

# **CERTIFICATE OF ANALYSIS**

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<b>Product Description:</b>	V-PLEX <sup>®</sup> COVID-19 Coronavirus Panel 2 Kit		
Kit Catalog Numbers:	K15369-Series; K15370-Series; K15371-Series; K15378-Series		
Kit Lot Number:	K0081858		
<b>Expiration Date</b> :	31 JUL 2023		

# **Kit Components:**

Description	Lot Number	Storage Temperature	<b>Expiration Date</b>
Coronavirus Plate 2	Z0056909	2-8°C	30 SEP 2023
SULFO-TAG <sup>™</sup> Anti-Human IgG Antibody	D00V0009	2-8°C	31 JUL 2024
SULFO-TAG <sup>™</sup> Anti-Human IgM Antibody	D00V0011	2-8°C	31 AUG 2024
SULFO-TAG <sup>™</sup> Anti-Human IgA Antibody	D00V0010	2-8°C	31 JUL 2024
Reference Standard 1	A0080286	$\leq$ -70°C	28 FEB 2026
Serology Control 1.1	A00C0771	$\leq$ -70°C	28 FEB 2026
Serology Control 1.2	A00C0772	$\leq$ -70°C	28 FEB 2026
Serology Control 1.3	A00C0773	$\leq$ -70°C	28 FEB 2026
SULFO-TAG <sup>™</sup> 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, IgM, IgA, and ACE2 kit.

### **Plate Uniformity Testing Results:**

Parameter	Precision			Uniformity	Signal
Metric	CV of Intra- plate Averages	Average Intra- plate CV	Max Intra- plate CV	Average Uniformity Metric	Average Signal
SARS-CoV-2 Spike	≤18%	$\leq 10\%$	≤13%	Pass	1,500 - 1,000,000
HCoV-NL63 Spike	$\leq 25\%$	$\leq 15\%$	≤18%	Pass	1,500 - 1,000,000
SARS-CoV-2 Nucleocapsid	$\leq 18\%$	$\leq 10\%$	$\leq 13\%$	Pass	1,500 - 1,000,000
SARS-CoV-1 Spike	$\leq 18\%$	$\leq 10\%$	≤13%	Pass	1,500 - 1,000,000
SARS-CoV-2 S1 NTD	$\leq 18\%$	$\leq 10\%$	$\leq 13\%$	Pass	1,500 - 1,000,000
HCoV-HKU1 Spike	$\leq 18\%$	$\leq 10\%$	≤13%	Pass	1,500 - 1,000,000
HCoV-OC43 Spike	$\leq 18\%$	$\leq 10\%$	≤13%	Pass	1,500 - 1,000,000
HCoV-229E Spike	$\leq 25\%$	$\leq 15\%$	≤18%	Pass	1,500 - 1,000,000
SARS-CoV-2 S1 RBD	$\leq 18\%$	$\leq 10\%$	$\leq 13\%$	Pass	1,500 - 1,000,000



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<b>Coating Confirmation Testing Results:</b>	

Spot	Description	Result
1	SARS-CoV-2 Spike	Pass
2	HCoV-NL63 Spike	Pass
3	SARS-CoV-2 Nucleocapsid	Pass
4	SARS-CoV-1 Spike	Pass
6	SARS-CoV-2 S1 NTD	Pass
7	HCoV-HKU1 Spike	Pass
8	HCoV-OC43 Spike	Pass
9	HCoV-229E Spike	Pass
10	SARS-CoV-2 S1 RBD	Pass

#### **Functional Testing Results:**

Sample Type	Calibrator	Controls		Samples	5
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%	$\pm 25\%$	0.80 - 1.2
HCoV-NL63 Spike	50 - 200%	70 - 130%	< 20%	$\pm 25\%$	0.80 - 1.2
SARS-CoV-2 Nucleocapsid	50 - 200%	70 - 130%	< 20%	$\pm 25\%$	0.80 - 1.2
SARS-CoV-1 Spike	50 - 200%	70 - 130%	< 20%	$\pm 25\%$	0.80 - 1.2
SARS-CoV-2 S1 NTD	50 - 200%	70 - 130%	< 20%	$\pm 25\%$	0.80 - 1.2
HCoV-HKU1 Spike	50 - 200%	70 - 130%	< 20%	$\pm 25\%$	0.80 - 1.2
HCoV-OC43 Spike	50 - 200%	70 - 130%	< 20%	$\pm 25\%$	0.80 - 1.2
HCoV-229E Spike	50 - 200%	70 - 130%	< 20%	± 25%	0.80 - 1.2
SARS-CoV-2 S1 RBD	50 - 200%	70 - 130%	< 20%	$\pm 25\%$	0.80 - 1.2

#### **Additional Comments:**

Functional testing was executed using Coronavirus Plate 2 (Z0056909), 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
<b>Review/Approval</b>	Karen Hamilla	Quality	dawn Hamille	12 OCT 2021