



CERTIFICATE OF ANALYSIS

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Product Description: V-PLEX[®] SARS-CoV-2 Panel 19 Kit
Kit Catalog Numbers: K15540-Series; K15541-Series; K15542-Series; K15543-Series;
 K15544-Series; K15545-Series; K15546-Series
Kit Lot Number: K0081848
Expiration Date: 31 JUL 2023

Kit Components:

Description	Lot Number	Storage Temperature	Expiration Date
SARS-CoV-2 Plate 19	Z0057050	2-8°C	29 FEB 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	D0081708	2-8°C	31 JUL 2023
ACE2 Calibration Reagent	A0080285	2-8°C	31 AUG 2024
SULFO-TAG [™] Anti-Human IgG Antibody	D00V0014	2-8°C	31 DEC 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, and ACE2 kit.

Plate Uniformity Testing Results:

Parameter	Precision			Uniformity	Signal
	CV of Intra-plate Averages	Average Intra-plate CV	Max Intra-plate CV		
SARS-CoV-2 Spike	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (B.1.621)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (AY.2) Alt Seq 1	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (B.1.617.2; AY.4) Alt Seq 2	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (C.37)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (AY.12)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (P.1)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (AY.1) Alt Seq 1	≤ 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 (B.1.617.2; AY.3; AY.5; AY.6; AY.7; AY.14) Alt Seq 1	≤ 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 (B.1.621)	Pass
3	SARS-CoV-2 Spike (AY.2) Alt Seq 1	Pass
4	SARS-CoV-2 Spike (B.1.617.2; AY.4) Alt Seq 2	Pass
5	SARS-CoV-2 Spike (C.37)	Pass
6	SARS-CoV-2 Spike (AY.12)	Pass
7	SARS-CoV-2 Spike (P.1)	Pass
8	SARS-CoV-2 Spike (AY.1) Alt Seq 1	Pass
9	SARS-CoV-2 Spike (B.1.351)	Pass
10	SARS-CoV-2 Spike (B.1.617.2; AY.3; AY.5; AY.6; AY.7; AY.14) Alt Seq 1	Pass

Note: Alternative S-GENE mutations for Spike of AY.1, AY.2, and B.1.617.2 are listed as “Alt Seq #.”

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 (B.1.621)	N/A	N/A	N/A	N/A	N/A
SARS-CoV-2 Spike (AY.2) Alt Seq 1	N/A	N/A	N/A	N/A	N/A
SARS-CoV-2 Spike (B.1.617.2; AY.4) Alt Seq 2	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (C.37)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (AY.12)	N/A	N/A	N/A	N/A	N/A
SARS-CoV-2 Spike (P.1)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (AY.1) Alt Seq 1	N/A	N/A	N/A	N/A	N/A
SARS-CoV-2 Spike (B.1.351)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (B.1.617.2; AY.3; AY.5; AY.6; AY.7; AY.14) Alt Seq 1	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2

Additional Comments:

Functional testing was executed using SARS-CoV-2 Plate 19 (Z0057050), SULFO-TAG Anti-Human IgG Antibody (D00V0014), Reference Standard 1 (A00808286), 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		06 DEC 2021