



CERTIFICATE OF ANALYSIS

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Product Description: V-PLEX Respiratory Panel 7 Kit
Kit Catalog Numbers: K15735U-Series; K15736U-Series
Kit Lot Number: K0082574
Expiration Date: 31 MAR 2027

Kit Components:

Description	Lot Number	Storage Temperature	Expiration Date
Respiratory Plate 7	Z0057518	2-8°C	31 MAR 2027
MSD GOLD SULFO-TAG™ Anti-Human IgG Antibody	D00V0036	2-8°C	31 MAR 2027
Reference Standard 2	A0080403	≤ -70°C	30 JUN 2034
Serology Control 2.1	A00C0959	≤ -70°C	30 JUN 2034
Serology Control 2.2	A00C0960	≤ -70°C	30 JUN 2034
Serology Control 2.3	A00C0961	≤ -70°C	30 JUN 2034
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, or IgA, 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
Flu A/Wisconsin/67/2022 H1	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 N	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (XBB.1.5 (v2))	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
Flu A/Ghana/39/2021 H5	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
RSV Pre-Fusion F	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
Flu A/Massachusetts/18/2022 H3	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
Flu B/Austria/2021 HA	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (KP.2)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000



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Coating Confirmation Testing Results:

Spot	Description	Result
1	SARS-CoV-2 Spike	Pass
2	Flu A/Wisconsin/67/2022 H1	Pass
3	SARS-CoV-2 N	Pass
5	SARS-CoV-2 Spike(XBB.1.5 (v2))	Pass
6	Flu A/Ghana/39/2021 H5	Pass
7	RSV Pre-Fusion F	Pass
8	Flu A/Massachusetts/18/2022 H3	Pass
9	Flu B/Austria/2021 HA	Pass
10	SARS-CoV-2 Spike (KP.2)	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 – 1.20
Flu A/Wisconsin/67/ 2022 H1	50 – 200%	70 – 130%	< 20%	±25%	0.80 – 1.20
SARS-CoV-2 N	50 – 200%	70 – 130%	< 20%	±25%	0.80 – 1.20
SARS-CoV-2 Spike (XBB.1.5 (v2))	50 – 200%	70 – 130%	< 20%	±25%	0.80 – 1.20
Flu A/Ghana/39/2021 H5	50 – 200%	70 – 130%	< 20%	N/A	N/A
RSV Pre-Fusion F	50 – 200%	70 – 130%	< 20%	±25%	0.80 – 1.20
Flu A/Massachusetts/18/ 2022 H3	50 – 200%	70 – 130%	< 20%	±25%	0.80 – 1.20
Flu B/Austria/2021 HA	50 – 200%	70 – 130%	< 20%	±25%	0.80 – 1.20
SARS-CoV-2 Spike (KP.2)	50 – 200%	70 – 130%	< 20%	±25%	0.80 – 1.20

Additional Comments:

Functional testing was executed using Respiratory Plate 7 (Z0057518), SULFO-TAG Anti-Human IgG Antibody (D00V0040), Reference Standard 2 (A0080403), and Serology Controls (A00C0959, A00C0960, A00C0961).

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		31 JAN 2025