

COVID-19 Proficiency Samples

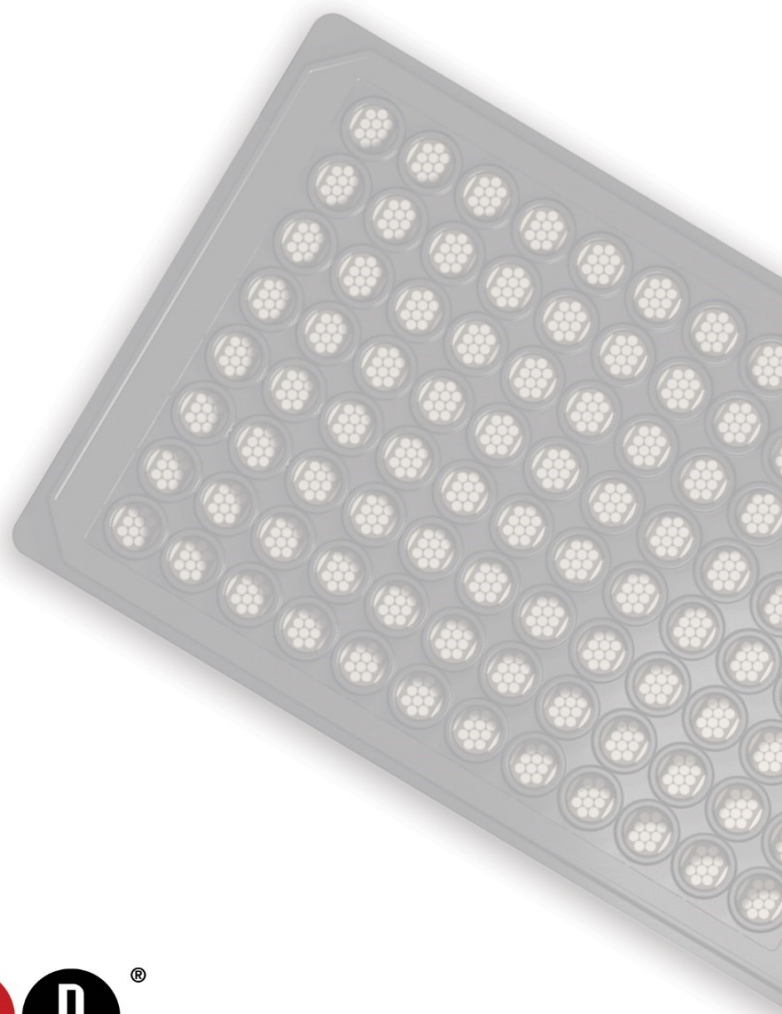
Products

COVID-19 Proficiency Sample Panel 1

COVID-19 Proficiency Sample Panel 2

COVID-19 Proficiency Sample Panel 3

Individual COVID-19 Proficiency Samples



MSD COVID-19 Proficiency Samples

Available as:

Panels (catalog numbers: C4417-1, C4418-1, and C4419-1)

or

Individual samples (catalog numbers: C50AED-1, C50AEF-1, C50AFR-1, C50AEG-1, C50AEH-1, C50AFS-1, C50AEJ-1, C50AEK-1, C50AFT-1, C50AEL-1, C50AEM-1, C50AFU-1, C50AEN-1, C50AEQ-1, C50AER-1, C50AES-1, C50AET-1, C50AEU-1, C50AEV-1, C50AFV-1, C50AEW-1, C50AEX-1, C50AEY-1, C50AEZ-1, C50AFA-1, C50AFB-1, C50AFC-1, C50AFD-1, C50AFW-1, C50AFE-1, C50AFF-1, C50AFG-1, C50AFH-1, C50AFJ-1, C50AFK-1, C50AFL-1, C50AFM-1, C50AFN-1, and C50AFP-1)

This package insert must be read in its entirety before using this product.

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NOT FOR USE IN DIAGNOSTIC PROCEDURES.

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Introduction

MSD COVID-19 Proficiency Samples are aliquots of human serum intended for use as test samples in MSD's V-PLEX® COVID-19 Serology Kits. They contain antibodies to antigens from SARS-CoV-2, SARS-1, MERS, circulating Coronaviruses, and other respiratory diseases. MSD provides assigned values for the concentration of antibodies in each sample, enabling users to assess their laboratory performance for testing, training, concordance studies, validations, and troubleshooting. Proficiency samples are available in panels (Table 1–3) or as individual samples (Table 4).

Kit Components

Table 1. COVID-19 Proficiency Sample Panel 1 (16 samples)

Reagent Description	Storage	Catalog Number	Size	Quantity
Proficiency Samples 134; 205; 277; 314; 370; 478; 503; 562; 577; 605; 678; 683; 812; 862; 920; 954	≤-70 °C	C4417-1	60 µL of each sample	16 Proficiency samples

Table 2. COVID-19 Proficiency Sample Panel 2 (34 samples)

Reagent Description	Storage	Catalog Number	Size	Quantity
Proficiency Samples 115; 134; 205; 244; 277; 314; 323; 356; 370; 418; 442; 478; 482; 493; 503; 512; 562; 577; 580; 596; 605; 623; 678; 683; 700; 711; 725; 796; 812; 856; 862; 887; 920; 954	≤-70 °C	C4418-1	60 µL of each sample	34 Proficiency samples

Table 3. COVID-19 Proficiency Sample Panel 3 (40 samples)

Reagent Description	Storage	Catalog Number	Size	Quantity
Proficiency Samples 102; 115; 134; 168; 205; 244; 277; 314; 323; 356; 370; 418; 435; 442; 478; 482; 493; 503; 512; 525; 562; 577; 580; 596; 605; 623; 678; 683; 700; 711; 725; 780; 796; 812; 856; 862; 887; 902; 920; 954	≤-70 °C	C4419-1	60 µL of each sample	40 Proficiency samples

Table 4. Individual COVID-19 Proficiency Samples

Reagent Description	Storage	Catalog Number	Size	Quantity
Proficiency Samples 102; 115; 134; 168; 205; 244; 277; 314; 323; 356; 370; 418; 435; 442; 478; 482; 493; 503; 512; 525; 562; 577; 580; 596; 605; 623; 678; 683; 700; 711; 725; 780; 796; 812; 856; 862; 887; 902; 920; 954	≤-70 °C	Multiple (see Table 5)	60 µL of each sample	1 vial of each sample

Additional Materials and Equipment

- ☐ Appropriately sized tubes for sample dilution
- ☐ Appropriate liquid handling equipment for desired throughput, capable of accurately dispensing 50 μ L and 500 μ L
- ☐ Diluent 100 (Catalog No. R50AA)
- ☐ Vortex mixer

Safety

MSD COVID-19 Proficiency samples contain human serum and are biosafety level 2 (BSL-2) products. Donors have been tested and found negative for HBsAg, HIV-1 and HIV-2 antibodies, and HCV. Use safe laboratory practices and wear gloves, safety glasses, and laboratory coats when handling kit components. Handle and dispose of all hazardous samples properly in accordance with local, state, and federal guidelines.

