



CERTIFICATE OF ANALYSIS

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Product Description: V-PLEX® SARS-CoV-2 Panel 7 Kit
Kit Catalog Numbers: K15437-Series
Kit Lot Number: K0081816
Expiration Date: 31 JAN 2024

Kit Components:

Description	Lot Number	Storage Temperature	Expiration Date
SARS-CoV-2 Plate 7	Z0057027	2-8°C	31 Jan 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™ Anti-Human IgG Antibody	D00V0014	2-8°C	31 Dec 2024
Diluent 100	Not Kit Specific	2-8°C	See Label
MSD Blocker A Kit	Not Kit Specific	Room Temperature	See Label
MSD GOLD Read Buffer B	Not Kit Specific	Room Temperature	See Label

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%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 S1 RBD (B.1.351)	≤ 25%	≤ 15%	≤ 18%	Fail	1,500 – 1,000,000
SARS-CoV-2 Nucleocapsid	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 S1 RBD (P.1)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 S1 RBD (B.1.1.7)	≤ 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%	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 S1 RBD (B.1.351)	Pass
3	SARS-CoV-2 Nucleocapsid	Pass
4	SARS-CoV-2 S1 RBD (P.1)	Pass
6	SARS-CoV-2 S1 RBD (B.1.1.7)	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 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%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 S1 RBD (B.1.351)	50 - 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Nucleocapsid	50 - 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 S1 RBD (P.1)	50 - 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 S1 RBD (B.1.1.7)	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 S1 RBD	50 - 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2

Additional Comments:

Functional testing was executed using SARS-CoV-2 Plate 7 (Z0057027), 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		24 APR 2023