



RFE MEMO

Page 1 of 1

Product Description(s): Serology Control Pack 1


Catalog Number(s) / Size(s): C4381-1

Lot Number: A00C0825, A00C0826, A00C0827

Based on additional testing, the original date of expiration for this Control Pack has been extended by 60 months. The expiration date of A00C0825, A00C0826, A00C0827 has been extended to 31 MAR 2032

The expiration dates for the following controls have been extended:

Description	Lot Number	Original Expiration Date	New Expiration Date
Serology Control 1.1	A00C0825	31 MAR 2027	31 MAR 2032
Serology Control 1.2	A00C0826	31 MAR 2027	31 MAR 2032
Serology Control 1.3	A00C0827	31 MAR 2027	31 MAR 2032

Function	Name	Signature	Date
Quality	Karen Hamilla		03 MAY 2024

This memo supersedes all other statements regarding date of expiration for this product.



EXTENSION MEMO


Page 1 of 1

Product Description(s): Reference Standard 1

Catalog Number(s) / Size(s): C00ADK-2

Lot Number: A0080286

Based on additional testing, the original date of expiration for this Reference Standard has been extended by 60 months. The expiration date of A0080286 has been extended to 28 FEB 2031.

Function	Name	Signature	Date
Quality	Karen Hamilla		06 MAY 2024

This memo supersedes all other statements regarding date of expiration for this product.



CERTIFICATE OF ANALYSIS

Page 1 of 2

Product Description: V-PLEX Respiratory Panel 1 Kit
Kit Catalog Numbers: K15365U-Series, K15366U-Series, K15367-Series
Kit Lot Number: K0082555
Expiration Date: 28 FEB 2027

Kit Components:

Description	Lot Number	Storage Temperature	Expiration Date
Respiratory Plate 1	Z0057507	2-8°C	28 FEB 2027
SULFO-TAG™ Anti-Human IgG Antibody	D00V0038	2-8°C	31 AUG 2027
Reference Standard 1	A0080286	≤ -70°C	28 FEB 2031
Serology Control 1.1	A00C0825	≤ -70°C	31 MAR 2032
Serology Control 1.2	A00C0826	≤ -70°C	31 MAR 2032
Serology Control 1.3	A00C0827	≤ -70°C	31 MAR 2032
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/2008 HA	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
Flu A/Shanghai/2013 H7	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
Flu A/Michigan/2015 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/2014 H3	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
Flu B/Phuket/2013 HA	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000



CERTIFICATE OF ANALYSIS

Page 2 of 2

Coating Confirmation Testing Results:

Spot	Description	Result
1	Flu B/Brisbane/2008 HA	Pass
2	Flu A/Shanghai/2013 H7	Pass
4	Flu A/Michigan/2015 H1	Pass
7	RSV Pre-Fusion F	Pass
8	Flu A/HongKong/2014 H3	Pass
10	Flu B/Phuket/2013 HA	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
Flu B/Brisbane/2008 HA	50 – 200%	70 – 130%	< 20%	±25%	0.80 – 1.20
Flu A/Shanghai/2013 H7	50 – 200%	70 – 130%	< 20%	N/A	N/A
Flu A/Michigan/2015 H1	50 – 200%	70 – 130%	< 20%	±25%	0.80 – 1.20
RSV Pre-Fusion F	50 – 200%	70 – 130%	< 20%	±25%	0.80 – 1.20
Flu A/HongKong/2014 H3	50 – 200%	70 – 130%	< 20%	±25%	0.80 – 1.20
Flu B/Phuket/2013 HA	50 – 200%	70 – 130%	< 20%	±25%	0.80 – 1.20

Additional Comments:

Functional testing was executed using Respiratory Plate 1 (Z0057507), SULFO-TAG Anti-Human IgG Antibody (D00V0038), Reference Standard 2 (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		22 NOV 2024