (in order to reach minimum test volume) can be tested using the 1:3 option. A diagnostic interpretation should not be made from a "Not Detected" result for serum or plasma specimens that have been diluted. Obtain a new, undiluted specimen and retest.</i> 3. Though rare, mutations within the highly conserved regions of the viral genome covered by the primers and/or probes in the Aptima HCV Quant Dx assay may result in failure to detect the virus.
Additional Information & Notes	<p>For Test 0380 Chronic Panel, HCVAb reactive results are automatically reflexed to HCV RNA NAAT. <u>May also be ordered as a stand-alone test, for example to confirm a rapid test result.</u></p> <p>HCV RNA Concentration: Negative Log10 Not Detected IU/mL Not Detected HCV RNA not detected by Rt-TMA (NAAT).</p> <p>RNA Concentration: Positive Log10 <1.00 IU/mL <10 HCV RNA detected by Rt-TMA (NAAT), below the Lower Limit of Quantification (LLoQ) of the assay. HCV RNA concentration less than 10 IU/mL (<1.00 Log10 IU/mL).</p> <p>RNA Concentration: Positive Log 10 (1.00 - 1.40) IU/mL (10 – 25) HCV RNA detected and quantified by Rt-TMA (NAAT). HCV RNA concentration is within the linear range of 10 to 25 IU/mL (1.00 to 1.40 Log10 IU/mL).</p> <p>RNA Concentration: Positive Log10 (1.40 - 8.00) IU/mL (25 – 100,000,000) HCV RNA detected and quantified by Rt-TMA (NAAT). HCV RNA concentration is within the linear range of 25 to 100,000,000 IU/mL (1.40 to 8.00 Log10 IU/mL). Current HCV infection.</p> <p>RNA Concentration: Positive Log10 (>8.00) IU/mL (>100,000,000) HCV RNA is detected above the Upper Limit of Quantification (uLoQ). Current HCV infection.</p> <p>RNA Concentration: Invalid. Specimen should be recollected and order Test 0390.</p>
Reference Range	Not Detected
Reference Lab	None
Reflex testing	None