



Extension Memo

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Product Description: V-PLEX® SARS-CoV-2 Panel 26 Kit
Catalog Number(s): K15593-Series; K15594-Series; K15595-Series; K15596-Series; K15597-Series; K15598-Series; K15599-Series
Lot Number: K0082046
New Expiration Date: 30 NOV 2025

Based on additional testing, the original date of expiration for this kit has been extended by 21 months.

The expiration dates for the following components have also been extended:

Description	Lot Number	Original Expiration Date	New Expiration Date
SARS-CoV-2 Plate 26	Z0057186	30 NOV 2024	30 NOV 2025
ACE2 Calibration Reagent 2	A0080327	31 OCT 2025	30 NOV 2025
SULFO-TAG™ Anti-Human IgG Antibody	D00V0025	30 SEP 2025	30 NOV 2025
SULFO-TAG™ Human ACE2 Protein	D0081760	31 JAN 2024	31 JAN 2026
Reference Standard 1	A0080286	28 FEB 2026	28 FEB 2031
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		05 Dec 2024



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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: K0082046
Expiration Date: 31 JAN 2024

Kit Components:

Description	Lot Number	Storage Temperature	Expiration Date
SARS-CoV-2 Plate 26	Z0057186	2-8°C	30 NOV 2024
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 2	A0080327	2-8°C	31 OCT 2025
SULFO-TAG™ Anti-Human IgG Antibody	D00V0025	2-8°C	30 SEP 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™ 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		
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)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
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)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
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 (Z0057186), SULFO-TAG Anti-Human IgG Antibody (D00V0025), 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 JUN 2022