



## CERTIFICATE OF ANALYSIS

Page 1 of 2

**Product Description:** V-PLEX® SARS-CoV-2 Panel 19 Kit  
**Kit Catalog Numbers:** K15540-Series; K15541-Series; K15542-Series; K15543-Series; K15544-Series; K15545-Series; K15546-Series  
**Kit Lot Number:** K0081898  
**Expiration Date:** 31 JUL 2023

### Kit Components:

Description	Lot Number	Storage Temperature	Expiration Date
SARS-CoV-2 Plate 19	Z0057067	2-8°C	30 APR 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		
SARS-CoV-2 Spike	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (B.1.621)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (AY.2) <b>Alt Seq1</b>	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (B.1.617.2; AY.4) <b>Alt Seq 2</b>	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (C.37)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (AY.12)	≤ 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 (AY.1) <b>Alt Seq 1</b>	≤ 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.1.617.2; AY.3; AY.5; AY.6; AY.7; AY.14) <b>Alt Seq 1</b>	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000



## CERTIFICATE OF ANALYSIS

Page 2 of 2

### Coating Confirmation Testing Results:

Spot	Description	Result
1	SARS-CoV-2 Spike	Pass
2	SARS-CoV-2 Spike (B.1.621)	Pass
3	SARS-CoV-2 Spike (AY.2) <b>Alt Seq1</b>	Pass
4	SARS-CoV-2 Spike (B.1.617.2; AY.4) <b>Alt Seq 2</b>	Pass
5	SARS-CoV-2 Spike (C.37)	Pass
6	SARS-CoV-2 Spike (AY.12)	Pass
7	SARS-CoV-2 Spike (P.1)	Pass
8	SARS-CoV-2 Spike (AY.1) <b>Alt Seq 1</b>	Pass
9	SARS-CoV-2 Spike (B.1.351)	Pass
10	SARS-CoV-2 Spike (B.1.617.2; AY.3; AY.5; AY.6; AY.7; AY.14) <b>Alt Seq 1</b>	Pass

**Note:** Alternative S-GENE mutations for Spike of AY.1, AY.2, and B.1.617.2 are listed as “**Alt Seq#.**”

### 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
SARS-CoV-2 Spike (B.1.621)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (AY.2) <b>Alt Seq1</b>	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (B.1.617.2; AY.4) <b>Alt Seq 2</b>	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (C.37)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (AY.12)	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 (AY.1) <b>Alt Seq 1</b>	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.1.617.2; AY.3; AY.5; AY.6; AY.7; AY.14) <b>Alt Seq 1</b>	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2

### Additional Comments:

Functional testing was executed using SARS-CoV-2 Plate 19 (Z0057067), SULFO-TAG Anti-Human IgG Antibody (D00V0014), 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
<b>Review/Approval</b>	Karen Hamilla	Quality		18 NOV 2021