Additional product-specific safety information is available in the applicable safety data sheet(s) (SDS), which can be obtained from MSD Customer Service or at www.mesoscale.com[®].

Recommended Protocol

Thaw samples on ice. Thawed samples should be equilibrated to room temperature before loading into the plates.

Sample plate layouts are shown in Figure 1 and Figure 2 (below) for duplicate and quadruplicate runs of proficiency samples.

Proficiency Sample Preparation

Prepare the proficiency samples by diluting with Diluent 100 (Catalog No. R50AA). For most applications, 500-fold or 5,000-fold dilution provides the optimal result. The recommended dilution of proficiency samples is 5,000-fold for IgG and IgA assays and 500-fold for IgM assays, although users should follow their own established protocols for serology sample testing. This protocol provides guidance for preparing 500-fold and 5,000-fold dilutions.

Note: Unused, thawed samples may be stored at $\leq -70^{\circ}\text{C}$ and are stable through five freeze-thaw cycles.

- ☐ To make an intermediate **1:10** dilution in a 2 mL tube, or 96-well plate, combine:
 - 10 μL of sample
 - 90 μL of Diluent 100
- ☐ To make a **1:500** dilution in a 2 mL tube, or 96-well deep well plate, combine:
 - 10 μL of the 1:10 dilution from Step 1
 - 490 μL of Diluent 100
- ☐ To make a **1:5,000** dilution in a 2 mL tube, or 96-well deep well plate, combine:
 - 30 μL of the 1:500 dilution from Step 2
 - 270 μL of Diluent 100

Proficiency Sample Addition

Prepare the Reference Standard 1 and Serology Controls using the guidance provided in the V-PLEX Serology Kits product inserts (96-well and 384-well kits).

- ☐ Add 50 μL /well (for 96-well kit) or 25 μL /well (for 384-well kit) of diluted proficiency samples to the plate.

Seal the plate with an adhesive plate seal and proceed with calibrators, controls, and sample incubation step.

Analysis of Results

Calibration curves used to calculate antibody concentrations are established by fitting the signals from the calibrators to a 4-parameter logistic (or sigmoidal dose-response) model with a $1/Y^2$ weighting. The best quantification of proficiency samples is achieved by generating a calibration curve for each plate using a minimum of two replicates at each calibrator level.

Antibody unit concentrations in diluted proficiency samples are determined from their electrochemiluminescent (ECL) signals by backfitting to the calibration curve. Correcting for dilution provides the final antibody concentrations in undiluted samples. For example, if proficiency samples are tested at a 5,000-fold dilution, multiply the backfitted concentrations by 5,000.

Each proficiency sample contains assigned concentrations of human IgG, IgM, and IgA antibodies against antigens in the V-PLEX Serology Kits.

Appendix A and **B** provide assigned values for proficiency samples in MSD arbitrary units (AU/mL) and WHO international units (BAU/mL).

Recommended Plate Layouts

	1	2	3	4	5	6	7	8	9	10	11	12
A	CAL-01		Control 1.1		Sample-05		Sample-13		Sample-21		Sample-29	
B	CAL-02		Control 1.2		Sample-06		Sample-14		Sample-22		Sample-30	
C	CAL-03		Control 1.3		Sample-07		Sample-15		Sample-23		Sample-31	
D	CAL-04		Blank		Sample-08		Sample-16		Sample-24		Sample-32	
E	CAL-05		Sample-01		Sample-09		Sample-17		Sample-25		Sample-33	
F	CAL-06		Sample-02		Sample-10		Sample-18		Sample-26		Sample-34	
G	CAL-07		Sample-03		Sample-11		Sample-19		Sample-27		Sample-35	
H	CAL-08		Sample-04		Sample-12		Sample-20		Sample-28		Sample-36	

	1	2	3	4	5	6	7	8	9	10	11	12
A	CAL-01		Control 1.1		Sample 3				Sample 11			
B	CAL-02		Control 1.2		Sample 4				Sample 12			
C	CAL-03		Control 1.3		Sample 5				Sample 13			
D	CAL-04		Blank		Sample 6				Sample 14			
E	CAL-05		Sample 1		Sample 7				Sample 15			
F	CAL-06				Sample 8				Sample 16			
G	CAL-07		Sample 2		Sample 9				Sample 17			
H	CAL-08				Sample 10				Sample 18			

Appendix A: Assigned values of concentration in MSD arbitrary units (AU/mL)

