



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: K0081577
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	A00C0731	≤ -70°C	30 JUN 2025
Serology Control 1.2	A00C0732	≤ -70°C	30 JUN 2025
Serology Control 1.3	A00C0733	≤ -70°C	30 JUN 2025
SULFO-TAG [™] Human ACE2 Protein	D00V0001	2-8°C	25 JUN 2022
ACE2 Calibration Reagent	A00V0001	2-8°C	31 DEC 2023
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		
B/Brisbane	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
H7/Shanghai	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
H1/Michigan	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
RSV Pre-F	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
H3/HongKong	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
B/Phuket	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000



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Coating Confirmation Testing Results:

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

Functional Testing Results:

Sample Type	Calibrator	Controls		Samples	
Metric	Average Signal Ratio Test:Reference	Control Recovery	Control Conc. CV	Average % Difference Test:Reference	Slope Test:Reference
B/Brisbane	50 – 200%	70 – 130%	< 25%	± 25%	0.80 – 1.2
H7/Shanghai	50 – 200%	70 – 130%	< 25%	± 25%	0.80 – 1.2
H1/Michigan	50 – 200%	70 – 130%	< 25%	± 25%	0.80 – 1.2
RSV Pre-F	50 – 200%	70 – 130%	< 25%	± 25%	0.80 – 1.2
H3/HongKong	50 – 200%	70 – 130%	< 25%	± 25%	0.80 – 1.2
B/Phuket	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		20 OCT 2020