



CERTIFICATE OF ANALYSIS

Page 1 of 2

Product Description: V-PLEX[®] COVID-19 Coronavirus Panel 3 Kit
Kit Catalog Numbers: K15400-Series; K15401-Series; K15402-Series; K15399-Series
Kit Lot Number: K0081584
Expiration Date: 25 JUN 2022

Kit Components:

Description	Lot Number	Storage Temperature	Expiration Date
Coronavirus Plate 3	Z0056799	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	A00C0731	≤ -70°C	30 JUN 2025
Serology Control 1.2	A00C0732	≤ -70°C	30 JUN 2025
Serology Control 1.3	A00C0733	≤ -70°C	30 JUN 2025
SULFO-TAG [™] Human ACE2 Protein	D00V0001	2-8°C	25 JUN 2022
ACE2 Calibration Reagent	A00V0001	2-8°C	31 DEC 2023
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, IgM, IgA, and ACE2 kit.

Plate Uniformity Testing Results:

Parameter	Precision			Uniformity	Signal
	CV of Intra-plate Averages	Average Intra-plate CV	Max Intra-plate CV		
CoV-2 Spike	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
NL63 Spike	≤ 25%	≤ 15%	≤ 18%	Pass	1,500 – 1,000,000
CoV-2 N	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
CoV-1 Spike	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
MERS Spike	≤ 25%	≤ 15%	≤ 18%	Pass	1,500 – 1,000,000
HKU1 Spike	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
OC43 Spike	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
229E Spike	≤ 25%	≤ 15%	≤ 18%	Pass	1,500 – 1,000,000
CoV-2 RBD	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000



CERTIFICATE OF ANALYSIS

Page 2 of 2

Coating Confirmation Testing Results:

Spot	Description	Result
1	CoV-2 Spike	Pass
2	NL63 Spike	Pass
3	CoV-2 N	Pass
4	CoV-1 Spike	Pass
6	MERS Spike	Pass
7	HKU1 Spike	Pass
8	OC43 Spike	Pass
9	229E Spike	Pass
10	CoV-2 RBD	Pass

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
CoV-2 Spike	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
NL63 Spike	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
CoV-2 N	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
CoV-1 Spike	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
MERS Spike	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
HKU1 Spike	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
OC43 Spike	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
229E Spike	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
CoV-2 RBD	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2

Additional Comments:

Functional testing was executed using Coronavirus Plate 3 (Z0056799), SULFO-TAG Anti-Human IgG Antibody (D00V0005), Reference Standard (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		20 OCT 2020