



Aptima[®] HIV-1 Quant DX Assay

Excellent precision and sensitivity for HIV-1 viral load monitoring.

Reliable quantitation. Deliver reliable, repeatable results with a robust test that accurately detects and monitors HIV-1.

Excellent sensitivity and high precision¹

Performance

LoD	12 copies/mL (3rd WHO International Standard)
LLoQ	30 copies/mL (Reaction volume: 0.5 mL plasma)
Linear range	30 copies/mL to 10 million copies/mL (3rd WHO International Standard)
Accuracy	External quality assessment panels used to verify accuracy across known standards—AcroMetrix, Qnostics, SeraCare, CAP, QCMD

Mean concentration (Log copies/mL)	SD Total	CV% Total
1.80	0.16	9.10
2.37	0.17	7.34
2.47 [†]	0.15	6.15
2.95	0.15	5.20
3.80	0.10	2.53
4.93	0.08	1.56
5.69	0.09	1.58
6.71	0.08	1.13



Assay precision provides confidence that increases in viral load are due to clinical changes with the patient, versus assay variation.²

Demand more from your HIV-1 assay

Product design			
Intended use	Diagnosis of primary HIV-1 infection Confirmation of HIV-1 infection HIV-1 viral load monitoring	Groups	M, N, O
Technology	Real-time transcription-mediated amplification (TMA)	Sample Types	Qualitative: Serum or Plasma Quantitative: Plasma
Target region	pol/LTR	Sample Input Volume	Primary tube (PPT, ACD, EDTA): 1.2 mL Secondary tube: 700 µL 240 µL with automated dilution factor

[†] Panel member was diluted 1:3 just prior to run. Reported result (shown here) has dilution factor of 3 applied automatically by the Panther[®] system.

The Aptima® HIV-1 Quant DX assay on the Panther® system combines assay performance and excellent automation for viral load monitoring.

Sample-to-result within a single integrated instrument

Key automation characteristics	
Random access	No more batching; load samples with different test orders as they arrive Run HIV with other assays at the same time
Primary tube processing	No need for aliquoting or manual sample transfer Tube flexibility: PPT, ACD and EDTA tubes validated
Flexible sample and reagent loading	Run multiple tests from a single sample No manual sample prep or barcode clips Automated barcode scanning of tubes allows positive sample identification
Rapid turnaround time with stat result option	First results in 2 hours, 41 minutes stat result option: ability to prioritise results
Automated QC analysis	Levey-Jennings plots to track and trend controls
Low sample volume option (240 µL) with automated dilution factor	Specified dilution factor automatically applied versus manual calculations

Ordering information

Aptima® Virology assay	Items	Quantity	Catalogue number
Aptima® HIV-1 Quant Dx Assay	Aptima HIV-1 Quant Dx Assay kit (1 assay box, 1 calibrator kit, 1 controls kit)	100 Tests	PRD-03000

Primary tube sampling

- ✓ Serum: SST, serum tubes
- ✓ Plasma: EDTA, ACD, PPT
- ✓ Dried blood spot (for HIV-1)

RUN ON
PANTHER®



References: 1. Aptima HIV-1 Quant Assay [package insert] #AW-11853-001. 2. Nair SV, Kim HC, Fortunko J, et al. Aptima HIV-1 Quant Dx—a fully automated assay for both diagnosis and quantification of HIV-1. J Clin Virol. 2016;77:46-54.