



CERTIFICATE OF ANALYSIS

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Product Description: V-PLEX[®] SARS-CoV-2 384 Kit
Kit Catalog Numbers: K25392-Series, K25393-Series, K25394-Series, K25395-Series
Kit Lot Number: K0081714
Expiration Date: 25 JUN 2022

Kit Components:

Description	Lot Number	Storage Temperature	Expiration Date
SARS-CoV-2 384 Plate	Z0056804	2-8°C	31 MAR 2023
SULFO-TAG [™] Anti-Human IgG Antibody	D00V0005	2-8°C	29 FEB 2024
SULFO-TAG [™] Anti-Human IgM Antibody	D0014233	2-8°C	31 OCT 2023
SULFO-TAG [™] Anti-Human IgA Antibody	D0014234	2-8°C	31 OCT 2023
Reference Standard 1	A00V0004	≤ -70°C	30 JUN 2025
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	D00V0001	2-8°C	25 JUN 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		
SARS-CoV-2 Spike	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Nucleocapsid	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 S1 RBD	≤ 18%	≤ 10%	≤ 13%	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 (Z0056804), SULFO-TAG Anti-Human IgG Antibody (D00V0005), Reference Standard 1 (A00V0004), and Serology Controls (A00C0731, A00C0732, A00C0733).

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		29 APR 2021