

## 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

### *Hologic Panther HIV-1 Quant Dx Test Specifications in Serum*

Test Name: HIV-1 Panther Quant Dx (Qualitative/Quantitative)				
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 qualitative detection and quantification of RNA from patients infected with HIV 1 (Group M, N and O).</p> <p>To aid in the diagnosis of acute and primary HIV-1. Specifically, qualitative detection of HIV-1 RNA in serum in individuals without antibodies to HIV-1</p> <p>As a supplemental test for confirmation of HIV-1 infection in specimens repeat reactive by U.S. Food and Drug Administration approved HIV immunoassays</p> <p>Test employed: commercially available test kit from Hologic: Panther HIV-1 Quant Dx Assay.</p> <p>Analytical measurement range: 30 to 10,000,000 copies/ml</p> <p><b>Reference Range:</b> Not Detected</p>	<p><b>Quantitative Testing:</b></p> <ul style="list-style-type: none"> <li>3mL of Serum</li> </ul> <p><b>Qualitative Testing:</b></p> <ul style="list-style-type: none"> <li>3 mL of Serum</li> </ul> <p><b>Serum Tubes (SST):</b> 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><b>Serum:</b> Store serum refrigerated (2-8°C) for overnight or same day delivery.</p> <p>Ship frozen if transport will take longer than same day or overnight. Store serum frozen (-70°C or colder).</p> <p>When shipping frozen, use 2+ lbs. dry ice per day of transport.</p> <p>Ship on 6 lbs. of additional dry ice in case of shipment delay.</p>	<p><b>Qualitative Testing: Serum:</b></p> <p>This test is FDA-approved for patient management.</p>	5 business days
			<p><b>Quantitative Testing: Serum:</b></p> <p><b>Contact Laboratory</b> Quantitative test using serum matrix requires Laboratory Director Approval.</p> <p>This test was developed, and its performance characteristics validated by the HIV Diagnostics and Reference Laboratory.</p> <p>The test has not been cleared or approved by the U.S. FDA for serum samples. HDRL is certified under the Clinical Laboratory Improvement Program, Department of Defense Instruction 6440.02 07 May 2024; HDRL meets the requirements to perform high complexity tests.</p>	

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