



CERTIFICATE OF ANALYSIS

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Product Description: V-PLEX[®] SARS-CoV-2 384 Panel 2 (IgG) Kit
Kit Catalog Numbers: K25420-Series
Kit Lot Number: K0081726
Expiration Date: 31 MAR 2022

Kit Components:

Description	Lot Number	Storage Temperature	Expiration Date
SARS-CoV-2 384 Plate 2	Z0056898	2-8°C	30 SEP 2023
SULFO-TAG [™] Anti-Human IgG Antibody	D00V0004	2-8°C	31 JAN 2024
Diluent 100	Y0270280	2-8°C	31 DEC 2022
Reference Standard 1	A0080270	≤ -70°C	30 SEP 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
MSD Blocker A	Y0181058	Room Temperature	31 DEC 2022
MSD Phosphate Buffer (5X)	Y0170112	Room Temperature	31 OCT 2022
Wash Buffer (20X)	Y0510015	Room Temperature	31 MAR 2022
MSD GOLD Read Buffer B	Y0800010	Room Temperature	31 DEC 2022

Plate Uniformity Testing Results:

Parameter	Precision			Uniformity	Signal
	Metric	CV of Intra-plate Averages	Average Intra-plate CV		
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 (B.1.351)	≤ 18%	≤ 13%	≤ 16%	Pass	1,500 – 1,000,000
SARS- CoV-2 Spike (B.1.351)	≤ 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 (B.1.351)	Pass
4	SARS- CoV-2 Spike (B.1.351)	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 (B.1.351)	50 – 200%	70 – 130%	< 25%	± 25%	0.80 – 1.2
SARS- CoV-2 Spike (B.1.351)	50 – 200%	70 – 130%	< 25%	± 25%	0.80 – 1.2

Additional Comments:

Functional testing was executed using SARS-CoV-2 384 Plate 2 (Z0056898), SULFO-TAG Anti-Human IgG Antibody (D00V0004), 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		06 MAY 2021