



RFE MEMO


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Product Description(s): SULFO-TAG™ Human ACE2 Protein

Catalog Number(s) / Size(s): D21ADG-3

Lot Number: D0081708

Based on additional testing, the original date of expiration for this detection antibody has been extended by 12 months. The expiration date of D0081708 has been extended to 31 JUL 2024.

Function	Name	Signature	Date
Quality	Karen Hamilla		28 MAR 2023

This memo supersedes all other statements regarding date of expiration for this product.



CERTIFICATE OF ANALYSIS

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Product Description: V-PLEX[®]SARS-CoV-2 Panel 34 Kit
Kit Catalog Numbers: K15690U-Series; K15691U-Series; K15693U-Series; K15694U-Series;
 K15695U-Series; K15696U-Series
Kit Lot Number: K0082293
Expiration Date: 31 Jul 2024

Kit Components:

Description	Lot Number	Storage Temperature	Expiration Date
SARS-CoV-2 Plate 34	Z0057376	2-8°C	31 Oct 2025
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	D0081708	2-8°C	31 Jul 2024
ACE2 Calibration Reagent	A0080327	2-8°C	31 Oct 2025
SULFO-TAG [™] Anti-Human IgG Antibody	D00V0029	2-8°C	31 Jul 2026
SULFO-TAG [™] Anti-Human IgM Antibody	Not Kit Specific	2-8°C	See Label
SULFO-TAG [™] Anti-Mouse IgG Antibody	Not Kit Specific	2-8°C	See Label
SULFO-TAG [™] 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
	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 Spike (B.1.1.529; BA.1)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (XBB.1)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (BF.7)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (XBB.1.5)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (BQ.1.1)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (BA.2.75)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (BN.1)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (BQ.1)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (BA.5)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000



CERTIFICATE OF ANALYSIS

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Coating Confirmation Testing Results:

Spot	Description	Result
1	SARS-CoV-2 Spike	Pass
2	SARS-CoV-2 Spike (B.1.1.529; BA.1)	Pass
3	SARS-CoV-2 Spike (XBB.1)	Pass
4	SARS-CoV-2 Spike (BF.7)	Pass
5	SARS-CoV-2 Spike (XBB.1.5)	Pass
6	SARS-CoV-2 Spike (BQ.1.1)	Pass
7	SARS-CoV-2 Spike (BA.2.75)	Pass
8	SARS-CoV-2 Spike (BN.1)	Pass
9	SARS-CoV-2 Spike (BQ.1)	Pass
10	SARS-CoV-2 Spike (BA.5)	Pass

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%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (B.1.1.529; BA.1)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (XBB.1)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (BF.7)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (XBB.1.5)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (BQ.1.1)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (BA.2.75)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (BN.1)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (BQ.1)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (BA.5)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2

Additional Comments:

Functional testing was executed using SARS-CoV-2 Plate 34 (Z0057376), SULFO-TAG Anti-Human IgG Antibody (D00V0029), Reference Standard 1 (A0080286), and Serology Controls (A00C0825, A00C0826, A00C0827).

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		19 JUN 2023