Proficiency Samples	IgG Concentration (AU/mL)			
	SARS-CoV-2 Spike	SARS-CoV-2 Nucleocapsid	SARS-CoV-2 S1 RBD	SARS-CoV-2 S1 NTD
Proficiency Sample 102	307,000	400,000	94,700	3,830
Proficiency Sample 115	137,000	408,000	47,600	2,030
Proficiency Sample 134	171,000	97,900	44,600	2,500
Proficiency Sample 168	61.4	6,070	39.1	2.02
Proficiency Sample 205	123,000	378,000	19,800	1,580
Proficiency Sample 244	104,000	118,000	38,200	1,420
Proficiency Sample 277	55.4	96.6	41.3	1.15
Proficiency Sample 314	103,000	259,000	23,600	1,060
Proficiency Sample 323	23,200	144,000	7,320	321
Proficiency Sample 356	26.5	101	7.31	0.406
Proficiency Sample 370	21,700	100,000	7,120	345
Proficiency Sample 418	21,700	67,300	8,180	214
Proficiency Sample 435	104	966	14.8	1.23
Proficiency Sample 442	70,300	90,400	17,800	1,190
Proficiency Sample 478	18,400	11,100	8,700	158
Proficiency Sample 482	46,000	25,800	20,600	425
Proficiency Sample 493	18,400	30,800	7,720	285
Proficiency Sample 503	16,200	67,200	4,880	306
Proficiency Sample 512	19,600	27,700	8,290	263
Proficiency Sample 525	38,100	44,800	13,500	584
Proficiency Sample 562	24.7	158	10.2	0.280
Proficiency Sample 577	39,700	32,700	15,300	558
Proficiency Sample 580	17,400	157,000	5,590	249
Proficiency Sample 596	24,700	238,000	9,040	464
Proficiency Sample 605	28,100	201,000	4,150	875
Proficiency Sample 623	26,400	103,000	8,260	438
Proficiency Sample 678	27,100	17,700	9,330	479
Proficiency Sample 683	16,300	83,900	4,030	193
Proficiency Sample 700	14,200	62,900	4,720	171
Proficiency Sample 711	29	761	13.7	0.551
Proficiency Sample 725	26,000	32,700	6,880	641
Proficiency Sample 780	251,000	334,000	76,100	3,910
Proficiency Sample 796	29,300	29,300	8,510	559
Proficiency Sample 812	25,000	59,600	7,610	332
Proficiency Sample 856	30,200	81,300	12,000	634
Proficiency Sample 862	272,000	200,000	85,600	5,720
Proficiency Sample 887	11,400	40,500	3,780	193
Proficiency Sample 902	21,600	49,300	5,520	334
Proficiency Sample 920	9,780	51,500	3,140	163
Proficiency Sample 954	6,370	9,490	3,280	73.4

Proficiency Samples	IgG Concentration (AU/mL)					
	SARS-CoV-1 Spike	MERS-CoV Spike	HCoV-HKU1 Spike	HCoV-229E Spike	HCoV-NL63 Spike	HCoV-OC43 Spike
Proficiency Sample 102	13,800	NA*	28,100	24,900	8,470	200,000
Proficiency Sample 115	8,050	8,040	9,830	38,100	8,330	170,000
Proficiency Sample 134	NA*	NA*	140,000	35,300	8,500	612,000
Proficiency Sample 168	56.7	162	4,800	62,600	11,700	45,600
Proficiency Sample 205	25,300	53,600	28,700	63,000	5,200	151,000
Proficiency Sample 244	3,680	204	13,700	3,740	1,140	107,000
Proficiency Sample 277	87.3	849	5,470	29,400	9,700	45,100
Proficiency Sample 314	51,100	100,000	88,000	46,100	10,700	390,000
Proficiency Sample 323	1,160	425	2,350	9,370	6,670	18,300
Proficiency Sample 356	98.0	32.2	3,900	44,900	848	9,840
Proficiency Sample 370	5,710	7,730	20,800	20,200	5,300	83,900
Proficiency Sample 418	3,190	26,700	42,300	10,200	3,120	73,600
Proficiency Sample 435	109	939	15,000	52,700	6,820	23,000
Proficiency Sample 442	4,340	702	9,460	16,800	2,430	42,400
Proficiency Sample 478	1,370	1,560	20,000	16,000	1,550	60,400
Proficiency Sample 482	11,000	14,000	42,500	124,000	5,360	200,000
Proficiency Sample 493	1,660	167	5,260	16,200	3,440	47,200
Proficiency Sample 503	1,770	1,820	8,250	12,600	4,020	63,900
Proficiency Sample 512	1,330	356	20,500	29,700	4,540	36,900
Proficiency Sample 525	4,610	474	19,200	60,900	27,500	73,500
Proficiency Sample 562	12.1	48.5	2,050	17,500	2,630	22,400
Proficiency Sample 577	4,320	10,600	21,900	27,000	6,120	143,000
Proficiency Sample 580	7,700	NA*	30,300	59,400	19,500	118,000
Proficiency Sample 596	2,970	NA*	19,300	20,300	3,200	22,500
Proficiency Sample 605	8,720	NA*	53,900	40,300	5,990	151,000
Proficiency Sample 623	5,790	NA*	75,800	29,600	7,600	205,000
Proficiency Sample 678	2,210	NA*	7,510	21,000	5,010	35,300
Proficiency Sample 683	2,140	NA*	21,200	44,100	13,400	98,500
Proficiency Sample 700	2,550	NA*	51,000	67,100	7,760	51,000
Proficiency Sample 711	20.3	180	64,900	11,600	3,120	35,000
Proficiency Sample 725	4,100	2,100	14,500	51,700	7,230	79,900
Proficiency Sample 780	27,600	33,000	30,400	52,900	17,600	145,000
Proficiency Sample 796	2,430	NA*	19,800	19,200	4,240	67,800
Proficiency Sample 812	4,470	NA*	9,950	26,400	3,990	45,000
Proficiency Sample 856	5,790	NA*	36,900	17,900	10,700	94,300
Proficiency Sample 862	14,500	NA*	58,500	11,800	5,780	263,000
Proficiency Sample 887	2,160	NA*	31,900	71,800	6,470	77,700
Proficiency Sample 902	6,690	13,500	12,200	18,300	4,880	101,000
Proficiency Sample 920	765	NA*	8,700	22,000	1,600	38,900
Proficiency Sample 954	827	NA*	13,000	39,200	4,470	55,800

NA* = not assigned. Sample ECL signals either are close to the lower end of the calibration curve or showed variable signals for concentration assignment.

