

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 Viral Load (COBAS AmpliPrep/COBAS TaqMan) Test Specification

Test Name: HCV RNA Real-Time PCR (Viral Load)				
Clinical Significance	Specimen Requirements	Transport/Storage Temperature	Test Approved For	Turn Around Time (After Receipt at HDRL)
<p>In vitro nucleic acid amplification test for quantitation of RNA from patients infected with HCV (Genotype 1-6).</p> <p>Intended for use in conjunction with clinical presentation and other laboratory markers.</p> <p>Test employed: FDA-approved, commercially available test kits: Roche COBAS AmpliPrep/ COBAS TaqMan HCV Test; analytical measurement range: 15-100,000,000 IU/ml</p>	<p>EDTA (lavender top) Plasma only, minimum volume of 3 ml</p> <p>Centrifuge at room temperature at 800-1600 x g for 20 minutes within 4 hours of blood collection.</p> <p>Store refrigerated (2-8°C) for overnight or same day delivery.</p>	<p>Ship frozen if transport will take longer than same day or overnight.</p> <p>EDTA Plasma: Store plasma frozen (-70°C or colder).</p> <p>When shipping frozen, 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 patient management.</p>	<p>5 business days</p>

Shipping Address: 9100 Brookville Road, BLDG 508, Silver Spring, MD 20910
• Tel: 301-319-3123 • Fax: 301-319-3502