

CERTIFICATE OF ANALYSIS

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Product Description: V-PLEX® SARS-CoV-2 Panel 2 Kit

Kit Catalog Numbers: K15383-Series; K15384-Series; K15385-Series; K15386-Series;

K15475Series; K15476-Series; K15477-Series

Kit Lot Number: K0082017 **Expiration Date**: 31 DEC 2022

Kit Components:

Description	Lot Number	Storage Temperature	Expiration Date
SARS CoV-2 Plate 2	Z0056738	2-8°C	31 DEC 2022
Reference Standard 1	A0080286	≤-70°C	28 FEB 2026
Serology Control 1.1	A00C0825	≤ -70°C	31 MAR 2027
Serology Control 1.2	A00C0826	≤-70°C	31 MAR 2027
Serology Control 1.3	A00C0827	≤ -70°C	31 MAR 2027
SULFO-TAG™ Human ACE2 Protein	D0081760	2-8°C	31 JAN 2024
ACE2 Calibration Reagent	A0080301	2-8°C	31 MAR 2025
SULFO-TAG™ Anti-Human IgG Antibody	D00V0024	2-8°C	31 AUG 2025
SULFO-TAG™ Anti-Human IgM Antibody	Not Kit Specific	2-8°C	See Label
SULFO-TAG™ Anti-Human IgA Antibody	Not Kit Specific	2-8°C	See Label
SULFO-TAG TM Anti-Mouse IgG Antibody	Not Kit Specific	2-8°C	See Label
SULFO-TAG TM Anti-Mouse IgM Antibody	Not Kit Specific	2-8°C	See Label
SULFO-TAG TM Anti-Mouse IgA Antibody	Not Kit Specific	2-8°C	See Label
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

See product insert regarding which components are provided with each IgG, IgA, IgM, or 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%	≤ 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
3	SARS CoV-2 Nucleocapsid	Pass
10	SARS CoV-2 S1 RBD	Pass

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Functional Testing Results:

Sample Type	Calibrator	Controls		Samples	
Metric	Avg Signal Ratio Test:Reference	Control Recovery	Control Conc. CV	Avg % 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 Plate 2 (Z0056738), SULFO-TAG Anti-Human IgG Antibody (D00V0002), 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	Haver Hamille	28 APR 2022

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