

VERSANT[®] HIV-1
Technical Sheet

University of Florida (By Siemens HIV RNA 3.0)

Test Mnemonic:	HIV-1
Test Order Number	N/A
Sample types:	Blood, serum/ plasma
Collect:	<p>Collect blood in sterile tubes containing EDTA, or (lavender) Plasma Preparation Tubes (PPT). The whole blood can be stored at room temperature (18° to 30°C) for up to 4 hours or according to collection tube manufacturer's instructions. Do not refrigerate.</p> <p>Remove plasma from cells within 4 hours of collection. Separate by centrifugation at 1000 x g for 10 to 15 minutes. Do not clarify plasma by filtration or further centrifugation. Samples collected in K2 PPT tubes should be frozen immediately after centrifugation or held at room temperature for up to 24 hours after centrifugation. Do not store tubes at 2° to 8°C after centrifugation prior to freezing. EDTA plasma may be stored at 2° to 8 °C for up to 48 hours before freezing at -60° to -80°C. Plasma may also be frozen at -20°C in a non-frost free freezer for up to 72 hours if a -60° to -80°C freezer is not available. Up to 3 freeze/thaw cycles of samples are acceptable. Handle all specimens as if capable of transmitting infection.</p>
Transport:	Ship 3 mL serum or plasma (minimum 1.5 mL) frozen on dry ice. Package and label in compliance with federal and international regulations covering the transport of clinical samples and etiological agents.
Unacceptable Conditions:	Specimen not frozen; heparinized plasma; PPT not centrifuged.
Methodology:	Seimens HIV-1 RNA 3.0 bDNA
Performed:	N/A
In house turn-around time:	5 business days
Reference Interval:	The dynamic range of this assay is 75 (1.9 log ₁₀ copies /mL) to 500,000 (5.7 log ₁₀ copies/mL).
Reference values:	<75 copies/ mL
Note:	The performance characteristics of this test are validated by the University of Florida, Diagnostic Reference Laboratories (UF DRL).The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions. The test is approved by the U.S. Food and Drug Administration (FDA). High-complexity testing of HIV-1 RNA 3.0 by UF DRL is authorized by CLIA as well as both state and federal licensure and certification.
CPT Code(s):	87536
Applications:	This test is intended for use in conjunction with the clinical evaluation and other laboratory markers as an indicator of disease prognosis and as a monitor of the efficacy of antiretroviral therapy.

Sensitivity & Specificity:

97.6% of clinical specificity;

Clinical sensitivity:

CD4+ Category (cells/mm ³)	N	% with Results > LoQ (75 HIV-1 RNA Copies/mL)	95% Lower Confidence Level	95% Upper Confidence Level
CD4+ < 200	302	98.7%	96.7%	99.6%
CD4+ 200-500	371	88.4%	83.2%	94.7%
CD4+ > 500	311	65.3%	59.7%	70.6%

The University of Florida Diagnostic Reference Laboratories maintains both state and federal licensure and certification.