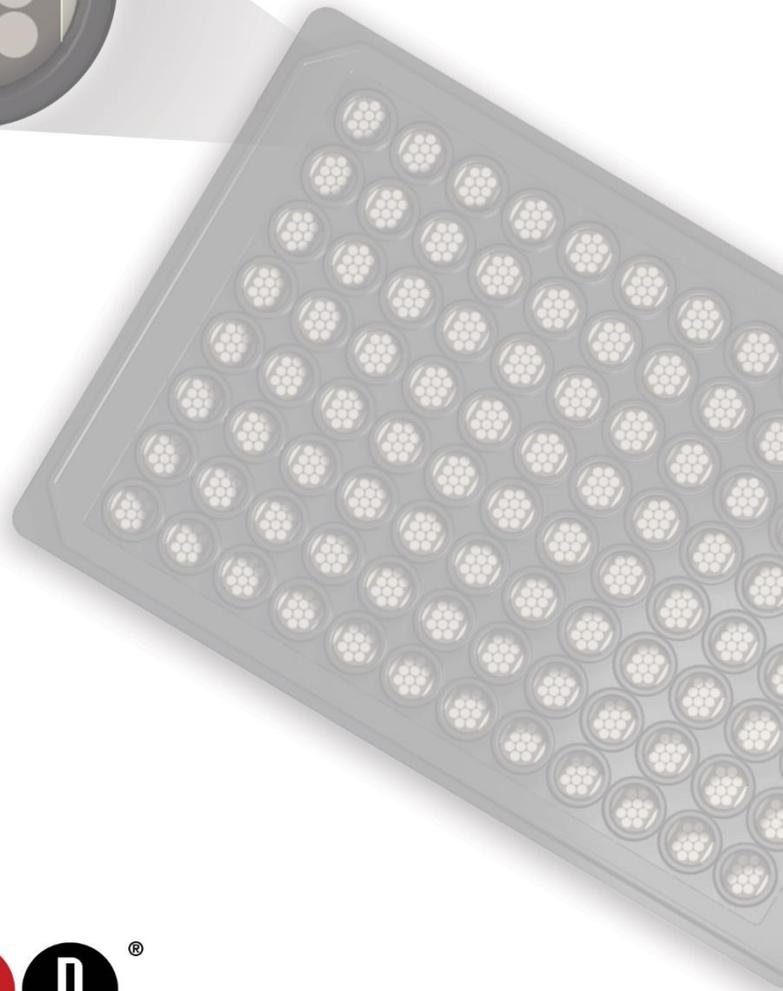


MSD[®] MULTI-SPOT Assay System

COVID-19 Serology Kits

V-PLEX[®]



V-PLEX[®] COVID-19 Serology Kits

The V-PLEX COVID-19 Serology Kits include multiple panels to detect antibodies to antigens from SARS-CoV-2, SARS-CoV-2 variants, SARS-1, MERS, circulating Coronaviruses, and other respiratory pathogens:

- The V-PLEX SARS-CoV-2 and Key Variant Panels focus on antigens from SARS-CoV-2, including variants of the SARS-CoV-2 virus
- The V-PLEX Coronavirus Panels add circulating Coronaviruses along with relevant antigens from the SARS-CoV-2 virus
- The V-PLEX Respiratory Panels include antigens for Influenza and RSV

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

FOR RESEARCH USE ONLY.

NOT FOR USE IN DIAGNOSTIC PROCEDURES.

Meso Scale Discovery

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Introduction

The V-PLEX COVID-19 Serology Kits measure the presence and amount of antibodies to SARS-CoV-2, SARS-CoV-2 variants, SARS, MERS, circulating Coronaviruses, and other respiratory pathogens. The kits are available as panels and detect isotypes (IgG, IgM, and IgA) of antigen-specific antibodies.

Principle of the Assay

The V-PLEX COVID-19 Serology Kits quantitatively measure antibodies to antigens related to SARS-CoV-2, including variants of the SARS-CoV-2 virus, SARS, MERS, circulating Coronaviruses, and other respiratory pathogens (Tables 1 and 2). Plates are provided with antigens on spots in the wells of a 96-well plate (Figure 1). Antibodies in the sample bind to the antigens on the spots and anti-human antibodies (IgG, IgM, or IgA) conjugated with MSD SULFO-TAG™ label are used for detection. The plate is read on an MSD instrument, which measures the light emitted from the MSD SULFO-TAG.

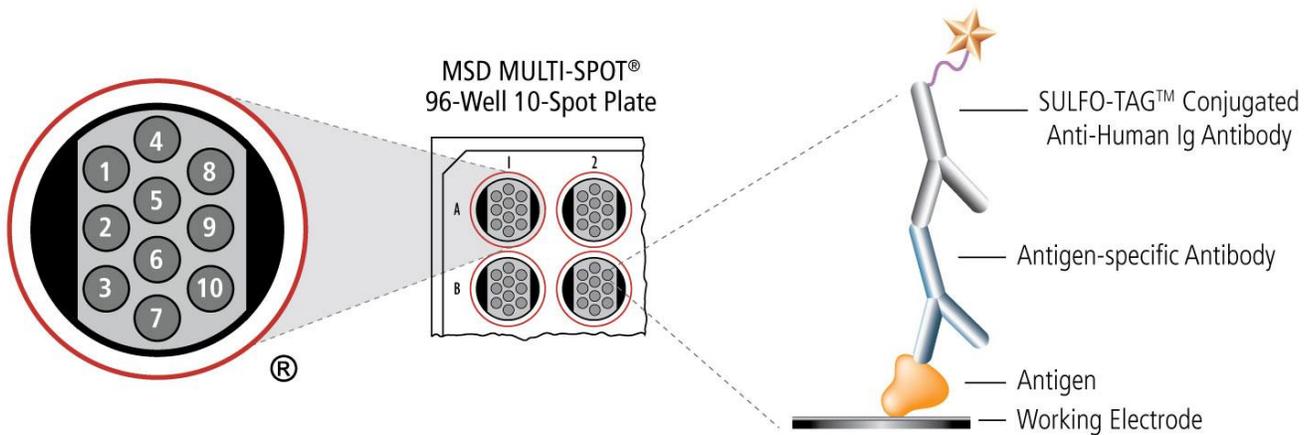


Figure 1. Schematic for V-PLEX COVID-19 Serology Kits.

Kit Components

V-PLEX COVID-19 Serology Kits are available as panels defined by a set of antigens coated on a 10-spot MULTI-SPOT® 96-well plate. A kit includes a reference standard for quantitation, controls, plate(s), one of the available detection antibodies (anti-human IgG, IgM, or IgA), and all other reagents necessary to conduct the assay.

Table 1 describes the available plates and the location of antigens on each plate. Table 2 shows the relationship between the V-PLEX COVID-19 Serology Kits and the plates included in those kits. Together, Table 1 and Table 2 help users select the kits that contain their preferred antigens. Table 3 provides a list of components included in each kit. Table 4 provides information about the SARS-CoV-2 variant antigens, including their amino acid modifications, lineages, and common designations.

Table 1. List of antigens and their spot assignments on the MULTI-SPOT 96-Well, 10-Spot plates

Plate Description	SARS-CoV-2 Plate 1	SARS-CoV-2 Plate 2	SARS-CoV-2 Plate 5	SARS-CoV-2 Plate 6	SARS-CoV-2 Plate 7
Spot 1	SARS-CoV-2 Spike	SARS-CoV-2 Spike	SARS-CoV-2 Spike	SARS-CoV-2 Spike	SARS-CoV-2 Spike
Spot 2	BSA	BSA	BSA	SARS-CoV-2 Spike (D614G)	SARS-CoV-2 S1 RBD (B.1.351; B.1.351.1)
Spot 3	SARS-CoV-2 Nucleocapsid	SARS-CoV-2 Nucleocapsid	SARS-CoV-2 Nucleocapsid	SARS-CoV-2 Nucleocapsid	SARS-CoV-2 Nucleocapsid
Spot 4	SARS-CoV-1 Spike	BSA	BSA	BSA	SARS-CoV-2 S1 RBD (P.1)
Spot 5	BSA	BSA	BSA	BSA	BSA
Spot 6	BSA	BSA	BSA	BSA	SARS-CoV-2 S1 RBD (B.1.1.7)
Spot 7	BSA	BSA	SARS-CoV-2 Spike (P.1)	SARS-CoV-2 Spike (P.1)	SARS-CoV-2 Spike (P.1)
Spot 8	SARS-CoV-2 S1 NTD	BSA	SARS-CoV-2 Spike (B.1.1.7)	SARS-CoV-2 Spike (B.1.1.7)	SARS-CoV-2 Spike (B.1.1.7)
Spot 9	BSA	BSA	SARS-CoV-2 Spike (B.1.351)	SARS-CoV-2 Spike (B.1.351)	SARS-CoV-2 Spike (B.1.351)
Spot 10	SARS-CoV-2 S1 RBD	SARS-CoV-2 S1 RBD	BSA	SARS-CoV-2 S1 RBD	SARS-CoV-2 S1 RBD

Plate Description	SARS-CoV-2 Plate 8	SARS-CoV-2 Plate 9	SARS-CoV-2 Plate 11	SARS-CoV-2 Plate 12
Spot 1	SARS-CoV-2 Spike	RBD (B.1.427; B.1.429; B.1.526.1)	RBD (B.1.427; B.1.429; B.1.526.1)	RBD (A.23.1)
Spot 2	SARS-CoV-2 S1 RBD (B.1.427; B.1.429; B.1.526.1)	RBD (B.1.351; B.1.351.1)	RBD (B.1.351; B.1.351.1)	RBD (C.37)
Spot 3	SARS-CoV-2 Nucleocapsid	RBD (B.1.525; B.1.526; B.1.618; P.2; R.1)	RBD (B.1.525; B.1.526; B.1.618; P.2; R.1)	RBD (B.1.525; B.1.526; B.1.618; P.2; R.1)
Spot 4	SARS-CoV-2 S1 RBD (B.1.525; B.1.526; B.1.618; P.2; R.1)	RBD (P.1)	RBD (P.1)	RBD (BV-1)
Spot 5	BSA	RBD (B.1.526.2)	RBD (B.1.526.2)	RBD (B.1.1.519)
Spot 6	SARS-CoV-2 S1 RBD (B.1.526.2)	RBD (B.1.1.7)	RBD (B.1.1.7)	RBD (A.VOI.V2)
Spot 7	BSA	RBD (B.1.1.7+E484K; P.3)	RBD (B.1.1.7+E484K; P.3)	RBD (B.1.1.7+E484K; P.3)
Spot 8	SARS-CoV-2 Spike (B.1.526)	RBD (B.1.617; B.1.617.1; B.1.617.3)	RBD (B.1.617; B.1.617.1; B.1.617.3)	RBD (B.1.617; B.1.617.1; B.1.617.3)
Spot 9	SARS-CoV-2 Spike (B.1.429)	RBD (B.1.214.2)	RBD (AY.3; AY.4; AY.4.2; AY.5; AY.6; AY.7; AY.12; AY.14; B.1.617.2; B.1.617.2+ΔY144)	RBD (AY.3; AY.4; AY.4.2; AY.5; AY.6; AY.7; AY.12; AY.14; B.1.617.2; B.1.617.2+ΔY144)
Spot 10	SARS-CoV-2 S1 RBD	SARS-CoV-2 S1 RBD	SARS-CoV-2 S1 RBD	SARS-CoV-2 S1 RBD

Table 1 (continued)

Plate Description	SARS-CoV-2 Plate 13	SARS-CoV-2 Plate 14	SARS-CoV-2 Plate 15
Spot 1	SARS-CoV-2 Spike	SARS-CoV-2 Spike	SARS-CoV-2 Spike
Spot 2	Spike (P.2)	Spike (A.23.1)	Spike (AY.1)
Spot 3	Spike (B.1.617.1)	Spike (A.VOI.V2)	Spike (AY.2)
Spot 4	Spike (B.1.617.2)	Spike (B.1.617.2; AY.3; AY.5; AY.6; AY.7; AY.14) Alt Seq 1	Spike (B.1.617.2+ΔY144)
Spot 5	Spike (B.1.617.3)	Spike (C.37)	Spike (B.1.620)
Spot 6	Spike (B.1.617)	Spike (R.1)	Spike (B.1.258.17)
Spot 7	Spike (P.1)	Spike (P.3)	Spike (B.1.466.2)
Spot 8	Spike (B.1.1.7)	Spike (B.1.525)	Spike (B.1.1.7+E484K)
Spot 9	Spike (B.1.351)	Spike (B.1.1.519)	Spike (B.1.351.1)
Spot 10	Spike (B.1.526.1)	Spike (BV-1)	Spike (B.1.618)

Note: Alternative S-GENE mutations for Spike of B.1.617.2 are listed as "Alt Seq #."

Plate Description	SARS-CoV-2 Plate 16	SARS-CoV-2 Plate 17	SARS-CoV-2 Plate 18	SARS-CoV-2 Plate 19
Spot 1	RBD (AY.1; AY.2)	SARS-CoV-2 Spike	SARS-CoV-2 Spike	SARS-CoV-2 Spike
Spot 2	RBD (B.1.351; B.1.351.1)	SARS-CoV-2 Spike (D614G)	Spike (P.2)	Spike (B.1.621)
Spot 3	RBD (B.1.525; B.1.526; B.1.618; P.2; R.1)	SARS-CoV-2 Nucleocapsid	Spike (B.1.617.1)	Spike (AY.2) Alt Seq 1
Spot 4	RBD (B.1.620)	SARS-CoV-2 Spike (B.1.617.2; AY.3; AY.5; AY.6; AY.7; AY.14) Alt Seq 1	Spike (B.1.617.2; AY.4) Alt Seq 2	Spike (B.1.617.2; AY.4) Alt Seq 2
Spot 5	BSA	BSA	Spike (B.1.617.3)	Spike (C.37)
Spot 6	BSA	BSA	Spike (B.1.617)	Spike (AY.12)
Spot 7	RBD (B.1.1.7+E484K; P.3)	SARS-CoV-2 Spike (P.1)	Spike (P.1)	Spike (P.1)
Spot 8	RBD (B.1.258.17; B.1.466.2)	SARS-CoV-2 Spike (B.1.1.7)	Spike (B.1.1.7)	Spike (AY.1) Alt Seq 1
Spot 9	RBD (AY.3; AY.4; AY.4.2; AY.5; AY.6; AY.7; AY.12; AY.14; B.1.617.2; B.1.617.2+ΔY144)	SARS-CoV-2 Spike (B.1.351)	Spike (B.1.351)	Spike (B.1.351)
Spot 10	SARS-CoV-2 S1 RBD	SARS-CoV-2 S1 RBD	Spike (B.1.526.1)	Spike (B.1.617.2; AY.3; AY.5; AY.6; AY.7; AY.14) Alt Seq 1

Note: Alternative S-GENE mutations for Spike of AY.1, AY.2, and B.1.617.2 are listed as "Alt Seq #."

Table 1 (continued)

Plate Description	SARS-CoV-2 Plate 20	SARS-CoV-2 Plate 22	SARS-CoV-2 Plate 23	SARS-CoV-2 Plate 24
Spot 1	SARS-CoV-2 Spike	RBD (B.1.1.529; BA.1; BA.1.15)	SARS-CoV-2 Spike	SARS-CoV-2 Spike
Spot 2	Spike (B.1.617.2 +4)	RBD (B.1.351; B.1.351.1)	Spike (B.1.1.529; BA.1; BA.1.15)	Spike (B.1.1.529; BA.1; BA.1.15)
Spot 3	Spike (B.1.617.2 +3)	BSA	Spike (AY.4.2)	SARS-CoV-2 Nucleocapsid
Spot 4	Spike (B.1.617.2; AY.4) Alt Seq 2	RBD (P.1)	Spike (B.1.617.2; AY.4) Alt Seq 2	Spike (B.1.617.2; AY.4) Alt Seq 2
Spot 5	Spike (B.1.617.2 +2)	BSA	BSA	BSA
Spot 6	Spike (B.1.617.2 +1)	RBD (B.1.1.7)	BSA	BSA
Spot 7	Spike (P.1)	BSA	Spike (P.1)	Spike (P.1)
Spot 8	Spike (B.1.1.7)	BSA	Spike (B.1.1.7)	Spike (B.1.1.7)
Spot 9	Spike (B.1.351)	RBD (AY.3; AY.4; AY.4.2; AY.5; AY.6; AY.7; AY.12; AY.14; B.1.617.2; B.1.617.2+ΔY144)	Spike (B.1.351)	Spike (B.1.351)
Spot 10	Spike (B.1.617.2; AY.3; AY.5; AY.6; AY.7; AY.14) Alt Seq 1	SARS-CoV-2 S1 RBD	Spike (B.1.617.2; AY.3; AY.5; AY.6; AY.7; AY.14) Alt Seq 1	SARS-CoV-2 S1 RBD

Note: Alternative S-GENE mutations for Spike of B.1.617.2 are listed as "Alt Seq #."

Plate Description	SARS-CoV-2 Plate 25	SARS-CoV-2 Plate 26	SARS-CoV-2 Plate 27	SARS-CoV-2 Plate 28
Spot 1	SARS-CoV-2 Spike	RBD (B.1.1.529; BA.1; BA.1.15)	SARS-CoV-2 Spike	RBD (BA.2.12.1)
Spot 2	Spike (B.1.1.529; BA.1; BA.1.15)	RBD (B.1.351; B.1.351.1)	Spike (BA.2.12.1)	RBD (B.1.351; B.1.351.1)
Spot 3	Spike (BA.2; BA.2.1; BA.2.2; BA.2.3; BA.2.5; BA.2.6; BA.2.7; BA.2.8; BA.2.10; BA.2.12)	RBD (BA.2; BA.2.1; BA.2.2; BA.2.3; BA.2.5; BA.2.6; BA.2.7; BA.2.8; BA.2.10; BA.2.10.1; BA.2.12)	Spike (BA.2; BA.2.1; BA.2.2; BA.2.3; BA.2.5; BA.2.6; BA.2.7; BA.2.8; BA.2.10; BA.2.12)	RBD (BA.2; BA.2.1; BA.2.2; BA.2.3; BA.2.5; BA.2.6; BA.2.7; BA.2.8; BA.2.10; BA.2.10.1; BA.2.12)
Spot 4	Spike (B.1.617.2; AY.4) Alt Seq 2	RBD (P.1)	Spike (B.1.617.2; AY.4) Alt Seq 2	RBD (BA.2+L452M)
Spot 5	Spike (BA.3)	BSA	Spike (BA.3)	RBD (BA.2+L452R)
Spot 6	Spike (BA.1+R346K; BA.1.1; BA.1.1.15)	RBD (B.1.1.7)	Spike (BA.2+L452M)	RBD (B.1.1.7)
Spot 7	Spike (BA.1+L452R)	BSA	Spike (BA.2+L452R)	RBD (BA.4; BA.5)
Spot 8	Spike (B.1.1.7)	RBD (BA.1.1; BA.1.1.15)	Spike (BA.4)	RBD (BA.3)
Spot 9	Spike (B.1.351)	RBD (AY.3; AY.4; AY.4.2; AY.5; AY.6; AY.7; AY.12; AY.14; B.1.617.2; B.1.617.2+ΔY144)	Spike (B.1.351)	RBD (AY.3; AY.4; AY.4.2; AY.5; AY.6; AY.7; AY.12; AY.14; B.1.617.2; B.1.617.2+Δ144)
Spot 10	Spike (B.1.640.2)	SARS-CoV-2 S1 RBD	Spike (BA.5)	SARS-CoV-2 S1 RBD

Note: Alternative S-GENE mutations for Spike of B.1.617.2 are listed as "Alt Seq #."

Table 1 (continued)

Plate Description	SARS-CoV-2 Plate 29	SARS-CoV-2 Plate 30	SARS-CoV-2 Plate 31	SARS-CoV-2 Plate 32	SARS-CoV-2 Plate 33
Spot 1	SARS-CoV-2 Spike	RBD (BA.2.12.1)	SARS-CoV-2 Spike	SARS-CoV-2 Spike	RBD (B.1.1.529; BA.1; BA.1.15)
Spot 2	Spike (BA.2.12.1)	RBD (B.1.351; B.1.351.1)	BSA	Spike (B.1.1.529; BA.1; BA.1.15)	RBD (BQ.1.1)
Spot 3	Spike (BA.2; BA.2.1; BA.2.2; BA.2.3; BA.2.5; BA.2.6; BA.2.7; BA.2.8; BA.2.10; BA.2.12)	RBD (BA.2; BA.2.1; BA.2.2; BA.2.3; BA.2.5; BA.2.6; BA.2.7; BA.2.8; BA.2.10; BA.2.10.1; BA.2.12)	SARS-CoV-2 Nucleocapsid	Spike (XBB.1)	RBD (BA.2.75.2)
Spot 4	Spike (B.1.617.2; AY.4) Alt Seq 2	BSA	BSA	Spike (BF.7)	RBD (BA.4.6; BF.7)
Spot 5	BSA	BSA	BSA	Spike (BA.2.75.2)	BSA
Spot 6	BSA	RBD (B.1.1.7)	BSA	Spike (BQ.1.1)	RBD (XBB.1)
Spot 7	Spike (BA.2.75)	RBD (BA.4; BA.5)	BSA	Spike (BA.2.75)	RBD (BA.4; BA.5)
Spot 8	Spike (BA.4)	RBD (BA.2.75)	Spike (BA.5)	Spike (BA.4.6)	RBD (BA.2.75)
Spot 9	Spike (B.1.351)	RBD (AY.3; AY.4; AY.4.2; AY.5; AY.6; AY.7; AY.12; AY.14; B.1.617.2; B.1.617.2+Δ144)	RBD (BA.4; BA.5)	Spike (BQ.1)	RBD (BQ.1)
Spot 10	Spike (BA.5)	SARS-CoV-2 S1 RBD	SARS-CoV-2 S1 RBD	Spike (BA.5)	SARS-CoV-2 S1 RBD

Note: Alternative S-GENE mutations for Spike of B.1.617.2 are listed as "Alt Seq #."

Plate Description	SARS-CoV-2 Plate 34	SARS-CoV-2 Plate 36	SARS-CoV-2 Plate 37	SARS-CoV-2 Plate 38
Spot 1	SARS-CoV-2 Spike	SARS-CoV-2 Spike	SARS-CoV-2 Spike	SARS-CoV-2 Spike
Spot 2	Spike (B.1.1.529; BA.1; BA.1.15)	Spike (B.1.1.529; BA.1; BA.1.15)	Spike (FL.1.5.1)	Spike (FL.1.5.1)
Spot 3	Spike (XBB.1)	SARS-CoV-2 Nucleocapsid	SARS-CoV-2 Nucleocapsid	SARS-CoV-2 Nucleocapsid
Spot 4	Spike (BF.7)	Spike (XBB.1.16.1)	Spike (BA.2.86)	Spike (BA.2.86)
Spot 5	Spike (XBB.1.5)	Spike (XBB.1.5)	Spike (XBB.1.5)	Spike (XBB.1.5)
Spot 6	Spike (BQ.1.1)	Spike (BQ.1.1)	Spike (EG.5.1)	Spike (EG.5.1)
Spot 7	Spike (BA.2.75)	Spike (XBB.1.16)	Spike (XBB.1.16)	Spike (JN.1)
Spot 8	Spike (BN.1)	Spike (XBB.2.3)	Spike (XBB.2.3)	Spike (JD.1.1)
Spot 9	Spike (BQ.1)	Spike (XBB.1)	Spike (XBB.1.16.6)	Spike (HV.1)
Spot 10	Spike (BA.5)	Spike (BA.5)	Spike (BA.5)	Spike (BA.5)

Table 1 (continued)

Plate Description	SARS-CoV-2 Plate 39	SARS-CoV-2 Key Variant Spike Plate 1	SARS-CoV-2 Key Variant RBD Plate 1	Coronavirus Plate 1
Spot 1	SARS-CoV-2 Spike	SARS-CoV-2 Spike	RBD (BA.2.12.1)	SARS-CoV-2 Spike
Spot 2	Spike (LB.1)	Spike (BA.2.12.1)	RBD (B.1.351; B.1.351.1)	Flu A/Hong Kong/2014 H3
Spot 3	SARS-CoV-2 Nucleocapsid	SARS-CoV-2 Nucleocapsid	SARS-CoV-2 Nucleocapsid	SARS-CoV-2 Nucleocapsid
Spot 4	Spike (BA.2.86)	Spike (BA.2.75)	RBD (B.1.1.529; BA.1; BA.1.15)	SARS-CoV-1 Spike
Spot 5	Spike (XBB.1.5 (v2))	Spike (BA.2; BA.2.1; BA.2.2; BA.2.3; BA.2.5; BA.2.6; BA.2.7; BA.2.8; BA.2.10; BA.2.12)	RBD (BA.2; BA.2.1; BA.2.2; BA.2.3; BA.2.5; BA.2.6; BA.2.7; BA.2.8; BA.2.10; BA.2.10.1; BA.2.12)	BSA
Spot 6	Spike (KP.3)	Spike (B.1.1.529; BA.1; BA.1.15)	RBD (B.1.1.7)	SARS-CoV-2 S1 NTD
Spot 7	Spike (JN.1 (v2))	Spike (B.1.617.2; AY.4) Alt Seq 2	RBD (AY.3; AY.4; AY.4.2; AY.5; AY.6; AY.7; AY.12; AY.14; B.1.617.2; B.1.617.2+ΔY144)	HCoV-HKU1 Spike
Spot 8	Spike (KP.2)	Spike (B.1.1.7)	RBD (BA.2.75)	HCoV-OC43 Spike
Spot 9	Spike (B.1.617.2)	Spike (B.1.351)	RBD (BA.4; BA.5)	MERS-CoV Spike
Spot 10	Spike (BA.5)	Spike (BA.5)	SARS-CoV-2 S1 RBD	SARS-CoV-2 S1 RBD

Note: Alternative S-GENE mutations for Spike of B.1.617.2 are listed as "Alt Seq #."

