



EXTENSION MEMO


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Product Description(s): Reference Standard 1

Catalog Number(s) / Size(s): C00ADK-2

Lot Number: A0080286

Based on additional testing, the original date of expiration for this Reference Standard has been extended by 60 months. The expiration date of A0080286 has been extended to 28 FEB 2031.

Function	Name	Signature	Date
Quality	Karen Hamilla		06 MAY 2024

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



RFE MEMO

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Product Description(s): Serology Control Pack 1


Catalog Number(s) / Size(s): C4381-1

Lot Number: A00C0825, A00C0826, A00C0827

Based on additional testing, the original date of expiration for this Control Pack has been extended by 60 months. The expiration date of A00C0825, A00C0826, A00C0827 has been extended to 31 MAR 2032

The expiration dates for the following controls have been extended:

Description	Lot Number	Original Expiration Date	New Expiration Date
Serology Control 1.1	A00C0825	31 MAR 2027	31 MAR 2032
Serology Control 1.2	A00C0826	31 MAR 2027	31 MAR 2032
Serology Control 1.3	A00C0827	31 MAR 2027	31 MAR 2032

Function	Name	Signature	Date
Quality	Karen Hamilla		03 MAY 2024

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 38 Kit
Kit Catalog Numbers: K0082519
Kit Lot Number: K15725U-Series; K15726U-Series; K15727U-Series
Expiration Date: 31 DEC 2026

Kit Components:

Description	Lot Number	Storage Temperature	Expiration Date
SARS-CoV-2 Plate 38	Z0057485	2-8°C	31 DEC 2026
SULFO-TAG™ Anti-Human IgG Antibody	D00V0033	2-8°C	28 FEB 2027
Reference Standard 1	A0080286	≤ -70°C	28 FEB 2031
Serology Control 1.1	A00C0825	≤ -70°C	31 MAR 2032
Serology Control 1.2	A00C0826	≤ -70°C	31 MAR 2032
Serology Control 1.3	A00C0827	≤ -70°C	31 MAR 2032
ACE2 Calibration Reagent	Not Kit Specific	≤ -70°C	See Label
SULFO-TAG™ Human ACE2 Protein	Not Kit Specific	2-8°C	See Label
SULFO-TAG™ Anti-Human IgG Antibody	Not Kit Specific	2-8°C	See Label
SULFO-TAG™ Anti-Human 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, 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 (FL.1.5.1)	≤ 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 Spike (BA.2.86)	≤ 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 (EG.5.1)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (JN.1)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (JD.1.1)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (HV.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 (FL.1.5.1)	Pass
3	SARS-CoV-2 Nucleocapsid	Pass
4	SARS-CoV-2 Spike (BA.2.86)	Pass
5	SARS-CoV-2 Spike (XBB.1.5)	Pass
6	SARS-CoV-2 Spike (EG.5.1)	Pass
7	SARS-CoV-2 Spike (JN.1)	Pass
8	SARS-CoV-2 Spike (JD.1.1)	Pass
9	SARS-CoV-2 Spike (HV.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 (FL.1.5.1)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Nucleocapsid	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (BA.2.86)	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 (EG.5.1)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (JN.1)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (JD.1.1)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (HV.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 Panel 38 (Z0057485), SULFO-TAG Anti-Human IgG Antibody (D00V0033), 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		20 AUG 2024