



CERTIFICATE OF ANALYSIS

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Product Description: Serology Control Pack 2

Control Pack Lot Number: CP000166

Catalog Number: C4731-1

Storage Temperature: ≤ -70 °C

Components	Lot Number	Expiration Date
Serology Control 2.1	A00C0959	30 JUN 2034
Serology Control 2.2	A00C0960	30 JUN 2034
Serology Control 2.3	A00C0961	30 JUN 2034

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

WHO/NIBSC Units: MSD Units					
Antigen	Isotype	Control 2.1	Control 2.2	Control 2.3	Unit of Measure
SARS-CoV-2 Spike	IgG	0.413	0.215	0.125	BAU/mL
SARS-CoV-2 Spike	IgA	0.228	0.116	0.0665	BAU/mL
SARS-CoV-2 N	IgG	0.118	0.0577	0.0346	BAU/mL
SARS-CoV-2 N	IgA	0.764	0.357	0.201	BAU/mL

Note: Controls 2.1, 2.2 and 2.3 are provided pre-diluted. Their assigned concentrations reflect the antibody concentrations in the as-provided vial material.

Concentration Assignment of IgG Antibodies (vial):

Assay	Control 2.1	Control 2.2	Control 2.3	Unit of Measure
SARS-CoV-2 Spike	47.9	24.6	14.8	AU/mL
SARS-CoV-2 N	54.8	27.7	15.9	AU/mL
SARS-CoV-2 Spike (B.1.1.529; BA.1)	9.74	4.76	2.69	AU/mL
SARS-CoV-2 Spike (B.1.1.7)	37.5	19.0	11.5	AU/mL
SARS-CoV-2 Spike (B.1.351)	31.5	16.1	9.33	AU/mL
SARS-CoV-2 Spike (B.1.617.2; AY.4)	42.5	21.7	12.4	AU/mL
SARS-CoV-2 Spike (BA.2)	15.6	7.80	4.56	AU/mL
SARS-CoV-2 Spike (BA.2.12.1)	14.3	7.26	4.14	AU/mL
SARS-CoV-2 Spike (BA.2.75)	9.48	4.62	2.76	AU/mL
SARS-CoV-2 Spike (BA.2.86)	9.05	4.37	2.57	AU/mL
SARS-CoV-2 Spike (BA.5)	16.3	7.98	4.60	AU/mL
SARS-CoV-2 Spike (EG.5.1)	8.64	4.27	2.48	AU/mL
SARS-CoV-2 Spike (FL.1.5.1)	9.01	4.46	2.56	AU/mL
SARS-CoV-2 Spike (HV.1)	10.1	4.91	2.84	AU/mL
SARS-CoV-2 Spike (JD.1.1)	10.8	5.33	3.15	AU/mL
SARS-CoV-2 Spike (JN.1)	9.25	4.44	2.47	AU/mL



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Assay	Control 2.1	Control 2.2	Control 2.3	Unit of Measure
SARS-CoV-2 Spike (XBB.1.16)	11.0	5.31	2.93	AU/mL
SARS-CoV-2 Spike (XBB.1.16.6)	7.96	3.92	2.31	AU/mL
SARS-CoV-2 Spike (XBB.1.5)	7.43	3.62	2.12	AU/mL
SARS-CoV-2 Spike (XBB.2.3)	12.6	5.88	3.39	AU/mL

Concentration Assignment of IgA Antibodies (vial):

Assay	Control 2.1	Control 2.2	Control 2.3	Unit of Measure
SARS-CoV-2 Spike	4.19	2.10	1.24	AU/mL
SARS-CoV-2 N	6.34	3.15	1.77	AU/mL
SARS-CoV-2 Spike (B.1.1.529; BA.1)	1.31	0.647	0.360	AU/mL
SARS-CoV-2 Spike (B.1.1.7)	3.41	1.65	0.969	AU/mL
SARS-CoV-2 Spike (B.1.351)	4.28	2.11	1.21	AU/mL
SARS-CoV-2 Spike (B.1.617.2; AY.4)	5.38	2.64	1.50	AU/mL
SARS-CoV-2 Spike (BA.2)	2.34	1.15	0.665	AU/mL
SARS-CoV-2 Spike (BA.2.12.1)	2.27	1.13	0.642	AU/mL
SARS-CoV-2 Spike (BA.2.75)	1.45	0.721	0.425	AU/mL
SARS-CoV-2 Spike (BA.2.86)	1.31	0.645	0.375	AU/mL
SARS-CoV-2 Spike (BA.5)	2.85	1.40	0.797	AU/mL
SARS-CoV-2 Spike (EG.5.1)	1.35	0.663	0.376	AU/mL
SARS-CoV-2 Spike (FL.1.5.1)	1.46	0.732	0.421	AU/mL
SARS-CoV-2 Spike (HV.1)	1.36	0.668	0.373	AU/mL
SARS-CoV-2 Spike (JD.1.1)	1.43	0.695	0.396	AU/mL
SARS-CoV-2 Spike (JN.1)	1.19	0.574	0.319	AU/mL
SARS-CoV-2 Spike (XBB.1.16)	1.28	0.641	0.364	AU/mL
SARS-CoV-2 Spike (XBB.1.16.6)	1.01	0.511	0.296	AU/mL
SARS-CoV-2 Spike (XBB.1.5)	1.30	0.644	0.374	AU/mL
SARS-CoV-2 Spike (XBB.2.3)	1.25	0.617	0.363	AU/mL

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		28 OCT 2024