



## CERTIFICATE OF ANALYSIS

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**Product Description:** V-PLEX® SARS-CoV-2 Key Variant Spike Panel 1 Kit  
**Kit Catalog Numbers:** K15651-Series; K15652-Series; K15653-Series; K15654-Series; K15655-Series; K15656-Series; K15657-Series  
**Kit Lot Number:** K0082223  
**Expiration Date:** 31 JAN 2024

### Kit Components:

Description	Lot Number	Storage Temperature	Expiration Date
SARS-CoV-2 Key Variant Spike Plate 1	Z0057329	2-8°C	31 JUL 2025
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	≤ -70°C	31 MAR 2027
SULFO-TAG™ Human ACE2 Protein	D0081760	2-8°C	31 JAN 2024
ACE2 Calibration Reagent 2	A0080327	2-8°C	31 OCT 2025
SULFO-TAG™ Anti-Human IgG Antibody	D00V0009	2-8°C	31 JUL 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 (BA.2.12.1)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Nucleocapsid	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (BA.2.75)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (BA.2)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (B.1.1.529; BA.1)	≤ 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 (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 (BA.5)	≤ 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 (BA.2.12.1)	Pass
3	SARS-CoV-2 Nucleocapsid	Pass
4	SARS-CoV-2 Spike (BA.2.75)	Pass
5	SARS-CoV-2 Spike (BA.2)	Pass
6	SARS-CoV-2 Spike (B.1.1.529; BA.1)	Pass
7	SARS-CoV-2 Spike (B.1.617.2; AY.4) <b>Alt Seq 2</b>	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 (BA.5)	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 (BA.2.12.1)	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-2 Spike (BA.2.75)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (BA.2)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (B.1.1.529; BA.1)	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 (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 (BA.5)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2

### Additional Comments:

Functional testing was executed using SARS-CoV-2 Key Variant Spike Plate 1 (Z0057329), SULFO-TAG Anti-Human IgG Antibody (D00V0009), 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
<b>Review/Approval</b>	Nithya Santhanam	Quality		07 Feb 2023