

**CERTIFICATE OF ANALYSIS****Product Description:** Serology Control Pack 1**Catalog Number:** C4381-1**Storage Temperature:** ≤-70°C

Components	Lot Number	Expiration Date
Serology Control 1.1	A00C0731	30 Jun 2025
Serology Control 1.2	A00C0732	30 Jun 2025
Serology Control 1.3	A00C0733	30 Jun 2025

Values are provided in two units - MSD Arbitrary Units/mL (AU/mL) and WHO Biological Arbitrary Units/mL (BAU/mL) (NIBSC 20/136).

Control Assignments based on WHO Standard (vial):

Assay	Isotype	Control 1.1	Control 1.2	Control 1.3	UOM
SARS-CoV-2 Nucleocapsid	IgG	0.0457	0.0078	0.0025	BAU/mL
SARS-CoV-2 S1 RBD		0.1952	0.0576	0.0148	BAU/mL
SARS-CoV-2 Spike		0.1504	0.0372	0.0133	BAU/mL
SARS-CoV-2 Nucleocapsid	IgM	0.0610	0.0300	0.0285	BAU/mL
SARS-CoV-2 S1 RBD		0.0110	0.0047	0.0068	BAU/mL
SARS-CoV-2 Spike		0.0187	0.0054	0.0077	BAU/mL
SARS-CoV-2 Nucleocapsid	IgA	0.1410	0.0237	0.0379	BAU/mL
SARS-CoV-2 S1 RBD		0.0394	0.0131	0.0085	BAU/mL
SARS-CoV-2 Spike		0.0768	0.0230	0.0103	BAU/mL

Control Assignments based on WHO Standard (1:5000 dilution adjusted):

Assay	Isotype	Control 1.1	Control 1.2	Control 1.3	UOM
SARS-CoV-2 Nucleocapsid	IgG	229	39.1	12.4	BAU/mL
SARS-CoV-2 S1 RBD		976	288	74.0	BAU/mL
SARS-CoV-2 Spike		752	186	66.7	BAU/mL
SARS-CoV-2 Nucleocapsid	IgM	305	150	143	BAU/mL
SARS-CoV-2 S1 RBD		55.2	23.3	34.0	BAU/mL
SARS-CoV-2 Spike		93.6	27.1	38.6	BAU/mL
SARS-CoV-2 Nucleocapsid	IgA	707	119	190	BAU/mL
SARS-CoV-2 S1 RBD		197	65.3	42.6	BAU/mL
SARS-CoV-2 Spike		384	115	51.5	BAU/mL

Note: Controls 1.1, 1.2, and 1.3 are provided pre-diluted. Their assigned concentrations reflect the antibody concentrations in the as-provided vial material. Dilution-adjusted concentrations that are comparable to the concentration of antibodies in undiluted samples are provided below.



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Concentration Assignment of IgG Antibodies (vialed):

Assay	Alternate Name	Control 1.1	Control 1.2	Control 1.3	UOM
SARS-CoV-2					
SARS-CoV-2 Nucleocapsid		19.4	3.31	1.05	AU/mL
SARS-CoV-2 S1 NTD		0.252	NA	NA	AU/mL
SARS-CoV-2 S1 RBD		7.18	2.12	0.545	AU/mL
SARS-CoV-2 Spike		16.7	4.13	1.48	AU/mL
SARS-CoV-2 S1 RBD (B.1.1.7)	N501Y	4.74	1.41	0.405	AU/mL
SARS-CoV-2 S1 RBD (B.1.351)	K417N, E484K, N501Y	1.41	0.490	0.174	AU/mL
SARS-CoV-2 S1 RBD (P.1)	K417T, E484K, N501Y	2.37	0.784	0.284	AU/mL
SARS-CoV-2 Spike (D614G)		16.6	3.99	1.90	AU/mL
SARS-CoV-2 Spike (B.1.1.7)		10.1	2.89	1.07	AU/mL
SARS-CoV-2 Spike (B.1.351)		4.81	1.36	0.931	AU/mL
SARS-CoV-2 Spike (P.1)		8.40	2.06	0.838	AU/mL
Other Coronaviruses					
SARS-CoV-1 Spike		1.27	0.431	0.385	AU/mL
MERS-CoV Spike		1.12	0.129	0.700	AU/mL
HCoV-229E Spike		7.59	2.20	2.97	AU/mL
HCoV-HKU1 Spike		7.67	1.48	2.39	AU/mL
HCoV-NL63 Spike		1.30	0.250	0.344	AU/mL
HCoV-OC43 Spike		12.8	4.03	10.6	AU/mL
Other Respiratory Viruses					
Flu A/HongKong H3		23.6	6.31	5.64	AU/mL
Flu A/Michigan H1		22.8	9.22	6.76	AU/mL
Flu A/Shanghai H7		4.36	1.85	0.626	AU/mL
Flu B/Brisbane HA		22.4	8.18	8.92	AU/mL
Flu B/Phuket HA		22.2	9.19	14.0	AU/mL
RSV Pre-Fusion F		22.5	10.5	13.9	AU/mL



