

SPECIMEN SUBMISSION GUIDELINES

HIV Diagnostics and Reference Laboratory, Diagnostics and Countermeasures Branch
Center for Infectious Disease Research, Walter Reed Army Institute of Research
508 Research Drive, Silver Spring, MD 20910

HCV RNA Qualitative Assay (APTIMA) Test Specification

Test Name: APTIMA HCV RNA Qualitative Assay				
Clinical Significance	Specimen Requirements	Transport/Storage Temperature	Test Approved For	Turn Around Time (After Receipt at HDRL)
<p>In vitro nucleic acid assay system for detection of HCV in human plasma.</p> <p>Intended for use as an aid in diagnosis of HCV infection, including acute or primary infection.</p> <p>Is used as a confirmatory test to confirm HCV infection in an individual whose specimen is repeatedly reactive for HCV antibodies.</p> <p>Qualitative HCV RNA testing may be used for identifying the endpoint of infection following antiviral treatment.</p> <p>Test employed: FDA-approved, commercially available test kit: Gen-Probe Aptima HCV RNA Qualitative Assay.</p> <p>Reference Range: Not Detected</p>	<p>Minimum of 3 ml plasma (frozen) or serum</p> <p>Centrifuge at room temperature according to tube manufacturer guidelines within separation times below:</p> <p>PPT Tubes: Centrifuge immediately or within 2 hours of collection at 1100 x g for 10 minutes minimum.</p> <p>EDTA Plasma: Store blood at 25°C until centrifuged. Centrifuge at 1300 x g for 10 minutes within 24 hours of blood collection. Ship frozen if transport longer than overnight delivery.</p> <p>Serum Tubes: Allow blood to clot in upright position for 30-60 minutes before centrifugation. If transferring to secondary tube, indicate "serum" on plastic screw-cap tube for transport.</p>	<p>Ship frozen (-20° or colder) if transport longer than same day or overnight delivery.</p> <p>Store refrigerated (2-8°C) for same day or overnight delivery. If transport longer than overnight, aliquot plasma, freeze at -70°C, then ship frozen on dry ice. Store plasma frozen (-70° or colder).</p> <p>Use 2+ lbs. dry ice per day of transport.</p> <p>Recommended: Ship on 6 lbs. dry ice in case of shipment delay.</p>	<p>FDA approved for molecular diagnosis of acute and primary HCV</p> <p>Not intended for use in screening blood or plasma donors</p>	<p>5 business days</p>

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