Proficiency Samples	IgG Concentration (AU/mL)					
	Flu A/Michigan H1	Flu A/Hong Kong H3	Flu A/Shanghai H7	Flu B/Brisbane HA	Flu B/Phuket HA	RSV Pre-Fusion F
Proficiency Sample 102	53,000	38,800	7,390	163,000	158,000	220,000
Proficiency Sample 115	99,000	58,300	8,390	117,000	107,000	180,000
Proficiency Sample 134	32,600	12,900	6,090	18,500	11,200	145,000
Proficiency Sample 168	127,000	52,700	4,530	85,800	237,000	133,000
Proficiency Sample 205	89,600	92,500	6,230	145,000	194,000	56,500
Proficiency Sample 244	39,400	17,400	1,220	30,500	53,700	87,100
Proficiency Sample 277	38,900	78,100	4,930	70,600	47,600	333,000
Proficiency Sample 314	91,000	63,900	7,010	296,000	194,000	476,000
Proficiency Sample 323	10,000	35,700	822	17,200	35,500	194,000
Proficiency Sample 356	80,400	63,700	1,190	47,400	27,000	86,900
Proficiency Sample 370	159,000	63,400	12,300	240,000	197,000	284,000
Proficiency Sample 418	149,000	25,900	782	110,000	656,000	179,000
Proficiency Sample 435	91,900	74,300	9,000	123,000	66,800	270,000
Proficiency Sample 442	84,100	196,000	4,620	29,400	41,800	128,000
Proficiency Sample 478	381,000	52,800	2,540	160,000	188,000	278,000
Proficiency Sample 482	124,000	178,000	37,600	84,900	90,300	411,000
Proficiency Sample 493	27,800	16,600	3,240	7,600	13,900	53,800
Proficiency Sample 503	56,800	23,500	5,710	79,100	39,100	96,100
Proficiency Sample 512	57,600	28,900	2,820	52,500	58,900	232,000
Proficiency Sample 525	115,000	70,900	15,100	351,000	159,000	596,000
Proficiency Sample 562	87,900	49,400	4,170	80,700	336,000	116,000
Proficiency Sample 577	106,000	236,000	6,780	98,300	45,600	78,100
Proficiency Sample 580	27,500	54,200	10,500	120,000	82,400	639,000
Proficiency Sample 596	48,600	23,400	3,390	94,700	96,900	120,000
Proficiency Sample 605	18,500	15,000	2,210	48,900	62,900	418,000
Proficiency Sample 623	25,400	24,100	3,800	144,000	71,100	292,000
Proficiency Sample 678	12,000	9,330	3,540	10,200	9,500	91,000
Proficiency Sample 683	94,800	60,200	4,900	104,000	98,000	248,000
Proficiency Sample 700	40,300	70,200	14,200	70,800	102,000	220,000
Proficiency Sample 711	76,900	42,800	5,570	94,400	113,000	147,000
Proficiency Sample 725	455,000	385,000	17,600	209,000	369,000	156,000
Proficiency Sample 780	49,200	143,000	43,100	103,000	37,100	301,000
Proficiency Sample 796	35,900	45,600	3,930	155,000	156,000	394,000
Proficiency Sample 812	31,300	45,100	4,940	22,800	19,300	236,000
Proficiency Sample 856	80,700	28,800	15,500	43,800	53,700	318,000
Proficiency Sample 862	72,000	13,300	22,400	124,000	67,200	194,000
Proficiency Sample 887	36,300	46,200	6,470	58,800	389,000	418,000
Proficiency Sample 902	57,000	28,000	22,000	114,000	217,000	190,000
Proficiency Sample 920	66,700	65,900	1,540	72,500	81,700	40,000
Proficiency Sample 954	28,800	5,690	3,650	61,000	37,800	90,200

NA* = not assigned. Sample ECL signals either are close to the lower end of the calibration curve or showed variable signals for concentration assignment.

Proficiency Samples	IgM Concentration (AU/mL)			
	SARS-CoV-2 Spike	SARS-CoV-2 Nucleocapsid	SARS-CoV-2 S1 RBD	SARS-CoV-2 S1 NTD
Proficiency Sample 102	4,790	984	2,450	506
Proficiency Sample 115	38,000	6,620	31,000	1,300
Proficiency Sample 134	8,010	2,680	6,640	306
Proficiency Sample 168	NA*	NA*	NA*	NA*
Proficiency Sample 205	36,300	4,620	40,400	1,010
Proficiency Sample 244	7,700	6,330	6,300	256
Proficiency Sample 277	NA*	NA*	NA*	NA*
Proficiency Sample 314	42,800	37,000	19,300	NA*
Proficiency Sample 323	8,690	1,680	6,930	359
Proficiency Sample 356	NA*	770	NA*	NA*
Proficiency Sample 370	27,200	470	34,100	86.9
Proficiency Sample 418	2,890	1,880	1,990	40.5
Proficiency Sample 435	NA*	NA*	NA*	NA*
Proficiency Sample 442	15,000	NA*	7,770	1,780
Proficiency Sample 478	1,750	663	1,640	63.0
Proficiency Sample 482	2,410	389	2,810	23.7
Proficiency Sample 493	1,310	2,060	746	186
Proficiency Sample 503	1,380	4,710	694	202
Proficiency Sample 512	2,720	310	1,640	30.9
Proficiency Sample 525	5,420	823	1,710	453
Proficiency Sample 562	NA*	NA*	NA*	NA*
Proficiency Sample 577	6,100	380	4,450	25.0
Proficiency Sample 580	4,180	4,370	1,520	670
Proficiency Sample 596	6,460	1,790	6,230	269
Proficiency Sample 605	9,150	553	9,410	120
Proficiency Sample 623	4,860	7,760	NA*	NA*
Proficiency Sample 678	1,610	686	1,290	60.0
Proficiency Sample 683	28,300	18,300	22,700	688
Proficiency Sample 700	2,830	23,800	8,500	90.3
Proficiency Sample 711	NA*	861	175	23.1
Proficiency Sample 725	5,200	1,280	5,600	175
Proficiency Sample 780	116,000	NA*	NA*	537
Proficiency Sample 796	2,460	260	2,100	31.9
Proficiency Sample 812	8,470	5,350	7,910	232
Proficiency Sample 856	6,580	265	3,910	516
Proficiency Sample 862	34,800	NA*	7,390	1,920
Proficiency Sample 887	3,510	5,060	2,660	213
Proficiency Sample 902	NA*	NA*	NA*	NA*
Proficiency Sample 920	2,350	690	1,640	36.5
Proficiency Sample 954	503	974	370	14.0

NA* = not assigned. Sample ECL signals either are close to the lower end of the calibration curve or showed variable signals for concentration assignment.

