



CERTIFICATE OF ANALYSIS

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Product Description: V-PLEX® SARS-CoV-2 Panel 13 Kit
Kit Catalog Numbers: K15463-Series, K15464-Series, K15465-Series, K15466-Series
Kit Lot Number: K0081814
Expiration Date: 31 DEC 2022

Kit Components:

Description	Lot Number	Storage Temperature	Expiration Date
SARS-CoV-2 Plate 13	Z0057026	2-8°C	31 JAN 2024
SULFO-TAG™ Anti-Human IgG Antibody	D00V0014	2-8°C	31 DEC 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
	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 P.2	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike B.1.617.1	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike B.1.617.2	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike B.1.617.3	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike B.1.617	≤ 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 B.1.1.7	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike B.1.351	≤ 18%	≤ 10%	≤ 13%	Fail	1,500 – 1,000,000
SARS-CoV-2 Spike B.1.526.1	≤ 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 P.2	Pass
3	SARS-CoV-2 Spike B.1.617.1	Pass
4	SARS-CoV-2 Spike B.1.617.2	Pass
5	SARS-CoV-2 Spike B.1.617.3	Pass
6	SARS-CoV-2 Spike B.1.617	Pass
7	SARS-CoV-2 Spike P.1	Pass
8	SARS-CoV-2 Spike B.1.1.7	Pass
9	SARS-CoV-2 Spike B.1.351	Pass
10	SARS-CoV-2 Spike B.1.526.1	Pass

Functional Testing Results:

Sample Type	Calibrator	Controls		Samples	
Metric	Average Signal Ratio Test:Reference	Control Recovery	Control Conc. CV	Average % Difference Test:Reference	Slope Test:Reference
SARS-CoV-2 Spike	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike P.2	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike B.1.617.1	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike B.1.617.2	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike B.1.617.3	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike B.1.617	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike P.1	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike B.1.1.7	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike B.1.351	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike B.1.526.1	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2

Additional Comments:

Functional testing was executed using SARS-CoV-2 Plate 13 (Z0057026), SULFO-TAG Anti-Human IgG Antibody (D00V0014), 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 OCT 2021