

CERTIFICATE OF ANALYSIS

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Product Description:	V-PLEX® COVID-19 Coronavirus Panel 3 Kit			
Kit Catalog Numbers:	K15399-Series; K15400-Series; K15401-Series; K15402-Series			
Kit Lot Number:	K0082370			
Expiration Date:	28 FEB 2026			

Kit Components:

Description	Lot Number	Storage Temperature	Expiration Date
Caronavirus Plate 2	Z0057408	2-8°C	28 FEB 2026
Reference Standard 1	A0080286	≤ -70°C	28 FEB 2026
Serology Control 1.1	A00C0825	≤ -70°C	31 MAR 2027
Serology Control 1.2	A00C0826	≤ -70°C	31 MAR 2027
Serology Control 1.3	A00C0827	\leq -70°C	31 MAR 2027
SULFO-TAG [™] Human ACE2 Protein	Not Kit Specific	2-8°C	See Label
ACE2 Calibration Reagent	Not Kit Specific	2-8°C	See Label
SULFO-TAG [™] Anti-Human IgG Antibody	D00V0030	2-8°C	31 DEC 2026
SULFO-TAG [™] Anti-Human IgM Antibody	Not Kit Specific	2-8°C	See Label
SULFO-TAG [™] Anti-Human IgA Antibody	Not Kit Specific	2-8°C	See Label
SULFO-TAG [™] Anti-Mouse IgG Antibody	Not Kit Specific	2-8°C	See Label
SULFO-TAG [™] Anti-Mouse IgM Antibody	Not Kit Specific	2-8°C	See Label
SULFO-TAG [™] Anti-Mouse IgA Antibody	Not Kit Specific	2-8°C	See Label
Diluent 100	Not Kit Specific	2-8°C	See Label
MSD Blocker A Kit	Not Kit Specific	Room Temperature	See Label
MSD GOLD Read Buffer B	Not Kit Specific	Room Temperature	See Label

See product insert regarding which components are provided with each IgG, IgA, IgM, or ACE2 kit.

Plate Uniformity Testing Results:

Param	Precision			Uniformity	Signal
Metric	CV of Intra- plate Averages	Average Intra-plate CV	Max Intra- plate CV	Average Uniformity Metric	Average Signal
SARS-CoV-2 Spike	≤18%	$\leq 10\%$	≤13%	Pass	1,500 - 1,000,000
HCoV-NL63 Spike	≤ 25%	≤15%	≤18%	Pass	1,500 - 1,000,000
SARS-CoV-2 Nucleocapsid	≤ 18%	$\leq 10\%$	≤13%	Pass	1,500 - 1,000,000
SARS-CoV-1 Spike	≤ 18%	$\leq 10\%$	≤13%	Pass	1,500 - 1,000,000
SARS-CoV-2 S1 NTD	≤18%	$\leq 10\%$	≤13%	Pass	1,500 - 1,000,000
HCoV-HKU1 Spike	≤18%	$\leq 10\%$	≤13%	Pass	1,500 - 1,000,000
HCoV-OC43 Spike	≤ 18%	$\leq 10\%$	≤13%	Pass	1,500 - 1,000,000
HCoV-229E Spike	≤ 25%	≤15%	≤18%	Pass	1,500 - 1,000,000
SARS-CoV-2 S1 RBD	≤ 18%	$\leq 10\%$	≤13%	Pass	1,500 - 1,000,000



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Spot	Description	Resul
1	SARS-CoV-2 Spike	Pass
2	HCoV-NL63 Spike	Pass
3	SARS-CoV-2 Nucleocapsid	Pass
4	SARS-CoV-1 Spike	Pass
6	SARS-CoV-2 S1 NTD	Pass
7	HCoV-HKU1 Spike	Pass
8	HCoV-OC43 Spike	Pass
9	HCoV-229E Spike	Pass
10	SARS-CoV-2 S1 RBD	Pass

Functional Testing Results:

Sample	Calibrator	Controls		Samples	
Metric	Avg Signal Ratio Test:Reference	Control Recovery	Control Conc. CV	Avg % Difference Test:Reference	Slope Test:Reference
SARS-CoV-2 Spike	50 - 200%	70 - 130%	< 20%	$\pm 25\%$	0.80 - 1.2
HCoV-NL63 Spike	50-200%	70-130%	< 20%	± 25%	0.80 - 1.2
SARS-CoV-2 Nucleocapsid	50 - 200%	70-130%	< 20%	$\pm 25\%$	0.80 - 1.2
SARS-CoV-1 Spike	50 - 200%	70-130%	< 20%	N/A	N/A
SARS-CoV-2 S1 NTD	50-200%	70-130%	< 20%	± 25%	0.80 - 1.2
HCoV-HKU1 Spike	50 - 200%	70-130%	< 20%	$\pm 25\%$	0.80 - 1.2
HCoV-OC43 Spike	50-200%	70-130%	< 20%	± 25%	0.80 - 1.2
HCoV-229E Spike	50 - 200%	70-130%	< 20%	$\pm 25\%$	0.80 - 1.2
SARS-CoV-2 S1 RBD	50-200%	70-130%	< 20%	± 25%	0.80 - 1.2

Additional Comments:

Functional testing was executed using Coronavirus Plate 2 (Z0057408), SULFO-TAG Anti-Human IgG Antibody (D00V0030), Reference Standard 1 (A0080286), and Serology Controls (A00C0825, A00C0826, A00C0827).

All kit components were manufactured and tested according to MSD documents. The lots listed in the Kit Components table meet MSD's specifications.

Statement:

The above product is intended for Research Use Only. Not for use in Diagnostic Procedures.

	Name	Function	Signature	Date
Review/Approval	Karen Hamilla	Quality	Haven Hamille	14 NOV 2023