Plate Description	Coronavirus Plate 2	Coronavirus Plate 3	Respiratory Plate 1	Respiratory Plate 4
Spot 1	SARS-CoV-2 Spike	SARS-CoV-2 Spike	Flu B/Brisbane/2008 HA	SARS-CoV-2 Spike
Spot 2	HCoV-NL63 Spike	HCoV-NL63 Spike	Flu A/Shanghai/2013 H7	Flu A/Wisconsin/2019 H1
Spot 3	SARS-CoV-2 Nucleocapsid	SARS-CoV-2 Nucleocapsid	BSA	SARS-CoV-2 Nucleocapsid
Spot 4	SARS-CoV-1 Spike	SARS-CoV-1 Spike	Flu A/Michigan/2015 H1	SARS-CoV-2 Spike (XBB.1.5)
Spot 5	BSA	BSA	BSA	Flu A/Shanghai/2013 H7
Spot 6	SARS-CoV-2 S1 NTD	MERS-CoV Spike	BSA	BSA
Spot 7	HCoV-HKU1 Spike	HCoV-HKU1 Spike	RSV Pre-Fusion F	RSV Pre-Fusion F
Spot 8	HCoV-OC43 Spike	HCoV-OC43 Spike	Flu A/Hong Kong/2014 H3	Flu A/Darwin/2021 H3
Spot 9	HCoV-229E Spike	HCoV-229E Spike	BSA	Flu B/Austria/2021 HA
Spot 10	SARS-CoV-2 S1 RBD	SARS-CoV-2 S1 RBD	Flu B/Phuket/2013 HA	Flu B/Phuket/2013 HA

Plate Description	Respiratory Plate 7
Spot 1	SARS-CoV-2 Spike
Spot 2	Flu A/Wisconsin/67/2022 H1
Spot 3	SARS-CoV-2 Nucleocapsid
Spot 4	BSA
Spot 5	SARS-CoV-2 Spike (XBB.1.5 (v2))
Spot 6	Flu A/Ghana/39/2021 H5
Spot 7	RSV Pre-Fusion F
Spot 8	Flu A/Massachusetts/18/2022 H3
Spot 9	Flu B/Austria/2021 HA
Spot 10	SARS-CoV-2 Spike (KP.2)

Table 2. Antigen plates included in V-PLEX COVID-19 Serology Kits

Kit	Plate Included
V-PLEX SARS-CoV-2 Panel 1 Kit	SARS-CoV-2 Plate 1
V-PLEX SARS-CoV-2 Panel 2 Kit	SARS-CoV-2 Plate 2
V-PLEX SARS-CoV-2 Panel 5 Kit	SARS-CoV-2 Plate 5
V-PLEX SARS-CoV-2 Panel 6 Kit	SARS-CoV-2 Plate 6
V-PLEX SARS-CoV-2 Panel 7 Kit	SARS-CoV-2 Plate 7
V-PLEX SARS-CoV-2 Panel 8 Kit	SARS-CoV-2 Plate 8
V-PLEX SARS-CoV-2 Panel 9 Kit	SARS-CoV-2 Plate 9
V-PLEX SARS-CoV-2 Panel 11 Kit	SARS-CoV-2 Plate 11
V-PLEX SARS-CoV-2 Panel 12 Kit	SARS-CoV-2 Plate 12
V-PLEX SARS-CoV-2 Panel 13 Kit	SARS-CoV-2 Plate 13
V-PLEX SARS-CoV-2 Panel 14 Kit	SARS-CoV-2 Plate 14
V-PLEX SARS-CoV-2 Panel 15 Kit	SARS-CoV-2 Plate 15
V-PLEX SARS-CoV-2 Panel 16 Kit	SARS-CoV-2 Plate 16
V-PLEX SARS-CoV-2 Panel 17 Kit	SARS-CoV-2 Plate 17
V-PLEX SARS-CoV-2 Panel 18 Kit	SARS-CoV-2 Plate 18
V-PLEX SARS-CoV-2 Panel 19 Kit	SARS-CoV-2 Plate 19
V-PLEX SARS-CoV-2 Panel 20 Kit	SARS-CoV-2 Plate 20
V-PLEX SARS-CoV-2 Panel 22 Kit	SARS-CoV-2 Plate 22
V-PLEX SARS-CoV-2 Panel 23 Kit	SARS-CoV-2 Plate 23
V-PLEX SARS-CoV-2 Panel 24 Kit	SARS-CoV-2 Plate 24
V-PLEX SARS-CoV-2 Panel 25 Kit	SARS-CoV-2 Plate 25
V-PLEX SARS-CoV-2 Panel 26 Kit	SARS-CoV-2 Plate 26
V-PLEX SARS-CoV-2 Panel 27 Kit	SARS-CoV-2 Plate 27
V-PLEX SARS-CoV-2 Panel 28 Kit	SARS-CoV-2 Plate 28
V-PLEX SARS-CoV-2 Panel 29 Kit	SARS-CoV-2 Plate 29
V-PLEX SARS-CoV-2 Panel 30 Kit	SARS-CoV-2 Plate 30
V-PLEX SARS-CoV-2 Panel 31 Kit	SARS-CoV-2 Plate 31
V-PLEX SARS-CoV-2 Panel 32 Kit	SARS-CoV-2 Plate 32
V-PLEX SARS-CoV-2 Panel 33 Kit	SARS-CoV-2 Plate 33
V-PLEX SARS-CoV-2 Panel 34 Kit	SARS-CoV-2 Plate 34
V-PLEX SARS-CoV-2 Panel 36 Kit	SARS-CoV-2 Plate 36
V-PLEX SARS-CoV-2 Panel 37 Kit	SARS-CoV-2 Plate 37
V-PLEX SARS-CoV-2 Panel 38 Kit	SARS-CoV-2 Plate 38
V-PLEX SARS-CoV-2 Panel 39 Kit	SARS-CoV-2 Plate 39
V-PLEX SARS-CoV-2 Key Variant Spike Panel 1 Kit	SARS-CoV-2 Key Variant Spike Plate 1
V-PLEX SARS-CoV-2 Key Variant RBD Panel 1 Kit	SARS-CoV-2 Key Variant RBD Plate 1
V-PLEX COVID-19 Coronavirus Panel 1 Kit	Coronavirus Plate 1
V-PLEX COVID-19 Coronavirus Panel 2 Kit	Coronavirus Plate 2
V-PLEX COVID-19 Coronavirus Panel 3 Kit	Coronavirus Plate 3
V-PLEX COVID-19 Respiratory Panel 2 Kit	Coronavirus Plate 2
	Respiratory Plate 1
V-PLEX COVID-19 Respiratory Panel 3 Kit	Coronavirus Plate 3
	Respiratory Plate 1
V-PLEX Respiratory Panel 1 Kit	Respiratory Plate 1

Kit	Plate Included
V-PLEX Respiratory Panel 4 Kit	Respiratory Plate 4
V-PLEX Respiratory Panel 7 Kit	Respiratory Plate 7

Table 3. Reagents and Components

Reagent	Storage	Catalog Number	Size	Quantity Supplied	
				5-Plate Kit	25-Plate Kit
MULTI-SPOT 96-Well, 10-Spot plate	2–8 °C	—	10-Spot	5 plates	25 plates
SULFO-TAG Anti-Human IgG, IgM or IgA Antibody (200X) [♦]	2–8 °C	D21ADF-3 D21ADD-3 D21ADE-3	200 µL		
SULFO-TAG Anti-Human IgG Antibody				1 vial	5 vials
SULFO-TAG Anti-Human IgM Antibody				1 vial	5 vials
SULFO-TAG Anti-Human IgA Antibody				1 vial	5 vials
MSD GOLD™ SULFO-TAG Anti-Human IgG Antibody (200X) [†]	2–8 °C	D21APR-3	200 µL	1 vial	5 vials
Diluent 100	2–8 °C	R50AA-3	1000 mL	1 bottle	5 bottles
MSD Wash Buffer (20X)	RT	R61AA-1	100 mL	1 bottle	5 bottles
Blocker A	RT	R93BA-2	250 mL	1 bottle	5 bottles
MSD Phosphate Buffer (5X)	RT	R93SA-2	50 mL	1 bottle	5 bottles
MSD GOLD Read Buffer B	RT	R60AM-2	90 mL	1 bottle	5 bottles
Microplate Adhesive Film	RT	—	—	15 sheets	75 sheets
Reference Standard 1*	≤-70 °C	C00ADK-2	1 mL	1 vial (IgG assay) 2 vials (IgM assay) 2 vials (IgA assay) [‡]	5 vials (IgG assay) 10 vials (IgM assay) 10 vials (IgA assay) [‡]
Reference Standard 2*	≤-70 °C	C00AUB-2	1 mL	1 vial (IgG assay) 2 vials (IgM assay) 2 vials (IgA assay) [‡]	5 vials (IgG assay) 10 vials (IgM assay) 10 vials (IgA assay) [‡]
Serology Control Pack 1*		C4381-1			
Serology Control 1.1	≤-70 °C		1 mL	1 vial	5 vials
Serology Control 1.2	≤-70 °C		1 mL	1 vial	5 vials
Serology Control 1.3	≤-70 °C		1 mL	1 vial	5 vials
Serology Control Pack 2*		C4731-1			
Serology Control 2.1	≤-70 °C		1 mL	1 vial	5 vials
Serology Control 2.2	≤-70 °C		1 mL	1 vial	5 vials
Serology Control 2.3	≤-70 °C		1 mL	1 vial	5 vials

RT = room temperature

[†] Kits containing Respiratory Plate 1 (Catalog # K15374U, K15405U, and K15367U) for IgA assay are provided with 1 vial (5-Plate Kit) and 5 vials (25-Plate kit) of Reference Standard 1

[♦] Kits use mouse monoclonal IgG, IgM, or IgA as detection antibody

[‡]MSD GOLD SULFO-TAG Anti-Human IgG Antibody (D21APR-3) is supplied with V-PLEX SARS-CoV-2 IgG Serology Assay Kits starting from Panel 38. MSD GOLD SULFO-TAG Anti-Human IgG Antibody (D21APR-6) is also available as a stand-alone product for use as a detection antibody in all other V-PLEX SARS-CoV-2 IgG Serology Assay Kits.

*Each V-PLEX COVID Serology Kit will include either Reference Standard 1 paired with Serology Control Pack 1 OR Reference Standard 2 paired with Serology Control Pack 2.

Table 4. Information about the SARS-CoV-2 variant antigens included in V-PLEX COVID-19 Serology Kits

SARS-CoV-2 Spike Antigens

Lineages	Amino Acid Modifications	Common Designation
A.23.1	F157L, V367F, Q613H, P681R	Uganda
A.VOI.V2	D80Y, ΔY144, ΔI210, D215G, Δ246-248, L249M, W258L, R346K, T478R, E484K, H655Y, P681H, Q957H	Tanzania
AY.1	T19R, Δ157/158, K417N, L452R, T478K, D614G, P681R, D950N	Delta sublineage
AY.1	(Alt Seq 1): T19R, T95I, G142D, E156G, Δ157/158, W258L, K417N, L452R, T478K, D614G, P681R, D950N	Delta sublineage
AY.2	T19R, V70F, G142D, Δ157/158, A222V, K417N, L452R, T478K, D614G, P681R, D950N	Delta sublineage

Lineages	Amino Acid Modifications	Common Designation
AY.2	(Alt Seq 1): T19R, V70F, G142D, E156G, Δ157/158, A222V, K417N, L452R, T478K, D614G, P681R, D950N	Delta sublineage
AY.4.2	T19R, T95I, G142D, Y145H, Δ156/157, R158G, A222V, L452R, T478K, D614G, P681R, D950N	Delta sublineage
AY.12	T19R, Δ156/157, R158G, L452R, T478K, D614G, P681R, D950N	Delta sublineage
BA.1+L452R	A67V, Δ69-70, T95I, G142D/Δ143-145, Δ211/L212I, ins214EPE, G339D, S371L, S373P, S375F, K417N, N440K, L452R, G446S, S477N, T478K, E484A, Q493R, G496S, Q498R, N501Y, Y505H, T547K, D614G, H655Y, N679K, P681H, N764K, D796Y, N856K, Q954H, N969K, L981F	Omicron sublineage
BA.1+R346K; BA.1.1; BA.1.1.15	A67V, Δ69-70, T95I, G142D/Δ143-145, Δ211/L212I, ins214EPE, G339D, R346K, S371L, S373P, S375F, K417N, N440K, G446S, S477N, T478K, E484A, Q493R, G496S, Q498R, N501Y, Y505H, T547K, D614G, H655Y, N679K, P681H, N764K, D796Y, N856K, Q954H, N969K, L981F	Omicron sublineages
BA.2; BA.2.1; BA.2.2; BA.2.3; BA.2.5; BA.2.6; BA.2.7; BA.2.8; BA.2.10; BA.2.12	T19I, (L24-A27)toS, G142D, V213G, G339D, S371F, S373P, S375F, T376A, D405N, R408S, K417N, N440K, S477N, T478K, E484A, Q493R, Q498R, N501Y, Y505H, D614G, H655Y, N679K, P681H, N764K, D796Y, Q954H, N969K	Omicron sublineages
BA.2+L452M	T19I, (L24-A27)toS, G142D, V213G, G339D, S371F, S373P, S375F, T376A, D405N, R408S, K417N, N440K, L452M, S477N, T478K, E484A, Q493R, Q498R, N501Y, Y505H, D614G, H655Y, N679K, P681H, N764K, D796Y, Q954H, N969K	Omicron sublineage
BA.2+L452R	T19I, (L24-A27)toS, G142D, V213G, G339D, S371F, S373P, S375F, T376A, D405N, R408S, K417N, N440K, L452R, S477N, T478K, E484A, Q493R, Q498R, N501Y, Y505H, D614G, H655Y, N679K, P681H, N764K, D796Y, Q954H, N969K	Omicron sublineage
BA.2.12.1	T19I, (L24-A27)toS, G142D, V213G, G339D, S371F, S373P, S375F, T376A, D405N, R408S, K417N, N440K, L452Q, S477N, T478K, E484A, Q493R, Q498R, N501Y, Y505H, D614G, H655Y, N679K, P681H, S704LN764K, D796Y, Q954H, N969K	Omicron sublineage
BA.2.75	T19I, L24-A27>S, G142D, K147E, W152R, F157L, I210V, V213G, G257S, G339H, S371F, S373P, S375F, T376A, D405N, R408S, K417N, N440K, G446S, N460K, S477N, T478K, E484A, Q498R, N501Y, Y505H, D614G, H655Y, N679K, P681H, N764K, D796Y, Q954H, N969K	Omicron sublineage
BA.2.75.2	T19I, L24-A27>S, G142D, K147E, W152R, F157L, I210V, V213G, G257S, G339H, R346T, S371F, S373P, S375F, T376A, D405N, R408S, K417N, N440K, G446S, N460K, S477N, T478K, E484A, F486S, Q498R, N501Y, Y505H, D614G, H655Y, N679K, P681H, N764K, D796Y, Q954H, N969K, D1199N	Omicron sublineage
BA.2.86	T19I, R21T, L24-A27>S, S50L, H69del, V70del, V127F, G142D, Y144del, F157S, R158G, N211del, L212I, V213G, L216F, H245N, A264D, I332V, G339H, K356T, S371F, S373P, S375F, T376A, R403K, D405N, R408S, K417N, N440K, V445H, G446S, N450D, L452W, N460K, S477N, T478K, N481K, V483del, E484K, F486P, Q498R, N501Y, Y505H, E554K, A570V, D614G, P621S, H655Y, I670V, N679K, P681R, N764K, D796Y, S939F, Q954H, N969K, P1143L	Omicron sublineage
BA.3	A67V, H69-V70del, T95I, G142D, V143-Y145del, (N211-L212)toI, G339D, S371F, S373P, S375F, D405N, K417N, N440K, G446S, S477N, T478K, E484A, Q493R, Q498R, N501Y, Y505H, D614G, H655Y, N679K, P681H, N764K, D796Y, Q954H, N969K	Omicron sublineage
BA.4	T19I, (L24-A27)toS, del69/70, G142D, V213G, G339D, S371F, S373P, S375F, T376A, D405N, R408S, K417N, N440K, L452R, S477N, T478K, E484A, F486V, Q498R, N501Y, Y505H, D614G, H655Y, N658S, N679K, P681H, N764K, D796Y, Q954H, N969K	Omicron sublineage
BA.4.6	V3G, T19I, L24-A27>S, H69-V70del, G142D, V213G, G339D, R346T, S371F, S373P, S375F, T376A, D405N, R408S, K417N, N440K, L452R, S477N, T478K, E484A, F486V, Q498R, N501Y, Y505H, D614G, H655Y, N658S, N679K, P681H, N764K, D796Y, Q954H, N969K	Omicron sublineage
BA.5	T19I, (L24-A27)toS, del69/70, G142D, V213G, G339D, S371F, S373P, S375F, T376A, D405N, R408S, K417N, N440K, L452R, S477N, T478K, E484A, F486V, Q498R, N501Y, Y505H, D614G, H655Y, N679K, P681H, N764K, D796Y, Q954H, N969K	Omicron sublineage
BF.7	T19I, L24-A27>S, H69-V70del, G142D, V213G, G339D, R346T, S371F, S373P, S375F, T376A, D405N, R408S, K417N, N440K, L452R, S477N, T478K, E484A, F486V, Q498R, N501Y, Y505H, D614G, H655Y, N679K, P681H, N764K, D796Y, Q954H, N969K	Omicron sublineage
BN.1	T19I, L24-A27>S, G142D, K147E, W152R, F157L, I210V, V213G, G257S, G339H, R346T, K356T, S371F, S373P, S375F, T376A, D405N, R408S, K417N, N440K, G446S, N460K, S477N, T478K, E484A, F490S, Q498R, N501Y, Y505H, D614G, H655Y, N679K, P681H, N764K, D796Y, Q954H, N969K	Omicron sublineage
BQ.1	T19I, L24-A27>S, H69-V70del, G142D, V213G, G339D, S371F, S373P, S375F, T376A, D405N, R408S, K417N, N440K, K444T, L452R, N460K, S477N, T478K, E484A, F486V, Q498R, N501Y, Y505H, D614G, H655Y, N679K, P681H, N764K, D796Y, Q954H, N969K	Omicron sublineage
BQ.1.1	T19I, L24-A27>S, H69-V70del, G142D, V213G, G339D, R346T, S371F, S373P, S375F, T376A, D405N, R408S, K417N, N440K, K444T, L452R, N460K, S477N, T478K, E484A, F486V, Q498R, N501Y, Y505H, D614G, H655Y, N679K, P681H, N764K, D796Y, Q954H, N969K	Omicron sublineage
BV-1	H69-V70, ΔY144, Q493R, N501Y, A570D, D614G, P681H, T716I, S982A, D1118H	Texas BV-1
B.1	D614G	-
B.1.1.519	T478K, D614G, P681H, T732A	Mexico/Texas BV-2
B.1.1.529; BA.1; BA.1.15	A67V, ΔH69-V70, T95I, G142D, Δ143-145, Δ211/L212I, ins214EPE, G339D, S371L, S373P, S375F, K417N, N440K, G446S, S477N, T478K, E484A, Q493R, G496S, Q498R, N501Y, Y505H, T547K, D614G, H655Y, N679K, P681H, N764K, D796Y, N856K, Q954H, N969K, L981F	Omicron sublineages
B.1.1.7	ΔH69-V70, ΔY144, N501Y, A570D, D614G, P681H, T716I, S982A, D1118H	Alpha
B.1.1.7+E484K	ΔH69-V70, ΔY144, E484K, N501Y, A570D, D614G, P681H, T716I, S982A, D1118H	U.K.
B.1.258.17	ΔH69-V70, L189F, N439K, D614G, V772I	Europe
B.1.351	L18F, D80A, D215G, Δ242-244, R246I, K417N, E484K, N501Y, D614G, A701V	Beta

Lineages	Amino Acid Modifications	Common Designation
B.1.351.1	D80A, D215G, K417N, E484K, N501Y, D614G, A701V	Botswana
B.1.429	S13I, W152C, L452R, D614G	Epsilon
B.1.466.2	W152R, N439K, D614G, P681R	Indonesia
B.1.525	Q52R, A67V, ΔH69-V70, ΔY144, E484K, Q677H, D614G, F888L	Eta
B.1.526	L5F, T95I, D253G, E484K, D614G, A701V	Iota
B.1.526.1	D80G, ΔY144, F157S, L452R, D614G, T859N, D950H	New York
B.1.617	L452R, E484Q, D614G	India
B.1.617.1	T95I, G142D, E154K, L452R, E484Q, D614G, P681R, Q1071H	Kappa
B.1.617.2	T19R, Δ157/158, L452R, T478K, D614G, P681R, D950N	Delta sublineage
B.1.617.2; AY.3; AY.5; AY.6; AY.7; AY.14	(Alt Seq 1): T19R, G142D, Δ156/157, R158G, L452R, T478K, D614G, P681R, D950N	Delta sublineages
B.1.617.2 +1	T19R, G142D, Δ156/157, R158G, L452R, T478K, E484K, D614G, P681R, D950N	Delta +1
B.1.617.2 +2	T19R, G142D, Δ156/157, R158G, L452R, T478K, E484K, N501Y, D614G, P681R, D950N	Delta +2
B.1.617.2 +3	T19R, G142D, Δ156/157, R158G, K417N, L452R, T478K, E484K, N501Y, D614G, P681R, D950N	Delta +3
B.1.617.2 +4	T19R, G142D, Δ156/157, R158G, K417N, N439K, L452R, T478K, E484K, N501Y, D614G, P681R, D950N	Delta +4
B.1.617.2; AY.4	(Alt Seq 2): T19R, T95I, G142D, Δ156/157, R158G, L452R, T478K, D614G, P681R, D950N	Delta sublineages
B.1.617.2+ΔY144	T19R, ΔY144, Δ157/158, L452R, T478K, D614G, P681R, D950N	Vietnam
B.1.617.3	T19R, G142D, L452R, E484Q, D614G, P681R, D950N	India
B.1.618	ΔY145/146, E484K, D614G	India
B.1.620	P26S, ΔH69-V70, V126A, ΔY144, Δ242-244, H245Y, S477N, E484K, D614G, P681H, T1027I, D1118H	Europe
B.1.621	T95I, Y144T, Y145S, ins146N, R346K, E484K, N501Y, D614G, P681H, D950N	Mu
B.1.640.2	P9L, E96Q, C136-Y144del, R190S, D215H, R346S, N394S, Y449N, E484K, F490S, N501Y, D614G, P681H, T859N, D1139H	France (IHU)
C.37	G75V, T76I, ΔR246, ΔS247, ΔY248, ΔL249, ΔT250, ΔP251, ΔG252, D253N, L452Q, F490S, D614G, T859N	Lambda
EG.5.1	T19I, L24-A27>S, Q52H, G142D, Y144del, H146Q, Q183E, V213E, G252V, G339H, R346T, L368I, S371F, S373P, S375F, T376A, D405N, R408S, K417N, N440K, V445P, G446S, F456L, N460K, S477N, T478K, E484A, F486P, F490S, Q498R, N501Y, Y505H, D614G, H655Y, N679K, P681H, N764K, D796Y, Q954H, N969K	Omicron sublineage
FL.1.5.1	T19I, L24-A27>S, G142D, Y144del, H146Q, Q183E, V213E, G252V, G339H, R346T, L368I, S371F, S373P, S375F, T376A, D405N, R408S, K417N, N440K, V445P, G446S, F456L, N460K, S477N, T478R, E484A, F486P, F490S, Q498R, N501Y, Y505H, D614G, H655Y, N679K, P681H, A701V, N764K, D796Y, Q954H, N969K	Omicron sublineage
HV.1	T19I, L24-A27>S, Q52H, V83A, G142D, Y144del, H146Q, F157L, Q183E, V213E, G252V, G339H, R346T, L368I, S371F, S373P, S375F, T376A, D405N, R408S, K417N, N440K, V445P, G446S, L452R, F456L, N460K, S477N, T478K, E484A, F486P, F490S, Q498R, N501Y, Y505H, D614G, H655Y, N679K, P681H, N764K, D796Y, Q954H, N969K	Omicron sublineage
JD.1.1	T19I, L24-A27>S, V83A, G142D, Y144del, H146Q, Q183E, V213E, G252V, G339H, R346T, L368I, S371F, S373P, S375F, T376A, D405N, R408S, K417N, N440K, V445P, G446S, L455F, F456L, N460K, A475V, S477N, T478K, E484A, F486P, F490S, Q498R, N501Y, Y505H, D614G, H655Y, N679K, P681H, N764K, D796Y, Q954H, N969K	Omicron sublineage
JN.1	T19I, R21T, L24-A27>S, S50L, H69del, V70del, V127F, G142D, Y144del, F157S, R158G, N211del, L212I, V213G, L216F, H245N, A264D, I332V, G339H, K356T, S371F, S373P, S375F, T376A, R403K, D405N, R408S, K417N, N440K, V445H, G446S, N450D, L452W, L455S, N460K, S477N, T478K, N481K, V483del, E484K, F486P, Q498R, N501Y, Y505H, E554K, A570V, D614G, P621S, H655Y, N679K, P681R, N764K, D796Y, S939F, Q954H, N969K, P1143L	Omicron sublineage
JN.1 (v2)	ins16MPLF, T19I, R21T, L24-A27>S, S50L, H69del, V70del, V127F, G142D, Y144del, F157S, R158G, N211del, L212I, V213G, L216F, H245N, A264D, I332V, G339H, K356T, S371F, S373P, S375F, T376A, R403K, D405N, R408S, K417N, N440K, V445H, G446S, N450D, L452W, L455S, N460K, S477N, T478K, N481K, V483del, E484K, F486P, Q498R, N501Y, Y505H, E554K, A570V, D614G, P621S, H655Y, N679K, P681R, N764K, D796Y, S939F, Q954H, N969K, P1143L	Omicron sublineage
KP.2	ins16MPLF, T19I, R21T, L24-A27>S, S50L, H69del, V70del, V127F, G142D, Y144del, F157S, R158G, N211del, L212I, V213G, L216F, H245N, A264D, I332V, G339H, R346T, K356T, S371F, S373P, S375F, T376A, R403K, D405N, R408S, K417N, N440K, V445H, G446S, N450D, L452W, L455S, F456L, N460K, S477N, T478K, N481K, V483del, E484K, F486P, Q498R, N501Y, Y505H, E554K, A570V, D614G, P621S, H655Y, N679K, P681R, N764K, D796Y, S939F, Q954H, N969K, V1104L, P1143L	Omicron sublineage
KP.3	ins16MPLF, T19I, R21T, L24-A27>S, S50L, H69del, V70del, V127F, G142D, Y144del, F157S, R158G, N211del, L212I, V213G, L216F, H245N, A264D, I332V, G339H, K356T, S371F, S373P, S375F, T376A, R403K, D405N, R408S, K417N, N440K, V445H, G446S, N450D, L452W, L455S, F456L, N460K, S477N, T478K, N481K, V483del, E484K, F486P, Q498R, N501Y, Y505H, E554K, A570V, D614G, P621S, H655Y, N679K, P681R, N764K, D796Y, S939F, Q954H, N969K, V1104L, P1143L	Omicron sublineage

