

## 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 RNA Qualitative Assay (APTIMA) Test Specification*

<b>Test Name: APTIMA HIV-1 RNA Qualitative Assay</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 assay system for detection of HIV-1 in human plasma.</p> <p>Intended for use as an aid in diagnosis of HIV-1 infection, including acute or primary infection.</p> <p>Presence of HIV-1 RNA in the plasma of patients without antibodies to HIV-1 is indicative of acute or primary HIV-1 infection.</p> <p>May also be used as an additional test, when it is reactive, to confirm HIV-1 infection in an individual whose specimen is repeatedly reactive for HIV-1 antibodies.</p> <p>Test employed: FDA-approved, commercially available test kit: Gen-Probe Aptima HIV-1 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 4 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 HIV-1</p> <p>Not intended for use in screening blood or plasma donors</p>	<p>5 business days</p>

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