

## 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

### *HIV-1 Viral Load (COBAS AmpliPrep/COBAS TaqMan) Test Specification*

<b>Test Name: HIV-1 RNA Real-Time PCR (Viral Load)</b>				
<b>Clinical Significance</b>	<b>Specimen Requirements</b>	<b>Transport/Storage Temperature</b>	<b>Test Approved For</b>	<b>Turn Around Time (After Receipt at HDRL)</b>
<p>In vitro nucleic acid amplification test for quantitation of RNA from patients infected with HIV-1 (Group M, subtypes A-H).</p> <p>Intended for use in conjunction with clinical presentation and other laboratory markers.</p> <p>Test employed: FDA-approved, commercially available test kit from Roche: COBAS AmpliPrep/ COBAS TaqMan HIV-1 Test; analytical measurement range: 20-10,000,000 copies/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 (NOT for diagnostic use)</p>	<p>5 business days</p>

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