



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: K0081713
Expiration Date: 25 JUN 2022

Kit Components:

Description	Lot Number	Storage Temperature	Expiration Date
Respiratory Plate 1	Z0056764	2-8°C	31 JAN 2023
SULFO-TAG [™] Anti-Human IgG Antibody	D00V0005	2-8°C	29 FEB 2024
SULFO-TAG [™] Anti-Human IgM Antibody	D0014233	2-8°C	31 OCT 2023
SULFO-TAG [™] Anti-Human IgA Antibody	D0014234	2-8°C	31 OCT 2023
Reference Standard 1	A00V0004	≤ -70°C	30 JUN 2025
Serology Control 1.1	A00C0771	≤ -70°C	28 FEB 2026
Serology Control 1.2	A00C0772	≤ -70°C	28 FEB 2026
Serology Control 1.3	A00C0773	≤ -70°C	28 FEB 2026
SULFO-TAG [™] Human ACE2 Protein	D00V0001	2-8°C	25 JUN 2022
ACE2 Calibration Reagent	A0080285	2-8°C	31 AUG 2024
MSD Blocker A Kit	Not Kit Specific	Room Temperature	See Label
Diluent 100	Not Kit Specific	2-8°C	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, IgM, IgA, and 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



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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

Functional Testing Results:

Sample Type	Calibrator	Controls		Samples	
		Average Signal Ratio Test:Reference	Control Recovery	Control Conc. CV	Average % Difference Test:Reference
Flu B/Brisbane HA	50 – 200%	70 – 130%	< 25%	± 25%	0.80 – 1.2
Flu A/Shanghai H7	50 – 200%	70 – 130%	< 25%	± 25%	0.80 – 1.2
Flu A/Michigan H1	50 – 200%	70 – 130%	< 25%	± 25%	0.80 – 1.2
RSV Pre-Fusion F	50 – 200%	70 – 130%	< 25%	± 25%	0.80 – 1.2
Flu A/HongKong H3	50 – 200%	70 – 130%	< 25%	± 25%	0.80 – 1.2
Flu B/Phuket HA	50 – 200%	70 – 130%	< 25%	± 25%	0.80 – 1.2

Additional Comments:

Functional testing was executed using Respiratory Plate 1 (Z0056764), SULFO-TAG Anti-Human IgG Antibody (D00V0005), Reference Standard (A00V0004), and Serology Controls (A00C0731, A00C0732, A00C0733).

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		30 APR 2021