

CERTIFICATE OF ANALYSIS

Page 1 of 2

Product Description:	V-PLEX [®] Respiratory Panel 1 Kit		
Kit Catalog Numbers:	K15365-Series; K15366-Series; K15367-Series; K15377-Series		
Kit Lot Number:	K0082037		
Expiration Date:	31 JAN 2024		

Kit Components:

Description	Lot Number	Storage Temperature	Expiration Date
Respiratory Plate 1	Z0057180	2-8°C	31 OCT 2024
Reference Standard 1	A0080286	\leq -70°C	28 FEB 2026
Serology Control 1.1	A00C0825	\leq -70°C	31 MAR 2027
Serology Control 1.2	A00C0826	\leq -70°C	31 MAR 2027
Serology Control 1.3	A00C0827	\leq -70°C	31 MAR 2027
SULFO-TAG [™] Human ACE2 Protein	D0081760	2-8°C	31 JAN 2024
ACE2 Calibration Reagent	A0080301	2-8°C	31 MAR 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
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, and ACE2 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
Flu B/Brisbane HA	$\leq 18\%$	$\leq 10\%$	≤13%	Pass	1,500 - 1,000,000
Flu A/Shanghai H7	$\leq 18\%$	$\leq 10\%$	≤13%	Pass	1,500 - 1,000,000
Flu A/Michigan H1	$\leq 18\%$	$\leq 10\%$	≤13%	Pass	1,500 - 1,000,000
RSV Pre-Fusion F	≤18%	$\leq 10\%$	≤13%	Pass	1,500 - 1,000,000
Flu A/HongKong H3	$\leq 18\%$	$\leq 10\%$	≤13%	Pass	1,500 - 1,000,000
Flu B/Phuket HA	$\leq 18\%$	$\leq 10\%$	≤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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Page 2 of 2

Functional Testing Results:

Sample Type	Calibrator	Controls		Samples	
Metric	Average 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%	$\pm 25\%$	0.80 - 1.2
Flu A/Shanghai H7	50 - 200%	70 - 130%	< 20%	$\pm 25\%$	0.78
Flu A/Michigan H1	50 - 200%	70 - 130%	< 20%	$\pm 25\%$	0.80 - 1.2
RSV Pre-Fusion F	50 - 200%	70 - 130%	< 20%	$\pm 25\%$	0.80 - 1.2
Flu A/HongKong H3	50 - 200%	70 - 130%	< 20%	$\pm 25\%$	0.80 - 1.2
Flu B/Phuket HA	50 - 200%	70 - 130%	< 20%	$\pm 25\%$	0.80 - 1.2

Additional Comments:

Functional testing was executed using Respiratory Plate 1 (Z0057180), 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	Kann Hamille	08 JUN 2022