Proficiency Samples	IgM Concentration (AU/mL)					
	SARS-CoV-1 Spike	MERS-CoV Spike	HCoV-HKU1 Spike	HCoV-229E Spike	HCoV-NL63 Spike	HCoV-OC43 Spike
Proficiency Sample 102	232	476	NA*	NA*	NA*	NA*
Proficiency Sample 115	477	1,460	317	192	NA*	NA*
Proficiency Sample 134	NA*	NA*	NA*	83.6	62.0	NA*
Proficiency Sample 168	NA*	23.1	NA*	NA*	NA*	21.5
Proficiency Sample 205	537	NA*	117	43.6	18.1	NA*
Proficiency Sample 244	146	98.1	58.9	NA*	NA*	NA*
Proficiency Sample 277	194	125	53.0	46.0	NA*	57.5
Proficiency Sample 314	1,100	213	326	77.2	35.3	113
Proficiency Sample 323	345	68.5	112	NA*	NA*	118
Proficiency Sample 356	NA*	44.0	30.9	62.7	NA*	24.7
Proficiency Sample 370	56.7	27.9	75.2	NA*	NA*	NA*
Proficiency Sample 418	NA*	91.3	NA*	NA*	24.0	NA*
Proficiency Sample 435	NA*	73.6	22.7	NA*	NA*	60.7
Proficiency Sample 442	633	32.1	288	NA*	NA*	31.2
Proficiency Sample 478	111	72.7	44.2	79.4	NA*	70.7
Proficiency Sample 482	67.2	28.7	21.0	NA*	NA*	59.5
Proficiency Sample 493	131	128	71.2	84.7	37.7	91.7
Proficiency Sample 503	81.1	143	170	162	19.5	108
Proficiency Sample 512	322	30.6	25.5	NA*	NA*	21.2
Proficiency Sample 525	237	37.1	32.0	51.8	NA*	40.8
Proficiency Sample 562	NA*	30.8	54.0	NA*	NA*	50.5
Proficiency Sample 577	183	392	350	128	NA*	NA*
Proficiency Sample 580	359	1,140	259	NA*	NA*	571
Proficiency Sample 596	705	331	79.3	89.2	37.3	154
Proficiency Sample 605	NA*	177	29.7	378	NA*	33.4
Proficiency Sample 623	NA*	305	NA*	279	NA*	245
Proficiency Sample 678	145	349	NA*	93.9	35.6	61.8
Proficiency Sample 683	NA*	993	NA*	88.7	26.8	NA*
Proficiency Sample 700	470	792	356	NA*	370	NA*
Proficiency Sample 711	54.6	750	213	85.3	29.9	NA*
Proficiency Sample 725	50.8	146	47.0	157	NA*	51.6
Proficiency Sample 780	262	25.6	70.8	NA*	NA*	79.7
Proficiency Sample 796	192	76.7	41.6	NA*	NA*	NA*
Proficiency Sample 812	59.1	124	168	70.5	26.9	NA*
Proficiency Sample 856	234	24.5	95.8	NA*	NA*	55.3
Proficiency Sample 862	731	1,280	NA*	NA*	76.4	NA*
Proficiency Sample 887	88.5	52.3	76.2	NA*	NA*	72.0
Proficiency Sample 902	NA*	42.9	NA*	NA*	NA*	40.0
Proficiency Sample 920	75.3	105	99.5	55.3	21.9	NA*
Proficiency Sample 954	NA*	38.7	NA*	NA*	NA*	NA*

NA* = not assigned. Sample ECL signals either are close to the lower end of the calibration curve or showed variable signals for concentration assignment.

Proficiency Samples	IgM Concentration (AU/mL)					
	Flu A/Michigan H1	Flu A/Hong Kong H3	Flu A/Shanghai H7	Flu B/Brisbane HA	Flu B/Phuket HA	RSV Pre-Fusion F
Proficiency Sample 102	96.2	NA*	72.4	NA*	NA*	335
Proficiency Sample 115	226	188	NA*	18,200	20,600	276
Proficiency Sample 134	778	56.2	93.9	10,700	11,900	523
Proficiency Sample 168	36.8	NA*	33.0	56.3	117	NA*
Proficiency Sample 205	48.8	32.1	39.5	19,200	18,400	393
Proficiency Sample 244	749	44.5	70.6	390	1,770	434
Proficiency Sample 277	87.5	28.1	NA*	951	1,500	216
Proficiency Sample 314	61.3	37.2	56.5	3,970	4,610	461
Proficiency Sample 323	276	33.9	43.3	1,090	1,510	297
Proficiency Sample 356	155	34.7	94.0	104	275	121
Proficiency Sample 370	202	27.0	NA*	1,770	2,210	238
Proficiency Sample 418	572	33.5	134	2,020	1,660	297
Proficiency Sample 435	58.5	NA*	NA*	222	208	73.2
Proficiency Sample 442	203	35.4	36.8	1,440	1,990	105
Proficiency Sample 478	292	28.2	NA*	153	477	129
Proficiency Sample 482	53.7	34.1	NA*	835	1,300	NA*
Proficiency Sample 493	172	41.2	43.8	1,100	1,860	215
Proficiency Sample 503	487	38.6	44.5	9,880	12,700	274
Proficiency Sample 512	158	23.9	NA*	84.4	254	134
Proficiency Sample 525	35.1	45.4	NA*	3,790	4,340	232
Proficiency Sample 562	66.2	39.3	NA*	55.3	192	215
Proficiency Sample 577	68.5	95.0	128	9,930	10,900	288
Proficiency Sample 580	715	318	210	NA*	NA*	NA*
Proficiency Sample 596	569	56.1	232	481	2,120	356
Proficiency Sample 605	256	42.3	NA*	1,230	1,670	116
Proficiency Sample 623	600	115	NA*	7,260	7,280	NA*
Proficiency Sample 678	NA*	97.7	61.0	3,300	4,900	189
Proficiency Sample 683	140	103	39.4	NA*	NA*	1,030
Proficiency Sample 700	1,590	247	NA*	7,270	8,810	1,020
Proficiency Sample 711	NA*	55.2	169	3,160	8,210	368
Proficiency Sample 725	145	NA*	271	462	682	170
Proficiency Sample 780	42.0	NA*	NA*	776	417	NA*
Proficiency Sample 796	137	NA*	NA*	579	2,070	448
Proficiency Sample 812	97.4	56.1	343	1,190	1,850	391
Proficiency Sample 856	165	42.1	NA*	102	297	192
Proficiency Sample 862	860	122	NA*	14,500	13,100	NA*
Proficiency Sample 887	NA*	NA*	30.8	113	151	203
Proficiency Sample 902	NA*	NA*	40.1	NA*	NA*	378
Proficiency Sample 920	366	NA*	138	2,210	2,210	893
Proficiency Sample 954	44.2	NA*	NA*	108	300	134

NA* = not assigned. Sample ECL signals either are close to the lower end of the calibration curve or showed variable signals for concentration assignment.

