



## CERTIFICATE OF ANALYSIS

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**Product Description:** V-PLEX® SARS-CoV-2 Panel 13 Kit  
**Kit Catalog Numbers:** K15463-Series, K15464-Series, K15465-Series, K15466-Series; K15512-Series; K15513-Series; K15514-Series  
**Kit Lot Number:** K0081940  
**Expiration Date:** 31 JUL 2023

### Kit Components:

Description	Lot Number	Storage Temperature	Expiration Date
SARS-CoV-2 Plate 13	Z0057062	2-8°C	31 MAY 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	D00V0014	2-8°C	31 DEC 2024
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:

Parameter	Precision			Uniformity	Signal
	CV of Intra-plate Averages	Average Intra-plate CV	Max Intra-plate CV	Average Uniformity Metric	Average Signal
SARS-CoV-2 Spike	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (P.2)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (B.1.617.1)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (B.1.617.2)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (B.1.617.3)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (B.1.617)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (P.1)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (B.1.1.7)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (B.1.351)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (B.1.526.1)	≤ 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	SARS-CoV-2 Spike (P.2)	Pass
3	SARS-CoV-2 Spike (B.1.617.1)	Pass
4	SARS-CoV-2 Spike (B.1.617.2)	Pass
5	SARS-CoV-2 Spike (B.1.617.3)	Pass
6	SARS-CoV-2 Spike (B.1.617)	Pass
7	SARS-CoV-2 Spike (P.1)	Pass
8	SARS-CoV-2 Spike (B.1.1.7)	Pass
9	SARS-CoV-2 Spike (B.1.351)	Pass
10	SARS-CoV-2 Spike (B.1.526.1)	Pass

### Functional Testing Results:

Sample Type	Calibrator	Controls		Samples	
Metric	Average Signal Ratio Test:Reference	Control Recovery	Control Conc. CV	Average % Difference Test:Reference	Slope Test:Reference
SARS-CoV-2 Spike	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (P.2)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (B.1.617.1)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (B.1.617.2)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (B.1.617.3)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (B.1.617)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (P.1)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (B.1.1.7)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (B.1.351)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (B.1.526.1)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2

### Additional Comments:

Functional testing was executed using Coronavirus Plate 3 (Z0057062), SULFO-TAG Anti-Human IgG Antibody (D00V0003), Reference Standard (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		14 JAN 2022