

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 – Cerebral Spinal Fluid (CSF)

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 HIV Associated Neurocognitive Disorder in conjunction with clinical presentation and other laboratory parameters of disease progression for the clinical management of HIV infected patients.</p> <p>Test employed: Panther HIV-1 Quant Dx Assay. Commercially available test kit from Hologic.</p> <p>Analytical measurement range: 30 to 10,000,000 copies/ml</p> <p>Reference Range: Not Detected</p>	<p>Collect 2 mL CSF in a sterile screw-capped container.</p> <p>Ship CSF frozen.</p> <p>Specimen Stability</p> <ul style="list-style-type: none"> • Room temperature: 24 hours • Refrigerated: 6 days • Frozen: 42 days 	<p>Sterile leak-proof container</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>This laboratory developed test was developed and its performance characteristics validated by the HIV Diagnostics and Reference Laboratory.</p> <p>This test has not been cleared or approved by the U.S. FDA for CSF samples. HDRL is certified under the Clinical Laboratory Improvement Program, Department of Defense Instruction 6440.02 07 May 2024</p> <p>HDRL meets the requirements to perform high complexity tests.</p>	<p>5 business days</p>

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