Quanterix™
The Science of Precision Health

Simoa® HIV p24 Advantage Kit
HD-1/HD-X Data Sheet

Item 102215

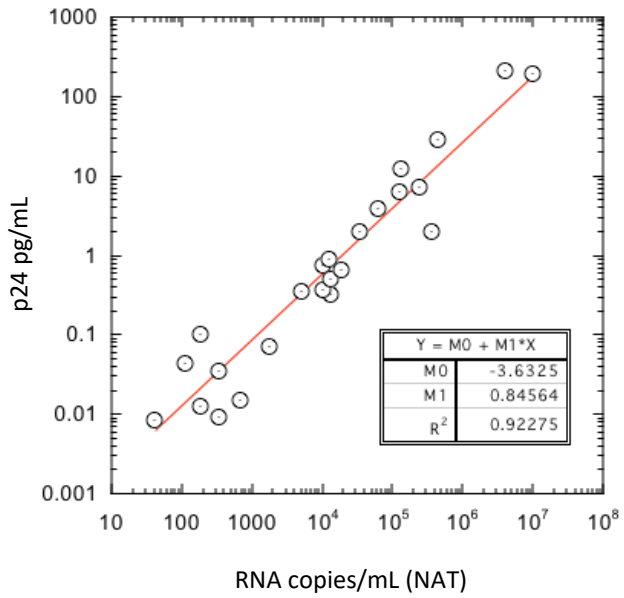
Description

The Human Immunodeficiency Virus (HIV) is the etiologic agent of acquired immunodeficiency syndrome. The gag protein p24 (MW 24kD) is the structural protein of the HIV capsid. There are approximately 2000 p24 molecules per HIV particle. During acute HIV infection, virus replicates exponentially, and p24 becomes detectable in blood. Prior to host antibody response to the virus, detectable p24 strongly correlates to detectable viral RNA. Following seroconversion, host antibodies form complexes with p24, complicating p24 measurement by immunoassay.

LLOQ	**0.010 pg/mL**
LOD	**0.0027 pg/mL** SD 0.0017 pg/mL
Dynamic range (serum and plasma)	0–~30 pg/mL (lot specific)
Diluted Sample volume*	124 µL per measurement
Tests per kit	96

***See Kit Instruction for details**

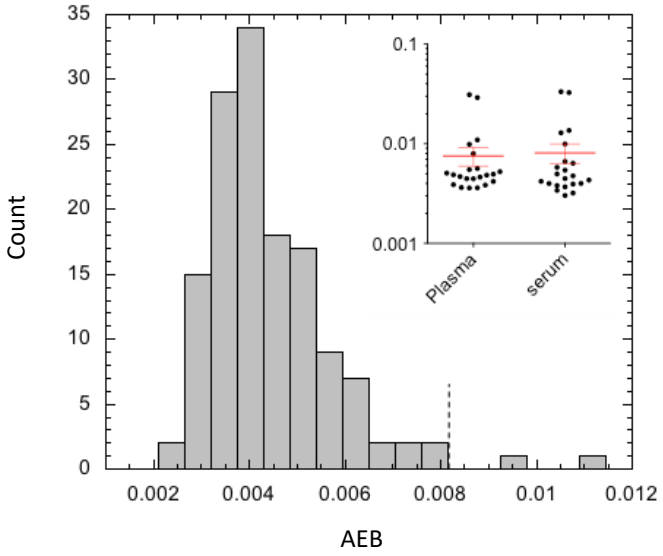
Simoa HIV p24 Assay/NAT Method Comparison: Method comparison between Simoa p24 assay and a commercially available nucleic acid test (NAT) method on 24 acute NAT yield samples, most of which were unreactive in conventional immunoassay. Samples ranged from 40 to 10 million RNA copies/mL in the NAT method.



Lower Limit of Quantification (LLOQ): Triplicate measurements of serially diluted calibrator were read back on the calibration curve over 1 reagent lot across 2 instruments (3 runs total).

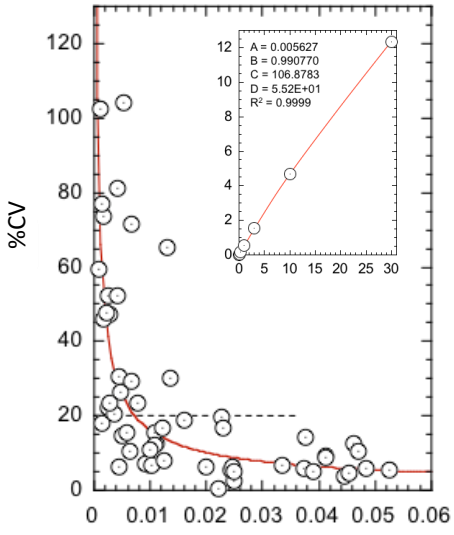
Limit of Detection (LOD): Calculated as 2.5 standard deviations from the mean of background signal read back on each calibration curve over 1 reagent lot across 4 instruments (6 runs total).

Endogenous Sample Reading: Histogram of measured signal from 139 normal serum and plasma samples. Dashed line depicts cutoff for estimating specificity. The cutoff was defined as 3SD above the mean Cal A background across 13 runs. ***Inset*:** Comparison of signals from a subset of matched serum and plasma samples.



Specificity: 95.1%. 7 out of 144 HIV negative samples gave signal above the cutoff.

Sample Dose CV Profile: Triplicate measurements of diluted serum samples assayed over multiple runs (58 measurements). Inset: Calibration curve with four-parameter curve fit parameters depicted.



Precision: Five samples consisting of three serum-based panels and two p24 controls were assayed in replicates of three at two separate times per day for five days using a single stored calibration curve and a single lot of reagents. Analysis of variance (fully nested ANOVA) results are summarized in the following table.

Sample	Mean (pg/mL)	Within run CV	Between run CV	Between day CV
Control 1	0.088	3.4%	2.3%	1.1%
Control 2	8.92	5.3%	3.8%	1.6%
Panel 1	0.148	4.0%	2.7%	2.7%
Panel 2	1.66	7.3%	1.6%	2.6%
Panel 3	15.18	9.5%	9.4%	0.0%

Spike and Recovery: p24 spiked into 6 serum samples at 2 and 20 pg/mL.

Admixture Linearity: HIV positive serum sample admixed with normal serum.

Dilution Linearity: HIV-positive serum was diluted 2x serially from Neat to 16x with Sample Diluent.

Endogenous Interferences: Bilirubin, hemoglobin, lipids.

Spike and Recovery (Serum/Plasma)	**Mean = 84.1%** Range: 78.1–93.1%
Admixture Linearity (mean of 10 levels)	**Mean = 102.2%** Range: 92.0–108.9
Dilution Linearity (16x)	**Mean = 110.4%** Range: 102.6–116.7%
Endogenous Interferences	**% Interference* < 16%**

*% interference at 2 pg/mL p24

The Simoa HIV p24 Advantage assay kit is formulated for use on the SR-X®, HD-1, or HD-X® platform. Data in this document was obtained from runs on the HD-1 platform unless otherwise noted. Some differences in performance claims between SR-X and HD-1/HD-X may be observed when comparing datasheets for these platforms. This may be due to experiments run at different time-points with different reagent lots and different samples, or it may be due to minor differences in antibody and analyte behavior in the different assay formats.