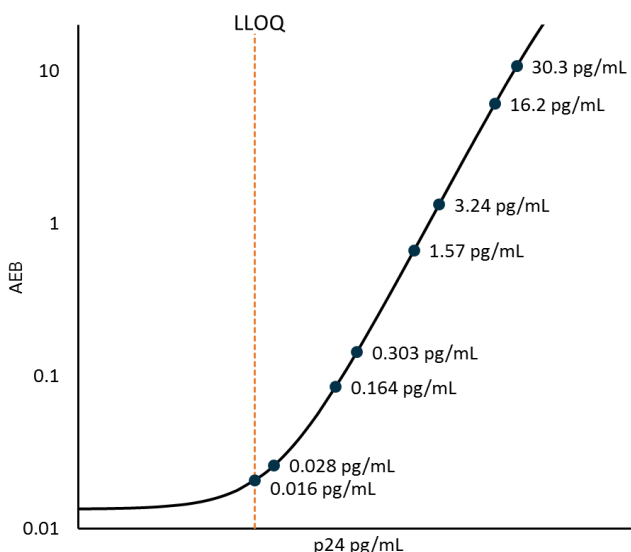


**Description**

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.

**Calibration Curve:** Calibrator concentrations and Lower Limit of Quantification depicted.



**Lower Limit of Quantification (LLOQ):** Triplicate measurements of serially diluted calibrator were read back on the calibration curve over 3 runs each for 1 reagent lot across 2 instruments (6 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 3 runs each for 1 reagent lot across 2 instruments (6 runs total).

<b>LLOQ</b>	<b>0.0160 pg/mL</b> pooled CV 7% mean recovery 110%
<b>LOD</b>	<b>0.0045 pg/mL</b> range 0.0008-0.0093 pg/mL
<b>Dynamic range</b>	0- ~30 pg/mL
<b>Sample volume*</b>	125 µL per measurement
<b>Tests per kit</b>	96

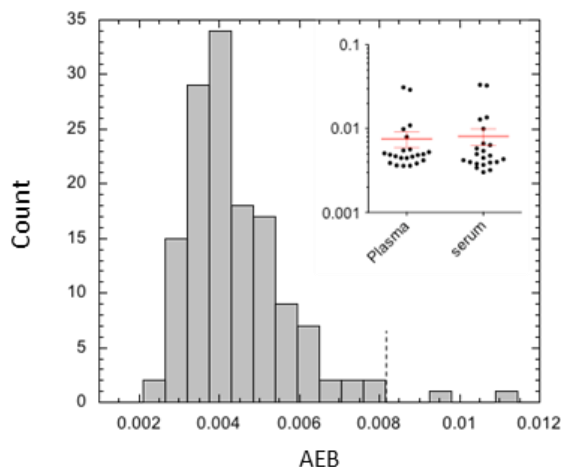
\*See Kit Instruction for details

**Precision:** Measurements of 3 serum or plasma based panels and 2 calibrator based controls. Triplicate measurements were made for 3 runs each for 1 reagent lot across 2 instruments (6 runs total, 18 measurements).

Sample	Mean (pg/mL)	Within run CV	Between run CV	Between inst CV
Control 1	0.155	15.6%	8.7%	6.0%
Control 2	15.2	4.5%	4.8%	4.3%
Panel 1	0.281	7.2%	7.0%	0.5%
Panel 2	2.59	4.2%	6.9%	7.8%
Panel 3	19.9	11.4%	6.7%	2.2%

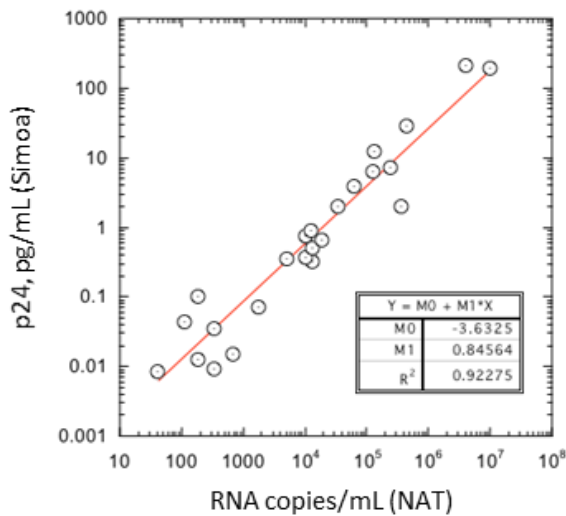
Note: Data in the following sections were obtained using the HD-1 Analyzer.

**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.



Sample Type	Mean P24 AEB	Median P24 AEB	% Above LOD
EDTA plasma	0.0072	0.0048	100%
Serum	0.0076	0.0046	100%

**Method comparison:** The Simoa p24 assay was compared to 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.



**Spike and Recovery:** 6 serum samples were spiked at high and low concentrations within the range of the assay and analyzed on HD-1.

**Dilution Linearity:** 1 spiked serum sample was diluted 2X serially to 16x with Sample Diluent.

<b>Spike and Recovery</b>	<b>84%</b> Range 78-93%
<b>Dilution Linearity (16x)</b>	<b>Mean = 110%</b> Range: 103-117%

The Simoa p24 assay kit is formulated for use on either the SR-X or HD-1 platform. Minor differences in performance claims between the HD-1 and SR-X may be observed when comparing datasheets for the two different platforms, due to experiments run at different time-points with different reagent lots and different samples. Data in this document was obtained from runs on the SR-X platform unless otherwise noted.