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Concentration Assignment of IgG Antibodies (1:5000 dilution-adjusted):

Assay	Alternate Name	Control 1.1	Control 1.2	Control 1.3	UOM
SARS-CoV-2					
SARS-CoV-2 Nucleocapsid		97000	16550	5250	AU/mL
SARS-CoV-2 S1 NTD		1260	NA	NA	AU/mL
SARS-CoV-2 S1 RBD		35900	10600	2725	AU/mL
SARS-CoV-2 Spike		83500	20650	7400	AU/mL
SARS-CoV-2 S1 RBD (B.1.1.7)	N501Y	23700	7050	2025	AU/mL
SARS-CoV-2 S1 RBD (B.1.351)	K417N, E484K, N501Y	7050	2450	870	AU/mL
SARS-CoV-2 S1 RBD (P.1)	K417T, E484K, N501Y	11850	3920	1420	AU/mL
SARS-CoV-2 Spike (D614G)		83000	19950	9500	AU/mL
SARS-CoV-2 Spike (B.1.1.7)		50500	14450	5350	AU/mL
SARS-CoV-2 Spike (B.1.351)		24050	6800	4655	AU/mL
SARS-CoV-2 Spike (P.1)		42000	10300	4190	AU/mL
Other Coronaviruses					
SARS-CoV-1 Spike		6350	2155	1925	AU/mL
MERS-CoV Spike		5600	645	3500	AU/mL
HCoV-229E Spike		37950	11000	14850	AU/mL
HCoV-HKU1 Spike		38350	7400	11950	AU/mL
HCoV-NL63 Spike		6500	1250	1720	AU/mL
HCoV-OC43 Spike		64000	20150	53000	AU/mL
Other Respiratory Viruses					
Flu A/HongKong H3		118000	31550	28200	AU/mL
Flu A/Michigan H1		114000	46100	33800	AU/mL
Flu A/Shanghai H7		21800	9250	3130	AU/mL
Flu B/Brisbane HA		112000	40900	44600	AU/mL
Flu B/Phuket HA		111000	45950	70000	AU/mL
RSV Pre-Fusion F		112500	52500	69500	AU/mL

Concentration Assignment of IgM Antibodies (viald):

Assay	Alternate Name	Control 1.1	Control 1.2	Control 1.3	UOM
SARS-CoV-2					
SARS-CoV-2 Nucleocapsid		0.462	0.227	0.216	AU/mL
SARS-CoV-2 S1 RBD		0.474	0.200	0.292	AU/mL
SARS-CoV-2 Spike		0.863	0.250	0.356	AU/mL
SARS-CoV-2 S1 RBD (B.1.1.7)	N501Y	0.320	0.134	0.192	AU/mL
SARS-CoV-2 S1 RBD (B.1.351)	K417N, E484K, N501Y	0.0494	0.0583	0.0797	AU/mL
SARS-CoV-2 S1 RBD (P.1)	K417T, E484K, N501Y	<LLOQ	0.423	<LLOQ	AU/mL
SARS-CoV-2 Spike (D614G)		1.00	0.283	0.372	AU/mL
SARS-CoV-2 Spike (B.1.1.7)		0.582	0.200	0.288	AU/mL
SARS-CoV-2 Spike (B.1.351)		0.174	0.0548	0.118	AU/mL
SARS-CoV-2 Spike (P.1)		0.285	0.0744	0.149	AU/mL



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Concentration Assignment of IgM Antibodies (1:5000 dilution-adjusted):

Assay	Alternate Name	Control 1.1	Control 1.2	Control 1.3	UOM
SARS-CoV-2					
SARS-CoV-2 Nucleocapsid		2310	1135	1080	AU/mL
SARS-CoV-2 S1 RBD		2370	1000	1460	AU/mL
SARS-CoV-2 Spike		4315	1250	1780	AU/mL
SARS-CoV-2 S1 RBD (B.1.1.7)	N501Y	1600	670	960	AU/mL
SARS-CoV-2 S1 RBD (B.1.351)	K417N, E484K, N501Y	247	291.5	398.5	AU/mL
SARS-CoV-2 S1 RBD (P.1)	K417T, E484K, N501Y	<LLOQ	2115	<LLOQ	AU/mL
SARS-CoV-2 Spike (D614G)		5000	1415	1860	AU/mL
SARS-CoV-2 Spike (B.1.1.7)		2910	1000	1440	AU/mL
SARS-CoV-2 Spike (B.1.351)		870	274	590	AU/mL
SARS-CoV-2 Spike (P.1)		1425	372	745	AU/mL

Concentration Assignment of IgA Antibodies (viald):

