



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: K0081971
Expiration Date: 31 JUL 2023

Kit Components:

Description	Lot Number	Storage Temperature	Expiration Date
Coronavirus Plate 3	Z0057118	2-8°C	31 JUL 2024
Reference Standard 1	A0080286	≤ -70°C	28 FEB 2026
Serology Control 1.1	A00C0771	≤ -70°C	28 FEB 2026
Serology Control 1.2	A00C0772	≤ -70°C	28 FEB 2026
Serology Control 1.3	A00C0773	≤ -70°C	28 FEB 2026
SULFO-TAG [™] Human ACE2 Protein	D0081708	2-8°C	31 JUL 2023
ACE2 Calibration Reagent	A0080301	2-8°C	31 MAR 2025
SULFO-TAG [™] Anti-Human IgG Antibody	D00V0019	2-8°C	30 APR 2025
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
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:

Parameter	Precision			Uniformity	Signal
	CV of Intra-plate Averages	Average Intra-plate CV	Max Intra-plate CV		
SARS-CoV-2 Spike	≤ 18%	≤ 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%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-1 Spike	≤ 18%	≥ 10%	≥ 13%	Fail	1,500 – 1,000,000
MERS-CoV Spike	≤ 25%	≤ 15%	≤ 18%	Fail	1,500 – 1,000,000
HCoV-HKU1 Spike	≤ 18%	≤ 10%	≤ 13%	Fail	1,500 – 1,000,000
HCoV-OC43 Spike	≤ 18%	≤ 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%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000



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Coating Confirmation Testing Results:

Spot	Description	Result
1	SARS-CoV-2 Spike	Pass
2	HCoV-NL63 Spike	Pass
3	SARS-CoV-2 Nucleocapsid	Pass
4	SARS-CoV-1 Spike	Pass
6	MERS-CoV Spike	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 Type	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%	± 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%	± 25%	0.80 – 1.2
SARS-CoV-1 Spike	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
MERS-CoV Spike	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
HCoV-HKU1 Spike	50 – 200%	70 – 130%	< 20%	± 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%	± 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 3 (Z0057118), SULFO-TAG Anti-Human IgG Antibody (D00V0019), Reference Standard 1 (A0080286), and Serology Controls (A00C0771, A00C0772, A00C0773).

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		18 MAR 2022