



CERTIFICATE OF ANALYSIS

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Product Description: V-PLEX[®] Respiratory Panel 4 Kit
Kit Catalog Numbers: K15707-Series
Kit Lot Number: K0082536
Expiration Date: 31 JAN 2027

Kit Components:

Description	Lot Number	Storage Temperature	Expiration Date
Respiratory Plate 4	Z0057489	2-8°C	31 JAN 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
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		
SARS-CoV-2 Spike	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
Flu A/Wisconsin/2019 H1	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Nucleocapsid	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
SARS-CoV-2 Spike (XBB.1.5)	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
Flu A/Shanghai/2013 H7	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
RSV Pre-Fusion F	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
Flu A/Darwin/2021 H3	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
Flu B/Austria/2021 HA	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000
Flu B/Phuket/2013 HA	≤ 18%	≤ 10%	≤ 13%	Pass	1,500 – 1,000,000



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Coating Confirmation Testing Results:

Spot	Description	Result
1	SARS-CoV-2 Spike	Pass
2	Flu A/Wisconsin/2019 H1	Pass
3	SARS-CoV-2 Nucleocapsid	Pass
4	SARS-CoV-2 Spike (XBB.1.5)	Pass
5	Flu A/Shanghai/2013 H7	Pass
7	RSV Pre-Fusion F	Pass
8	Flu A/Darwin/2021 H3	Pass
9	Flu B/Austria/2021 HA	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
SARS-CoV-2 Spike	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
Flu A/Wisconsin/2019 H1	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Nucleocapsid	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
SARS-CoV-2 Spike (XBB.1.5)	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
Flu A/Shanghai/2013 H7	50 – 200%	70 – 130%	< 20%	N/A	N/A
RSV Pre-Fusion F	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
Flu A/Darwin/2021 H3	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
Flu B/Austria/2021 HA	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2
Flu B/Phuket/2013 HA	50 – 200%	70 – 130%	< 20%	± 25%	0.80 – 1.2

Additional Comments:

Functional testing was executed using Respiratory Plate 4 (Z0057489), SULFO-TAG Anti-Human IgG Antibody (D00V0038), 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		09 OCT 2024



EXTENSION MEMO


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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.



October 2023

Re: Serology Control Pack 1 (Catalog No. C4381-1), Lot No. A00C0825, A00C0826 and A00C0827 Revised Concentrations

Dear Valued Customer,

As part of our process for continuous product improvement, we periodically review the performance specifications of V-PLEX[®] products. As we accumulate data from additional lots, if the larger data set indicates a change to a more accurate value, we update the product accordingly.

We recently reviewed the data for the controls in our Serology Control Pack 1 Lot No. A00C0825, A00C0826, A00C0827. We decided to reassign the values of the IgG Control 1.1, Control 1.2 and Control 1.3 for the SARS-CoV-2 Spike (AY.4.2) analyte as the larger data set provides more accurate values for these controls. Additionally, a reassignment for the MERS-CoV Spike analyte is required for IgG Control 1.2 (lot A00C0826). The values for Controls 1.1 and 1.3 for the MERS-CoV Spike analyte are also included in the tables, although those values have not been revised.

The revised (Table 1 and Table 2) and original (Table 3 and 4) values for the controls are listed below.

Table 1: Revised concentration assignment of IgG Antibodies (vial)

Assay	Control 1.1	Control 1.2	Control 1.3	Unit of Measure
SARS-CoV-2 Spike (AY.4.2)	10.9	4.04	1.19	AU/mL
MERS-CoV Spike	>ULOQ	0.231	0.260	AU/mL

Table 2: Revised concentration assignment of IgG Antibodies (1:5000 dilution adjusted)

Assay	Control 1.1	Control 1.2	Control 1.3	Unit of Measure
SARS-CoV-2 Spike (AY.4.2)	54500	20200	5950	AU/mL
MERS-CoV Spike	>ULOQ	1155	1300	AU/mL

Table 3: Original concentration assignment of IgG Antibodies (vial)

Assay	Control 1.1	Control 1.2	Control 1.3	Unit of Measure
SARS-CoV-2 Spike (AY.4.2)	9.85	3.48	0.940	AU/mL
MERS-CoV Spike	>ULOQ	0.207	0.260	AU/mL

Table 4: Original concentration assignment of IgG Antibodies (1:5000 dilution adjusted)

Assay	Control 1.1	Control 1.2	Control 1.3	Unit of Measure
SARS-CoV-2 Spike (AY.4.2)	49250	17400	4700	AU/mL
MERS-CoV Spike	>ULOQ	1035	1300	AU/mL



For the Serology Control Pack 1 Lot No. A00C0825, A00C0826 and A00C0827 there is also an update in control concentration assignments for some of our Serology assays. Due to an error in preparing the certificate of analysis, we initially provided inaccurate control concentration assignments for the IgM and IgA assays listed in Tables 5 and 6. After we identified the error, we corrected the control values of the affected analytes. The revised (Table 5) and original (Table 6) values for Controls 1.1, 1.2, and 1.3 are listed below.

Assay										
Detector	IgM					IgA				
Units = AU/mL	SARS-CoV-2 Spike (B.1.640.2)	SARS-CoV-2 Spike (BA.1 + L452R)	SARS-CoV-2 Spike (BA.1 + R346K)	SARS-CoV-2 Spike (BA.2)	SARS-CoV-2 Spike (BA.3)	SARS-CoV-2 Spike (B.1.640.2)	SARS-CoV-2 Spike (BA.1 + L452R)	SARS-CoV-2 Spike (BA.1 + R346K)	SARS-CoV-2 Spike (BA.2)	SARS-CoV-2 Spike (BA.3)
Control 1.1 (A00C0825)	1.72	0.442	0.271	0.819	0.266	0.782	0.224	0.129	0.557	0.141
Control 1.2 (A00C0826)	0.228	0.0962	<LLOQ	0.114	0.0518	0.0981	0.0319	<LLOQ	0.157	<LLOQ
Control 1.3 (A00C0827)	0.185	<LLOQ	<LLOQ	0.0712	<LLOQ	0.0797	<LLOQ	<LLOQ	0.103	<LLOQ

Table 5. Revised concentrations

Assay										
Detector	IgM					IgA				
Units = AU/mL	SARS-CoV-2 Spike (B.1.640.2)	SARS-CoV-2 Spike (BA.1 + L452R)	SARS-CoV-2 Spike (BA.1 + R346K)	SARS-CoV-2 Spike (BA.2)	SARS-CoV-2 Spike (BA.3)	SARS-CoV-2 Spike (B.1.640.2)	SARS-CoV-2 Spike (BA.1 + L452R)	SARS-CoV-2 Spike (BA.1 + R346K)	SARS-CoV-2 Spike (BA.2)	SARS-CoV-2 Spike (BA.3)
Control 1.1 (A00C0825)	1.79	0.478	0.294	0.789	0.282	4.00	1.10	0.602	2.71	0.682
Control 1.2 (A00C0826)	0.225	0.0808	0.0495	0.165	0.0517	1.69	0.484	0.247	0.752	0.281
Control 1.3 (A00C0827)	0.186	0.0394	0.0234	0.113	0.0342	0.538	0.133	0.0751	0.258	0.085

Table 6. Original concentrations

If you have any questions or concerns, please contact MSD Scientific Support at +1 240-314-2798 or scientificsupport@mesoscale.com.

Sincerely,

MSD Quality Assurance



RFE MEMO

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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.