



CERTIFICATE OF ANALYSIS

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Product Description: V-PLEX[®] SARS-CoV-2 Panel 39 Kit
Kit Catalog Numbers: K15738-Series; K15739-Series; K15740-Series
Kit Lot Number: K0082617
Expiration Date: 30 APR 2027

Kit Components:

Description	Lot Number	Storage Temperature	Expiration Date
SARS-CoV-2 Plate 39	Z0057523	2-8°C	30 APR 2027
MSD GOLD SULFO-TAG [™] Anti-Human IgG Antibody	D00V0040	2-8°C	30 APR 2028
Reference Standard 2	A0080403	≤ -70°C	30 JUN 2034
Serology Control 2.1	A00C0959	≤ -70°C	30 JUN 2034
Serology Control 2.2	A00C0960	≤ -70°C	30 JUN 2034
Serology Control 2.3	A00C0961	≤ -70°C	30 JUN 2034
ACE2 Calibration Reagent 3	Not Kit Specific	≤ -70°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, or ACE2 kit.

Plate Uniformity Testing Results:

Parameter	Precision			Uniformity	Signal
	Metric	CV of Intra-plate Averages	Average Intra-plate CV		
SARS-CoV-2 Spike	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (LB.1)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 N	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (BA.2.86)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike(XBB.1.5 (v2))	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (KP.3)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (JN.1 (v2))	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (KP.2)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (B.1.617.2; AY.4)	≤ 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 (LB.1)	Pass
3	SARS-CoV-2 N	Pass
4	SARS-CoV-2 Spike (BA.2.86)	Pass
5	SARS-CoV-2 Spike(XBB.1.5 (v2))	Pass
6	SARS-CoV-2 Spike (KP.3)	Pass
7	SARS-CoV-2 Spike (JN.1 (v2))	Pass
8	SARS-CoV-2 Spike (KP.2)	Pass
9	SARS-CoV-2 Spike (B.1.617.2; AY.4)	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 (LB.1)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 N	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (BA.2.86)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike(XBB.1.5 (v2))	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (KP.3)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (JN.1 (v2))	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (KP.2)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (B.1.617.2; AY.4)	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 39 (Z0057523), SULFO-TAG Anti-Human IgG Antibody (D00V0040), Reference Standard 2 (A0080403), and Serology Controls (A00C0959, A00C0960, A00C0961).

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		29 JAN 2025