



CERTIFICATE OF ANALYSIS

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Product Description: V-PLEX® SARS-CoV-2 Key Variant RBD Panel 1 Kit
Kit Catalog Numbers: K15659-Series; K15660-Series; K15661-Series; K15662-Series; K15663-Series; K15664-Series; K15665-Series
Kit Lot Number: K0082164
Expiration Date: 31 JUL 2023

Kit Components:

Description	Lot Number	Storage Temperature	Expiration Date
SARS-CoV-2 Key Variant RBD Plate 1	Z0057278	2-8°C	30 APR 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	D0081708	2-8°C	31 JUL 2023
ACE2 Calibration Reagent 2	A0080327	2-8°C	31 OCT 2025
SULFO-TAG™ Anti-Human IgG Antibody	D00V0008	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		
RBD (BA.2.12.1)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
RBD (B.1.351.1) (Beta)	≤ 25%	≤ 15%	≤ 18%	Pass	1,500 – 1,000,000
SARS-CoV-2 Nucleocapsid	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
RBD (Omicron; BA.1)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
RBD (Omicron; BA.2)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
RBD (B.1.1.7) (Alpha)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
RBD (Delta)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
RBD (BA.2.75)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
RBD (BA.4;BA.5)	≤ 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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Coating Confirmation Testing Results:

Spot	Description	Result
1	RBD (BA.2.12.1)	Pass
2	RBD (B.1.351.1) (Beta)	Pass
3	SARS-CoV-2 Nucleocapsid	N/A
4	RBD (Omicron; BA.1)	Pass
5	RBD (Omicron; BA.2)	Pass
6	RBD (B.1.1.7) (Alpha)	Pass
7	RBD (Delta)	Pass
8	RBD (BA.2.75)	Pass
9	RBD (BA.4;BA.5)	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 (BA.2.12.1)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
RBD (B.1.351.1) (Beta)	50 – 200%	70 – 130%	< 20%	>25%	>1.2
SARS-CoV-2 Nucleocapsid	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
RBD (Omicron; BA.1)	50 – 200%	>130%	< 20%	± 25%	0.80 – 1.2
RBD (Omicron; BA.2)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
RBD (B.1.1.7) (Alpha)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
RBD (Delta)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
RBD (BA.2.75)	50 – 200%	> 130%	< 20%	± 25%	0.80 – 1.2
RBD (BA.4;BA.5)	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 Key Variant RBD Plate 1 (Z0057278), SULFO-TAG Anti-Human IgG Antibody (D00V0008), 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		30 NOV 2022