



CERTIFICATE OF ANALYSIS

Page 1 of 2

Product Description: V-PLEX® SARS-CoV-2 Panel 26 Kit
Kit Catalog Numbers: K15593-Series; K15594-Series; K15595-Series; K15596-Series;
 K15597Series; K15598-Series; K15599-Series
Kit Lot Number: K0082046
Expiration Date: 31 JAN 2024

Kit Components:

Description	Lot Number	Storage Temperature	Expiration Date
SARS-CoV-2 Plate 26	Z0057186	2-8°C	30 NOV 2024
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	D00V0025	2-8°C	30 SEP 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		
RBD (Omicron; BA.1)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
RBD (Beta)	≤ 25%	≤ 15%	≤ 18%	Pass	1,500 – 1,000,000
RBD (Omicron; BA.2)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
RBD (Gamma)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
RBD (Alpha)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
RBD (Omicron; BA.1.1)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
RBD (Delta)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 S1 RBD	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000



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Page 2 of 2

Coating Confirmation Testing Results:

Spot	Description	Result
1	RBD (Omicron; BA.1)	Pass
2	RBD (Beta)	Pass
3	RBD (Omicron; BA.2)	Pass
4	RBD (Gamma)	Pass
6	RBD (Alpha)	Pass
8	RBD (Omicron; BA.1.1)	Pass
9	RBD (Delta)	Pass
10	SARS-CoV-2 S1 RBD	Pass

RBD indicates SARS-CoV-2 Receptor Binding Domain with mutation(s) listed.

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
RBD (Omicron; BA.1)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
RBD (Beta)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
RBD (Omicron; BA.2)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
RBD (Gamma)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
RBD (Alpha)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
RBD (Omicron; BA.1.1)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
RBD (Delta)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 S1 RBD	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2

Additional Comments:

Functional testing was executed using SARS-CoV-2 Plate 26 (Z0057186), SULFO-TAG Anti-Human IgG Antibody (D00V0025), 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		20 JUN 2022