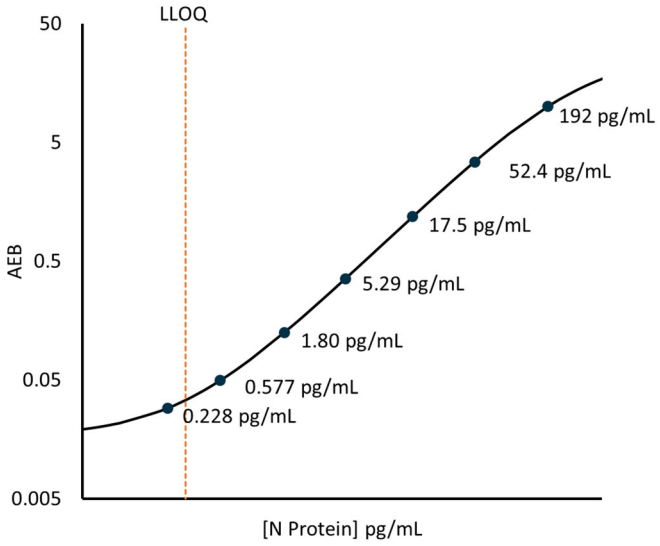
Simoa® SARS CoV-2 N Protein Advantage Kit
HD-X Data Sheet

Item 103806

Description

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) nucleocapsid protein is a viral protein encoded by the *N* gene in SARS-CoV-2 RNA. SARS-CoV-2 is a member of the *Betacoronavirus* genus of viruses and has 88% sequence identity with two bat-derived SARS-like CoVs. SARS-CoV-2 is the causative agent of COVID-19, a primarily respiratory illness characterized by fever, cough, and shortness of breath that can lead to life-threatening complications. SARS CoV-2 nucleocapsid protein is a target for viral antigen detection of COVID-19.

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



Minimum Required Dilution (MRD)

Diluted Sample Volume	100 µL per measurement
Nasopharyngeal (NP) Swab Dilution	1:4
Tests per kit	96

See Kit Instruction for details.

Lower Limit of Quantification (LLOQ): Triplicate measurements of serially diluted calibrator were read back on the calibration curve over 3 runs per lot, for 2 reagent lots across 2 instruments (12 runs total). The functional LLOQ (fLLOQ) values below are for NP swabs.

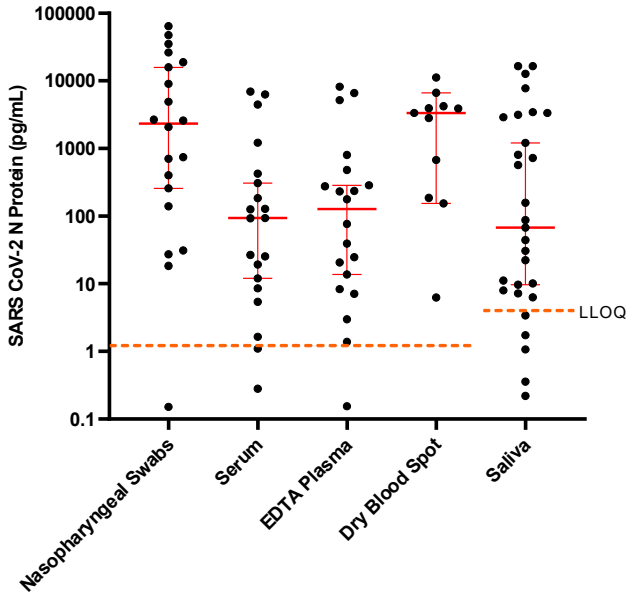
Limit of Detection (LOD): Calculated as 2.5 standard deviations from the mean of background signal read back on each calibration curve over 3 runs per lot, for 2 reagent lots across 2 instruments (12 runs total).

Assay Range: The upper end of the dynamic range is equal to the top calibrator concentration multiplied by MRD. The ranges below are for NP swabs.

Analytical LLOQ	**0.313 pg/mL** pooled CV 14.3% mean recovery 102%
Functional LLOQ (NP swabs)	**1.25 pg/mL**
LOD	**0.099 pg/mL** range 0.046 – 0.204 pg/mL
Dynamic Range* (NP swabs)	0 – ~800 pg/mL

* Samples that read above the dynamic range may need to be diluted further to achieve concentrations within readable range

Endogenous Sample Reading: PCR positive nasopharyngeal swabs in saline (n=20), matched serum and EDTA plasma (n=20), dry blood spot (DBS) (n=11) and saliva (n=29) were measured. Bars depict median with interquartile range. Orange line represents functional LLOQ.



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Sample Type*	Mean** N Protein pg/mL	Median N Protein pg/mL	% Above LOD	% Above LLOQ
NP swab	12200	2338	95%	95%
Serum	1133	93.4	100%	90%
EDTA Plasma	1261	127	100%	95%
DBS	3376	3349	100%	100%
Saliva	2701	67.8	100%	90%

* Serum, EDTA plasma, dried blood spot and saliva were not validated matrices and data is shown for information only.
** Values below LLOQ were not included in the mean.

Precision: Measurements of 3 recombinant protein spiked serum-based panels and 2 calibrator-based controls. Triplicate measurements were made for 3 runs each for 2 reagent lot across 2 instruments (12 runs total, 36 measurements).

Note: Serum-based panels were selected due to the unavailability of bulk volumes of nasopharyngeal swabs.

Sample	Mean (pg/mL)	Within run CV	Between run CV	Between inst CV	Between Lot CV
Control 1	4.88	7.7%	9.1%	0.1%	25.0%
Control 2	123	7.0%	6.1%	6.1%	19.7%
Panel 1	3.88	8.2%	8.5%	5.9%	14.5%
Panel 2	73.8	3.1%	5.8%	0.1%	12.9%
Panel 3	156	4.9%	3.7%	0.4%	14.0%

Spike and Recovery: 2 endogenous nasopharyngeal swab samples were spiked with virus at high and low concentrations within the range of the assay and analyzed on HD-X.

Dilution Linearity: 2 endogenous and 4 virus spiked nasopharyngeal swab samples were diluted 2x serially from MRD (4x) to 256x with Sample Diluent.

Spike and Recovery	**Mean 87.0%** range 67.6–115%
Dilution Linearity (Endogenous NP Swab 256x)	**Mean 115%** range 95.5–139%
Dilution Linearity (Spiked NP Swab, 256x)	**Mean 122%** range 93.4–212%

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