



CERTIFICATE OF ANALYSIS

Product Description: Reference Standard 1

Catalog Number: C00ADK-2

Lot Number: A0080270

Storage Temperature: ≤-70°C

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

For Use

Concentration Assignment of IgG Antibodies:

IgG: Use at 1:10 for all plate types

Assay	Alternate Name	Conc. of IgG (vial)	Conc. of IgG (1:10)	Unit of Measure
SARS-CoV-2				
SARS-CoV-2 Nucleocapsid		800	80.0	AU/mL
SARS-CoV-2 S1 NTD		10.0	1.00	AU/mL
SARS-CoV-2 S1 RBD		300	30.0	AU/mL
SARS-CoV-2 Spike		700	70.0	AU/mL
SARS-CoV-2 S1 RBD (B.1.1.7)	N501Y	200	20.0	AU/mL
SARS-CoV-2 S1 RBD (B.1.214.2)	Q414K, N450K	110	11.0	AU/mL
SARS-CoV-2 S1 RBD (B.1.351)	K417N, E484K, N501Y	63.0	6.30	AU/mL
SARS-CoV-2 S1 RBD (B.1.427)	L452R	180	18.0	AU/mL
SARS-CoV-2 S1 RBD (B.1.429)	L452R	180	18.0	AU/mL
SARS-CoV-2 S1 RBD (B.1.525)	E484K	120	12.0	AU/mL
SARS-CoV-2 S1 RBD (B.1.526)	E484K	120	12.0	AU/mL
SARS-CoV-2 S1 RBD (B.1.526.1)	L452R	180	18.0	AU/mL
SARS-CoV-2 S1 RBD (B.1.526.2)	S477N	250	25.0	AU/mL
SARS-CoV-2 S1 RBD (B.1.617)	L452R, E484Q	140	14.0	AU/mL
SARS-CoV-2 S1 RBD (B.1.617.1)	L452R, E484Q	140	14.0	AU/mL
SARS-CoV-2 S1 RBD (B.1.617.3)	L452R, E484Q	140	14.0	AU/mL
SARS-CoV-2 S1 RBD (P.1)	K417T, E484K, N501Y	100	10.0	AU/mL
SARS-CoV-2 S1 RBD (P.2)	E484K	120	12.0	AU/mL
SARS-CoV-2 S1 RBD (P.3)	E484K, N501Y	67.0	6.70	AU/mL
SARS-CoV-2 Spike (D614G)		720	72.0	AU/mL
SARS-CoV-2 Spike (B.1.1.7)		470	47.0	AU/mL
SARS-CoV-2 Spike (B.1.351)		210	21.0	AU/mL
SARS-CoV-2 Spike (B.1.429)		450	45.0	AU/mL
SARS-CoV-2 Spike (B.1.526)		460	46.0	AU/mL
SARS-CoV-2 Spike (P.1)		360	36.0	AU/mL
Other Coronaviruses				
SARS-CoV-1 Spike		50.0	5.00	AU/mL
MERS-CoV Spike		50.0	5.00	AU/mL
HCoV-229E Spike		300	30.0	AU/mL
HCoV-HKU1 Spike		300	30.0	AU/mL
HCoV-NL63 Spike		50.0	5.00	AU/mL
HCoV-OC43 Spike		500	50.0	AU/mL
Other Respiratory Viruses				
Flu A/HongKong H3		1000	100	AU/mL
Flu A/Michigan H1		1000	100	AU/mL
Flu A/Shanghai H7		200	20.0	AU/mL
Flu B/Brisbane HA		1000	100	AU/mL
Flu B/Phuket HA		1000	100	AU/mL
RSV Pre-Fusion F		1000	100	AU/mL



CERTIFICATE OF ANALYSIS

For Use

Concentration Assignment of IgM Antibodies:

IgM: Use as vialled for all plate types

Assay	Alternate Name	Conc. of IgM (vialled)	Unit of Measure
SARS-CoV-2			
SARS-CoV-2 Nucleocapsid		20.0	AU/mL
SARS-CoV-2 S1 NTD		2.00	AU/mL
SARS-CoV-2 S1 RBD		20.0	AU/mL
SARS-CoV-2 Spike		40.0	AU/mL
SARS-CoV-2 S1 RBD (B.1.1.7)	N501Y	14.0	AU/mL
SARS-CoV-2 S1 RBD (B.1.351)	K417N, E484K, N501Y	1.70	AU/mL
SARS-CoV-2 S1 RBD (B.1.427)	L452R	13.0	AU/mL
SARS-CoV-2 S1 RBD (B.1.429)	L452R	13.0	AU/mL
SARS-CoV-2 S1 RBD (B.1.525)	E484K	2.70	AU/mL
SARS-CoV-2 S1 RBD (B.1.526)	E484K	2.70	AU/mL
SARS-CoV-2 S1 RBD (B.1.526.1)	L452R	13.0	AU/mL
SARS-CoV-2 S1 RBD (B.1.526.2)	S477N	16.0	AU/mL
SARS-CoV-2 S1 RBD (P.1)	K417T, E484K, N501Y	1.70	AU/mL
SARS-CoV-2 S1 RBD (P.2)	E484K	2.70	AU/mL
SARS-CoV-2 Spike (D614G)		44.0	AU/mL
SARS-CoV-2 Spike (B.1.1.7)		28.0	AU/mL
SARS-CoV-2 Spike (B.1.351)		7.40	AU/mL
SARS-CoV-2 Spike (B.1.429)		24.0	AU/mL
SARS-CoV-2 Spike (B.1.526)		25.0	AU/mL
SARS-CoV-2 Spike (P.1)		12.0	AU/mL
Other Coronaviruses			
SARS-CoV-1 Spike		2.00	AU/mL
MERS-CoV Spike		4.00	AU/mL
HCoV-229E Spike		1.00	AU/mL
HCoV-HKU1 Spike		1.00	AU/mL
HCoV-NL63 Spike		0.20	AU/mL
HCoV-OC43 Spike		1.00	AU/mL
Other Respiratory Viruses			
Flu A/HongKong H3		1.00	AU/mL
Flu A/Michigan H1		10.0	AU/mL
Flu A/Shanghai H7		1.00	AU/mL
Flu B/Brisbane HA		60.0	AU/mL
Flu B/Phuket HA		80.0	AU/mL
RSV Pre-Fusion F		5.00	AU/mL



