



CERTIFICATE OF ANALYSIS

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Product Description: V-PLEX[®] SARS-CoV-2 Panel 27 Kit
Kit Catalog Numbers: K15606-Series; K15607-Series; K15608-Series; K15609-Series; K15610-Series; K15611-Series; K15612-Series
Kit Lot Number: K0082109
Expiration Date: 31 JAN 2024

Kit Components:

Description	Lot Number	Storage Temperature	Expiration Date
SARS-CoV-2 Plate 27	Z0057243	2-8°C	31 JAN 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	D00V0027	2-8°C	30 NOV 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
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 Spike (BA.2)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (AY.4)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (BA.3)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (BA.2+L452M)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (BA.2+L452R)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (BA.4)	≤ 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 Spike (BA.2)	Pass
4	SARS-CoV-2 Spike (AY.4)	Pass
5	SARS-CoV-2 Spike (BA.3)	Pass
6	SARS-CoV-2 Spike (BA.2+L452M)	Pass
7	SARS-CoV-2 Spike (BA.2+L452R)	Pass
8	SARS-CoV-2 Spike (BA.4)	Pass
9	SARS-CoV-2 Spike (B.1.351)	Pass
10	SARS-CoV-2 Spike (BA.5)	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
SARS-CoV-2 Spike (BA.2.12.1)	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 (AY.4)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (BA.3)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (BA.2+L452M)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (BA.2+L452R)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (BA.4)	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 Plate 27 (Z0057243), SULFO-TAG Anti-Human IgG Antibody (D00V0027), 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		06 SEP 2022