Proficiency Samples	IgA Concentration (AU/mL)			
	SARS-CoV-2 Spike	SARS-CoV-2 Nucleocapsid	SARS-CoV-2 S1 RBD	SARS-CoV-2 S1 NTD
Proficiency Sample 102	9,480	33,600	8,310	1,660
Proficiency Sample 115	4,810	2,270	2,580	1,450
Proficiency Sample 134	9,110	4,510	4,630	2,730
Proficiency Sample 168	NA*	NA*	NA*	NA*
Proficiency Sample 205	3,890	15,000	1,820	669
Proficiency Sample 244	20,900	20,700	16,100	1,310
Proficiency Sample 277	NA*	NA*	NA*	NA*
Proficiency Sample 314	12,900	27,300	3,830	1,590
Proficiency Sample 323	2,680	4,860	1,140	622
Proficiency Sample 356	2,730	NA*	2,160	335
Proficiency Sample 370	2,400	9,440	1,890	263
Proficiency Sample 418	1,410	564	818	227
Proficiency Sample 435	NA*	NA*	NA*	NA*
Proficiency Sample 442	3,210	3,390	1,800	1,330
Proficiency Sample 478	3,520	2,270	3,490	348
Proficiency Sample 482	4,940	287	1,470	255
Proficiency Sample 493	1,720	1,140	928	359
Proficiency Sample 503	1,220	1,910	900	246
Proficiency Sample 512	5,420	789	2,460	2,100
Proficiency Sample 525	13,000	4,260	11,100	727
Proficiency Sample 562	NA*	NA*	NA*	NA*
Proficiency Sample 577	11,600	392	7,210	532
Proficiency Sample 580	6,000	2,510	1,510	516
Proficiency Sample 596	945	715	896	146
Proficiency Sample 605	14,000	2,910	8,090	3,120
Proficiency Sample 623	4,710	11,500	2,590	1,560
Proficiency Sample 678	1,300	669	556	257
Proficiency Sample 683	5,690	24,300	3,520	755
Proficiency Sample 700	15,200	1,690	11,100	344
Proficiency Sample 711	NA*	NA*	NA*	NA*
Proficiency Sample 725	6,440	1,060	5,060	1,470
Proficiency Sample 780	42,200	3,060	36,200	9,570
Proficiency Sample 796	683	254	327	194
Proficiency Sample 812	2,370	2,940	1,580	440
Proficiency Sample 856	2,830	2,800	1,490	728
Proficiency Sample 862	54,100	80,700	5,380	23,900
Proficiency Sample 887	3,090	567	3,210	440
Proficiency Sample 902	2,060	818	2,170	NA*
Proficiency Sample 920	1,420	1,500	796	323
Proficiency Sample 954	1,280	11,000	870	275

NA* = not assigned. Sample ECL signals either are close to the lower end of the calibration curve or showed variable signals for concentration assignment.

Proficiency Samples	IgA Concentration (AU/mL)					
	SARS-CoV-1 Spike	MERS-CoV Spike	HCoV-HKU1 Spike	HCoV-229E Spike	HCoV-NL63 Spike	HCoV-OC43 Spike
Proficiency Sample 102	2,800	869	7,530	23,200	9,950	32,400
Proficiency Sample 115	726	648	2,490	NA*	1,040	16,500
Proficiency Sample 134	8,760	7,540	27,700	1,870	3,660	49,500
Proficiency Sample 168	NA*	NA*	NA*	3,470	407	1,540
Proficiency Sample 205	NA*	2,890	3,130	2,060	536	11,000
Proficiency Sample 244	NA*	1,850	16,900	3,660	662	58,800
Proficiency Sample 277	NA*	1,670	3,330	5,920	4,020	14,500
Proficiency Sample 314	5,140	NA*	4,080	4,830	2,780	15,400
Proficiency Sample 323	NA*	3,460	995	829	463	2,620
Proficiency Sample 356	391	NA*	1,350	7,710	665	NA*
Proficiency Sample 370	NA*	1,200	1,220	6,230	601	NA*
Proficiency Sample 418	146	1,110	373	505	136	557
Proficiency Sample 435	NA*	NA*	977	3,360	NA*	1,490
Proficiency Sample 442	NA*	1,090	2,980	509	286	2,550
Proficiency Sample 478	236	1,660	1,130	2,260	286	5,780
Proficiency Sample 482	181	NA*	2,210	3,140	802	6,380
Proficiency Sample 493	187	1,360	1,010	2,310	451	NA*
Proficiency Sample 503	189	NA*	2,690	624	1,840	5,920
Proficiency Sample 512	151	579	1,120	3,850	410	1,560
Proficiency Sample 525	419	3,900	8,610	49,500	11,800	10,500
Proficiency Sample 562	NA*	NA*	1,570	4,010	1,530	1,160
Proficiency Sample 577	507	NA*	2,890	1,830	1,040	4,970
Proficiency Sample 580	4,190	NA*	6,690	3,150	1,800	52,400
Proficiency Sample 596	151	1,400	405	915	258	1,040
Proficiency Sample 605	2,910	NA*	6,410	4,520	1,120	11,700
Proficiency Sample 623	1,390	NA*	NA*	4,830	1,730	12,500
Proficiency Sample 678	171	1,960	567	819	1,450	2,770
Proficiency Sample 683	374	NA*	3,640	NA*	942	18,900
Proficiency Sample 700	370	NA*	4,190	3,190	1,530	9,720
Proficiency Sample 711	NA*	NA*	8,580	2,830	463	1,810
Proficiency Sample 725	321	1,640	677	2,330	866	5,030
Proficiency Sample 780	686	NA*	1,470	1,790	NA*	4,090
Proficiency Sample 796	NA*	139	NA*	44.6	NA*	95.5
Proficiency Sample 812	131	2,250	2,000	2,850	394	2,070
Proficiency Sample 856	420	NA*	1,900	1,010	929	2,970
Proficiency Sample 862	2,380	NA*	9,910	94,900	15,200	17,300
Proficiency Sample 887	158	1,080	1,320	1,530	108	3,050
Proficiency Sample 902	1,040	NA*	802	2,100	388	3,190
Proficiency Sample 920	114	1,490	202	2,120	10,700	899
Proficiency Sample 954	183	1,330	16,200	2,540	2,120	4,790

NA* = not assigned. Sample ECL signals either are close to the lower end of the calibration curve or showed variable signals for concentration assignment.