Lineages	Amino Acid Modifications	Common Designation
LB.1	ins16MPLF, T19I, R21T, L24-A27>S, S31del, S50L, H69del, V70del, V127F, G142D, Y144del, F157S, R158G, Q183H, N211del, L212I, V213G, L216F, H245N, A264D, I332V, G339H, R346T, K356T, S371F, S373P, S375F, T376A, R403K, D405N, R408S, K417N, N440K, V445H, G446S, N450D, L452W, L455S, F456L, N460K, S477N, T478K, N481K, V483del, E484K, F486P, Q498R, N501Y, Y505H, E554K, A570V, D614G, P621S, H655Y, N679K, P681R, N764K, D796Y, S939F, Q954H, N969K, P1143L	Omicron sublineage
P.1	L18F, T20N, P26S, D138Y, R190S, K417T, E484K, N501Y, D614G, H655Y, T1027I, V1176F	Gamma
P.2	E484K, D614G, V1176F	Zeta
P.3	Δ141-143, E484K, N501Y, D614G, P681H, E1092K, H1101Y, V1176F	Philippines
R.1	W152L, E484K, D614G, G769V	Kentucky
XBB.1	T19I, L24-A27>S, G142D, Y144del, H146Q, Q183E, V213E, G252V, G339H, R346T, L368I, S371F, S373P, S375F, T376A, D405N, R408S, K417N, N440K, V445P, G446S, N460K, S477N, T478K, E484A, F486S, F490S, Q498R, N501Y, Y505H, D614G, H655Y, N679K, P681H, N764K, D796Y, Q954H, N969K	Omicron sublineage
XBB.1.16	T19I, L24-A27>S, G142D, Y144del, H146Q, E180V, Q183E, V213E, G252V, G339H, R346T, L368I, S371F, S373P, S375F, T376A, D405N, R408S, K417N, N440K, V445P, G446S, N460K, S477N, T478R, E484A, F486P, F490S, Q498R, N501Y, Y505H, D614G, H655Y, N679K, P681H, N764K, D796Y, Q954H, N969K	Omicron sublineage
XBB.1.16.1	T19I, L24-A27>S, G142D, Y144del, H146Q, E180V, Q183E, V213E, G252V, G339H, R346T, L368I, S371F, S373P, S375F, T376A, D405N, R408S, K417N, N440K, V445P, G446S, N460K, S477N, T478R, E484A, F486P, F490S, Q498R, N501Y, Y505H, T547I, D614G, H655Y, N679K, P681H, N764K, D796Y, Q954H, N969K	Omicron sublineage
XBB.1.16.6	T19I, L24-A27>S, G142D, Y144del, H146Q, E180V, Q183E, V213E, G252V, G339H, R346T, L368I, S371F, S373P, S375F, T376A, D405N, R408S, K417N, N440K, V445P, G446S, F456L, N460K, S477N, T478R, E484A, F486P, F490S, Q498R, N501Y, Y505H, D614G, H655Y, N679K, P681H, N764K, D796Y, Q954H, N969K	Omicron sublineage
XBB.1.5	T19I, L24-A27>S, G142D, Y144del, H146Q, Q183E, V213E, G252V, G339H, R346T, L368I, S371F, S373P, S375F, T376A, D405N, R408S, K417N, N440K, V445P, G446S, N460K, S477N, T478K, E484A, F486P, F490S, Q498R, N501Y, Y505H, D614G, H655Y, N679K, P681H, N764K, D796Y, Q954H, N969K	Omicron sublineage
XBB.1.5 v2	T19I, L24-A27>S, V83A, G142D, Y144del, H146Q, Q183E, V213E, G252V, G339H, R346T, L368I, S371F, S373P, S375F, T376A, D405N, R408S, K417N, N440K, V445P, G446S, N460K, S477N, T478K, E484A, F486P, F490S, Q498R, N501Y, Y505H, D614G, H655Y, N679K, P681H, N764K, D796Y, Q954H, N969K	Omicron sublineage
XBB.2.3	T19I, L24-A27>S, G142D, Y144del, H146Q, Q183E, V213E, D253G, G339H, R346T, L368I, S371F, S373P, S375F, T376A, D405N, R408S, K417N, N440K, V445P, G446S, N460K, S477N, T478K, E484A, F486P, F490S, Q498R, N501Y, Y505H, P521S, D614G, H655Y, N679K, P681H, N764K, D796Y, Q954H, N969K	Omicron sublineage

- = Not applicable

Note: Alternative S-GENE mutations for Spike of AY.1, AY.2, and B.1.617.2 are listed as "Alt Seq #."

SARS-CoV-2 S1 RBD Antigens

Lineages	Amino Acid Modifications	Common Designation
A.23.1	V367F	Uganda
A.VOI.V2	R346K, T478R, E484K	Tanzania
AY.1; AY.2	K417N, L452R, T478K	Delta sublineages
AY.3; AY.4; AY.4.2; AY.5; AY.6; AY.7; AY.12; AY.14; B.1.617.2; B.1.617.2+ΔY144	L452R, T478K	Delta sublineages
BA.2; BA.2.1; BA.2.2; BA.2.3; BA.2.5; BA.2.6; BA.2.7; BA.2.8; BA.2.10; BA.2.10.1; BA.2.12	G339D, S371F, S373P, S375F, T376A, D405N, R408S, K417N, N440K, S477N, T478K, E484A, Q493R, Q498R, N501Y, Y505H	Omicron sublineages
BA.2+L452M	G339D, S371F, S373P, S375F, T376A, D405N, R408S, K417N, N440K, L452M, S477N, T478K, E484A, Q493R, Q498R, N501Y, Y505H	Omicron sublineage
BA.2+L452R	G339D, S371F, S373P, S375F, T376A, D405N, R408S, K417N, N440K, L452R, S477N, T478K, E484A, Q493R, Q498R, N501Y, Y505H	Omicron sublineage
BA.2.12.1	G339D, S371F, S373P, S375F, T376A, D405N, R408S, K417N, N440K, L452Q, S477N, T478K, E484A, Q493R, Q498R, N501Y, Y505H	Omicron sublineage
BA.2.75	G339H, S371F, S373P, S375F, T376A, D405N, R408S, K417N, N440K, G446S, N460K, S477N, T478K, E484A, Q498R, N501Y, Y505H	Omicron sublineage
BA.2.75.2	G339H, R346T, S371F, S373P, S375F, T376A, D405N, R408S, K417N, N440K, G446S, N460K, S477N, T478K, E484A, F486S, Q498R, N501Y, Y505H	Omicron sublineage
BA.3	G339D, S371F, S373P, S375F, D405N, K417N, N440K, G446S, S477N, T478K, E484A, Q493R, Q498R, N501Y, Y505H	Omicron sublineage
BA.4; BA.5	G339D, S371F, S373P, S375F, T376A, D405N, R408S, K417N, N440K, L452R, S477N, T478K, E484A, F486V, Q498R, N501Y, Y505H	Omicron sublineages
BA.4.6; BF.7	G339D, R346T, S371F, S373P, S375F, T376A, D405N, R408S, K417N, N440K, L452R, S477N, T478K, E484A, F486V, Q498R, N501Y, Y505H	Omicron sublineages
BQ.1	G339D, S371F, S373P, S375F, T376A, D405N, R408S, K417N, N440K, K444T, L452R, N460K, S477N, T478K, E484A, F486V, Q498R, N501Y, Y505H	Omicron sublineage
BQ.1.1	G339D, R346T, S371F, S373P, S375F, T376A, D405N, R408S, K417N, N440K, K444T, L452R, N460K, S477N, T478K, E484A, F486V, Q498R, N501Y, Y505H	Omicron sublineage
BV-1	Q493R, N501Y	Texas BV-1
B.1.1.519	T478K	Mexico/Texas BV-2
B.1.1.529; BA.1; BA.1.15	G339D, S371L, S373P, S375F, K417N, N440K, G446S, S477N, T478K, E484A, Q493R, G496S, Q498R, N501Y, Y505H	Omicron sublineages
BA.1.1; BA.1.1.15	G339D, R346K, S371L, S373P, S375F, K417N, N440K, G446S, S477N, T478K, E484A, Q493R, G496S, Q498R, N501Y, Y505H	Omicron sublineages
B.1.1.7	N501Y	Alpha
B.1.1.7+E484K; P.3	E484K, N501Y	U.K.; Philippines
B.1.214.2	Q414K, N450K	Belgium
B.1.258.17; B.1.466.2	N439K	Europe; Indonesia
B.1.351; B.1.351.1	K417N, E484K, N501Y	Beta ; Botswana
B.1.427; B.1.429; B.1.526.1	L452R	Epsilon lineages; New York
B.1.525; B.1.526; B.1.618; P.2; R.1	E484K	Eta ; Iota ; India; Zeta ; Kentucky
B.1.526.2	S477N	New York
B.1.617; B.1.617.1; B.1.617.3	L452R, E484Q	India; Kappa ; India
B.1.620	S477N, E484K	Europe
C.37	L452Q, F490S	Lambda
P.1	K417T, E484K, N501Y	Gamma
XBB.1	G339H, R346T, L368I, S371F, S373P, S375F, T376A, D405N, R408S, K417N, N440K, V445P, G446S, N460K, S477N, T478K, E484A, F486S, F490S, Q498R, N501Y, Y505H	Omicron sublineage

Additional Materials and Equipment

- Appropriately sized tubes for reagent preparation
- Deionized water
- 0.2 μM filter needed for Blocker A preparation
- 96-well plates
- Microtiter plate shaker capable of shaking at ~ 700 rpm
- Microcentrifuge tubes for making serial dilutions
- Automated plate washer or other efficient multi-channel pipetting equipment for washing 96-well plates
- Appropriate liquid handling equipment for desired throughput capable of accurately dispensing 50 μL and 150 μL into a 96-well microplate
- Vortex mixer

Safety

Reference Standard 1 and Serology Control Pack 1 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[®].

Best Practices

- Mixing or substituting reagents from different sources or different kit lots is not recommended. Lot information is provided in the lot-specific certificate of analysis (COA).
- Assay incubation steps should be performed at 20-26 °C to maximize consistency in signals between runs.
- Avoid prolonged exposure of the detection ACE2 protein (stock or diluted) to light. During the antibody incubation step, plates do not need to be shielded from light except for direct sunlight.
- Avoid bubbles in wells at all pipetting steps as they may lead to variable results. Bubbles introduced when adding read buffer may interfere with signal detection.
- Do not touch the pipette tip on the bottom of the wells when pipetting into the MSD plate.
- Use reverse pipetting when necessary to avoid introduction of bubbles. For empty wells, pipette gently to the bottom corner. Do not touch the pipette tip to the bottom of the wells when pipetting into the MSD plate.
- Plate shaking should be vigorous, with a rotary motion between 500-1,000 rpm. Binding reactions may reach equilibrium sooner if shaken in the middle of this range (~700 rpm) or above.
- When performing manual plate washing using a multi-channel pipette, plates should be washed using at least 150 μ L of wash buffer per well. Excess residual volume after washing should be removed by gently tapping the plate on a paper towel.
- Do not allow plates to dry after washing steps. Solutions associated with the next assay step should be added to the plate immediately after washing.
- Make sure that the read buffer is at room temperature when adding to the plate.
- To improve interplate precision, keep time intervals consistent between adding read buffer and reading the plate. Unless otherwise directed, read the plate as soon as possible after adding read buffer.
- Do not shake the plate after adding read buffer.
- Remove the plate seals before reading the plate.
- If the sample results are above the top of the calibration curve, dilute the samples, and repeat the assay.
- We do not recommend using a partial plate when running this panel.

Recommended Protocol

Bring all plates and diluents to room temperature. Thaw samples, reference standard, and controls on ice. Thawed reference standard and controls should be equilibrated to room temperature before loading into the plates.

A sample plate layout is shown in Figure 4 (below).

Prepare Blocker A Solution

Follow the preparation procedure in the product insert provided with the Blocker A Kit to prepare the Blocker A solution. You may store unused Blocker A solution according to the instructions in the Blocker A product insert available at www.mesoscale.com.

Prepare Wash Buffer

MSD provides 100 mL of Wash Buffer as a 20X stock solution. Dilute the stock solution before use. PBS + 0.05% Tween-20 can be used as an alternative to MSD Wash Buffer.

For one plate, combine:

- 15 mL of MSD Wash Buffer (20X)
- 285 mL of deionized water

Assay and Antibody Diluent

Use Diluent 100 as assay and antibody diluent.

STEP 1: Prepare Plate

- Remove the plate from its packaging.
- Add 150 μ L/well of Blocker A solution to the plate.
- Seal the plate with an adhesive plate seal and incubate at room temperature with shaking (~700 rpm) for at least 30 minutes.

During this time, prepare calibrators, controls, and samples.

Calibrator Preparation

The kits include a serum-based reference standard, Reference Standard 1 or 2, which is used to establish a calibration curve in the assay. The calibration curve is used for calculating the concentration of human IgG, IgM, and IgA against multiple antigens in the V-PLEX COVID-19 Serology Kits.

We recommend a 7-point calibration curve with 4-fold serial dilution steps and a zero calibrator blank. Thaw Reference Standard 1 or 2 on ice, equilibrate to room temperature, and then add to Diluent 100 to make the calibrator curve solutions.

Appendices A, B, and C provide assigned values for calibrators in MSD arbitrary units (AU/mL) and WHO international units (BAU/mL).

Notes:

- For the IgG assays, Reference Standard 1 or 2 requires a 10-fold dilution to create the highest calibrator point (CAL-01).
- For the IgM assays, neat (undiluted) Reference Standard 1 or 2 should be used as the highest calibrator point (CAL-01).
- For the IgA assays, neat (undiluted) Reference Standard 1 or 2 should be used as the highest calibrator point (CAL-01), with the exception that a 10-fold dilution of Reference Standard 1 should be used to create the highest calibrator point (CAL-01) for Respiratory Plate 1.
 - Respiratory Plate 1 is included in the V-PLEX COVID-19 Respiratory Panel 2 (IgA) Kit (Catalog # K15374U), and V-PLEX COVID-19 Respiratory Panel 3 (IgA) Kit (Catalog # K15405U). Generation of two independent calibration curves is recommended when running these panels: a) one calibration curve with CAL-01 prepared using neat (undiluted) Reference Standard 1, and b) a second calibration curve with CAL-01 prepared using 10-fold diluted Reference Standard 1. The calibration curve prepared using 10-fold diluted Reference Standard 1 should be used on Respiratory Plate 1.
- Respiratory Plate 1 is also included in the V-PLEX Respiratory Panel 1 (IgA) Kit (Catalog # K15367U). The calibration curve for this kit is prepared by using 10-fold diluted Reference Standard 1 as CAL-01.

CAL-01 Preparation: Reference Standard 1, 10-fold dilution:

Prepare the highest calibrator solution (CAL-01) by diluting Reference Standard 1 or 2 **10-fold**, as shown below (Figure 2):

- ☐ Add 20 μL of the Reference Standard 1 or 2 to 180 μL of Diluent 100. Vortex briefly to mix. Label the vial as CAL-01.

CAL-01 Preparation: Reference Standard 1, Neat:

Use Reference Standard 1 or 2 without dilution (neat) as the highest calibrator solution (CAL-01), as shown below (Figure 3).

- ☐ Vortex Reference Standard 1 or 2 briefly and spin down before opening the tube. Pipette 200 μL of Reference Standard 1 or 2 into a tube and label as CAL-01.

CAL-02 to CAL-08 Preparation:

To prepare 7 calibrator solutions for the IgG, IgM, and IgA assays, plus a zero calibrator for up to 2 replicates, perform the following:

- ☐ Prepare the next calibrator (CAL-02) by adding 50 μL of CAL-01 (IgG, IgM, or IgA) to 150 μL of Diluent 100. Vortex briefly to mix.
- ☐ Repeat 4-fold serial dilutions (50 μL previous calibrator into 150 μL Diluent 100) to generate CAL-03 through CAL-07.
- ☐ Use Diluent 100 as the blank (CAL-08).

Note: Stock calibrator is stable for 5 years from the date of manufacture when stored at ≤ -70 °C. The thawed calibrator is stable through five freeze-thaw cycles. Excess diluted calibrator should be discarded after use.

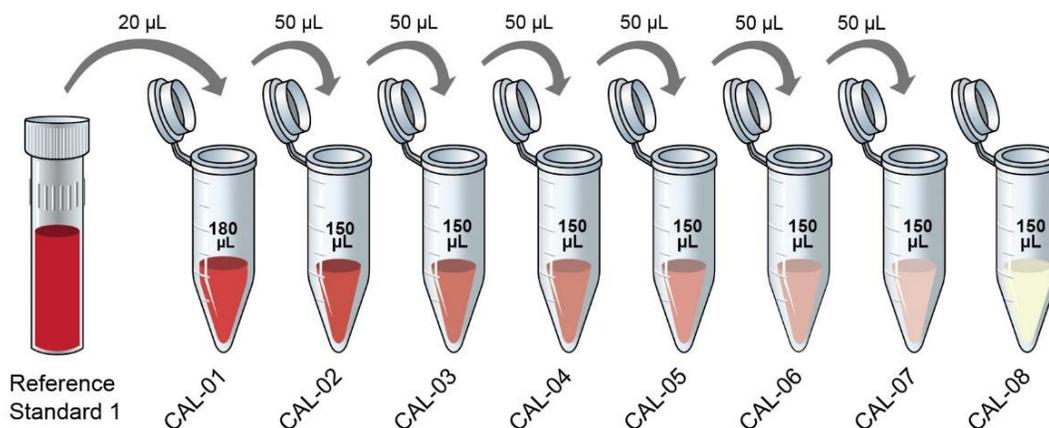


Figure 2. Dilution schema for the preparation of calibrator solutions using a 10-fold dilution of the Reference Standard 1 or 2 to generate CAL-01.

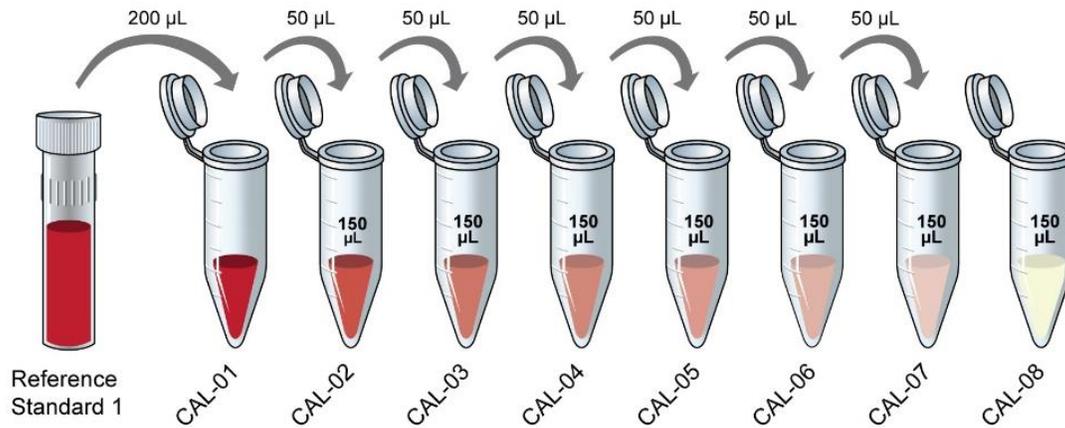


Figure 3. Dilution schema for the preparation of calibrator solutions by using the Reference Standard 1 or 2 as neat (undiluted) to generate CAL-01.

Control Preparation

Serology Control Pack 1 or 2 consists of three levels of controls, each containing assigned concentrations of human IgG, IgM, and IgA against antigens in the V-PLEX COVID-19 Serology Kits. Refer to **Appendix D** for the assigned values in MSD arbitrary units (AU/mL) and **Appendix E** for the assigned values in the WHO international units (BAU/mL).

Each control is supplied at the working concentration. Do not dilute prior to use.

Thaw the control on ice and equilibrate to room temperature. Vortex briefly and spin down before loading controls into the plate.

Note: Stock control is stable for 5 years from the date of manufacture when stored at ≤ -70 °C. Thawed control is stable through five freeze-thaw cycles.

Sample Preparation

Prepare the samples by diluting with Diluent 100. The optimal dilution for serum and plasma samples should be determined empirically by the user. Typically, samples are measured at a dilution between 100-fold and 10,000-fold. The lower dilution keeps negative or low samples in the measurable range; higher dilutions prevent saturation of signal with strongly positive samples. This protocol provides guidance for preparing 100-fold and 5,000-fold dilutions, a common choice in vaccine and epidemiological studies.

Note: Saliva and upper respiratory samples are more variable in their composition than serum and plasma samples. Users should run a pilot dilution series to determine the optimal dilution for their saliva and upper respiratory samples.

This protocol provides guidance for preparing both a 100-fold and 5,000-fold diluted sample.

1. 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
2. To make a 1:100 dilution in a 2 mL tube, or 96-well deep well plate, combine:
 - 15 µL of the 1:10 dilution from Step 1.
 - 135 µL of Diluent 100
3. To make a 1:5,000 dilution in a 2 mL tube, or 96-well deep well plate, combine:

10 μL of the 1:100 dilution from Step 2.
490 μL of Diluent 100

STEP 2: Calibrators, Controls, and Sample Addition

After the Blocker A incubation step, wash the plate 3 times with at least 150 μL /well of 1X MSD Wash buffer.

- Add 50 μL /well of diluted samples, calibrators, and controls to the plate.
- Seal the plate with an adhesive plate seal and incubate at room temperature with shaking (~700 rpm) for 2 hours.

During this time, prepare detection antibody solution.

Detection Antibody Solution Preparation

Detection antibody is provided as a 200X stock solution. The working solution is 1X. You will need 6 mL per plate.

To prepare a 1X solution of detection antibody, combine:

- 5,970 μL of Diluent 100
- 30 μL of 200X SULFO-TAG Anti-Human Ig Antibody or 200X MSD GOLD SULFO-TAG anti-human IgG Antibody

Note: The MSD GOLD SULFO-TAG Anti-Human IgG Antibody (D21APR-3) is supplied with V-PLEX SARS-CoV-2 IgG Serology Assay Kits starting from Panel 38. The antibody is a recombinant monoclonal antibody that binds human immunoglobulin G (IgG), serving as an effective detection reagent in the V-PLEX SARS-CoV-2 IgG Serology Assay Kits. Learn more about the MSD GOLD SULFO-TAG Anti-Human IgG Antibody at www.mesoscale.com.

STEP 3: Detection Antibody Addition

After the sample incubation step, wash the plate 3 times with at least 150 μL /well of 1X MSD Wash buffer.

- Add 50 μL /well of 1X detection antibody solution to the plate.
- Seal the plate with an adhesive plate seal and incubate at room temperature with shaking (~700 rpm) for 1 hour.

STEP 4: Read Buffer Addition

After the detection antibody incubation step, wash the plate 3 times with at least 150 μL /well of 1X MSD Wash buffer.

MSD provides MSD GOLD Read Buffer B ready for use. Do not dilute.

- Add 150 μL /well of the MSD GOLD Read Buffer B to the plate.
- Read the plate on the MSD instrument. No incubation in read buffer is required before reading the plate. Read plate immediately after adding read buffer. Do not shake the plate after adding read buffer.

STEP 5: 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. Best quantification of unknown 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 controls and diluted samples are determined from their ECL signals by backfitting to the calibration curve.

For samples, correcting for dilution provides the final antibody concentrations in undiluted samples (in AU/ml). For example, if 1,000-fold diluted samples are tested, multiply the backfitted concentrations by 1,000.

Controls 1.1, 1.2, 1.3, 2.1, 2.2, and 2.3 are provided pre-diluted for ease of use. Their assigned concentrations reflect the antibody concentrations in the as-provided material. Multiplying the backfitted concentrations of the controls by 5,000 will provide dilution-adjusted concentrations (in AU/mL) that are comparable to concentrations of antibodies in undiluted serum and plasma samples.

