

### **CERTIFICATE OF ANALYSIS**

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**Product Description:** V-PLEX® SARS-CoV-2 Panel 26 Kit

Kit Catalog Numbers: K15593-Series; K15594-Series; K15595-Series; K15596-Series; K15597-

Series; K15598-Series; K15599-Series

**Kit Lot Number**: K0082035 **Expiration Date**: 31 JAN 2024

## **Kit Components:**

Description	Lot Number	<b>Storage Temperature</b>	<b>Expiration Date</b>
SARS-CoV-2 Plate 26	Z0057162	2-8°C	30 SEP 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™ Human ACE2 Protein	D0081760	2-8°C	31 JAN 2024
ACE2 Calibration Reagent 2	A0080327	2-8°C	31 OCT 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 <sup>TM</sup> Anti-Human IgA Antibody	Not Kit Specific	2-8°C	See Label
SULFO-TAG <sup>TM</sup> Anti-Mouse IgG Antibody	Not Kit Specific	2-8°C	See Label
SULFO-TAG <sup>TM</sup> Anti-Mouse IgM Antibody	Not Kit Specific	2-8°C	See Label
SULFO-TAG™ 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
RBD (Omicron; BA.1)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 - 1,000,000
RBD (Beta)	≤ 25%	≤ 15%	≤ 18%	Pass	1,500 – 1,000,000
RBD (Omicron; BA.2)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 - 1,000,000
RBD (Gamma)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
RBD (Alpha)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
RBD (Omicron; BA.1.1)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 - 1,000,000
RBD (Delta)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 S1 RBD	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 - 1,000,000

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# **Coating Confirmation Testing Results:**

Spot	Description	Result	
1	RBD (Omicron; BA.1)	Pass	
2	RBD (Beta)	Pass	
3	RBD (Omicron; BA.2)	Pass	
4	RBD (Gamma)	Pass	
6	RBD (Alpha)	Pass	
8	RBD (Omicron; BA.1.1)	Pass	
9	RBD (Delta)	Pass	
10	SARS-CoV-2 S1 RBD	Pass	

**RBD** indicates SARS-CoV-2 Receptor Binding Domain with mutation(s) listed.

### **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
RBD (Omicron; BA.1)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 - 1.2
RBD (Beta)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 - 1.2
RBD (Omicron; BA.2)	N/A	N/A	N/A	N/A	N/A
RBD (Gamma)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 - 1.2
RBD (Alpha)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 - 1.2
RBD (Omicron; BA.1.1)	N/A	N/A	N/A	N/A	N/A
RBD (Delta)	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 26 (Z0057162), SULFO-TAG Anti-Human IgG Antibody (D00V0024), 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	Haven Hamille	13 JUN 2022

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