

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

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 infection; specifically, qualitative detection of HIV-1 RNA in serum or plasma 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. Analytical measurement range: 30 to 10,000,000 copies/ml</p> <p>Reference Range: Not Detected</p>	<p>Quantitative Testing:</p> <ul style="list-style-type: none"> • 3mL of Plasma <p>Qualitative Testing:</p> <ul style="list-style-type: none"> • 3 mL of Plasma <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.</p>	<p>EDTA / PPT:</p> <p>Store plasma 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>Store plasma 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>FDA approved for patient management:</p> <p>Quantitative Testing in Plasma</p> <p>Qualitative Testing in Plasma</p>	5 business days

Shipping Address: 508 Research Drive, Silver Spring, MD 20910

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