Calibration

Reference Standard 1 or 2 is calibrated against the WHO International Standard (NIBSC code: 20/136). To convert MSD assigned concentration units (AU/mL) to WHO/NIBSC units in binding antibody units (BAU/mL), use the equation below:

$$\text{WHO/NIBSC International Standard Units (BAU/mL)} = \text{MSD Units (AU/mL)} \times \text{conversion factor}$$

Table 5. Calibration of MSD Reference Standard 1 or 2 against the WHO International Standard (NIBSC code: 20/136)

Lot Numbers A00V0004 and A0080270 (Reference Standard 1)

Antigens	IgG			IgM			IgA		
	MSD Units AU/mL	WHO Units BAU/mL	Conversion factor*	MSD Units AU/mL	WHO Units BAU/mL	Conversion factor*	MSD Units AU/mL	WHO Units BAU/mL	Conversion factor*
SARS-CoV-2 Nucleocapsid	800	1.89	0.00236	20	2.64	0.132	50	5.57	0.111
SARS-CoV-2 S1 RBD	300	8.16	0.0272	20	0.466	0.0233	20	1.56	0.0782
SARS-CoV-2 Spike	700	6.31	0.00901	40	0.867	0.0217	50	3.09	0.0619

* Conversion factor = WHO/NIBSC Units: MSD Units

Lot Number A0080286 (Reference Standard 1)

Antigens	IgG			IgM			IgA		
	MSD Units AU/mL	WHO Units BAU/mL	Conversion factor*	MSD Units AU/mL	WHO Units BAU/mL	Conversion factor*	MSD Units AU/mL	WHO Units BAU/mL	Conversion factor*
SARS-CoV-2 Nucleocapsid	700	1.65	0.00236	49	6.47	0.132	110	12.2	0.111
SARS-CoV-2 S1 RBD	290	7.89	0.0272	98	2.28	0.0233	60	4.69	0.0782
SARS-CoV-2 Spike	720	6.49	0.00901	130	2.82	0.0217	87	5.39	0.0619

* Conversion factor = WHO/NIBSC Units: MSD Units

Lot Number A0080286 (Reference Standard 2)

Antigens	IgG			IgM			IgA		
	MSD Units AU/mL	WHO Units BAU/mL	Conversion factor*	MSD Units AU/mL	WHO Units BAU/mL	Conversion factor*	MSD Units AU/mL	WHO Units BAU/mL	Conversion factor*
SARS-CoV-2 Nucleocapsid	885	2.09	0.00236	-	-	-	62.0	6.88	0.111
SARS-CoV-2 Spike	1270	11.4	0.00901	-	-	-	227	14.1	0.0619

* Conversion factor = WHO/NIBSC Units: MSD Units

Protocol at a Glance

Note: Bring all plates and diluents to room temperature. Thaw samples, reference standard, and controls on ice. Thawed reference standard and controls should be equilibrated to room temperature before loading into the plates.

- Add Blocker A solution; incubate for at least 30 minutes, wash.
- Add samples, calibrators, and controls. Incubate for 2 hours and wash.
- Add Detection Antibody solution. Incubate for 1 hour and wash.
- Add Read Buffer and analyze plate.

Plate Layout

	1	2	3	4	5	6	7	8	9	10	11	12
A	CAL-01		Control 1.1		Sample-06		Sample-14		Sample-22		Sample-30	
B	CAL-02		Control 1.2		Sample-07		Sample-15		Sample-23		Sample-31	
C	CAL-03		Control 1.3		Sample-08		Sample-16		Sample-24		Sample-32	
D	CAL-04		Sample-01		Sample-09		Sample-17		Sample-25		Sample-33	
E	CAL-05		Sample-02		Sample-10		Sample-18		Sample-26		Sample-34	
F	CAL-06		Sample-03		Sample-11		Sample-19		Sample-27		Sample-35	
G	CAL-07		Sample-04		Sample-12		Sample-20		Sample-28		Sample-36	
H	CAL-08		Sample-05		Sample-13		Sample-21		Sample-29		Sample-37	

Figure 4. Sample plate layout that can be used for the assay. Each sample, control, and calibrator is measured in duplicate in side-by-side wells.

Appendix A: Top of the Curve Assignment

The table below shows the assignments for calibrator 1 (CAL-01) for IgG, IgM, and IgA antibodies to antigens in Reference Standard 1 or 2. The assignments for Reference Standard 1 (lot number A0080286) differ from previous lots and are presented in a separate table below.

Lot Numbers A00V0004 and A0080270 (Reference Standard 1)

Antigens	Alternate Spot Name	Top of the curve assignment for Calibrator 1 (CAL-01)					
		IgG		IgM		IgA	
		MSD AU/mL	WHO BAU/mL	MSD AU/mL	WHO BAU/mL	MSD AU/mL	WHO BAU/mL
SARS-CoV-2 Nucleocapsid	-	80	0.189	20	2.64	50	5.55
SARS-CoV-2 S1 NTD	-	1.0	-	2.0	-	20	-
SARS-CoV-2 S1 RBD	-	30	0.816	20	0.466	20	1.56
SARS-CoV-2 Spike	-	70	0.631	40	0.868	50	3.10
SARS-CoV-2 S1 RBD (B.1.1.7)	N501Y; RBD (Alpha)	20	-	14	-	14	-
SARS-CoV-2 S1 RBD (B.1.214.2)	Q414K, N450K	11	-	-	-	-	-
SARS-CoV-2 S1 RBD (B.1.351; B.1.351.1)	K417N, E484K, N501Y; RBD (Beta)	6.3	-	1.7	-	3.4	-
SARS-CoV-2 S1 RBD (B.1.427; B.1.429; B.1.526.1)	L452R	18	-	13	-	14	-
SARS-CoV-2 S1 RBD (B.1.525; B.1.526; B.1.618; P.2; R.1)	E484K	12	-	2.7	-	7.0	-
SARS-CoV-2 S1 RBD (B.1.526.2)	S477N	25	-	16	-	19	-
SARS-CoV-2 S1 RBD (B.1.617; B.1.617.1; B.1.617.3)	L452R, E484Q	14	-	-	-	-	-
SARS-CoV-2 S1 RBD (P.1)	K417T, E484K, N501Y; RBD (Gamma)	10	-	1.7	-	6.4	-
SARS-CoV-2 S1 RBD (B.1.1.7+E484K; P.3)	E484K, N501Y	6.7	-	-	-	-	-
SARS-CoV-2 Spike (D614G)	-	72	-	44	-	57	-
SARS-CoV-2 Spike (B.1.1.7)	-	47	-	28	-	33	-
SARS-CoV-2 Spike (B.1.351)	-	21	-	7.4	-	23	-
SARS-CoV-2 Spike (B.1.429)	-	45	-	24	-	32	-
SARS-CoV-2 Spike (B.1.526)	-	46	-	25	-	38	-
SARS-CoV-2 Spike (P.1)	-	36	-	12	-	22	-
SARS-CoV-1 Spike	-	5.0	-	2.0	-	10	-
MERS-CoV Spike	-	5.0	-	4.0	-	10	-
HCoV-229E Spike	-	30	-	1.0	-	40	-
HCoV-HKU1 Spike	-	30	-	1.0	-	130	-
HCoV-NL63 Spike	-	5.0	-	0.2	-	10	-
HCoV-OC43 Spike	-	50	-	1.0	-	220	-
Flu A/Hong Kong/2014 H3	-	100	-	1.0	-	20	-
Flu A/Michigan/2015 H1	-	100	-	10	-	30	-
Flu A/Shanghai/2013 H7	-	20	-	1.0	-	1.0	-
Flu B/Brisbane/2008 HA	-	100	-	60	-	120	-
Flu B/Phuket/2013 HA	-	100	-	80	-	70	-
RSV Pre-Fusion F	-	100	-	5.0	-	50	-

- = Not available

Lot Number A0080286 (Reference Standard 1)

Antigens	Alternate Spot Name	Top of the curve assignment for Calibrator 1 (CAL-01)					
		IgG		IgM		IgA	
		MSD AU/mL	WHO BAU/mL	MSD AU/mL	WHO BAU/mL	MSD AU/mL	WHO BAU/mL
SARS-CoV-2 Nucleocapsid	-	70	0.165	49	6.47	110	12.2
SARS-CoV-2 S1 NTD	-	0.9	-	4.6	-	15	-
SARS-CoV-2 S1 RBD	-	29	0.789	98	2.28	60	4.69
SARS-CoV-2 Spike	-	72	0.649	130	2.82	87	5.39
SARS-CoV-2 S1 RBD (A.23.1)	V367F	33	-	110	-	72	-

Antigens	Alternate Spot Name	Top of the curve assignment for Calibrator 1 (CAL-01)					
		IgG		IgM		IgA	
		MSD AU/mL	WHO BAU/mL	MSD AU/mL	WHO BAU/mL	MSD AU/mL	WHO BAU/mL
SARS-CoV-2 S1 RBD (A.VOI.V2)	R346K, T478R, E484K	4.8	-	25	-	12	-
SARS-CoV-2 S1 RBD (AY.1; AY.2)	K417N, L452R, T478K	13	-	100	-	38	-
SARS-CoV-2 S1 RBD (AY.3; AY.4; AY.4.2; AY.5; AY.6; AY.7; AY.12; AY.14; B.1.617.2; B.1.617.2+ΔY144)	L452R, T478K; RBD (Delta)	14	-	100	-	37	-
SARS-CoV-2 S1 RBD (BA.1.1; BA.1.1.15)	RBD (Omicron; BA.1.1)	1.1	-	3.3	-	2.6	-
SARS-CoV-2 S1 RBD (BA.2; BA.2.1; BA.2.2; BA.2.3; BA.2.5; BA.2.6; BA.2.7; BA.2.8; BA.2.10; BA.2.10.1; BA.2.12)	RBD (Omicron; BA.2)	2.6	-	7.2	-	5.0	-
SARS-CoV-2 S1 RBD (BA.2+L452M)	RBD (BA.2+L452M)	2.3	-	6.3	-	4.2	-
SARS-CoV-2 S1 RBD (BA.2+L452R)	RBD (BA.2+L452R)	1.6	-	6.7	-	3.9	-
SARS-CoV-2 S1 RBD (BA.2.12.1)	RBD (BA.2.12.1)	2.2	-	7.7	-	4.5	-
SARS-CoV-2 S1 RBD (BA.2.75)	RBD (BA.2.75)	1.4	-	5.6	-	3.7	-
SARS-CoV-2 S1 RBD (BA.2.75.2)	RBD (BA.2.75.2)	1.2	-	6.6	-	2.5	-
SARS-CoV-2 S1 RBD (BA.3)	RBD (BA.3)	1.4	-	4.0	-	3.0	-
SARS-CoV-2 S1 RBD (BA.4; BA.5)	RBD (BA.4; BA.5)	2.1	-	15	-	4.7	-
SARS-CoV-2 S1 RBD (BA.4.6; BF.7)	RBD (BA.4.6; BF.7)	2.0	-	10	-	4.1	-
SARS-CoV-2 S1 RBD (BQ.1)	RBD (BQ.1)	1.9	-	4.5	-	3.5	-
SARS-CoV-2 S1 RBD (BQ.1.1)	RBD (BQ.1.1)	1.8	-	7.3	-	3.5	-
SARS-CoV-2 S1 RBD (BV.1)	Q493R, N501Y	13	-	60	-	40	-
SARS-CoV-2 S1 RBD (B.1.1.519)	T478K	25	-	69	-	49	-
SARS-CoV-2 S1 RBD (B.1.1.529; BA.1; BA.1.15)	RBD (Omicron); RBD (Omicron; BA.1)	1.7	-	4.1	-	3.3	-
SARS-CoV-2 S1 RBD (B.1.1.7)	N501Y; RBD (Alpha)	18	-	49	-	43	-
SARS-CoV-2 S1 RBD (B.1.1.7+E484K; P.3)	E484K, N501Y	4.2	-	24	-	8.8	-
SARS-CoV-2 S1 RBD (B.1.214.2)	Q414K, N450K	17	-	62	-	26	-
SARS-CoV-2 S1 RBD (B.1.258.17; B.1.466.2)	N439K	10	-	60	-	25	-
SARS-CoV-2 S1 RBD (B.1.351; B.1.351.1)	K417N, E484K, N501Y; RBD (Beta)	4.4	-	18	-	6.2	-
SARS-CoV-2 S1 RBD (B.1.427; B.1.429; B.1.526.1)	L452R	16	-	64	-	33	-
SARS-CoV-2 S1 RBD (B.1.525; B.1.526; B.1.618; P.2; R.1)	E484K	7.3	-	32	-	11	-
SARS-CoV-2 S1 RBD (B.1.526.2)	S477N	27	-	87	-	58	-
SARS-CoV-2 S1 RBD (B.1.617; B.1.617.1; B.1.617.3)	L452R, E484Q	12	-	38	-	22	-
SARS-CoV-2 S1 RBD (B.1.620)	S477N, E484K	4.8	-	35	-	11	-
SARS-CoV-2 S1 RBD (C.37)	L452Q, F490S	9.1	-	25	-	25	-
SARS-CoV-2 S1 RBD (P.1)	K417T, E484K, N501Y; RBD (Gamma)	7.0	-	-	-	11	-
SARS-CoV-2 S1 RBD (XBB.1)	RBD (XBB.1)	1.1	-	5.3	-	2.6	-
SARS-CoV-2 Spike (D614G)	-	83	-	140	-	98	-
SARS-CoV-2 Spike (A.23.1)	-	85	-	150	-	100	-
SARS-CoV-2 Spike (A.VOI.V2)	-	23	-	42	-	41	-
SARS-CoV-2 Spike (AY.1)	-	32	-	86	-	55	-
SARS-CoV-2 Spike (AY.1) Alt Seq 1	-	32	-	98	-	55	-
SARS-CoV-2 Spike (AY.2)	-	36	-	110	-	64	-
SARS-CoV-2 Spike (AY.2) Alt Seq 1	-	30	-	84	-	49	-
SARS-CoV-2 Spike (AY.4.2)	-	37	-	120	-	58	-
SARS-CoV-2 Spike (AY.12)	-	33	-	85	-	51	-
SARS-CoV-2 Spike (BA.1+L452R)	-	6.6	-	15	-	6.8	-
SARS-CoV-2 Spike (BA.1+R346K; BA.1.1; BA.1.1.15)	-	3.9	-	10	-	4.0	-
SARS-CoV-2 Spike (BA.2; BA.2.1; BA.2.2; BA.2.3; BA.2.5; BA.2.6; BA.2.7; BA.2.8; BA.2.10; BA.2.12)	-	12	-	27	-	18	-
SARS-CoV-2 Spike (BA.2+L452M)	-	12	-	25	-	17	-
SARS-CoV-2 Spike (BA.2+L452R)	-	10	-	25	-	14	-
SARS-CoV-2 Spike (BA.2.12.1)	-	11	-	27	-	17	-
SARS-CoV-2 Spike (BA.2.75)	-	5.7	-	8.8	-	11	-
SARS-CoV-2 Spike (BA.2.75.2)	-	5.2	-	7.9	-	11	-
SARS-CoV-2 Spike (BA.2.86)	-	5.1	-	-	-	11	-
SARS-CoV-2 Spike (BA.3)	-	4.3	-	9.5	-	4.5	-
SARS-CoV-2 Spike (BA.4)	-	10	-	29	-	15	-
SARS-CoV-2 Spike (BA.4.6)	-	8.4	-	24	-	13	-
SARS-CoV-2 Spike (BA.5)	-	11	-	34	-	17	-
SARS-CoV-2 Spike (BF.7)	-	8.0	-	20	-	14	-

Antigens	Alternate Spot Name	Top of the curve assignment for Calibrator 1 (CAL-01)					
		IgG		IgM		IgA	
		MSD AU/mL	WHO BAU/mL	MSD AU/mL	WHO BAU/mL	MSD AU/mL	WHO BAU/mL
SARS-CoV-2 Spike (BN.1)	-	4.7	-	6.9	-	-	-
SARS-CoV-2 Spike (BQ.1)	-	8.1	-	18	-	12	-
SARS-CoV-2 Spike (BQ.1.1)	-	7.8	-	17	-	12	-
SARS-CoV-2 Spike (BV-1)	-	33	-	60	-	55	-
SARS-CoV-2 Spike (B.1.1.519)	-	63	-	110	-	76	-
SARS-CoV-2 Spike (B.1.1.529; BA.1; BA.1.15)	-	5.9	-	7.2	-	13	-
SARS-CoV-2 Spike (B.1.1.7)	-	44	-	87	-	62	-
SARS-CoV-2 Spike (B.1.1.7+E484K)	-	31	-	57	-	60	-
SARS-CoV-2 Spike (B.1.258.17)	-	77	-	150	-	100	-
SARS-CoV-2 Spike (B.1.351)	-	25	-	29	-	36	-
SARS-CoV-2 Spike (B.1.351.1)	-	45	-	93	-	62	-
SARS-CoV-2 Spike (B.1.429)	-	32	-	100	-	57	-
SARS-CoV-2 Spike (B.1.466.2)	-	60	-	120	-	85	-
SARS-CoV-2 Spike (B.1.525)	-	30	-	57	-	51	-
SARS-CoV-2 Spike (B.1.526)	-	46	-	76	-	60	-
SARS-CoV-2 Spike (B.1.526.1)	-	32	-	120	-	62	-
SARS-CoV-2 Spike (B.1.617)	-	49	-	72	-	73	-
SARS-CoV-2 Spike (B.1.617.1)	-	30	-	45	-	44	-
SARS-CoV-2 Spike (B.1.617.2)	-	28	-	100	-	50	-
SARS-CoV-2 Spike (B.1.617.2; AY.3; AY.5; AY.6; AY.7; AY.14) Alt Seq 1	-	37	-	120	-	63	-
SARS-CoV-2 Spike (B.1.617.2 +1)	-	25	-	34	-	38	-
SARS-CoV-2 Spike (B.1.617.2 +2)	-	21	-	29	-	33	-
SARS-CoV-2 Spike (B.1.617.2 +3)	-	24	-	40	-	40	-
SARS-CoV-2 Spike (B.1.617.2 +4)	-	21	-	30	-	33	-
SARS-CoV-2 Spike (B.1.617.2; AY.4) Alt Seq 2	-	40	-	140	-	68	-
SARS-CoV-2 Spike (B.1.617.2+ΔY144)	-	30	-	100	-	53	-
SARS-CoV-2 Spike (B.1.617.3)	-	37	-	56	-	52	-
SARS-CoV-2 Spike (B.1.618)	-	36	-	53	-	59	-
SARS-CoV-2 Spike (B.1.620)	-	17	-	31	-	32	-
SARS-CoV-2 Spike (B.1.621)	-	25	-	43	-	39	-
SARS-CoV-2 Spike (B.1.640.2)	-	21	-	61	-	26	-
SARS-CoV-2 Spike (C.37)	-	28	-	57	-	41	-
SARS-CoV-2 Spike (EG.5.1)	-	6.3	-	-	-	12	-
SARS-CoV-2 Spike (FL.1.5.1)	-	6.4	-	-	-	13	-
SARS-CoV-2 Spike (HV.1)	-	7.3	-	-	-	11	-
SARS-CoV-2 Spike (JD.1.1)	-	7.9	-	-	-	12	-
SARS-CoV-2 Spike (JN.1)	-	5.2	-	-	-	9.5	-
SARS-CoV-2 Spike (P.1)	-	29	-	53	-	44	-
SARS-CoV-2 Spike (P.2)	-	41	-	61	-	55	-
SARS-CoV-2 Spike (P.3)	-	13	-	20	-	22	-
SARS-CoV-2 Spike (R.1)	-	33	-	41	-	46	-
SARS-CoV-2 Spike (XBB.1)	-	5.4	-	6.4	-	10	-
SARS-CoV-2 Spike (XBB.1.16)	-	7.5	-	-	-	-	-
SARS-CoV-2 Spike (XBB.1.16.1)	-	6.0	-	-	-	-	-
SARS-CoV-2 Spike (XBB.1.16.6)	-	5.8	-	-	-	-	-
SARS-CoV-2 Spike (XBB.1.5)	-	5.1	-	5.3	-	10	-
SARS-CoV-2 Spike (XBB.2.3)	-	7.3	-	-	-	-	-
SARS-CoV-1 Spike	-	10	-	4.5	-	20	-
MERS-CoV Spike	-	22	-	3.7	-	51	-
HCoV-229E Spike	-	68	-	1.9	-	74	-
HCoV-HKU1 Spike	-	37	-	8.6	-	100	-
HCoV-NL63 Spike	-	8.1	-	-	-	35	-
HCoV-OC43 Spike	-	160	-	3.6	-	260	-
Flu A/Darwin/2021 H3	-	58	-	-	-	-	-
Flu A/Hong Kong/2014 H3	-	180	-	0.69	-	11	-
Flu A/Michigan/2015 H1	-	140	-	8.1	-	16	-
Flu A/Wisconsin/2019 H1	-	95	-	-	-	-	-

Antigens	Alternate Spot Name	Top of the curve assignment for Calibrator 1 (CAL-01)					
		IgG		IgM		IgA	
		MSD AU/mL	WHO BAU/mL	MSD AU/mL	WHO BAU/mL	MSD AU/mL	WHO BAU/mL
Flu B/Austria/2021 HA	-	92	-	-	-	-	-
Flu A/Shanghai/2013 H7	-	12	-	2.1	-	3.6	-
Flu B/Brisbane/2008 HA	-	170	-	28	-	32	-
Flu B/Phuket/2013 HA	-	240	-	42	-	40	-
RSV Pre-Fusion F	-	310	-	8.0	-	43	-

- = Not available

Note: Alternative S-GENE mutations for Spike of AY.1, AY.2, and B.1.617.2 are listed as "Alt Seq #."

Lot Numbers A0080403 (Reference Standard 2)

Antigens	Alternate Spot Name	Top of the curve assignment for Calibrator 1 (CAL-01)			
		IgG		IgA	
		MSD AU/mL	WHO BAU/mL	MSD AU/mL	WHO BAU/mL
SARS-CoV-2 Nucleocapsid	-	88	0.209	227	-
SARS-CoV-2 Spike	-	127	1.14	62	-
SARS-CoV-2 Spike (B.1.1.529; BA.1)	-	29	-	62	-
SARS-CoV-2 Spike (B.1.1.7)	-	89	-	158	-
SARS-CoV-2 Spike (B.1.351)	-	77	-	148	-
SARS-CoV-2 Spike (B.1.617.2; AY.4)	-	90	-	212	-
SARS-CoV-2 Spike (BA.2)	-	46	-	143	-
SARS-CoV-2 Spike (BA.2.12.1)	-	45	-	128	-
SARS-CoV-2 Spike (BA.2.75)	-	27	-	70	-
SARS-CoV-2 Spike (BA.2.86)	-	33	-	67	-
SARS-CoV-2 Spike (BA.5)	-	63	-	165	-
SARS-CoV-2 Spike (EG.5.1)	-	31	-	78	-
SARS-CoV-2 Spike (FL.1.5.1)	-	33	-	77	-
SARS-CoV-2 Spike (HV.1)	-	36	-	73	-
SARS-CoV-2 Spike (JD.1.1)	-	36	-	78	-
SARS-CoV-2 Spike (JN.1)	-	29	-	57	-
SARS-CoV-2 Spike (JN.1 (v2))	-	32	-	58	-
SARS-CoV-2 Spike (KP.2)	-	29	-	55	-
SARS-CoV-2 Spike (KP.3)	-	32	-	52	-
SARS-CoV-2 Spike (LB.1)	-	22	-	47	-
SARS-CoV-2 Spike (XBB.1.16)	-	42	-	73	-
SARS-CoV-2 Spike (XBB.1.16.6)	-	28	-	58	-
SARS-CoV-2 Spike (XBB.1.5)	-	28	-	72	-
SARS-CoV-2 Spike (XBB.2.3)	-	47	-	72	-
SARS-CoV-2 Spike(XBB.1.5 (v2))	-	42	-	67	-
RSV Pre-Fusion F	-	103	-	286	-
Flu A/Wisconsin/67/2022 H1	-	80	-	98	-
Flu A/Ghana/39/2021 H5	-	9.7	-	26	-
Flu A/Massachusetts/18/2022 H3	-	56	-	312	-
Flu B/Austria/2021 HA	-	88	-	313	-

- = Not available

Appendix B: Values for Reference Standard 1 in WHO/NIBSC units (BAU/mL)

The tables below show the WHO/NIBSC units (BAU/mL) for IgG, IgM, and IgA antibodies to antigens in Reference Standard 1 or 2. The WHO/NIBSC assignments for Reference Standard 1 (lot number A0080286) differ from previous lots and are presented in separate tables below.