Proficiency Samples	IgA Concentration (AU/mL)					
	Flu A/Michigan H1	Flu A/Hong Kong H3	Flu A/Shanghai H7	Flu B/Brisbane HA	Flu B/Phuket HA	RSV Pre-Fusion F
Proficiency Sample 102	20,000	17,200	11,800	5,530	11,400	108,000
Proficiency Sample 115	4,110	2,000	993	8,110	7,370	15,800
Proficiency Sample 134	1,620	NA*	7,230	3,840	2,720	132,000
Proficiency Sample 168	1,530	1,420	262	2,050	1,750	8,360
Proficiency Sample 205	1,070	2,460	366	7,320	28,500	17,000
Proficiency Sample 244	10,700	22,700	14,100	5,800	7,630	29,600
Proficiency Sample 277	10,200	NA*	1,490	5,370	5,500	51,500
Proficiency Sample 314	628	3,540	485	253,000	14,300	77,300
Proficiency Sample 323	440	6,020	195	552	1,880	19,300
Proficiency Sample 356	779	NA*	268	2,440	1,970	4,170
Proficiency Sample 370	12,200	7,260	6,970	2,430	2,200	119,000
Proficiency Sample 418	2,780	1,030	148	6,300	4,060	8,260
Proficiency Sample 435	2,340	2,410	1,160	4,470	3,670	6,370
Proficiency Sample 442	1,690	11,300	731	22,500	34,500	33,400
Proficiency Sample 478	4,270	3,130	273	3,630	5,120	14,000
Proficiency Sample 482	1,790	3,530	2,310	8,860	5,370	67,000
Proficiency Sample 493	12,000	4,060	690	14,800	20,300	33,600
Proficiency Sample 503	1,370	3,680	2,640	5,600	2,670	25,400
Proficiency Sample 512	853	820	41.3	5,410	3,810	25,700
Proficiency Sample 525	17,500	56,800	3,660	58,400	53,600	77,600
Proficiency Sample 562	2,460	2,940	1,850	1,800	8,010	20,900
Proficiency Sample 577	2,160	10,100	4,940	8,890	8,450	19,000
Proficiency Sample 580	2,250	9,750	1,350	8,460	11,300	23,200
Proficiency Sample 596	653	653	350	1,700	2,260	7,690
Proficiency Sample 605	757	1,080	239	48,400	46,000	43,000
Proficiency Sample 623	5,200	1,330	839	6,440	4,370	14,800
Proficiency Sample 678	762	154	120	2,420	2,730	7,590
Proficiency Sample 683	9,820	8,530	2,950	17,500	54,200	48,800
Proficiency Sample 700	2,750	898	713	10,600	7,300	10,900
Proficiency Sample 711	6,930	1,230	645	8,700	8,210	19,100
Proficiency Sample 725	13,300	6,200	204	103,000	222,000	44,900
Proficiency Sample 780	1,280	6,830	2,750	2,510	872	5,440
Proficiency Sample 796	16.1	217	21.5	29.1	36.6	1,170
Proficiency Sample 812	371	2,550	2,700	3,090	2,590	61,000
Proficiency Sample 856	1,840	1,120	779	835	896	51,600
Proficiency Sample 862	4,380	NA*	1,110	30,800	19,200	146,000
Proficiency Sample 887	160	3,840	647	692	2,320	27,500
Proficiency Sample 902	4,240	4,800	2,620	1,540	2,370	13,900
Proficiency Sample 920	10,900	2,750	391	36,700	85,900	6,320
Proficiency Sample 954	1,930	234	335	2,580	1,120	6,950

NA* = not assigned. Sample ECL signals either are close to the lower end of the calibration curve or showed variable signals for concentration assignment.

Appendix B: Assigned values of concentration in WHO/NIBSC units (BAU/mL)

Proficiency Samples	IgG Concentration (BAU/mL)		
	SARS-CoV-2 Spike	SARS-CoV-2 Nucleocapsid	SARS-CoV-2 S1 RBD
Proficiency Sample 102	2,766	944	2,576
Proficiency Sample 115	1,234	963	1,295
Proficiency Sample 134	1,541	231	1,213
Proficiency Sample 168	0.553	14.3	1.06
Proficiency Sample 205	1,108	892	539
Proficiency Sample 244	937	278	1,039
Proficiency Sample 277	0.499	0.228	1.12
Proficiency Sample 314	928	611	642
Proficiency Sample 323	209	340	199
Proficiency Sample 356	0.239	0.238	0.199
Proficiency Sample 370	196	236	194
Proficiency Sample 418	196	159	222
Proficiency Sample 435	0.937	2.28	0.403
Proficiency Sample 442	633	213	484
Proficiency Sample 478	166	26.2	237
Proficiency Sample 482	414	60.9	560
Proficiency Sample 493	166	72.7	210
Proficiency Sample 503	146	159	133
Proficiency Sample 512	177	65.4	225
Proficiency Sample 525	343	106	367
Proficiency Sample 562	0.223	0.373	0.277
Proficiency Sample 577	358	77.2	416
Proficiency Sample 580	157	371	152
Proficiency Sample 596	223	562	246
Proficiency Sample 605	253	474	113
Proficiency Sample 623	238	243	225
Proficiency Sample 678	244	41.8	254
Proficiency Sample 683	147	198	110
Proficiency Sample 700	128	148	128
Proficiency Sample 711	0.261	1.80	0.373
Proficiency Sample 725	234	77.2	187
Proficiency Sample 780	2,262	788	2,070
Proficiency Sample 796	264	69.1	231
Proficiency Sample 812	225	141	207
Proficiency Sample 856	272	192	326
Proficiency Sample 862	2,451	472	2,328
Proficiency Sample 887	102.7	95.6	102.8
Proficiency Sample 902	195	116	150
Proficiency Sample 920	88.1	122	85.4
Proficiency Sample 954	57.4	22.4	89.2

