![MSD logo]

CERTIFICATE OF ANALYSIS

Product Description: V-PLEX® SARS-CoV-2 Panel 14 Kit
Kit Catalog Numbers: K15468-Series; K15469-Series; K15470-Series; K15471-Series
Kit Lot Number: K0081791
Expiration Date: 31 DEC 2022

Kit Components:

Description	Lot Number	Storage Temperature	Expiration Date
SARS-CoV-2 Plate 14	Z0057010	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
Metric	CV of Intra-plate Averages	Average Intra-plate CV	Max Intra-plate CV	Average Uniformity Metric	Average Signal
SARS-CoV-2 Spike	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (A.23.1)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (A.VOI.V2)	≤ 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 (C.37)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (R.1)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (P.3)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (B.1.525)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (B.1.1.519)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (BV-1)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000

CERTIFICATE OF ANALYSIS

Coating Confirmation Testing Results:

Spot	Description	Result
1	SARS-CoV-2 Spike	Pass
2	SARS-CoV-2 Spike (A.23.1)	Pass
3	SARS-CoV-2 Spike (A.VOI.V2)	Pass
4	SARS-CoV-2 Spike (B.1.617.2)	Pass
5	SARS-CoV-2 Spike (C.37)	Pass
6	SARS-CoV-2 Spike (R.1)	Pass
7	SARS-CoV-2 Spike (P.3)	Pass
8	SARS-CoV-2 Spike (B.1.525)	Pass
9	SARS-CoV-2 Spike (B.1.1.519)	Pass
10	SARS-CoV-2 Spike (BV-1)	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
SARS-CoV-2 Spike	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (A.23.1)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (A.VOI.V2)	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 (C.37)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (R.1)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (P.3)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (B.1.525)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (B.1.1.519)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (BV-1)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2

Additional Comments:

Functional testing was executed using SARS-CoV-2 Plate 14 (Z0057010), 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	*Karen Hamilla*	13 AUG 2021