Lot Numbers A00V0004 and A0080270 (Reference Standard 1)

IgG Concentration (BAU/mL)								
Antigens	CAL 01	CAL 02	CAL 03	CAL 04	CAL 05	CAL 06	CAL 07	CAL 08
SARS-CoV-2 Nucleocapsid	0.189	0.0473	0.0118	0.00295	0.000738	0.000185	0.0000461	0
SARS-CoV-2 S1 RBD	0.816	0.204	0.051	0.0128	0.00319	0.000797	0.000199	0
SARS-CoV-2 Spike	0.631	0.158	0.039	0.00986	0.00246	0.000616	0.000154	0

IgM Concentration (BAU/mL)								
Antigens	CAL 01	CAL 02	CAL 03	CAL 04	CAL 05	CAL 06	CAL 07	CAL 08
SARS-CoV-2 Nucleocapsid	2.64	0.66	0.165	0.0413	0.0103	0.00258	0.000645	0
SARS-CoV-2 S1 RBD	0.466	0.117	0.0291	0.00728	0.001820	0.000455	0.000114	0
SARS-CoV-2 Spike	0.868	0.217	0.0543	0.0136	0.00339	0.000848	0.000212	0

IgA Concentration (BAU/mL)								
Antigens	CAL 01	CAL 02	CAL 03	CAL 04	CAL 05	CAL 06	CAL 07	CAL 08
SARS-CoV-2 Nucleocapsid	5.55	1.39	0.347	0.0867	0.0217	0.00542	0.00135	0
SARS-CoV-2 S1 RBD	1.56	0.39	0.0975	0.0244	0.00609	0.00152	0.000381	0
SARS-CoV-2 Spike	3.10	0.775	0.194	0.0484	0.0121	0.00303	0.000757	0

Lot Number A0080286 (Reference Standard 1)

IgG Concentration (BAU/mL)								
Antigens	CAL 01	CAL 02	CAL 03	CAL 04	CAL 05	CAL 06	CAL 07	CAL 08
SARS-CoV-2 Nucleocapsid	0.165	0.0413	0.0103	0.00258	0.000645	0.000161	0.0000403	0
SARS-CoV-2 S1 RBD	0.789	0.197	0.0493	0.0123	0.00308	0.000770	0.000193	0
SARS-CoV-2 Spike	0.649	0.162	0.0405	0.010	0.00253	0.000634	0.000158	0

IgM Concentration (BAU/mL)								
Antigens	CAL 01	CAL 02	CAL 03	CAL 04	CAL 05	CAL 06	CAL 07	CAL 08
SARS-CoV-2 Nucleocapsid	6.47	1.62	0.404	0.101	0.0253	0.00632	0.00158	0
SARS-CoV-2 S1 RBD	2.28	0.571	0.143	0.0357	0.00892	0.00223	0.000557	0
SARS-CoV-2 Spike	2.82	0.705	0.176	0.0441	0.0110	0.00275	0.000689	0

IgA Concentration (BAU/mL)								
Antigens	CAL 01	CAL 02	CAL 03	CAL 04	CAL 05	CAL 06	CAL 07	CAL 08
SARS-CoV-2 Nucleocapsid	12.2	3.05	0.763	0.191	0.0477	0.0119	0.00298	0
SARS-CoV-2 S1 RBD	4.69	1.17	0.293	0.0733	0.0183	0.00458	0.00115	0
SARS-CoV-2 Spike	5.39	1.35	0.337	0.0841	0.0210	0.00526	0.00131	0

Lot Numbers A0080403 (Reference Standard 2)

IgG Concentration (BAU/mL)								
Antigens	CAL 01	CAL 02	CAL 03	CAL 04	CAL 05	CAL 06	CAL 07	CAL 08
SARS-CoV-2 Nucleocapsid	0.209	0.0522	0.0131	0.00326	0.000816	0.000204	0.0000510	0
SARS-CoV-2 Spike	1.14	0.286	0.0715	0.0179	0.00447	0.00112	0.000279	0

IgA Concentration (BAU/mL)								
Antigens	CAL 01	CAL 02	CAL 03	CAL 04	CAL 05	CAL 06	CAL 07	CAL 08
SARS-CoV-2 Nucleocapsid	6.88	1.72	0.430	0.108	0.0269	0.00672	0.00168	0
SARS-CoV-2 Spike	14.1	3.51	0.878	0.220	0.0549	0.0137	0.00343	0

Appendix C: Values for Serology Controls in MSD Arbitrary units (AU/mL)

The tables below show the assigned values for the concentration of IgG, IgM, and IgA antibodies in Serology Control 1.1, Serology Control 1.2, Serology Control 1.3, Serology Control 2.1, Serology Control 2.2, and Serology Control 2.3. The assignments for Serology Control 1.1 (lot numbers A00C0771 and A00C0825), Serology Control 1.2 (lot numbers A00C0772 and A00C0826), and Serology Control 1.3 (lot numbers A00C0773 and A00C0827) differ from previous lots and are presented in separate tables below.

Lot Numbers A00C0731/A00C0732/A00C0733 (Serology Control 1)

Antigens	Alternate Spot Name	Concentration of IgG (vialcd)			Unit of Measure
		Serology Control 1.1	Serology Control 1.2	Serology Control 1.3	
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; RBD (Alpha)	4.74	1.41	0.405	AU/mL
SARS-CoV-2 S1 RBD (B.1.351; B.1.351.1)	K417N, E484K, N501Y; RBD (Beta)	1.41	0.490	0.174	AU/mL
SARS-CoV-2 S1 RBD (P.1)	K417T, E484K, N501Y; RBD (Gamma)	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
SARS-CoV-1 Spike	-	1.27	0.431	0.385	AU/mL
MERS-CoV Spike	-	1.12	0.129	0.70	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	0.25	0.344	AU/mL
HCoV-OC43 Spike	-	12.8	4.03	10.6	AU/mL
Flu A/Hong Kong/2014 H3	-	23.6	6.31	5.64	AU/mL
Flu A/Michigan/2015 H1	-	22.8	9.22	6.76	AU/mL
Flu A/Shanghai/2013 H7	-	4.36	1.85	0.626	AU/mL
Flu B/Brisbane/2008 HA	-	22.4	8.18	8.92	AU/mL
Flu B/Phuket/2013 HA	-	22.2	9.19	14.0	AU/mL
RSV Pre-Fusion F	-	22.5	10.5	13.9	AU/mL

- = Not available

NA* = not assigned. Control ECL signals are close to the lower end of the calibration curve for concentration assignment

Antigens	Alternate Spot Name	Concentration of IgM (viald)			Unit of Measure
		Serology Control 1.1	Serology Control 1.2	Serology Control 1.3	
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; RBD (Alpha)	0.320	0.134	0.192	AU/mL
SARS-CoV-2 S1 RBD (B.1.351; B.1.351.1)	K417N, E484K, N501Y; RBD (Beta)	0.0494	0.0583	0.0797	AU/mL
SARS-CoV-2 S1 RBD (P.1)	K417T, E484K, N501Y; RBD (Gamma)	NA*	0.423	NA*	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

- = Not available

NA* = not assigned. Control ECL signals are close to the lower end of the calibration curve for concentration assignment

Antigens	Alternate Spot Name	Concentration of IgA (viald)			Unit of Measure
		Serology Control 1.1	Serology Control 1.2	Serology Control 1.3	
SARS-CoV-2 Nucleocapsid	-	1.27	0.213	0.340	AU/mL
SARS-CoV-2 S1 NTD	-	0.501	0.16	0.0344	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; RBD (Alpha)	0.317	0.0934	0.0612	AU/mL
SARS-CoV-2 S1 RBD (B.1.351; B.1.351.1)	K417N, E484K, N501Y; RBD (Beta)	0.0709	0.027	0.0144	AU/mL
SARS-CoV-2 S1 RBD (P.1)	K417T, E484K, N501Y; RBD (Gamma)	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	0.110	AU/mL
SARS-CoV-2 Spike (B.1.351)	-	0.496	0.150	0.0614	AU/mL
SARS-CoV-2 Spike (P.1)	-	0.481	0.117	0.0849	AU/mL
SARS-CoV-1 Spike	-	0.256	0.133	0.138	AU/mL
MERS-CoV Spike	-	0.24	0.13	0.224	AU/mL
HCoV-229E Spike	-	0.977	0.503	0.727	AU/mL
HCoV-HKU1 Spike	-	3.22	1.14	0.29	AU/mL
HCoV-NL63 Spike	-	0.254	0.327	0.565	AU/mL
HCoV-OC43 Spike	-	5.33	2.04	0.968	AU/mL
Flu A/Hong Kong/2014 H3	-	4.81	2.90	2.96	AU/mL
Flu A/Michigan/2015 H1	-	7.26	2.75	1.02	AU/mL
Flu A/Shanghai/2013 H7	-	0.25	0.154	0.226	AU/mL
Flu B/Brisbane/2008 HA	-	29.6	11.4	1.62	AU/mL
Flu B/Phuket/2013 HA	-	16.5	6.75	2.24	AU/mL
RSV Pre-Fusion F	-	11.9	4.10	2.25	AU/mL

- = Not available

Lot Numbers A00C0771/A00C0772/A00C0773 and A00C0825/A00C0826/A00C0827 (Serology Control 1)

Antigens	Alternate Spot Name	Concentration of IgG (vial)			Unit of Measure
		Serology Control 1.1	Serology Control 1.2	Serology Control 1.3	
SARS-CoV-2 Nucleocapsid	-	22.9	7.59	4.54	AU/mL
SARS-CoV-2 S1 NTD	-	0.271	0.144	0.03	AU/mL
SARS-CoV-2 S1 RBD	-	9.54	3.42	0.85	AU/mL
SARS-CoV-2 Spike	-	22.7	9.74	2.19	AU/mL
SARS-CoV-2 S1 RBD (A.23.1)	V367F	9.77	3.73	0.921	AU/mL
SARS-CoV-2 S1 RBD (A.V01.V2)	R346K, T478R, E484K	1.35	0.757	0.201	AU/mL
SARS-CoV-2 S1 RBD (AY.1; AY.2)	K417N, L452R, T478K	3.67	1.85	0.475	AU/mL
SARS-CoV-2 S1 RBD (AY.3; AY.4; AY.4.2; AY.5; AY.6; AY.7; AY.12; AY.14; B.1.617.2; B.1.617.2+ΔY144)	L452R, T478K; RBD (Delta)	3.97	1.74	0.508	AU/mL
SARS-CoV-2 S1 RBD (BA.1.1; BA.1.1.15)	RBD (Omicron; BA.1.1)	0.289	0.138	0.0493	AU/mL
SARS-CoV-2 S1 RBD (BA.2; BA.2.1; BA.2.2; BA.2.3; BA.2.5; BA.2.6; BA.2.7; BA.2.8; BA.2.10; BA.2.10.1; BA.2.12)	RBD (Omicron; BA.2)	0.749	0.325	0.112	AU/mL
SARS-CoV-2 S1 RBD (BA.2+L452M)	RBD (BA.2+L452M)	0.620	0.291	0.0915	AU/mL
SARS-CoV-2 S1 RBD (BA.2+L452R)	RBD (BA.2+L452R)	0.452	0.203	0.0612	AU/mL
SARS-CoV-2 S1 RBD (BA.2.12.1)	RBD (BA.2.12.1)	0.610	0.297	0.0903	AU/mL
SARS-CoV-2 S1 RBD (BA.2.75)	RBD (BA.2.75)	0.403	0.191	0.0589	AU/mL
SARS-CoV-2 S1 RBD (BA.2.75.2)	RBD (BA.2.75.2)	0.293	0.167	0.0472	AU/mL
SARS-CoV-2 S1 RBD (BA.3)	RBD (BA.3)	0.378	0.178	0.0547	AU/mL
SARS-CoV-2 S1 RBD (BA.4; BA.5)	RBD (BA.4; BA.5)	0.586	0.280	0.0837	AU/mL
SARS-CoV-2 S1 RBD (BA.4.6; BF.7)	RBD (BA.4.6; BF.7)	0.560	0.286	0.0835	0.560
SARS-CoV-2 S1 RBD (BQ.1)	RBD (BQ.1)	0.553	0.280	0.0840	0.553
SARS-CoV-2 S1 RBD (BQ.1.1)	RBD (BQ.1.1)	0.546	0.263	0.0796	0.546
SARS-CoV-2 S1 RBD (BV-1)	Q493R, N501Y	3.76	1.48	0.521	AU/mL
SARS-CoV-2 S1 RBD (B.1.1.519)	T478K	7.10	2.66	0.624	AU/mL
SARS-CoV-2 S1 RBD (B.1.1.529; BA.1; BA.1.15)	RBD (Omicron); RBD (Omicron; BA.1)	0.436	0.176	0.0638	AU/mL
SARS-CoV-2 S1 RBD (B.1.1.7)	N501Y; RBD (Alpha)	6.08	2.12	0.755	AU/mL
SARS-CoV-2 S1 RBD (B.1.1.7+E484K; P.3)	E484K, N501Y	1.30	0.510	0.204	AU/mL
SARS-CoV-2 S1 RBD (B.1.214.2)	Q414K, N450K	4.71	2.11	0.505	AU/mL
SARS-CoV-2 S1 RBD (B.1.258.17; B.1.466.2)	N439K	2.67	1.06	0.340	AU/mL
SARS-CoV-2 S1 RBD (B.1.351; B.1.351.1)	K417N, E484K, N501Y; RBD (Beta)	1.35	0.552	0.173	AU/mL
SARS-CoV-2 S1 RBD (B.1.427; B.1.429; B.1.526.1)	L452R	4.77	2.27	0.668	AU/mL
SARS-CoV-2 S1 RBD (B.1.525; B.1.526; B.1.618; P.2; R.1)	E484K	2.09	0.925	0.298	AU/mL
SARS-CoV-2 S1 RBD (B.1.526.2)	S477N	9.04	3.48	0.85	AU/mL
SARS-CoV-2 S1 RBD (B.1.617; B.1.617.1; B.1.617.3)	L452R, E484Q	3.24	1.69	0.580	AU/mL
SARS-CoV-2 S1 RBD (B.1.620)	S477N, E484K	1.37	0.571	0.205	AU/mL
SARS-CoV-2 S1 RBD (C.37)	L452Q, F490S	2.81	1.17	0.419	AU/mL
SARS-CoV-2 S1 RBD (P.1)	K417T, E484K, N501Y; RBD (Gamma)	2.27	0.90	0.315	AU/mL
SARS-CoV-2 S1 RBD (XBB.1)	RBD (XBB.1)	0.329	0.158	0.0454	AU/mL
SARS-CoV-2 Spike (D614G)	-	24.4	9.51	2.45	AU/mL
SARS-CoV-2 Spike (A.23.1)	-	24.8	12.4	2.33	AU/mL
SARS-CoV-2 Spike (AY.1)	-	9.55	4.12	1.06	AU/mL
SARS-CoV-2 Spike (AY.1) Alt Seq 1	-	8.54	3.62	0.995	AU/mL
SARS-CoV-2 Spike (AY.2)	-	11.1	4.10	1.11	AU/mL
SARS-CoV-2 Spike (AY.2) Alt Seq 1	-	8.90	3.62	0.945	AU/mL
SARS-CoV-2 Spike (AY.4.2)	-	9.85	3.48	0.940	AU/mL
SARS-CoV-2 Spike (AY.12)	-	9.44	3.97	0.997	AU/mL
SARS-CoV-2 Spike (A.V01.V2)	-	6.51	3.07	0.796	AU/mL
SARS-CoV-2 Spike (BA.1+L452R)	-	1.95	1.02	0.26	AU/mL
SARS-CoV-2 Spike (BA.1+R346K; BA.1.1; BA.1.1.15)	-	1.07	0.504	0.155	AU/mL
SARS-CoV-2 Spike (BA.2; BA.2.1; BA.2.2; BA.2.3; BA.2.5; BA.2.6; BA.2.7; BA.2.8; BA.2.10; BA.2.12)	-	3.43	1.11	0.367	AU/mL
SARS-CoV-2 Spike (BA.2+L452M)	-	3.55	1.24	0.400	AU/mL
SARS-CoV-2 Spike (BA.2+L452R)	-	2.93	1.04	0.319	AU/mL
SARS-CoV-2 Spike (BA.2.12.1)	-	3.24	1.13	0.353	AU/mL
SARS-CoV-2 Spike (BA.2.75)	-	1.68	0.764	0.197	AU/mL

Antigens	Alternate Spot Name	Concentration of IgG (viald)			Unit of Measure
		Serology Control 1.1	Serology Control 1.2	Serology Control 1.3	
SARS-CoV-2 Spike (BA.2.75.2)	-	1.54	0.782	0.189	AU/mL
SARS-CoV-2 Spike (BA.2.86)	-	1.37	0.693	0.19	AU/mL
SARS-CoV-2 Spike (BA.3)	-	1.21	0.547	0.162	AU/mL
SARS-CoV-2 Spike (BA.4)	-	2.76	1.19	0.309	AU/mL
SARS-CoV-2 Spike (BA.4.6)	-	2.39	1.06	0.251	AU/mL
SARS-CoV-2 Spike (BA.5)	-	3.15	1.35	0.354	AU/mL
SARS-CoV-2 Spike (BF.7)	-	2.27	0.975	0.240	AU/mL
SARS-CoV-2 Spike (BN.1)	-	1.37	0.801	0.200	AU/mL
SARS-CoV-2 Spike (BQ.1)	-	2.41	1.01	0.252	AU/mL
SARS-CoV-2 Spike (BQ.1.1)	-	2.26	0.995	0.243	AU/mL
SARS-CoV-2 Spike (BV.1)	-	9.23	3.78	1.08	AU/mL
SARS-CoV-2 Spike (B.1.1.519)	-	17.4	6.56	1.59	AU/mL
SARS-CoV-2 Spike (B.1.1.529; BA.1; BA.1.15)	-	1.700	0.791	0.214	AU/mL
SARS-CoV-2 Spike (B.1.1.7)	-	13.9	5.50	1.62	AU/mL
SARS-CoV-2 Spike (B.1.1.7+E484K)	-	8.93	4.01	1.13	AU/mL
SARS-CoV-2 Spike (B.1.258.17)	-	23.5	10.2	2.32	AU/mL
SARS-CoV-2 Spike (B.1.351)	-	7.12	3.31	0.798	AU/mL
SARS-CoV-2 Spike (B.1.351.1)	-	13.4	7.97	1.37	AU/mL
SARS-CoV-2 Spike (B.1.429)	-	9.31	3.93	1.14	AU/mL
SARS-CoV-2 Spike (B.1.466.2)	-	18.3	7.89	1.79	AU/mL
SARS-CoV-2 Spike (B.1.525)	-	8.04	3.66	1.01	AU/mL
SARS-CoV-2 Spike (B.1.526)	-	13.7	5.84	1.34	AU/mL
SARS-CoV-2 Spike (B.1.526.1)	-	9.31	4.71	1.12	AU/mL
SARS-CoV-2 Spike (B.1.617)	-	14.4	6.17	1.54	AU/mL
SARS-CoV-2 Spike (B.1.617.1)	-	8.96	4.12	0.975	AU/mL
SARS-CoV-2 Spike (B.1.617.2)	-	8.02	2.83	0.815	AU/mL
SARS-CoV-2 Spike (B.1.617.2; AY.3; AY.5; AY.6; AY.7; AY.14) Alt Seq 1	-	9.93	3.69	1.01	AU/mL
SARS-CoV-2 Spike (B.1.617.2 +1)	-	6.87	2.96	0.778	AU/mL
SARS-CoV-2 Spike (B.1.617.2 +2)	-	5.73	2.52	0.621	AU/mL
SARS-CoV-2 Spike (B.1.617.2 +3)	-	6.67	3.01	0.731	AU/mL
SARS-CoV-2 Spike (B.1.617.2 +4)	-	6.01	2.45	0.598	AU/mL
SARS-CoV-2 Spike (B.1.617.2; AY.4) Alt Seq 2	-	11.0	3.96	1.15	AU/mL
SARS-CoV-2 Spike (B.1.617.2+ΔY144)	-	8.80	3.41	0.983	AU/mL
SARS-CoV-2 Spike (B.1.617.3)	-	10.4	4.44	0.990	AU/mL
SARS-CoV-2 Spike (B.1.618)	-	10.8	4.23	1.11	AU/mL
SARS-CoV-2 Spike (B.1.620)	-	5.03	2.14	0.649	AU/mL
SARS-CoV-2 Spike (B.1.621)	-	7.02	3.59	0.764	AU/mL
SARS-CoV-2 Spike (B.1.640.2)	-	6.07	2.93	0.923	AU/mL
SARS-CoV-2 Spike (C.37)	-	7.68	3.78	0.982	AU/mL
SARS-CoV-2 Spike (EG.5.1)	-	1.75	0.968	0.214	AU/mL
SARS-CoV-2 Spike (FL.1.5.1)	-	1.82	1.04	0.226	AU/mL
SARS-CoV-2 Spike (HV.1)	-	2.16	1.18	0.274	AU/mL
SARS-CoV-2 Spike (JD.1.1)	-	2.40	1.08	0.265	AU/mL
SARS-CoV-2 Spike (JN.1)	-	1.55	0.631	0.187	AU/mL
SARS-CoV-2 Spike (P.1)	-	8.49	5.10	0.947	AU/mL
SARS-CoV-2 Spike (P.2)	-	12.1	5.29	1.36	AU/mL
SARS-CoV-2 Spike (P.3)	-	3.57	1.54	0.424	AU/mL
SARS-CoV-2 Spike (R.1)	-	9.15	3.96	0.977	AU/mL
SARS-CoV-2 Spike (XBB.1)	-	1.52	0.887	0.193	AU/mL
SARS-CoV-2 Spike (XBB.1.16)	-	2.27	1.06	0.271	AU/mL
SARS-CoV-2 Spike (XBB.1.16.1)	-	1.80	0.879	0.220	AU/mL
SARS-CoV-2 Spike (XBB.1.16.6)	-	1.62	0.832	0.19	AU/mL
SARS-CoV-2 Spike (XBB.1.5)	-	1.52	0.866	0.205	AU/mL
SARS-CoV-2 Spike (XBB.2.3)	-	2.21	0.780	0.264	AU/mL
SARS-CoV-1 Spike	-	3.20	0.628	0.285	AU/mL
MERS-CoV Spike	-	>ULOQ	0.231	0.260	AU/mL
HCoV-229E Spike	-	21.7	4.86	1.16	AU/mL
HCoV-HKU1 Spike	-	11.3	3.01	0.963	AU/mL

Antigens	Alternate Spot Name	Concentration of IgG (viald)			Unit of Measure
		Serology Control 1.1	Serology Control 1.2	Serology Control 1.3	
HCoV-NL63 Spike	-	2.60	0.641	0.185	AU/mL
HCoV-OC43 Spike	-	>ULOQ	6.98	3.82	AU/mL
Flu A/Darwin/2021 H3	-	17.4	4.49	0.962	AU/mL
Flu A/Hong Kong/2014 H3	-	59.8	14.3	3.06	AU/mL
Flu A/Michigan/2015 H1	-	43.9	6.06	2.80	AU/mL
Flu A/Wisconsin/2019 H1	-	29.3	5.78	2.07	AU/mL
Flu B/Austria/2021 HA	-	28.6	10.6	1.32	AU/mL
Flu A/Shanghai/2013 H7	-	3.88	1.00	0.398	AU/mL
Flu B/Brisbane/2008 HA	-	53.0	9.47	2.27	AU/mL
Flu B/Phuket/2013 HA	-	71.9	10.6	3.03	AU/mL
RSV Pre-Fusion F	-	91.2	15.7	6.76	AU/mL

>ULOQ = above the upper limit of quantification; <LLOQ = below the lower limit of quantification (see appendix F)

- = Not available

Note: Alternative S-GENE mutations for Spike of AY.1, AY.2, and B.1.617.2 are listed as "Alt Seq #."

