



CERTIFICATE OF ANALYSIS

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Product Description: V-PLEX[®] SARS-CoV-2 384 Panel 1 Kit
Kit Catalog Numbers: K25392-Series; K25393-Series; K25394-Series; K25395-Series;
Kit Lot Number: K0081857
Expiration Date: 31 JUL 2023

Kit Components:

Description	Lot Number	Storage Temperature	Expiration Date
SARS-CoV-2 384 Plate 1	Z0056884	2-8°C	31 AUG 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	D0081708	2-8°C	31 JUL 2023
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
SARS-CoV-2 Spike	≤ 18%	≤ 13%	≤ 16%	Pass	1,500 – 1,000,000
SARS-CoV-2 Nucleocapsid	≤ 18%	≤ 13%	≤ 16%	Pass	1,500 – 1,000,000
SARS-CoV-2 S1 RBD	≤ 18%	≤ 13%	≤ 16%	Pass	1,500 – 1,000,000

Coating Confirmation Testing Results:

Spot	Description	Result
1	SARS-CoV-2 Spike	Pass
2	SARS-CoV-2 Nucleocapsid	Pass
3	SARS-CoV-2 S1 RBD	Pass



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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%	< 25%	± 25%	0.80 – 1.2
SARS-CoV-2 Nucleocapsid	50 – 200%	70 – 130%	< 25%	± 25%	0.80 – 1.2
SARS-CoV-2 S1 RBD	50 – 200%	70 – 130%	< 25%	± 25%	0.80 – 1.2

Additional Comments:

Functional testing was executed using SARS-CoV-2 384 Plate 1 (Z0056884), SULFO-TAG Anti-Human IgG Antibody (D00V0009), Reference Standard 1 (A0080270), 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		08 OCT 2021