Simoa® SARS-CoV-2 Spike IgG Advantage Kit

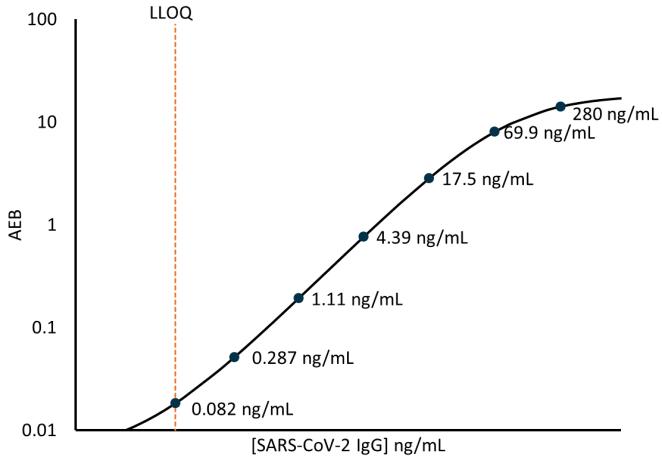
HD-X Data Sheet Item 103769

Description

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) is a recently identified coronavirus strain responsible for the Coronavirus Disease 2019 (COVID-19) and pandemic. SARS-CoV-2 is transmitted mainly through droplets and surface contact routes. The virus infects human cells through interaction between angiotensin converting enzyme 2 (ACE2) on respiratory cells and spike or S-protein on the outer envelope of the virion particle.

The Simoa™ SARS-CoV-2 Spike IgG Advantage Kit is intended for the detection of human IgG antibodies to the SARS-CoV-2 spike protein in serum or EDTA plasma. The kit detects IgG antibodies that may be indicative of an immune response to SARS-CoV-2 in patients suspected of previous SARS-CoV-2 infection, or for the detection of IgG seroconversion in patients following known recent SARS-CoV-2 exposure.

Calibration Curve: Calibrator concentrations and Lower Limit of Quantification depicted (calibrator levels may change for different manufacturing lots).



Minimum Required Dilution (MRD)

Diluted Sample Volume	100 µL per measurement
Serum and Plasma Dilution	1:1000
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 12 runs each for 2 reagent lots across 2 instruments. The functional LLOQ (fLLOQ) values below are for serum and plasma.

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

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

Analytical LLOQ	**0.082 ng/mL** pooled CV 19.8% mean recovery 98.1%
Functional LLOQ (serum and plasma)	**82.0 ng/mL**
LOD	**0.015 ng/mL** range 0.004–0.038 ng/mL
Dynamic Range (serum and plasma)	0 – 280 µg/mL

Endogenous Sample Reading: Pre-pandemic serum samples (n=96) were measured. Serum or EDTA plasma samples (n=96) that tested PCR positive for COVID-19 were measured and range from 0-71 days between PCR positive test and sample collection. Bars depict median with interquartile range. Dotted orange line represents functional LLOQ.

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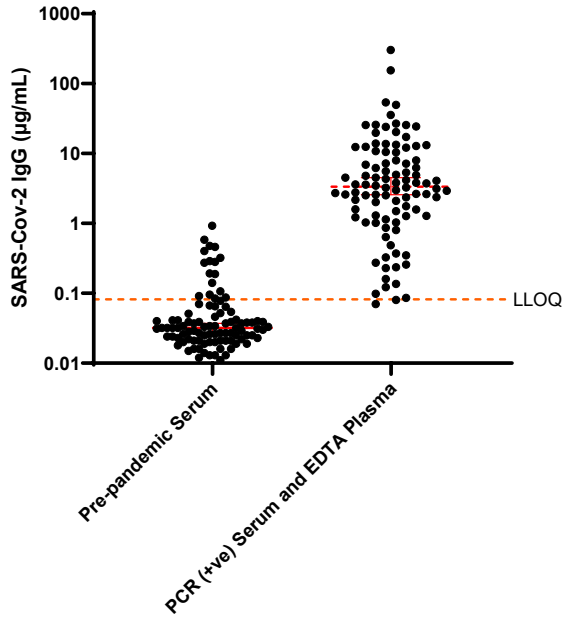

Sample Type	Mean SARS-CoV-2 IgG µg/mL	Median SARS-CoV-2 IgG µg/mL	% Above LOD	% Above LLOQ
Pre-pandemic Serum	0.077	0.032	92.7%	17.7%
PCR Positive Serum and Plasma	11.8	3.36	100%	97.9%

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

Sample	Mean (µg/mL)	Within run CV	Between run CV	Between inst CV	Between Lot CV
Control 1	0.350	6.4%	5.1%	5.3%	3.2%
Control 2	3.07	2.8%	6.8%	2.6%	8.6%
Control 3	17.0	3.4%	8.3%	6.1%	0.1%
Panel 1	0.638	3.8%	2.6%	4.5%	3.7%
Panel 2	2.08	4.3%	3.8%	2.6%	2.4%
Panel 3	6.91	3.1%	1.5%	4.6%	9.4%
Panel 4	5.07	3.8%	2.5%	6.2%	1.0%

Spike and Recovery: 2 serum and 2 EDTA plasma samples were spiked at high and low concentrations within the range of the assay and analyzed on HD-X.

Dilution Linearity: 2 endogenous serum and 2 endogenous EDTA plasma samples were diluted 2x serially from MRD (1,000x) to 32,000x with sample diluent.

Spike and Recovery (Serum)	**Mean 90.7%** range 73.1–107%
Spike and Recovery (Plasma)	**Mean 93.8%** range 70.3–105%
Dilution Linearity (Serum, 32000x)	**Mean 98.2%** range 48.7–143%
Dilution Linearity (Plasma, 32000x)	**Mean 101%** range 60.1–136%

Cross-reactivity: A respiratory panel (n=36) and a coronavirus panel (n=31) with known antibodies against Influenza, RSV, Adenovirus, Pneumonia**,** HCoV-229E, HCoV-NL63, HCoV-HKU1 and HCoV-OC43 were evaluated. Samples that tested positive for Hepatitis B (n=10), Hepatitis C (n=10), Herpes Simplex Virus (HSV) (n=10), and Human Immunodeficiency Virus (HIV) (n=10) were also analyzed.

Sample Type	Mean SARS-CoV-2 IgG µg/mL	Median SARS-CoV-2 IgG µg/mL
Respiratory Panel	0.142	0.100
Coronavirus Panel	0.155	0.068
Hep B (+ve)	0.082	0.041
Hep C (+ve)	0.063	0.044
HSV (+ve)	0.282	0.050
HIV(+ve)	0.082	0.047

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Curve Storage: Measurements of 2 serum-based, 2 plasma-based panels and 3 calibrator-based controls. Triplicate measurements were made for 6 runs at 5 individual days (Run 1 and 2 were run at two separate times on Day 1) on the same instrument using one lot of reagents (6 runs within 8 days total).

Drift: Measurements of one serum-based, one plasma-based panels and 2 calibrator-based controls. Controls and panels were run across three plates with a total of 54 replicates per sample.

Curve Storage	**Mean Bias: 4.1%** range 3.1–7.0%
Drift (Three-plate Variance)	**Plate 1:** 11.5% **Plate 1+2:** 9.6% **Plate 1+2+3:** 3.6%
Drift (Three-plate Precision)	**Mean: 0.5%** range 0–1.9%

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