Antigens	Alternate Spot Name	Concentration of IgM (viald)			Unit of Measure
		Serology Control 1.1	Serology Control 1.2	Serology Control 1.3	
SARS-CoV-2 Nucleocapsid	-	1.34	0.322	0.472	AU/mL
SARS-CoV-2 S1 NTD	-	0.152	0.077	0.026	AU/mL
SARS-CoV-2 S1 RBD	-	3.13	0.691	0.457	AU/mL
SARS-CoV-2 Spike	-	3.70	1.21	0.614	AU/mL
SARS-CoV-2 S1 RBD (A.23.1)	V367F	3.18	0.755	0.542	AU/mL
SARS-CoV-2 S1 RBD (A.V01.V2)	R346K, T478R, E484K	1.52	0.057	0.674	AU/mL
SARS-CoV-2 S1 RBD (AY.1; AY.2)	K417N, L452R, T478K	2.80	0.723	0.208	AU/mL
SARS-CoV-2 S1 RBD (AY.3; AY.4; AY.4.2; AY.5; AY.6; AY.7; AY.12; AY.14; B.1.617.2; B.1.617.2+ΔY144)	L452R, T478K; RBD (Delta)	2.79	0.634	0.215	AU/mL
SARS-CoV-2 S1 RBD (BA.1.1; BA.1.1.15)	RBD (Omicron; BA.1.1)	0.0888	0.0218	0.0154	AU/mL
SARS-CoV-2 S1 RBD (BA.2; BA.2.1; BA.2.2; BA.2.3; BA.2.5; BA.2.6; BA.2.7; BA.2.8; BA.2.10; BA.2.10.1; BA.2.12)	RBD (Omicron; BA.2)	0.195	0.0327	0.0382	AU/mL
SARS-CoV-2 S1 RBD (BA.2+L452M)	RBD (BA.2+L452M)	0.173	<LLOQ	<LLOQ	AU/mL
SARS-CoV-2 S1 RBD (BA.2+L452R)	RBD (BA.2+L452R)	0.189	0.0300	<LLOQ	AU/mL
SARS-CoV-2 S1 RBD (BA.2.12.1)	RBD (BA.2.12.1)	0.210	<LLOQ	<LLOQ	AU/mL
SARS-CoV-2 S1 RBD (BA.2.75)	RBD (BA.2.75)	0.146	0.0321	0.0299	AU/mL
SARS-CoV-2 S1 RBD (BA.2.75.2)	RBD (BA.2.75.2)	0.158	0.0273	0.0245	AU/mL
SARS-CoV-2 S1 RBD (BA.3)	RBD (BA.3)	0.103	<LLOQ	<LLOQ	AU/mL
SARS-CoV-2 S1 RBD (BA.4; BA.5)	RBD (BA.4; BA.5)	<LLOQ	<LLOQ	<LLOQ	AU/mL
SARS-CoV-2 S1 RBD (BA.4.6; BF.7)	RBD (BA.4.6; BF.7)	0.236	0.0521	0.0340	AU/mL
SARS-CoV-2 S1 RBD (BQ.1)	RBD (BQ.1)	0.114	0.0418	0.0227	AU/mL
SARS-CoV-2 S1 RBD (BQ.1.1)	RBD (BQ.1.1)	0.186	<LLOQ	<LLOQ	AU/mL
SARS-CoV-2 S1 RBD (BV-1)	Q493R, N501Y	2.49	0.552	0.335	AU/mL
SARS-CoV-2 S1 RBD (B.1.1.519)	T478K	1.99	0.462	0.347	AU/mL
SARS-CoV-2 S1 RBD (B.1.1.529; BA.1; BA.1.15)	RBD (Omicron); RBD (Omicron; BA.1)	0.109	0.0233	0.0238	AU/mL
SARS-CoV-2 S1 RBD (B.1.1.7)	N501Y; RBD (Alpha)	1.49	0.378	0.252	AU/mL
SARS-CoV-2 S1 RBD (B.1.1.7+E484K; P.3)	E484K, N501Y	0.957	0.127	0.256	AU/mL
SARS-CoV-2 S1 RBD (B.1.214.2)	Q414K, N450K	1.92	0.497	0.236	AU/mL
SARS-CoV-2 S1 RBD (B.1.258.17; B.1.466.2)	N439K	1.56	0.387	0.291	AU/mL
SARS-CoV-2 S1 RBD (B.1.351; B.1.351.1)	K417N, E484K, N501Y; RBD (Beta)	<LLOQ	<LLOQ	<LLOQ	AU/mL
SARS-CoV-2 S1 RBD (B.1.427; B.1.429; B.1.526.1)	L452R	1.80	0.441	0.172	AU/mL
SARS-CoV-2 S1 RBD (B.1.525; B.1.526; B.1.618; P.2; R.1)	E484K	0.526	0.105	0.0947	AU/mL
SARS-CoV-2 S1 RBD (B.1.526.2)	S477N	1.56	0.397	0.273	AU/mL
SARS-CoV-2 S1 RBD (B.1.617; B.1.617.1; B.1.617.3)	L452R, E484Q	1.10	0.211	0.578	AU/mL
SARS-CoV-2 S1 RBD (B.1.620)	S477N, E484K	1.37	0.559	0.438	AU/mL
SARS-CoV-2 S1 RBD (C.37)	L452Q, F490S	1.86	0.323	0.187	AU/mL
SARS-CoV-2 S1 RBD (P.1)	K417T, E484K, N501Y; RBD (Gamma)	<LLOQ	<LLOQ	<LLOQ	AU/mL
SARS-CoV-2 S1 RBD (XBB.1)	RBD (XBB.1)	<LLOQ	<LLOQ	<LLOQ	AU/mL
SARS-CoV-2 Spike (D614G)	-	4.12	1.41	0.642	AU/mL
SARS-CoV-2 Spike (A.23.1)	-	4.32	1.99	0.764	AU/mL

Antigens	Alternate Spot Name	Concentration of IgM (vial)			Unit of Measure
		Serology Control 1.1	Serology Control 1.2	Serology Control 1.3	
SARS-CoV-2 Spike (A.V01.V2)	-	1.22	0.249	0.261	AU/mL
SARS-CoV-2 Spike (AY.1)	-	2.50	0.679	0.222	AU/mL
SARS-CoV-2 Spike (AY.1) Alt Seq 1	-	2.38	0.813	0.225	AU/mL
SARS-CoV-2 Spike (AY.2)	-	3.22	0.843	0.270	AU/mL
SARS-CoV-2 Spike (AY.2) Alt Seq 1	-	2.28	0.683	0.198	AU/mL
SARS-CoV-2 Spike (AY.4.2)	-	3.52	0.907	0.281	AU/mL
SARS-CoV-2 Spike (AY.12)	-	2.18	0.696	0.189	AU/mL
SARS-CoV-2 Spike (BA.1+L452R)	-	0.442	0.0962	<LLOQ	AU/mL
SARS-CoV-2 Spike (BA.1+R346K; BA.1.1; BA.1.1.15)	-	0.271	<LLOQ	<LLOQ	AU/mL
SARS-CoV-2 Spike (BA.2; BA.2.1; BA.2.2; BA.2.3; BA.2.5; BA.2.6; BA.2.7; BA.2.8; BA.2.10; BA.2.12)	-	0.819	0.114	0.0712	AU/mL
SARS-CoV-2 Spike (BA.2+L452M)	-	0.673	0.128	0.0642	AU/mL
SARS-CoV-2 Spike (BA.2+L452R)	-	0.692	0.132	0.0636	AU/mL
SARS-CoV-2 Spike (BA.2.12.1)	-	0.751	0.141	0.0696	AU/mL
SARS-CoV-2 Spike (BA.2.75)	-	0.234	0.0801	<LLOQ	AU/mL
SARS-CoV-2 Spike (BA.2.75.2)	-	0.217	0.0793	0.0248	AU/mL
SARS-CoV-2 Spike (BA.3)	-	0.266	0.0518	<LLOQ	AU/mL
SARS-CoV-2 Spike (BA.4)	-	0.760	0.142	0.0672	AU/mL
SARS-CoV-2 Spike (BA.4.6)	-	0.642	0.109	0.0574	AU/mL
SARS-CoV-2 Spike (BA.5)	-	0.874	0.164	0.0816	AU/mL
SARS-CoV-2 Spike (BF.7)	-	0.571	0.0869	0.0445	AU/mL
SARS-CoV-2 Spike (BN.1)	-	0.200	0.0993	<LLOQ	AU/mL
SARS-CoV-2 Spike (BQ.1)	-	0.500	0.0998	0.0394	AU/mL
SARS-CoV-2 Spike (BQ.1.1)	-	0.468	0.0973	0.0387	AU/mL
SARS-CoV-2 Spike (BV-1)	-	1.68	0.570	0.239	AU/mL
SARS-CoV-2 Spike (B.1.1.519)	-	3.07	1.00	0.454	AU/mL
SARS-CoV-2 Spike (B.1.1.529; BA.1; BA.1.15)	-	0.209	0.0404	0.0209	AU/mL
SARS-CoV-2 Spike (B.1.1.7)	-	2.64	0.78	0.387	AU/mL
SARS-CoV-2 Spike (B.1.1.7+E484K)	-	1.63	0.572	0.318	AU/mL
SARS-CoV-2 Spike (B.1.258.17)	-	4.48	1.91	0.684	AU/mL
SARS-CoV-2 Spike (B.1.351)	-	0.88	0.437	0.093	AU/mL
SARS-CoV-2 Spike (B.1.351.1)	-	0.88	0.437	0.093	AU/mL
SARS-CoV-2 Spike (B.1.429)	-	3.19	0.641	0.246	AU/mL
SARS-CoV-2 Spike (B.1.466.2)	-	3.66	1.37	0.500	AU/mL
SARS-CoV-2 Spike (B.1.525)	-	1.52	0.540	0.262	AU/mL
SARS-CoV-2 Spike (B.1.526)	-	2.01	1.01	0.341	AU/mL
SARS-CoV-2 Spike (B.1.526.1)	-	3.28	0.796	0.384	AU/mL
SARS-CoV-2 Spike (B.1.617)	-	1.92	0.955	0.314	AU/mL
SARS-CoV-2 Spike (B.1.617.1)	-	1.25	0.548	0.159	AU/mL
SARS-CoV-2 Spike (B.1.617.2)	-	2.74	0.518	0.165	AU/mL
SARS-CoV-2 Spike (B.1.617.2; AY.3; AY.5; AY.6; AY.7; AY.14) Alt Seq 1	-	3.23	0.819	0.239	AU/mL
SARS-CoV-2 Spike (B.1.617.2 +1)	-	0.912	0.443	0.0881	AU/mL
SARS-CoV-2 Spike (B.1.617.2 +2)	-	0.763	0.414	0.0724	AU/mL
SARS-CoV-2 Spike (B.1.617.2 +3)	-	0.950	0.494	0.0916	AU/mL
SARS-CoV-2 Spike (B.1.617.2 +4)	-	0.786	0.409	0.0850	AU/mL
SARS-CoV-2 Spike (B.1.617.2; AY.4) Alt Seq 2	-	3.73	1.02	0.276	AU/mL
SARS-CoV-2 Spike (B.1.617.2+ΔY144)	-	2.77	0.644	0.243	AU/mL
SARS-CoV-2 Spike (B.1.617.3)	-	1.48	0.634	0.140	AU/mL
SARS-CoV-2 Spike (B.1.618)	-	1.56	0.596	0.187	AU/mL
SARS-CoV-2 Spike (B.1.620)	-	0.878	0.157	0.101	AU/mL
SARS-CoV-2 Spike (B.1.621)	-	1.13	0.569	0.254	AU/mL
SARS-CoV-2 Spike (B.1.640.2)	-	1.72	0.228	0.185	AU/mL
SARS-CoV-2 Spike (C.37)	-	1.59	0.482	0.155	AU/mL
SARS-CoV-2 Spike (P.1)	-	1.56	0.799	0.214	AU/mL
SARS-CoV-2 Spike (P.2)	-	1.98	0.819	0.273	AU/mL
SARS-CoV-2 Spike (P.3)	-	0.553	0.144	0.0442	AU/mL
SARS-CoV-2 Spike (R.1)	-	1.16	0.603	0.236	AU/mL
SARS-CoV-2 Spike (XBB.1)	-	0.181	0.0341	0.0290	AU/mL

Antigens	Alternate Spot Name	Concentration of IgM (viald)			Unit of Measure
		Serology Control 1.1	Serology Control 1.2	Serology Control 1.3	
SARS-CoV-2 Spike (XBB.1.5)	-	0.157	<LLOQ	<LLOQ	AU/mL
SARS-CoV-1 Spike	-	0.138	<LLOQ	<LLOQ	AU/mL
MERS-CoV Spike	-	0.10	<LLOQ	<LLOQ	AU/mL
HCoV-229E Spike	-	<LLOQ	<LLOQ	<LLOQ	AU/mL
HCoV-HKU1 Spike	-	0.21	<LLOQ	<LLOQ	AU/mL
HCoV-NL63 Spike	-	<LLOQ	<LLOQ	<LLOQ	AU/mL
HCoV-OC43 Spike	-	0.108	0.041	<LLOQ	AU/mL
Flu A/Hong Kong/2014 H3	-	<LLOQ	<LLOQ	<LLOQ	AU/mL
Flu A/Michigan/2015 H1	-	0.292	0.08	<LLOQ	AU/mL
Flu A/Shanghai/2013 H7	-	<LLOQ	<LLOQ	<LLOQ	AU/mL
Flu B/Brisbane/2008 HA	-	1.07	0.52	0.087	AU/mL
Flu B/Phuket/2013 HA	-	1.50	0.685	0.132	AU/mL
RSV Pre-Fusion F	-	0.308	<LLOQ	<LLOQ	AU/mL

>ULOQ = above the upper limit of quantification; <LLOQ = below the lower limit of quantification (see appendix F)

- = Not available

Note: Alternative S-GENE mutations for Spike of AY.1, AY.2, and B.1.617.2 are listed as "Alt Seq #."

Antigens	Alternate Spot Name	Concentration of IgA (viald)			Unit of Measure
		Serology Control 1.1	Serology Control 1.2	Serology Control 1.3	
SARS-CoV-2 Nucleocapsid	-	3.44	0.185	0.875	AU/mL
SARS-CoV-2 S1 NTD	-	0.52	0.186	0.072	AU/mL
SARS-CoV-2 S1 RBD	-	1.85	0.285	0.975	AU/mL
SARS-CoV-2 Spike	-	2.68	0.609	0.877	AU/mL
SARS-CoV-2 S1 RBD (A.23.1)	V367F	2.08	0.283	0.783	AU/mL
SARS-CoV-2 S1 RBD (A.V01.V2)	R346K, T478R, E484K	0.336	0.0811	0.0633	AU/mL
SARS-CoV-2 S1 RBD (AY.1; AY.2)	K417N, L452R, T478K	1.14	0.254	0.220	AU/mL
SARS-CoV-2 S1 RBD (AY.3; AY.4; AY.4.2; AY.5; AY.6; AY.7; AY.12; AY.14; B.1.617.2; B.1.617.2+ΔY144)	L452R, T478K; RBD (Delta)	1.07	0.215	0.223	AU/mL
SARS-CoV-2 S1 RBD (BA.1.1; BA.1.1.15)	RBD (Omicron; BA.1.1)	0.0896	0.0250	0.0506	AU/mL
SARS-CoV-2 S1 RBD (BA.2; BA.2.1; BA.2.2; BA.2.3; BA.2.5; BA.2.6; BA.2.7; BA.2.8; BA.2.10; BA.2.10.1; BA.2.12)	RBD (Omicron; BA.2)	0.165	0.0455	0.0976	AU/mL
SARS-CoV-2 S1 RBD (BA.2+L452M)	RBD (BA.2+L452M)	0.138	<LLOQ	<LLOQ	AU/mL
SARS-CoV-2 S1 RBD (BA.2+L452R)	RBD (BA.2+L452R)	0.149	<LLOQ	<LLOQ	AU/mL
SARS-CoV-2 S1 RBD (BA.2.12.1)	RBD (BA.2.12.1)	0.160	<LLOQ	<LLOQ	AU/mL
SARS-CoV-2 S1 RBD (BA.2.75)	RBD (BA.2.75)	0.108	<LLOQ	0.0478	AU/mL
SARS-CoV-2 S1 RBD (BA.2.75.2)	RBD (BA.2.75.2)	0.0900	<LLOQ	0.122	AU/mL
SARS-CoV-2 S1 RBD (BA.3)	RBD (BA.3)	0.112	<LLOQ	0.0858	AU/mL
SARS-CoV-2 S1 RBD (BA.4; BA.5)	RBD (BA.4; BA.5)	0.169	0.0433	<LLOQ	AU/mL
SARS-CoV-2 S1 RBD (BA.4.6; BF.7)	RBD (BA.4.6; BF.7)	0.153	0.0434	0.0670	AU/mL
SARS-CoV-2 S1 RBD (BQ.1)	RBD (BQ.1)	0.147	0.0476	0.0259	AU/mL
SARS-CoV-2 S1 RBD (BQ.1.1)	RBD (BQ.1.1)	0.155	0.0490	0.0775	AU/mL
SARS-CoV-2 S1 RBD (BV-1)	Q493R, N501Y	1.16	0.167	0.65	AU/mL
SARS-CoV-2 S1 RBD (B.1.1.519)	T478K	1.36	0.222	0.572	AU/mL
SARS-CoV-2 S1 RBD (B.1.1.529; BA.1; BA.1.15)	RBD (Omicron); RBD (Omicron; BA.1)	0.0966	0.0261	0.0969	AU/mL
SARS-CoV-2 S1 RBD (B.1.1.7)	N501Y; RBD (Alpha)	1.44	0.228	0.635	AU/mL
SARS-CoV-2 S1 RBD (B.1.1.7+E484K; P.3)	E484K, N501Y	0.492	0.0662	0.106	AU/mL
SARS-CoV-2 S1 RBD (B.1.214.2)	Q414K, N450K	1.24	0.176	0.551	AU/mL
SARS-CoV-2 S1 RBD (B.1.258.17; B.1.466.2)	N439K	0.741	0.133	0.507	AU/mL
SARS-CoV-2 S1 RBD (B.1.351; B.1.351.1)	K417N, E484K, N501Y; RBD (Beta)	0.201	0.04	0.043	AU/mL
SARS-CoV-2 S1 RBD (B.1.427; B.1.429; B.1.526.1)	L452R	1.03	0.216	0.194	AU/mL
SARS-CoV-2 S1 RBD (B.1.525; B.1.526; B.1.618; P.2; R.1)	E484K	0.316	0.0591	0.0733	AU/mL
SARS-CoV-2 S1 RBD (B.1.526.2)	S477N	1.68	0.259	0.653	AU/mL
SARS-CoV-2 S1 RBD (B.1.617; B.1.617.1; B.1.617.3)	L452R, E484Q	1.03	0.185	0.189	AU/mL
SARS-CoV-2 S1 RBD (B.1.620)	S477N, E484K	0.388	0.0624	0.0891	AU/mL
SARS-CoV-2 S1 RBD (C.37)	L452Q, F490S	0.784	0.148	0.0942	AU/mL
SARS-CoV-2 S1 RBD (P.1)	K417T, E484K, N501Y; RBD (Gamma)	0.386	0.08	0.086	AU/mL
SARS-CoV-2 S1 RBD (XBB.1)	RBD (XBB.1)	0.121	<LLOQ	<LLOQ	AU/mL

Antigens	Alternate Spot Name	Concentration of IgA (viald)			Unit of Measure
		Serology Control 1.1	Serology Control 1.2	Serology Control 1.3	
SARS-CoV-2 Spike (D614G)	-	2.99	1.04	0.815	AU/mL
SARS-CoV-2 Spike (A.23.1)	-	2.93	0.940	0.889	AU/mL
SARS-CoV-2 Spike (A.V01.V2)	-	1.31	0.496	0.222	AU/mL
SARS-CoV-2 Spike (AY.1)	-	1.69	0.611	0.290	AU/mL
SARS-CoV-2 Spike (AY.1) Alt Seq 1	-	1.46	0.609	0.285	AU/mL
SARS-CoV-2 Spike (AY.2)	-	2.00	0.859	0.367	AU/mL
SARS-CoV-2 Spike (AY.2) Alt Seq 1	-	1.46	0.620	0.265	AU/mL
SARS-CoV-2 Spike (AY.4.2)	-	1.72	0.726	0.311	AU/mL
SARS-CoV-2 Spike (AY.12)	-	1.45	0.649	0.272	AU/mL
SARS-CoV-2 Spike (BA.1+L452R)	-	0.224	0.0319	<LLOQ	AU/mL
SARS-CoV-2 Spike (BA.1+R346K; BA.1.1; BA.1.1.15)	-	0.129	<LLOQ	<LLOQ	AU/mL
SARS-CoV-2 Spike (BA.2; BA.2.1; BA.2.2; BA.2.3; BA.2.5; BA.2.6; BA.2.7; BA.2.8; BA.2.10; BA.2.12)	-	0.557	0.157	0.103	AU/mL
SARS-CoV-2 Spike (BA.2+L452M)	-	0.517	0.205	0.100	AU/mL
SARS-CoV-2 Spike (BA.2+L452R)	-	0.422	0.169	0.0594	AU/mL
SARS-CoV-2 Spike (BA.2.12.1)	-	0.517	0.215	0.0758	AU/mL
SARS-CoV-2 Spike (BA.2.75)	-	0.337	<LLOQ	<LLOQ	AU/mL
SARS-CoV-2 Spike (BA.2.75.2)	-	0.325	0.0880	0.0922	AU/mL
SARS-CoV-2 Spike (BA.2.86)	-	0.298	0.0688	0.0502	AU/mL
SARS-CoV-2 Spike (BA.3)	-	0.141	<LLOQ	<LLOQ	AU/mL
SARS-CoV-2 Spike (BA.4)	-	0.416	0.180	<LLOQ	AU/mL
SARS-CoV-2 Spike (BA.4.6)	-	0.365	0.133	0.0719	AU/mL
SARS-CoV-2 Spike (BA.5)	-	0.484	0.186	<LLOQ	AU/mL
SARS-CoV-2 Spike (BF.7)	-	0.406	0.112	0.0551	AU/mL
SARS-CoV-2 Spike (BQ.1)	-	0.375	0.138	<LLOQ	AU/mL
SARS-CoV-2 Spike (BQ.1.1)	-	0.368	0.122	0.0642	AU/mL
SARS-CoV-2 Spike (BV-1)	-	1.54	0.498	0.611	AU/mL
SARS-CoV-2 Spike (B.1.1.519)	-	2.13	0.714	0.706	AU/mL
SARS-CoV-2 Spike (B.1.1.529; BA.1; BA.1.15)	-	0.435	0.0676	0.0524	AU/mL
SARS-CoV-2 Spike (B.1.1.7)	-	2.00	0.55	0.64	AU/mL
SARS-CoV-2 Spike (B.1.1.7+E484K)	-	1.74	0.608	0.292	AU/mL
SARS-CoV-2 Spike (B.1.258.17)	-	3.02	1.29	0.929	AU/mL
SARS-CoV-2 Spike (B.1.351)	-	1.12	0.391	0.161	AU/mL
SARS-CoV-2 Spike (B.1.351.1)	-	1.89	0.792	0.306	AU/mL
SARS-CoV-2 Spike (B.1.429)	-	2.04	0.730	0.332	AU/mL
SARS-CoV-2 Spike (B.1.466.2)	-	2.67	0.839	0.927	AU/mL
SARS-CoV-2 Spike (B.1.525)	-	1.43	0.496	0.224	AU/mL
SARS-CoV-2 Spike (B.1.526)	-	1.57	0.916	0.312	AU/mL
SARS-CoV-2 Spike (B.1.526.1)	-	1.76	0.594	0.284	AU/mL
SARS-CoV-2 Spike (B.1.617)	-	2.05	1.04	0.375	AU/mL
SARS-CoV-2 Spike (B.1.617.1)	-	1.29	0.503	0.184	AU/mL
SARS-CoV-2 Spike (B.1.617.2)	-	1.37	0.663	0.265	AU/mL
SARS-CoV-2 Spike (B.1.617.2; AY.3; AY.5; AY.6; AY.7; AY.14) Alt Seq 1	-	1.79	0.740	0.344	AU/mL
SARS-CoV-2 Spike (B.1.617.2 +1)	-	1.02	0.493	0.139	AU/mL
SARS-CoV-2 Spike (B.1.617.2 +2)	-	0.862	0.464	0.116	AU/mL
SARS-CoV-2 Spike (B.1.617.2 +3)	-	1.08	0.548	0.150	AU/mL
SARS-CoV-2 Spike (B.1.617.2 +4)	-	0.895	0.519	0.129	AU/mL
SARS-CoV-2 Spike (B.1.617.2; AY.4) Alt Seq 2	-	1.87	0.846	0.371	AU/mL
SARS-CoV-2 Spike (B.1.617.2+ΔY144)	-	1.60	0.628	0.251	AU/mL
SARS-CoV-2 Spike (B.1.617.3)	-	1.42	0.925	0.277	AU/mL
SARS-CoV-2 Spike (B.1.618)	-	1.83	0.792	0.307	AU/mL
SARS-CoV-2 Spike (B.1.620)	-	0.947	0.281	0.150	AU/mL
SARS-CoV-2 Spike (B.1.621)	-	1.12	0.588	0.204	AU/mL
SARS-CoV-2 Spike (B.1.640.2)	-	0.782	0.0981	0.0797	AU/mL
SARS-CoV-2 Spike (C.37)	-	1.15	0.483	0.159	AU/mL
SARS-CoV-2 Spike (EG.5.1)	-	0.347	0.0934	0.034	AU/mL
SARS-CoV-2 Spike (FL.1.5.1)	-	0.380	0.086	0.0372	AU/mL
SARS-CoV-2 Spike (HV.1)	-	0.321	0.0867	0.0212	AU/mL

Antigens	Alternate Spot Name	Concentration of IgA (viald)			Unit of Measure
		Serology Control 1.1	Serology Control 1.2	Serology Control 1.3	
SARS-CoV-2 Spike (JD.1.1)	-	0.338	0.118	<LLOQ	AU/mL
SARS-CoV-2 Spike (JN.1)	-	0.249	0.0875	0.0404	AU/mL
SARS-CoV-2 Spike (P.1)	-	1.41	0.398	0.183	AU/mL
SARS-CoV-2 Spike (P.2)	-	1.97	0.79	0.323	AU/mL
SARS-CoV-2 Spike (P.3)	-	0.613	0.229	0.0893	AU/mL
SARS-CoV-2 Spike (R.1)	-	1.31	0.600	0.218	AU/mL
SARS-CoV-2 Spike (XBB.1)	-	0.298	0.0662	0.0298	AU/mL
SARS-CoV-2 Spike (XBB.1.5)	-	0.30	0.0899	0.0301	AU/mL
SARS-CoV-1 Spike	-	0.633	0.086	0.074	AU/mL
MERS-CoV Spike	-	1.49	1.40	0.134	AU/mL
HCoV-229E Spike	-	2.28	0.618	0.218	AU/mL
HCoV-HKU1 Spike	-	3.36	1.04	0.292	AU/mL
HCoV-NL63 Spike	-	1.22	0.343	<LLOQ	AU/mL
HCoV-OC43 Spike	-	8.72	3.16	1.04	AU/mL
Flu A/Hong Kong/2014 H3	-	3.68	0.328	0.209	AU/mL
Flu A/Michigan/2015 H1	-	5.43	0.392	0.1	AU/mL
Flu A/Shanghai/2013 H7	-	>ULOQ	0.145	<LLOQ	AU/mL
Flu B/Brisbane/2008 HA	-	10.4	1.90	0.512	AU/mL
Flu B/Phuket/2013 HA	-	12.9	1.83	0.745	AU/mL
RSV Pre-Fusion F	-	14.5	3.62	0.871	AU/mL

>ULOQ = above the upper limit of quantification; <LLOQ = below the lower limit of quantification (see appendix F)

- = Not available

Note: Alternative S-GENE mutations for Spike of AY.1, AY.2, and B.1.617.2 are listed as "Alt Seq #."