CERTIFICATE OF ANALYSIS

For Use

IgA: Use at 1:10 for Respiratory Plate 1;
Use as vialled for all other plate types

Concentration Assignment of IgA Antibodies:

Assay	Alternate Name	Conc. of IgA (vialled)	Conc. of IgA (1:10)	Unit of Measure
SARS-CoV-2				
SARS-CoV-2 Nucleocapsid		50.0	5.00	AU/mL
SARS-CoV-2 S1 NTD		20.0	2.00	AU/mL
SARS-CoV-2 S1 RBD		20.0	2.00	AU/mL
SARS-CoV-2 Spike		50.0	5.00	AU/mL
SARS-CoV-2 S1 RBD (B.1.1.7)	N501Y	14.0	1.40	AU/mL
SARS-CoV-2 S1 RBD (B.1.351)	K417N, E484K, N501Y	3.40	0.34	AU/mL
SARS-CoV-2 S1 RBD (B.1.427)	L452R	14.0	1.40	AU/mL
SARS-CoV-2 S1 RBD (B.1.429)	L452R	14.0	1.40	AU/mL
SARS-CoV-2 S1 RBD (B.1.525)	E484K	7.00	0.70	AU/mL
SARS-CoV-2 S1 RBD (B.1.526)	E484K	7.00	0.70	AU/mL
SARS-CoV-2 S1 RBD (B.1.526.1)	L452R	14.0	1.40	AU/mL
SARS-CoV-2 S1 RBD (B.1.526.2)	S477N	19.0	1.90	AU/mL
SARS-CoV-2 S1 RBD (P.1)	K417T, E484K, N501Y	6.40	0.64	AU/mL
SARS-CoV-2 S1 RBD (P.2)	E484K	7.00	0.70	AU/mL
SARS-CoV-2 Spike (D614G)		57.0	5.70	AU/mL
SARS-CoV-2 Spike (B.1.1.7)		33.0	3.30	AU/mL
SARS-CoV-2 Spike (B.1.351)		23.0	2.30	AU/mL
SARS-CoV-2 Spike (B.1.429)		32.0	3.20	AU/mL
SARS-CoV-2 Spike (B.1.526)		38.0	3.80	AU/mL
SARS-CoV-2 Spike (P.1)		22.0	2.20	AU/mL
Other Coronaviruses				
SARS-CoV-1 Spike		10.0	1.00	AU/mL
MERS-CoV Spike		10.0	1.00	AU/mL
HCoV-229E Spike		40.0	4.00	AU/mL
HCoV-HKU1 Spike		130	13.0	AU/mL
HCoV-NL63 Spike		10.0	1.00	AU/mL
HCoV-OC43 Spike		220	22.0	AU/mL
Other Respiratory Viruses				
Flu A/HongKong H3		200	20.00	AU/mL
Flu A/Michigan H1		300	30.0	AU/mL
Flu A/Shanghai H7		10.0	1.00	AU/mL
Flu B/Brisbane HA		1200	120	AU/mL
Flu B/Phuket HA		700	70.0	AU/mL
RSV Pre-Fusion F		500	50.0	AU/mL



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WHO/NIBSC Units: MSD Units				
Antigen	Antibodies	Vialed	1:10	Unit of Measure
SARS-CoV-2 Spike	IgG	6.31	0.631	BAU/mL
SARS-CoV-2 Nucleocapsid		1.89	0.189	BAU/mL
SARS-CoV-2 S1 RBD		8.16	0.816	BAU/mL
SARS-CoV-2 Spike	IgM	0.868		BAU/mL
SARS-CoV-2 Nucleocapsid		2.64		BAU/mL
SARS-CoV-2 S1 RBD		0.466		BAU/mL
SARS-CoV-2 Spike	IgA	3.10	0.310	BAU/mL
SARS-CoV-2 Nucleocapsid		5.55	0.555	BAU/mL
SARS-CoV-2 S1 RBD		1.56	0.156	BAU/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		11 JUN 2021