	IgM Concentration (BAU/mL)		
Proficiency Samples	SARS-CoV-2 Spike	SARS-CoV-2 Nucleocapsid	SARS-CoV-2 S1 RBD
Proficiency Sample 102	104	103	57.1
Proficiency Sample 115	825	874	722
Proficiency Sample 134	174	354	155
Proficiency Sample 168	NA*	NA*	NA*
Proficiency Sample 205	788	610	941
Proficiency Sample 244	167	836	147
Proficiency Sample 277	NA*	NA*	NA*
Proficiency Sample 314	929	4884	450
Proficiency Sample 323	189	222	161
Proficiency Sample 356	NA*	102	NA*
Proficiency Sample 370	590	62.0	795
Proficiency Sample 418	62.7	248	46.4
Proficiency Sample 435	NA*	NA*	NA*
Proficiency Sample 442	326	NA*	181
Proficiency Sample 478	40.0	87.5	38.2
Proficiency Sample 482	53.0	51.3	65.5
Proficiency Sample 493	28.4	272	17.4
Proficiency Sample 503	29.9	622	16.2
Proficiency Sample 512	59.0	40.9	38.2
Proficiency Sample 525	118	109	39.8
Proficiency Sample 562	NA*	NA*	NA*
Proficiency Sample 577	132	50.2	104
Proficiency Sample 580	90.7	577	35.4
Proficiency Sample 596	140	236	145
Proficiency Sample 605	199	73.0	219
Proficiency Sample 623	105	1024	NA*
Proficiency Sample 678	34.9	90.6	30.1
Proficiency Sample 683	614	2416	529
Proficiency Sample 700	61.4	3142	198
Proficiency Sample 711	NA*	114	4.08
Proficiency Sample 725	113	169	130
Proficiency Sample 780	2517	NA*	NA*
Proficiency Sample 796	53.4	34.3	48.9
Proficiency Sample 812	184	706	184
Proficiency Sample 856	143	35.0	91.1
Proficiency Sample 862	755	NA*	172
Proficiency Sample 887	76.2	668	62.0
Proficiency Sample 902	NA*	NA*	NA*
Proficiency Sample 920	51.0	91.1	38.2
Proficiency Sample 954	10.9	129	8.62

NA*= not assigned. Sample ECL signals either are close to the lower end of the calibration curve or showed variable signals for concentration assignment.

	IgA Concentration (BAU/mL)		
Proficiency Samples	SARS-CoV-2 Spike	SARS-CoV-2 Nucleocapsid	SARS-CoV-2 S1 RBD
Proficiency Sample 102	587	3730	650
Proficiency Sample 115	298	252	202
Proficiency Sample 134	564	501	362
Proficiency Sample 168	NA*	NA*	NA*
Proficiency Sample 205	241	1665	142
Proficiency Sample 244	1294	2298	1259
Proficiency Sample 277	NA*	NA*	NA*
Proficiency Sample 314	799	3030	300
Proficiency Sample 323	166	539	89.1
Proficiency Sample 356	169	NA*	169
Proficiency Sample 370	149	1048	148
Proficiency Sample 418	87.3	62.6	64.0
Proficiency Sample 435	NA*	NA*	NA*
Proficiency Sample 442	199	376	141
Proficiency Sample 478	218	252	273
Proficiency Sample 482	306	31.9	115
Proficiency Sample 493	106	127	72.6
Proficiency Sample 503	75.5	212	70.4
Proficiency Sample 512	355	87.6	192
Proficiency Sample 525	805	473	868
Proficiency Sample 562	NA*	NA*	NA*
Proficiency Sample 577	718	43.5	564
Proficiency Sample 580	371	279	118
Proficiency Sample 596	58.5	79.4	70.1
Proficiency Sample 605	867	323	633
Proficiency Sample 623	292	1277	203
Proficiency Sample 678	80.5	74.3	43.5
Proficiency Sample 683	352	2697	275
Proficiency Sample 700	941	188	868
Proficiency Sample 711	NA*	NA*	NA*
Proficiency Sample 725	399	118	396
Proficiency Sample 780	2612	340	2831
Proficiency Sample 796	42.3	28.2	25.6
Proficiency Sample 812	147	326	124
Proficiency Sample 856	175	311	117
Proficiency Sample 862	3349	8958	421
Proficiency Sample 887	191	62.9	251
Proficiency Sample 902	128	90.8	170
Proficiency Sample 920	87.9	167	62.2
Proficiency Sample 954	79.2	1221	68.0

NA*= not assigned. Sample ECL signals either are close to the lower end of the calibration curve or showed variable signals for concentration assignment.

Catalog Numbers

Table 5. Catalog numbers associated with the COVID-19 Proficiency Samples

Products	Catalog No.
COVID-19 Proficiency Sample Panel 1	C4417-1
COVID-19 Proficiency Sample Panel 2	C4418-1
COVID-19 Proficiency Sample Panel 3	C4419-1
Proficiency Sample 102	C50AED-1
Proficiency Sample 115	C50AEE-1
Proficiency Sample 134	C50AEF-1
Proficiency Sample 168	C50AFR-1
Proficiency Sample 205	C50AEG-1
Proficiency Sample 244	C50AEH-1
Proficiency Sample 277	C50AFS-1
Proficiency Sample 314	C50AEJ-1
Proficiency Sample 323	C50AEK-1
Proficiency Sample 356	C50AFT-1
Proficiency Sample 370	C50AEL-1
Proficiency Sample 418	C50AEM-1
Proficiency Sample 435	C50AFU-1
Proficiency Sample 442	C50AEN-1
Proficiency Sample 478	C50AEQ-1
Proficiency Sample 482	C50AER-1
Proficiency Sample 493	C50AES-1
Proficiency Sample 503	C50AET-1
Proficiency Sample 512	C50AEU-1
Proficiency Sample 525	C50AEV-1
Proficiency Sample 562	C50AFV-1
Proficiency Sample 577	C50AEW-1
Proficiency Sample 580	C50AEX-1
Proficiency Sample 596	C50AEY-1
Proficiency Sample 605	C50AEZ-1
Proficiency Sample 623	C50AFA-1
Proficiency Sample 678	C50AFB-1
Proficiency Sample 683	C50AFC-1
Proficiency Sample 700	C50AFD-1
Proficiency Sample 711	C50AFW-1
Proficiency Sample 725	C50AFE-1
Proficiency Sample 780	C50AED-1
Proficiency Sample 796	C50AEE-1
Proficiency Sample 812	C50AEF-1
Proficiency Sample 856	C50AFR-1
Proficiency Sample 862	C50AEG-1
Proficiency Sample 887	C50AEH-1
Proficiency Sample 902	C50AFS-1
Proficiency Sample 920	C50AEJ-1
Proficiency Sample 954	C50AEK-1