Lot Numbers A00C0959/A00C0960/A00C0961 (Serology Control 2)

Antigens	Alternate Spot Name	Concentration of IgG (viald)			Unit of Measure
		Serology Control 2.1	Serology Control 2.2	Serology Control 2.3	
SARS-CoV-2 Spike	-	47.9	24.6	14.8	AU/mL
SARS-CoV-2 Nucleocapsid	-	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
SARS-CoV-2 Spike (JN.1 (v2))	-	971	4.65	2.73	AU/mL
SARS-CoV-2 Spike (KP.2)	-	8.14	4.14	2.36	AU/mL
SARS-CoV-2 Spike (KP.3)	-	8.95	4.12	2.44	AU/mL
SARS-CoV-2 Spike (LB.1)	-	791	3.79	2.11	AU/mL
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.1.5 (v2))	-	102	5.10	2.84	AU/mL
SARS-CoV-2 Spike (XBB.2.3)	-	12.6	5.88	3.39	AU/mL
RSV Pre-Fusion F	-	90.0	42.9	23.3	AU/mL
Flu A/Wisconsin/67/2022 H1	-	74.9	26.6	21.0	AU/mL
SARS-CoV-2 Spike(XBB.1.5 (v2))	-	10.2	5.10	2.84	AU/mL
Flu A/Ghana/39/2021 H5	-	5.59	2.86	1.63	AU/mL

Antigens	Alternate Spot Name	Concentration of IgG (viald)			Unit of Measure
		Serology Control 2.1	Serology Control 2.2	Serology Control 2.3	
Flu A/Massachusetts/18/2022 H3	-	21.2	11.5	6.63	AU/mL
Flu B/Austria/2021 HA	-	78.5	38.2	22.4	AU/mL

- = Not available

Antigens	Alternate Spot Name	Concentration of IgA (viald)			Unit of Measure
		Serology Control 2.1	Serology Control 2.2	Serology Control 2.3	
SARS-CoV-2 Spike	-	4.19	2.10	1.24	AU/mL
SARS-CoV-2 Nucleocapsid	-	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 (JN.1 (v2))	-	1.24	0.607	0.353	AU/mL
SARS-CoV-2 Spike (KP.2)	-	0.909	0.464	0.268	AU/mL
SARS-CoV-2 Spike (KP.3)	-	1.11	0.491	0.310	AU/mL
SARS-CoV-2 Spike (LB.1)	-	0.903	0.440	0.254	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.1.5 (v2))	-	1.30	0.641	0.370	AU/mL
SARS-CoV-2 Spike (XBB.2.3)	-	1.25	0.617	0.363	AU/mL
RSV Pre-Fusion F	-	25.7	12.9	7.59	AU/mL
Flu A/Wisconsin/67/2022 H1	-	9.39	4.68	2.72	AU/mL
SARS-CoV-2 Spike(XBB.1.5 (v2))	-	1.30	0.641	0.370	AU/mL
Flu A/Ghana/39/2021 H5	-	1.26	0.657	0.386	AU/mL
Flu A/Massachusetts/18/2022 H3	-	2.76	1.48	0.881	AU/mL
Flu B/Austria/2021 HA	-	4.82	2.60	1.52	AU/mL

- = Not available

Appendix D: Values for Serology Controls in WHO/NIBSC units (BAU/mL)

The tables below show the WHO/NIBSC units (BAU/mL) for IgG, IgM, and IgA antibodies in Serology Control 1.1, Serology Control 1.2, Serology Control 1.3, Serology Control 2.1, Serology Control 2.2, and Serology Control 2.3. The WHO/NIBSC assignments for Serology Control 1.1 (lot numbers A00C0771 and A00C0825), Serology Control 1.2 (lot numbers A00C0772 and A00C0826), and Serology Control 1.3 (lot numbers A00C0773 and A00C0827) differ from previous lots and are presented in separate tables below.

Lot Numbers A00C0731/A00C0732/A00C0733 (Serology Control 1)

Antigen	Concentration of IgG (vialcd)			Unit of Measure
	Serology Control 1.1	Serology Control 1.2	Serology Control 1.3	
SARS-CoV-2 Nucleocapsid	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

Antigen	Concentration of IgM (vialcd)			Unit of Measure
	Serology Control 1.1	Serology Control 1.2	Serology Control 1.3	
SARS-CoV-2 Nucleocapsid	0.061	0.030	0.0285	BAU/mL
SARS-CoV-2 S1 RBD	0.011	0.0047	0.0068	BAU/mL
SARS-CoV-2 Spike	0.0187	0.0054	0.0077	BAU/mL

Antigen	Concentration of IgA (vialcd)			Unit of Measure
	Serology Control 1.1	Serology Control 1.2	Serology Control 1.3	
SARS-CoV-2 Nucleocapsid	0.1414	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	0.023	0.0103	BAU/mL

Lot Numbers A00C0771/A00C0772/A00C0773 and A00C0825/A00C0826/A00C0827 (Serology Control 1)

Antigen	Concentration of IgG (vialcd)			Unit of Measure
	Serology Control 1.1	Serology Control 1.2	Serology Control 1.3	
SARS-CoV-2 Nucleocapsid	0.054	0.0179	0.0107	BAU/mL
SARS-CoV-2 S1 RBD	0.2595	0.093	0.0231	BAU/mL
SARS-CoV-2 Spike	0.2045	0.0878	0.0197	BAU/mL

Antigen	Concentration of IgM (vialcd)			Unit of Measure
	Serology Control 1.1	Serology Control 1.2	Serology Control 1.3	
SARS-CoV-2 Nucleocapsid	0.1769	0.0425	0.0623	BAU/mL
SARS-CoV-2 S1 RBD	0.0729	0.0161	0.0106	BAU/mL
SARS-CoV-2 Spike	0.0803	0.0263	0.0133	BAU/mL

Antigen	Concentration of IgA (vialcd)			Unit of Measure
	Serology Control 1.1	Serology Control 1.2	Serology Control 1.3	
SARS-CoV-2 Nucleocapsid	0.3818	0.0205	0.0971	BAU/mL
SARS-CoV-2 S1 RBD	0.1447	0.0223	0.0762	BAU/mL
SARS-CoV-2 Spike	0.1659	0.0377	0.0543	BAU/mL

Lot Numbers A00C0959/A00C0960/A00C0961 (Serology Control 2)

Antigen	Concentration of IgG (viald)			Unit of Measure
	Serology Control 2.1	Serology Control 2.2	Serology Control 2.3	
SARS-CoV-2 Nucleocapsid	0.118	0.0577	0.0346	BAU/mL
SARS-CoV-2 Spike	0.413	0.215	0.125	BAU/mL

Antigen	Concentration of IgA (viald)			Unit of Measure
	Serology Control 2.1	Serology Control 2.2	Serology Control 2.3	
SARS-CoV-2 Nucleocapsid	0.764	0.357	0.201	BAU/mL
SARS-CoV-2 Spike	0.228	0.116	0.0665	BAU/mL

Appendix E: Analytical Sensitivity

Limits of quantification (LOQ) were estimated based on the Reference Standard 1 or 2 performance over multiple runs. The table below shows the in-well quantitative range for each assay. Multiplying the LLOQ and ULOQ values in the table by the sample dilution factor will provide dilution-adjusted limits of quantification.

Reference Standard 1

Antigen	Alternate Spot Name	LLOQ and ULOQ concentration in MSD arbitrary units (AU/mL)					
		IgG		IgM		IgA	
		LLOQ	ULOQ	LLOQ	ULOQ	LLOQ	ULOQ
SARS-CoV-2 Nucleocapsid	-	0.046	80	0.083	5.0	0.06	50
SARS-CoV-2 S1 NTD	-	0.003	1.0	0.021	1.2	0.064	20
SARS-CoV-2 S1 RBD	-	0.035	30	0.071	8.0	0.14	20
SARS-CoV-2 Spike	-	0.049	70	0.123	8.0	0.062	50
SARS-CoV-2 S1 RBD (A.23.1)	V367F	0.035	33	0.035	110	0.043	72
SARS-CoV-2 S1 RBD (A.V01.V2)	R346K, T478R, E484K	0.018	4.8	10.7	25	0.027	12
SARS-CoV-2 S1 RBD (AY.1; AY.2)	K417N, L452R, T478K	0.038	13	0.036	100	0.023	38
SARS-CoV-2 S1 RBD (AY.3; AY.4; AY.4.2; AY.5; AY.6; AY.7; AY.12; AY.14; B.1.617.2; B.1.617.2+ΔY144)	L452R, T478K; RBD (Delta)	0.029	14	0.034	100	0.026	37
SARS-CoV-2 S1 RBD (BA.1.1; BA.1.1.15)	RBD (Omicron; BA.1.1)	0.036	1.1	0.051	3.3	0.049	2.6
SARS-CoV-2 S1 RBD (BA.2; BA.2.1; BA.2.2; BA.2.3; BA.2.5; BA.2.6; BA.2.7; BA.2.8; BA.2.10; BA.2.10.1; BA.2.12)	RBD (Omicron; BA.2)	0.022	2.6	0.034	7.2	0.05	5.0
SARS-CoV-2 S1 RBD (BA.2+L452M)	RBD (BA.2+L452M)	0.033	2.3	0.046	6.3	0.074	4.2
SARS-CoV-2 S1 RBD (BA.2+L452R)	RBD (BA.2+L452R)	0.019	1.6	0.030	6.7	0.044	3.9
SARS-CoV-2 S1 RBD (BA.2.12.1)	RBD (BA.2.12.1)	0.020	2.2	0.045	7.7	0.064	4.5
SARS-CoV-2 S1 RBD (BA.2.75)	RBD (BA.2.75)	0.026	1.4	0.022	5.6	0.036	3.7
SARS-CoV-2 S1 RBD (BA.2.75.2)	RBD (BA.2.75.2)	0.016	1.2	0.022	6.6	0.038	2.5
SARS-CoV-2 S1 RBD (BA.3)	RBD (BA.3)	0.042	1.4	0.064	4.0	0.040	3.0
SARS-CoV-2 S1 RBD (BA.4; BA.5)	RBD (BA.4; BA.5)	0.019	2.1	1.238	15	0.043	4.7
SARS-CoV-2 S1 RBD (BA.4.6; BF.7)	RBD (BA.4.6; BF.7)	0.019	2.0	0.019	10	0.037	4.1
SARS-CoV-2 S1 RBD (BQ.1)	RBD (BQ.1)	0.017	1.9	0.021	4.5	0.016	3.5
SARS-CoV-2 S1 RBD (BQ.1.1)	RBD (BQ.1.1)	0.014	1.8	0.075	7.3	0.034	3.5
SARS-CoV-2 S1 RBD (BV.1)	Q493R, N501Y	0.032	13	1.11	76	0.036	40
SARS-CoV-2 S1 RBD (B.1.1.519)	T478K	0.029	25	0.03	69	0.047	49
SARS-CoV-2 S1 RBD (B.1.1.529; BA.1; BA.1.15)	RBD (Omicron); RBD (Omicron; BA.1)	0.023	1.7	0.036	4.1	0.042	3.3
SARS-CoV-2 S1 RBD (B.1.1.7)	N501Y; RBD (Alpha)	0.224	20	0.019	3.5	0.028	14
SARS-CoV-2 S1 RBD (B.1.1.7+E484K; P.3)	E484K, N501Y	0.044	6.7	1.678	24	0.077	8.8
SARS-CoV-2 S1 RBD (B.1.214.2)	Q414K, N450K	0.053	11	0.051	62	0.039	26
SARS-CoV-2 S1 RBD (B.1.258.17; B.1.466.2)	N439K	0.044	10	0.091	15	0.026	6.25
SARS-CoV-2 S1 RBD (B.1.351; B.1.351.1)	K417N, E484K, N501Y;	0.053	6.3	NA*	NA*	0.035	3.4

Antigen	Alternate Spot Name	LLOQ and ULOQ concentration in MSD arbitrary units (AU/mL)					
		IgG		IgM		IgA	
		LLOQ	ULOQ	LLOQ	ULOQ	LLOQ	ULOQ
	RBD (Beta)						
SARS-CoV-2 S1 RBD (B.1.427; B.1.429; B.1.526.1)	L452R	0.030	18	0.031	3.25	0.057	14
SARS-CoV-2 S1 RBD (B.1.525; B.1.526; B.1.618; P.2; R.1)	E484K	0.022	12	0.042	0.675	0.054	7
SARS-CoV-2 S1 RBD (B.1.526.2)	S477N	0.029	25	0.028	4.0	0.038	19
SARS-CoV-2 S1 RBD (B.1.617; B.1.617.1; B.1.617.3)	L452R, E484Q	0.098	14	3.23	38	0.12	22
SARS-CoV-2 S1 RBD (B.1.620)	S477N, E484K	0.023	4.8	2.927	35	0.051	11
SARS-CoV-2 S1 RBD (C.37)	L452Q, F490S	0.019	9.1	0.028	60	0.036	25
SARS-CoV-2 S1 RBD (P.1)	K417T, E484K, N501Y; RBD (Gamma)	0.091	10	0.071	3.0	0.035	6.4
SARS-CoV-2 S1 RBD (XBB.1)	RBD (XBB.1)	0.017	1.1	0.154	5.3	0.053	2.6
SARS-CoV-2 Spike (D614G)	-	0.044	72	0.051	11	0.014	57
SARS-CoV-2 Spike (A.23.1)	-	0.036	85	0.046	150	0.065	100
SARS-CoV-2 Spike (A.V01.V2)	-	0.059	23	0.126	42	0.07	41
SARS-CoV-2 Spike (AY.1)	-	0.037	32	0.061	86	0.037	55
SARS-CoV-2 Spike (AY.1) Alt Seq 1	-	0.048	32	0.084	98	0.082	55
SARS-CoV-2 Spike (AY.2)	-	0.046	36	0.073	110	0.098	64
SARS-CoV-2 Spike (AY.2) Alt Seq 1	-	0.046	30	0.087	84	0.045	49
SARS-CoV-2 Spike (AY.4.2)	-	0.044	37	0.033	120	0.041	58
SARS-CoV-2 Spike (AY.12)	-	0.040	33	0.054	85	0.017	51
SARS-CoV-2 Spike (BA.1+L452R)	-	0.04	6.6	0.078	15	0.029	6.8
SARS-CoV-2 Spike (BA.1+R346K; BA.1.1; BA.1.1.15)	-	0.146	3.9	0.081	10	0.025	4.0
SARS-CoV-2 Spike (BA.2; BA.2.1; BA.2.2; BA.2.3; BA.2.5; BA.2.6; BA.2.7; BA.2.8; BA.2.10; BA.2.12)	-	0.062	12	0.044	27	0.065	18
SARS-CoV-2 Spike (BA.2+L452M)	-	0.027	12	0.030	25	0.028	17
SARS-CoV-2 Spike (BA.2+L452R)	-	0.037	10	0.037	25	0.031	14
SARS-CoV-2 Spike (BA.2.12.1)	-	0.033	11	0.044	27	0.028	17
SARS-CoV-2 Spike (BA.2.75)	-	0.039	5.7	0.030	8.8	0.069	11
SARS-CoV-2 Spike (BA.2.75.2)	-	0.018	5.2	0.021	7.9	0.051	11
SARS-CoV-2 Spike (BA.2.86)	-	0.015	5.1	-	-	0.041	11
SARS-CoV-2 Spike (BA.3)	-	0.361	4.3	0.033	9.5	0.036	4.5
SARS-CoV-2 Spike (BA.4)	-	0.051	10	0.036	29	0.141	15
SARS-CoV-2 Spike (BA.4.6)	-	0.034	8.4	0.022	24	0.060	13
SARS-CoV-2 Spike (BA.5)	-	0.034	11	0.038	34	0.061	17
SARS-CoV-2 Spike (BF.7)	-	0.042	8.0	0.023	20	0.030	14
SARS-CoV-2 Spike (BN.1)	-	0.026	4.7	0.056	6.9	-	-
SARS-CoV-2 Spike (BQ.1)	-	0.034	8.1	0.027	18	0.045	13
SARS-CoV-2 Spike (BQ.1.1)	-	0.024	7.8	0.027	17	0.034	12
SARS-CoV-2 Spike (BV.1)	-	0.036	33	0.087	60	0.058	55
SARS-CoV-2 Spike (B.1.1.519)	-	0.045	63	0.07	110	0.049	76
SARS-CoV-2 Spike (B.1.1.529; BA.1; BA.1.15)	-	0.029	5.9	0.065	7.2	0.043	13
SARS-CoV-2 Spike (B.1.1.7)	-	0.07	47	0.039	7.0	0.069	33
SARS-CoV-2 Spike (B.1.1.7+E484K)	-	0.039	31	0.079	57	0.038	60
SARS-CoV-2 Spike (B.1.258.17)	-	0.03	77	0.048	150	0.029	100
SARS-CoV-2 Spike (B.1.351)	-	0.072	21	0.054	7.4	0.057	23
SARS-CoV-2 Spike (B.1.351.1)	-	0.053	45	0.098	93	0.048	62
SARS-CoV-2 Spike (B.1.429)	-	0.035	45	0.085	6	0.05	32
SARS-CoV-2 Spike (B.1.466.2)	-	0.082	60	0.052	120	0.058	85
SARS-CoV-2 Spike (B.1.525)	-	0.063	27	0.043	50	0.086	46
SARS-CoV-2 Spike (B.1.526)	-	0.071	46	0.168	6.25	0.064	38
SARS-CoV-2 Spike (B.1.526.1)	-	0.047	32	0.11	120	0.096	62
SARS-CoV-2 Spike (B.1.617)	-	0.042	49	0.063	72	0.064	73
SARS-CoV-2 Spike (B.1.617.1)	-	0.061	30	0.062	45	0.117	44
SARS-CoV-2 Spike (B.1.617.2)	-	0.045	28	0.093	100	0.058	50
SARS-CoV-2 Spike (B.1.617.2; AY.3; AY.5; AY.6; AY.7; AY.14) Alt Seq 1	-	0.091	37	0.136	120	0.081	63
SARS-CoV-2 Spike (B.1.617.2 +1)	-	0.033	25	0.046	34	0.053	38
SARS-CoV-2 Spike (B.1.617.2 +2)	-	0.037	21	0.087	29	0.047	33
SARS-CoV-2 Spike (B.1.617.2 +3)	-	0.034	24	NA*	NA*	0.049	40
SARS-CoV-2 Spike (B.1.617.2 +4)	-	0.028	21	0.077	30	0.055	33

Antigen	Alternate Spot Name	LLOQ and ULOQ concentration in MSD arbitrary units (AU/mL)					
		IgG		IgM		IgA	
		LLOQ	ULOQ	LLOQ	ULOQ	LLOQ	ULOQ
SARS-CoV-2 Spike (B.1.617.2; AY.4) Alt Seq 2	-	0.064	40	0.079	140	0.118	17
SARS-CoV-2 Spike (B.1.617.2+ΔY144)	-	0.09	30	0.057	100	0.074	53
SARS-CoV-2 Spike (B.1.617.3)	-	0.038	37	0.071	56	0.075	52
SARS-CoV-2 Spike (B.1.618)	-	0.071	36	0.031	53	0.046	59
SARS-CoV-2 Spike (B.1.620)	-	0.032	17	0.021	31	0.062	32
SARS-CoV-2 Spike (B.1.621)	-	0.048	25	0.025	43	0.070	39
SARS-CoV-2 Spike (B.1.640.2)	-	0.061	21	0.057	61	0.017	26
SARS-CoV-2 Spike (C.37)	-	0.065	28	0.063	57	0.058	41
SARS-CoV-2 Spike (EG.5.1)	-	0.013	6.3	-	-	0.029	12
SARS-CoV-2 Spike (FL.1.5.1)	-	0.009	6.4	-	-	0.036	13
SARS-CoV-2 Spike (HV.1)	-	0.013	7.3	-	-	0.0035	11
SARS-CoV-2 Spike (JD.1.1)	-	0.0073	7.9	-	-	0.074	12
SARS-CoV-2 Spike (JN.1)	-	0.026	5.2	-	-	0.031	9.5
SARS-CoV-2 Spike (P.1)	-	0.032	36	0.071	3.0	0.049	22
SARS-CoV-2 Spike (P.2)	-	0.057	41	0.032	61	0.039	55
SARS-CoV-2 Spike (P.3)	-	0.028	13	0.02	20	0.731	22
SARS-CoV-2 Spike (R.1)	-	0.058	33	0.072	41	0.048	46
SARS-CoV-2 Spike (XBB.1)	-	0.023	5.4	0.029	6.4	0.014	10
SARS-CoV-2 Spike (XBB.1.16)	-	0.033	7.5	-	-	-	-
SARS-CoV-2 Spike (XBB.1.16.1)	-	0.034	6.0	-	-	-	-
SARS-CoV-2 Spike (XBB.1.16.6)	-	0.017	5.8	-	-	-	-
SARS-CoV-2 Spike (XBB.1.5)	-	0.045	5.1	0.037	5.3	0.019	10
SARS-CoV-2 Spike (XBB.2.3)	-	0.023	7.3	-	-	-	-
SARS-CoV-1 Spike	-	0.055	5.0	0.10	0.50	0.073	10
MERS-CoV Spike	-	0.033	5.0	0.046	3.6	0.100	10
HCoV-229E Spike	-	0.04	30	0.087	0.25	0.063	40
HCoV-HKU1 Spike	-	0.284	30	0.041	0.40	0.113	130
HCoV-NL63 Spike	-	0.042	5.0	0.033	0.07	0.07	10
HCoV-OC43 Spike	-	1.32	50	0.041	0.25	0.055	220
Flu A/Darwin/2021 H3	-	0.07	58	-	-	-	-
Flu A/Hong Kong/2014 H3	-	0.06	100	0.123	0.20	0.072	20
Flu A/Michigan/2015 H1	-	0.076	100	0.061	2.5	0.057	30
Flu A/Wisconsin/2019 H1	-	0.02	95	-	-	-	-
Flu B/Austria/2021 HA	-	0.03	92	-	-	-	-
Flu A/Shanghai/2013 H7	-	0.054	6.6	0.123	0.33	0.123	1.0
Flu B/Brisbane/2008 HA	-	0.063	100	0.071	15	0.057	120
Flu B/Phuket/2013 HA	-	0.04	100	0.073	20	0.059	70
RSV Pre-Fusion F	-	0.06	100	0.235	1.25	0.095	50

- = Not available

NA* = Not assigned

Note: Alternative S-GENE mutations for Spike of AY.1, AY.2, and B.1.617.2 are listed as "Alt Seq #."

Reference Standard 2

Antigen	Alternate Spot Name	LLOQ and ULOQ concentration in MSD arbitrary units (AU/mL)			
		IgG		IgA	
		LLOQ	ULOQ	LLOQ	ULOQ
SARS-CoV-2 Nucleocapsid	-	0.05	80	0.06	50
SARS-CoV-2 Spike	-	0.05	70	0.06	50
SARS-CoV-2 Spike (JN.1 (v2))	-	0.03	30	0.03	55
SARS-CoV-2 Spike (KP.2)	-	0.08	27	0.10	50
SARS-CoV-2 Spike (KP.3)	-	0.02	25	0.02	55
SARS-CoV-2 Spike (LB.1)	-	0.01	20	0.02	50
SARS-CoV-2 Spike (XBB1.5 (v2))	-	0.05	40	0.07	65
RSV Pre-Fusion F	-	0.09	100	0.15	280
Flu A/Ghana/39/2021 H5	-	0.10	9	0.10	22

Antigen	Alternate Spot Name	LLOQ and ULOQ concentration in MSD arbitrary units (AU/mL)			
		IgG		IgA	
		LLOQ	ULOQ	LLOQ	ULOQ
Flu A/Massachusetts/18/2022 H3	-	0.08	50	0.15	300
Flu A/Wisconsin/67/2022 H1	-	0.08	80	0.10	90
Flu B/Austria/2021 HA	-	0.09	85	0.15	300

- = Not available

Appendix F: Sensitivity and Specificity

Sensitivity, specificity, and cutoff values were established for three SARS-CoV-2 antigens using receiver operating characteristic curve (ROC) analysis. Pre-2019 (N=200) and PCR-confirmed COVID-19 samples (N=214) were commercially sourced, and the PCR-positive samples were grouped by time from initial positive test: 0 to 14 and 15+ days. The cutoff values shown in the table below were determined based on samples run at 5,000-fold dilution.

