



CERTIFICATE OF ANALYSIS

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Product Description: V-PLEX[®] Respiratory Panel 1 Kit
Kit Catalog Numbers: K15365-Series; K15366-Series; K15367-Series; K15377-Series
Kit Lot Number: K0082206
Expiration Date: 31 JAN 2024

Kit Components:

Description	Lot Number	Storage Temperature	Expiration Date
Respiratory Plate 1	Z0057316	2-8°C	30 JUN 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	D0081760	2-8°C	31 JAN 2024
ACE2 Calibration Reagent	A0080309	2-8°C	30 APR 2025
SULFO-TAG [™] Anti-Human IgG Antibody	D00V0004	2-8°C	31 JAN 2024
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
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		
Flu B/Brisbane HA	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
Flu A/Shanghai H7	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
Flu A/Michigan H1	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
RSV Pre-Fusion F	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
Flu A/HongKong H3	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
Flu B/Phuket HA	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000

Coating Confirmation Testing Results:

Spot	Description	Result
1	Flu B/Brisbane HA	Pass
2	Flu A/Shanghai H7	Pass
4	Flu A/Michigan H1	Pass
7	RSV Pre-Fusion F	Pass
8	Flu A/HongKong H3	Pass
10	Flu B/Phuket HA	Pass



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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
Flu B/Brisbane HA	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
Flu A/Shanghai H7	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
Flu A/Michigan H1	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
RSV Pre-Fusion F	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
Flu A/HongKong H3	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
Flu B/Phuket HA	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2

Additional Comments:

Functional testing was executed using Respiratory Plate 1 (Z0057316), SULFO-TAG Anti-Human IgG Antibody (D00V0004), 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		24 JAN 2023