Assay	Alternate Name	Control 1.1	Control 1.2	Control 1.3	UOM
SARS-CoV-2					
SARS-CoV-2 Nucleocapsid		1.27	0.213	0.340	AU/mL
SARS-CoV-2 S1 NTD		0.501	0.160	0.034*	AU/mL
SARS-CoV-2 S1 RBD		0.504	0.167	0.109	AU/mL
SARS-CoV-2 Spike		1.24	0.371	0.166	AU/mL
SARS-CoV-2 S1 RBD (B.1.1.7)	N501Y	0.317	0.0934	0.0612	AU/mL
SARS-CoV-2 S1 RBD (B.1.351)	K417N, E484K, N501Y	0.0709	0.027	0.0144	AU/mL
SARS-CoV-2 S1 RBD (P.1)	K417T, E484K, N501Y	0.136	0.053	0.0325	AU/mL
SARS-CoV-2 Spike (D614G)		1.27	0.372	0.161	AU/mL
SARS-CoV-2 Spike (B.1.1.7)		0.662	0.193	0.11	AU/mL
SARS-CoV-2 Spike (B.1.351)		0.496	0.15	0.0614	AU/mL
SARS-CoV-2 Spike (P.1)		0.481	0.117	0.0849	AU/mL
Other Coronaviruses					
SARS-CoV-1 Spike		0.256	0.133	0.138	AU/mL
MERS-CoV Spike		0.240	0.130	0.224	AU/mL
HCoV-229E Spike		0.977	0.503	0.727	AU/mL
HCoV-HKU1 Spike		3.22	1.14	0.290	AU/mL
HCoV-NL63 Spike		0.254	0.327	0.565	AU/mL
HCoV-OC43 Spike		5.33	2.04	0.968	AU/mL
Other Respiratory Viruses					
Flu A/HongKong H3		4.81	2.90	2.96	AU/mL
Flu A/Michigan H1		7.26	2.75	1.02	AU/mL
Flu A/Shanghai H7		0.250	0.154	0.226	AU/mL
Flu B/Brisbane HA		29.6	11.4	1.62	AU/mL
Flu B/Phuket HA		16.5	6.75	2.24	AU/mL
RSV Pre-Fusion F		11.9	4.10	2.25	AU/mL

* Control ECL signals are close to the lower end of the calibration curve; measured and assigned concentration values are expected to be variable.



CERTIFICATE OF ANALYSIS

Concentration Assignment of IgA Antibodies (1:5000 dilution-adjusted):

Assay	Alternate Name	Control 1.1	Control 1.2	Control 1.3	UOM
SARS-CoV-2					
SARS-CoV-2 Nucleocapsid		6350	1065	1700	AU/mL
SARS-CoV-2 S1 NTD		2505	800	172*	AU/mL
SARS-CoV-2 S1 RBD		2520	835	545	AU/mL
SARS-CoV-2 Spike		6200	1855	830	AU/mL
SARS-CoV-2 S1 RBD (B.1.1.7)	N501Y	1585	467	306	AU/mL
SARS-CoV-2 S1 RBD (B.1.351)	K417N, E484K, N501Y	354.5	135	72	AU/mL
SARS-CoV-2 S1 RBD (P.1)	K417T, E484K, N501Y	680	265	162.5	AU/mL
SARS-CoV-2 Spike (D614G)		6350	1860	805	AU/mL
SARS-CoV-2 Spike (B.1.1.7)		3310	965	550	AU/mL
SARS-CoV-2 Spike (B.1.351)		2480	750	307	AU/mL
SARS-CoV-2 Spike (P.1)		2405	585	424.5	AU/mL
Other Coronaviruses					
SARS-CoV-1 Spike		1280	665	690	AU/mL
MERS-CoV Spike		1200	650	1120	AU/mL
HCoV-229E Spike		4885	2515	3635	AU/mL
HCoV-HKU1 Spike		16100	5700	1450	AU/mL
HCoV-NL63 Spike		1270	1635	2825	AU/mL
HCoV-OC43 Spike		26650	10200	4840	AU/mL
Other Respiratory Viruses					
Flu A/HongKong H3		24050	14500	14800	AU/mL
Flu A/Michigan H1		36300	13750	5100	AU/mL
Flu A/Shanghai H7		1250	770	1130	AU/mL
Flu B/Brisbane HA		148000	57000	8100	AU/mL
Flu B/Phuket HA		82500	33750	11200	AU/mL
RSV Pre-Fusion F		59500	20500	11250	AU/mL

* Control ECL signals are close to the lower end of the calibration curve; measured and assigned concentration values are expected to be variable.

This product was manufactured and tested according to MSD documents. This lot meets MSD's specifications. This product is intended for Research Use Only. Not for use in Diagnostic Procedures.

	Name	Function	Signature	Date
Review/Approval	Karen Hamilla	Quality		24 JUN 2021