



CERTIFICATE OF ANALYSIS

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Product Description: V-PLEX[®] SARS-CoV-2 Panel 11 Kit
Kit Catalog Numbers: K15455-Series; K15456-Series; K15457-Series; K15458-Series
Kit Lot Number: K0081786
Expiration Date: 31 DEC 2022

Kit Components:

Description	Lot Number	Storage Temperature	Expiration Date
SARS-CoV-2 Plate 11	Z0056998	2-8°C	31 DEC 2023
SULFO-TAG [™] Anti-Human IgG Antibody	D00V0009	2-8°C	31 JUL 2024
SULFO-TAG [™] Anti-Human IgM Antibody	D00V0011	2-8°C	31 AUG 2024
SULFO-TAG [™] Anti-Human IgA Antibody	D00V0010	2-8°C	31 JUL 2024
Reference Standard 1	A0080286	≤ -70°C	28 FEB 2026
Serology Control 1.1	A00C0771	≤ -70°C	28 FEB 2026
Serology Control 1.2	A00C0772	≤ -70°C	28 FEB 2026
Serology Control 1.3	A00C0773	≤ -70°C	28 FEB 2026
SULFO-TAG [™] Human ACE2 Protein	D0081619	2-8°C	31 DEC 2022
ACE2 Calibration Reagent	A0080285	2-8°C	31 AUG 2024
MSD Blocker A Kit	Not Kit Specific	Room Temperature	See Label
Diluent 100	Not Kit Specific	2-8°C	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, and 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
RBD (L452R)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
RBD (K417N, E484K, N501Y)	≤ 25%	≤ 15%	≤ 18%	Pass	1,500 – 1,000,000
RBD (E484K)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
RBD (K417T, E484K, N501Y)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
RBD (S477N)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
RBD (N501Y)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
RBD (E484K, N501Y)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
RBD (L452R, E484Q)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
RBD (L452R, T478K)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 S1 RBD	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000

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



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Coating Confirmation Testing Results:

Spot	Description	Result
1	RBD (L452R)	Pass
2	RBD (K417N, E484K, N501Y)	Pass
3	RBD (E484K)	Pass
4	RBD (K417T, E484K, N501Y)	Pass
5	RBD (S477N)	Pass
6	RBD (N501Y)	Pass
7	RBD (E484K, N501Y)	Pass
8	RBD (L452R, E484Q)	Pass
9	RBD (L452R, T478K)	Pass
10	SARS-CoV-2 S1 RBD	Pass

Functional Testing Results:

Sample Type	Calibrator	Controls		Samples	
Metric	Average Signal Ratio Test:Reference	Control Recovery	Control Conc. CV	Avg % Difference Test:Reference	Slope Test:Reference
RBD (L452R)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
RBD (K417N, E484K, N501Y)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
RBD (E484K)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
RBD (K417T, E484K, N501Y)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
RBD (S477N)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
RBD (N501Y)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
RBD (E484K, N501Y)	50 – 200%	70 – 130%	< 20%	34.4%	1.31
RBD (L452R, E484Q)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
RBD (L452R, T478K)	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 11 (Z0056998), SULFO-TAG Anti-Human IgG Antibody (D00V0009), Reference Standard 1 (A0080286), and Serology Controls (A00C0771, A00C0772, A00C0773).

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		05 AUG 2021