Antigen	IgG				
	Cutoff Value*	Units	Early Sensitivity (Day 0-14)†	Late Sensitivity (Day 15+)†	Specificity†
SARS-CoV-2 Nucleocapsid	5,000	AU/mL	71.1% (54.1%–84.6%)	93.8% (89.1%–96.8%)	100.0% (98.2%–100%)
SARS-CoV-2 S1 RBD	538	AU/mL	71.1% (54.1%–84.6%)	98.3% (95.1%–99.6%)	98.5% (95.7%–99.7%)
SARS-CoV-2 Spike	1,960	AU/mL	84.2% (68.7%–94.0%)	98.3% (95.1%–99.6%)	99.5% (97.2%–100%)

*Dilution-adjusted sample concentration. Cutoff values provided for RUO purposes only

†95% Confidence Interval shown in parenthesis

Appendix G

Coated Antigens

Antigens	Antigen Description *	Antigen Modifications
SARS-CoV-2 Nucleocapsid	Severe Acute Respiratory Syndrome Coronavirus 2 Nucleocapsid Protein	Full length Nucleocapsid; C-terminal His-Tag
SARS-CoV-2 S1 NTD	Severe Acute Respiratory Syndrome Coronavirus 2 N-Terminal Domain of the S1 subunit	Q14-L303 of the SARS-CoV-2 Spike Sequence; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 S1 RBD	Severe Acute Respiratory Syndrome Coronavirus 2 Receptor Binding Domain of the S1 subunit	R319-F541 of the SARS-CoV-2 Spike Sequence; C-terminal His-Tag
SARS-CoV-2 Spike	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 S1 RBD (A.23.1)	Severe Acute Respiratory Syndrome Coronavirus 2 Receptor Binding Domain of the S1 subunit Uganda variant A.23.1 lineage	R319-F541 of the SARS-CoV-2 Spike Sequence; C-terminal His-Tag
SARS-CoV-2 S1 RBD (A.V01.V2)	Severe Acute Respiratory Syndrome Coronavirus 2 Receptor Binding Domain of the S1 subunit Mexico/Texas BV-2 variant B.1.1.519 lineage	R319-F541 of the SARS-CoV-2 Spike Sequence; C-terminal His-Tag
SARS-CoV-2 S1 RBD (AY.1; AY.2)	Severe Acute Respiratory Syndrome Coronavirus 2 Receptor Binding Domain of the S1 subunit Delta variant AY.1 and AY.2 sublineages	R319-F541 of the SARS-CoV-2 Spike Sequence; C-terminal His-Tag
SARS-CoV-2 S1 RBD (AY.3; AY.4; AY.4.2; AY.5; AY.6; AY.7; AY.12; AY.14; B.1.617.2; B.1.617.2+ΔY144)	Severe Acute Respiratory Syndrome Coronavirus 2 Receptor Binding Domain of the S1 subunit Delta variant AY.3, AY.4, AY.4.2, AY.5, AY.6, AY.7, AY.12, AY.14, B.1.617.2, and B.1.617.2+ΔY144 sublineages	R319-F541 of the SARS-CoV-2 Spike Sequence; C-terminal His-Tag
SARS-CoV-2 S1 RBD (BA.1.1; BA.1.1.15)	Severe Acute Respiratory Syndrome Coronavirus 2 Receptor Binding Domain of the S1 subunit Omicron variant BA.1.1 and BA.1.1.15 sublineages	R319-F541 of the SARS-CoV-2 Spike Sequence; C-terminal His-Tag
SARS-CoV-2 S1 RBD (BA.2; BA.2.1; BA.2.2; BA.2.3; BA.2.5; BA.2.6; BA.2.7; BA.2.8; BA.2.10; BA.2.10.1; BA.2.12)	Severe Acute Respiratory Syndrome Coronavirus 2 Receptor Binding Domain of the S1 subunit Omicron variant BA.2, BA.2.1, BA.2.2, BA.2.3, BA.2.5, BA.2.6, BA.2.7, BA.2.8, BA.2.10, BA.2.10.1, and BA.2.12 sublineages	R319-F541 of the SARS-CoV-2 Spike Sequence; C-terminal His-Tag
SARS-CoV-2 S1 RBD (BA.2+L452M)	Severe Acute Respiratory Syndrome Coronavirus 2 Receptor Binding Domain of the S1 subunit Omicron variant BA.2+L452M sublineage	R319-F541 of the SARS-CoV-2 Spike Sequence; C-terminal His-Tag;
SARS-CoV-2 S1 RBD (BA.2+L452R)	Severe Acute Respiratory Syndrome Coronavirus 2 Receptor Binding Domain of the S1 subunit Omicron variant BA.2+L452R sublineage	R319-F541 of the SARS-CoV-2 Spike Sequence; C-terminal His-Tag
SARS-CoV-2 S1 RBD (BA.2.12.1)	Severe Acute Respiratory Syndrome Coronavirus 2 Receptor Binding Domain of the S1 subunit Omicron variant BA.2.12.1 sublineage	R319-F541 of the SARS-CoV-2 Spike Sequence; C-terminal His-Tag
SARS-CoV-2 S1 RBD (BA.2.75)	Severe Acute Respiratory Syndrome Coronavirus 2 Receptor Binding Domain of the S1 subunit Omicron variant BA.2.75 sublineage	R319-F541 of the SARS-CoV-2 Spike Sequence; C-terminal His-Tag
SARS-CoV-2 S1 RBD (BA.2.75.2)	Severe Acute Respiratory Syndrome Coronavirus 2 Receptor Binding Domain of the S1 subunit Omicron variant BA.2.75.2 sublineage	R319-F541 of the SARS-CoV-2 Spike Sequence; C-terminal His-Tag
SARS-CoV-2 S1 RBD (BA.3)	Severe Acute Respiratory Syndrome Coronavirus 2 Receptor Binding Domain of the S1 subunit Omicron variant BA.3 sublineage	R319-F541 of the SARS-CoV-2 Spike Sequence; C-terminal His-Tag
SARS-CoV-2 S1 RBD (BA.4; BA.5)	Severe Acute Respiratory Syndrome Coronavirus 2 Receptor Binding Domain of the S1 subunit Omicron variant BA.4 and BA.5 sublineages	R319-F541 of the SARS-CoV-2 Spike Sequence; C-terminal His-Tag
SARS-CoV-2 S1 RBD (BA.4.6; BF.7)	Severe Acute Respiratory Syndrome Coronavirus 2 Receptor Binding Domain of the S1 subunit Omicron variant BA.4.6 and BF.7 sublineages	R319-F541 of the SARS-CoV-2 Spike Sequence; C-terminal His-Tag
SARS-CoV-2 S1 RBD (BQ.1)	Severe Acute Respiratory Syndrome Coronavirus 2 Receptor Binding Domain of the S1 subunit Omicron variant BQ.1 sublineage	R319-F541 of the SARS-CoV-2 Spike Sequence; C-terminal His-Tag
SARS-CoV-2 S1 RBD (BQ.1.1)	Severe Acute Respiratory Syndrome Coronavirus 2 Receptor Binding Domain of the S1 subunit Omicron variant BQ.1.1 sublineage	R319-F541 of the SARS-CoV-2 Spike Sequence; C-terminal His-Tag
SARS-CoV-2 S1 RBD (BV-1)	Severe Acute Respiratory Syndrome Coronavirus 2 Receptor Binding Domain of the S1 subunit Texas BV-1 variant	R319-F541 of the SARS-CoV-2 Spike Sequence; C-terminal His-Tag
SARS-CoV-2 S1 RBD (B.1.1.519)	Severe Acute Respiratory Syndrome Coronavirus 2 Receptor Binding Domain of the S1 subunit Mexico/Texas BV-2 variant B.1.1.519 lineage	R319-F541 of the SARS-CoV-2 Spike Sequence; C-terminal His-Tag
SARS-CoV-2 S1 RBD (B.1.1.529; BA.1; BA.1.15)	Severe Acute Respiratory Syndrome Coronavirus 2 Receptor Binding Domain of the S1 subunit Omicron variant B.1.1.529, BA.1, and BA.1.15 sublineages	R319-F541 of the SARS-CoV-2 Spike Sequence; C-terminal His-Tag
SARS-CoV-2 S1 RBD (B.1.1.7)	Severe Acute Respiratory Syndrome Coronavirus 2 Receptor Binding Domain of the S1 subunit Alpha Variant B.1.1.7 lineage	R319-F541 of the SARS-CoV-2 Spike Sequence; C-terminal His-Tag

Antigens	Antigen Description *	Antigen Modifications
SARS-CoV-2 S1 RBD (B.1.1.7+E484K; P3)	Severe Acute Respiratory Syndrome Coronavirus 2 Receptor Binding Domain of the S1 subunit U.K. variant B.1.1.7+E484K lineage and Philippines variant P.3 lineage	R319-F541 of the SARS-CoV-2 Spike Sequence; C-terminal His-Tag
SARS-CoV-2 S1 RBD (B.1.214.2)	Severe Acute Respiratory Syndrome Coronavirus 2 Receptor Binding Domain of the S1 subunit Belgium variant B.1.214.2 lineage	R319-F541 of the SARS-CoV-2 Spike Sequence; C-terminal His-Tag
SARS-CoV-2 S1 RBD (B.1.258.17; B.1.466.2)	Severe Acute Respiratory Syndrome Coronavirus 2 Receptor Binding Domain of the S1 subunit Europe variant B.1.258.17 lineage and Indonesia variant B.1.466.2 lineage	R319-F541 of the SARS-CoV-2 Spike Sequence; C-terminal His-Tag
SARS-CoV-2 S1 RBD (B.1.351; B.1.351.1)	Severe Acute Respiratory Syndrome Coronavirus 2 Receptor Binding Domain of the S1 subunit Beta variant B.1.351 lineage and Botswana variant B.1.351.1 lineage	R319-F541 of the SARS-CoV-2 Spike Sequence; C-terminal His-Tag
SARS-CoV-2 S1 RBD (B.1.427; B.1.429; B.1.526.1)	Severe Acute Respiratory Syndrome Coronavirus 2 Receptor Binding Domain of the S1 subunit Epsilon variant B.1.427 and B.1.429 lineages, and New York variant B.1.526.1 lineage	R319-F541 of the SARS-CoV-2 Spike Sequence; C-terminal His-Tag; L452R
SARS-CoV-2 S1 RBD (B.1.525; B.1.526; B.1.618; P.2; R.1)	Severe Acute Respiratory Syndrome Coronavirus 2 Receptor Binding Domain of the S1 subunit Eta variant B.1.525 lineage, Iota variant B.1.526 lineage, India variant B.1.618 lineage, Zeta variant P.2 lineage, and Kentucky variant R.1 lineage	R319-F541 of the SARS-CoV-2 Spike Sequence; C-terminal His-Tag; E484K
SARS-CoV-2 S1 RBD (B.1.526.2)	Severe Acute Respiratory Syndrome Coronavirus 2 Receptor Binding Domain of the S1 subunit New York variant B.1.526.2 lineage	R319-F541 of the SARS-CoV-2 Spike Sequence; C-terminal His-Tag
SARS-CoV-2 S1 RBD (B.1.617; B.1.617.1; B.1.617.3)	Severe Acute Respiratory Syndrome Coronavirus 2 Receptor Binding Domain of the S1 subunit India variant B.1.617 and B.1.617.3 lineages, and Kappa variant B.1.617.1 lineage	R319-F541 of the SARS-CoV-2 Spike Sequence; C-terminal His-Tag
SARS-CoV-2 S1 RBD (B.1.620)	Severe Acute Respiratory Syndrome Coronavirus 2 Receptor Binding Domain of the S1 subunit Europe variant B.1.620 lineage	R319-F541 of the SARS-CoV-2 Spike Sequence; C-terminal His-Tag
SARS-CoV-2 S1 RBD (C.37)	Severe Acute Respiratory Syndrome Coronavirus 2 Receptor Binding Domain of the S1 subunit Lambda variant C.37 lineage	R319-F541 of the SARS-CoV-2 Spike Sequence; C-terminal His-Tag
SARS-CoV-2 S1 RBD (P.1)	Severe Acute Respiratory Syndrome Coronavirus 2 Receptor Binding Domain of the S1 subunit Gamma variant P.1 lineage	R319-F541 of the SARS-CoV-2 Spike Sequence; C-terminal His-Tag
SARS-CoV-2 S1 RBD (XBB.1)	Severe Acute Respiratory Syndrome Coronavirus 2 Receptor Binding Domain of the S1 subunit Omicron variant XBB.1 sublineage	R319-F541 of the SARS-CoV-2 Spike Sequence; C-terminal His-Tag
SARS-CoV-2 Spike (D614G)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein D614G	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (A.23.1)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Uganda variant A.23.1 lineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (A.VOI.V2)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Tanzania variant A variant of interest	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (AY.1)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Delta variant AY.1 sublineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (AY.1) Alt Seq 1	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Delta variant AY.1 sublineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag; Alt Seq 1
SARS-CoV-2 Spike (AY.2)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Delta variant AY.2 sublineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (AY.2) Alt Seq 1	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Delta variant AY.2 sublineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag; Alt Seq 1
SARS-CoV-2 Spike (AY.4.2)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Delta variant AY.4.2 sublineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (AY.12)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Delta variant AY.12 sublineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (BA.1+L452R)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Omicron variant BA.1+L452R sublineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (BA.1+R346K; BA.1.1; BA.1.1.15)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Omicron variant BA.1+R346K, BA.1.1, and BA.1.1.15 sublineages	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (BA.2; BA.2.1; BA.2.2; BA.2.3; BA.2.5; BA.2.6; BA.2.7; BA.2.8; BA.2.10; BA.2.12)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Omicron variant BA.2, BA.2.1, BA.2.2, BA.2.3, BA.2.5, BA.2.6, BA.2.7, BA.2.8, BA.2.10, and BA.2.12 sublineages	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (BA.2+L452M)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Omicron variant BA.2+L452M sublineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (BA.2+L452R)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Omicron variant BA.2+L452R sublineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag

Antigens	Antigen Description *	Antigen Modifications
SARS-CoV-2 Spike (BA.2.12.1)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Omicron variant BA.2.12.1 sublineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (BA.2.75)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Omicron variant BA.2.75 sublineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (BA.2.75.2)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Omicron variant BA.2.75.2 sublineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (BA.2.86)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Omicron variant BA.2.86 sublineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (BA.3)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Omicron variant BA.3 sublineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (BA.4)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Omicron variant BA.4 sublineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (BA.4.6)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Omicron variant BA.4.6 sublineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (BA.5)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Omicron variant BA.5 sublineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (BF.7)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Omicron variant BF.7 sublineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (BN.1)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Omicron variant BN.1 sublineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (BQ.1)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Omicron variant BQ.1 sublineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (BQ.1.1)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Omicron variant BQ.1.1 sublineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (BV-1)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Texas BV-1 variant	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (B.1.1.519)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Mexico/Texas BV-2 variant B.1.1.519 lineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (B.1.1.529; BA.1; BA.1.15)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Omicron variant B.1.1.529, BA.1, and BA.1.15 sublineages	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (B.1.1.7)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Alpha variant B.1.1.7 lineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (B.1.1.7+E484K)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein U.K. variant B.1.1.7+E484K lineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (B.1.258.17)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Europe variant B.1.258.17 lineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (B.1.351)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Beta variant B.1.351 lineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (B.1.351.1)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Botswana variant B.1.351.1 lineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (B.1.429)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Epsilon variant B.1.429 lineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (B.1.466.2)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Indonesia variant B.1.466.2 lineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (B.1.525)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Eta variant B.1.525 lineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (B.1.526)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Iota variant B.1.526 lineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (B.1.526.1)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein New York variant B.1.526.2 lineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (B.1.617)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein India variant B.1.617 lineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (B.1.617.1)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Kappa variant B.1.617.1 lineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (B.1.617.2)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Delta variant B.1.617.2 sublineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (B.1.617.2; AY.3; AY.5; AY.6; AY.7; AY.14) Alt Seq 1	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Delta variant B.1.617.2, AY.3, AY.5, AY.6, AY.7, and AY.14 sublineages	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag; Alt Seq 1

Antigens	Antigen Description *	Antigen Modifications
SARS-CoV-2 Spike (B.1.617.2 +1)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Delta +1 variant	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (B.1.617.2 +2)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Delta +2 variant	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (B.1.617.2 +3)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Delta +3 variant	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (B.1.617.2 +4)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Delta +4 variant	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (B.1.617.2; AY.4) Alt Seq 2	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Delta variant B.1.617.2 and AY.4 sublineages	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag; Alt Seq 2
SARS-CoV-2 Spike (B.1.617.2+ΔY144)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Vietnam variant B.1.617.2+ΔY144 lineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (B.1.617.3)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein India variant B.1.617.3 lineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (B.1.618)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein India variant B.1.618 lineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (B.1.620)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Europe variant B.1.620 lineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (B.1.621)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Mu variant B.1.621 lineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (B.1.640.2)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein France (IHU) variant B.1.640.2 lineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (C.37)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Lambda variant C.37 lineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (EG.5.1)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Omicron variant EG.5.1 sublineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (FL.1.5.1)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Omicron variant FL.1.5.1 sublineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (HV.1)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Omicron variant HV.1 sublineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (JD.1.1)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Omicron variant JD.1.1 sublineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (JN.1)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Omicron variant JN.1 sublineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (JN.1 (v2))	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Omicron variant JN.1 sublineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (KP.2)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Omicron variant KP.2 sublineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (KP.3)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Omicron variant KP.3 sublineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (LB.1)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Omicron variant LB.1 sublineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (P.1)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Gamma variant P.1 lineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (P.2)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Zeta variant P.2 lineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (P.3)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Philippines variant P.3 lineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (R.1)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Kentucky variant R.1 lineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (XBB.1)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Omicron variant XBB.1 sublineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (XBB.1.16)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Omicron variant XBB.1.16 sublineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (XBB.1.16.1)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Omicron variant XBB.1.16.1 sublineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (XBB.1.16.6)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Omicron variant XBB.1.16.6 sublineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag

Antigens	Antigen Description *	Antigen Modifications
SARS-CoV-2 Spike (XBB.1.5)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Omicron variant XBB.1.5 sublineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (XBB.1.5 (v2))	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Omicron variant XBB.1.5 sublineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-2 Spike (XBB.2.3)	Severe Acute Respiratory Syndrome Coronavirus 2 Spike Protein Omicron variant XBB.2.3 sublineage	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
SARS-CoV-1 Spike	Severe Acute Respiratory Syndrome Coronavirus 1 Spike Protein	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
MERS-CoV Spike	Middle East Respiratory Syndrome Coronavirus Spike Protein	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
HCoV-229E Spike	Human Coronavirus 229E Spike Protein	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
HCoV-HKU1 Spike	Human Coronavirus HKU1 Spike Protein	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
HCoV-NL63 Spike	Human Coronavirus NL63 Spike Protein	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
HCoV-OC43 Spike	Human Coronavirus OC43 Spike Protein	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
Flu A/Darwin/2021 H3	Influenza A Hemagglutinin Protein from A/Darwin/6/2021 (H3N2)	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
Flu A/Ghana/39/2021 H5	Influenza A Hemagglutinin Protein from A/Ghana/39/2021 (H5N1)	T replacing the furin cleavage site KRRK; T4 fibrin trimerization motif, TEV protease site
Flu A/Hong Kong/2014 H3	Influenza A Hemagglutinin Protein from A/Hong Kong/4801/2014 (H3N2)	Soluble ectodomain with T4 trimerization domain; C-terminal His-Tag
Flu A/Massachusetts/18/2022 H3	Influenza A Hemagglutinin Protein from A/Massachusetts/18/2022 (H3N2)	T4 fibrin trimerization motif, TEV protease site
Flu A/Michigan/2015 H1	Influenza A Hemagglutinin Protein from A/Michigan/45/2015 (H1N1)	Soluble ectodomain with T4 trimerization domain; C-terminal His-Tag
Flu A/Wisconsin/2019 H1	Influenza A Hemagglutinin Protein from A/Wisconsin/588/2019 (H1N1)	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
Flu A/Wisconsin/67/2022 H1	Influenza A Hemagglutinin Protein from A/Wisconsin/67/2022 (H1N1)	T4 fibrin trimerization motif, TEV protease site
Flu A/Shanghai/2013 H7	Influenza A Hemagglutinin Protein from A/Shanghai/2/2013 (H7N9)	Soluble ectodomain with T4 trimerization domain; C-terminal His-Tag
Flu B/Austria/2021 HA	Influenza B Hemagglutinin Protein from B/Austria/1359417/2021 (B Victoria Lineage)	Soluble ectodomain with T4 trimerization domain; C-terminal Strep-Tag and His-Tag
Flu B/Brisbane/2008 HA	Influenza B Hemagglutinin Protein from B/Brisbane/60/2008 (B Victoria Lineage)	Soluble ectodomain with T4 trimerization domain; C-terminal His-Tag
Flu B/Phuket/2013 HA	Influenza B Hemagglutinin Protein from B/Phuket/3073/2013 (B Yamagata Lineage)	Soluble ectodomain with T4 trimerization domain; C-terminal His-Tag
RSV Pre-Fusion F	Respiratory Syncytial Virus Pre-Fusion F Protein	Soluble ectodomain with T4 trimerization domain; C-terminal His-Tag and Strep-Tag

*EXPI293 cell line used as an expression system

Note: Alternative S-GENE mutations for Spike of AY.1, AY.2, and B.1.617.2 are listed as "Alt Seq #."

Catalog Numbers

Table 6. Catalog Number for V-PLEX COVID-19 Serology Kits

Kit Name	IgG		IgM		IgA	
	5-Plate Kit	25-Plate Kit	5-Plate Kit	25-Plate Kit	5-Plate Kit	25-Plate Kit
Multiplex Kits on the MULTI-SPOT 96-Well, 10-Spot plate						
V-PLEX SARS-CoV-2 Panel 1 Kit	K15359U-2	K15359U-4	K15360U-2	K15360U-4	K15361U-2	K15361U-4
V-PLEX SARS-CoV-2 Panel 2 Kit	K15383U-2	K15383U-4	K15384U-2	K15384U-4	K15385U-2	K15385U-4
V-PLEX SARS-CoV-2 Panel 5 Kit	K15429U-2	K15429U-4	K15430U-2	K15430U-4	K15431U-2	K15431U-4
V-PLEX SARS-CoV-2 Panel 6 Kit	K15433U-2	K15433U-4	K15434U-2	K15434U-4	K15435U-2	K15435U-4
V-PLEX SARS-CoV-2 Panel 7 Kit	K15437U-2	K15437U-4	K15438U-2	K15438U-4	K15439U-2	K15439U-4
V-PLEX SARS-CoV-2 Panel 8 Kit	K15444U-2	K15444U-4	K15445U-2	K15445U-4	K15446U-2	K15446U-4
V-PLEX SARS-CoV-2 Panel 9 Kit	K15448U-2	K15448U-4	K15449U-2	K15449U-4	K15450U-2	K15450U-4
V-PLEX SARS-CoV-2 Panel 11 Kit	K15455U-2	K15455U-4	K15456U-2	K15456U-4	K15457U-2	K15457U-4
V-PLEX SARS-CoV-2 Panel 12 Kit	K15459U-2	K15459U-4	K15460U-2	K15460U-4	K15461U-2	K15461U-4
V-PLEX SARS-CoV-2 Panel 13 Kit	K15463U-2	K15463U-4	K15464U-2	K15464U-4	K15465U-2	K15465U-4
V-PLEX SARS-CoV-2 Panel 14 Kit	K15468U-2	K15468U-4	K15469U-2	K15469U-4	K15470U-2	K15470U-4
V-PLEX SARS-CoV-2 Panel 15 Kit	K15499U-2	K15499U-4	K15500U-2	K15501U-4	K15501U-2	K15501U-4
V-PLEX SARS-CoV-2 Panel 16 Kit	K15516U-2	K15516U-4	K15517U-2	K15517U-4	K15518U-2	K15518U-4
V-PLEX SARS-CoV-2 Panel 17 Kit	K15524U-2	K15524U-4	K15525U-2	K15525U-4	K15526U-2	K15526U-4
V-PLEX SARS-CoV-2 Panel 18 Kit	K15532U-2	K15532U-4	K15533U-2	K15533U-4	K15534U-2	K15534U-4
V-PLEX SARS-CoV-2 Panel 19 Kit	K15540U-2	K15540U-4	K15541U-2	K15541U-4	K15542U-2	K15542U-4
V-PLEX SARS-CoV-2 Panel 20 Kit	K15551U-2	K15551U-4	K15552U-2	K15552U-4	K15553U-2	K15553U-4
V-PLEX SARS-CoV-2 Panel 22 Kit	K15559U-2	K15559U-4	K15560U-2	K15560U-4	K15561U-2	K15561U-4
V-PLEX SARS-CoV-2 Panel 23 Kit	K15567U-2	K15567U-4	K15568U-2	K15568U-4	K15569U-2	K15569U-4
V-PLEX SARS-CoV-2 Panel 24 Kit	K15575U-2	K15575U-4	K15576U-2	K15576U-4	K15577U-2	K15577U-4
V-PLEX SARS-CoV-2 Panel 25 Kit	K15583U-2	K15583U-4	K15584U-2	K15584U-4	K15585U-2	K15585U-4
V-PLEX SARS-CoV-2 Panel 26 Kit	K15593U-2	K15593U-4	K15594U-2	K15594U-4	K15595U-2	K15595U-4
V-PLEX SARS-CoV-2 Panel 27 Kit	K15606U-2	K15606U-4	K15607U-2	K15607U-4	K15608U-2	K15608U-4
V-PLEX SARS-CoV-2 Panel 28 Kit	K15614U-2	K15614U-4	K15615U-2	K15615U-4	K15616U-2	K15616U-4
V-PLEX SARS-CoV-2 Panel 29 Kit	K15624U-2	K15624U-4	K15625U-2	K15625U-4	K15626U-2	K15626U-4
V-PLEX SARS-CoV-2 Panel 30 Kit	K15632U-2	K15632U-4	K15633U-2	K15633U-4	K15634U-2	K15634U-4
V-PLEX SARS-CoV-2 Panel 31 Kit	K15642U-2	K15642U-4	K15643U-2	K15643U-4	K15644U-2	K15644U-4
V-PLEX SARS-CoV-2 Panel 32 Kit	K15668U-2	K15668U-4	K15669U-2	K15669U-4	K15670U-2	K15670U-4
V-PLEX SARS-CoV-2 Panel 33 Kit	K15676U-2	K15676U-4	K15677U-2	K15677U-4	K15678U-2	K15678U-4
V-PLEX SARS-CoV-2 Panel 34 Kit	K15690U-2	K15690U-4	K15691U-2	K15691U-4	-	-
V-PLEX SARS-CoV-2 Panel 36 Kit	K15715U-2	K15715U-4	-	-	-	-
V-PLEX SARS-CoV-2 Panel 37 Kit	K15721U-2	K15721U-4	-	-	-	-
V-PLEX SARS-CoV-2 Panel 38 Kit	K15725U-2	K15725U-4	-	-	K15726U-2	K15726U-4
V-PLEX SARS-CoV-2 Panel 39 Kit	K15738U-2	K15738U-4	-	-	K15739U-2	K15739U-4
V-PLEX SARS-CoV-2 Key Variant Spike Panel 1 Kit	K15651U-2	K15651U-4	K15652U-2	K15652U-4	K15653U-2	K15653U-4
V-PLEX SARS-CoV-2 Key Variant RBD Panel 1 Kit	K15659U-2	K15659U-4	K15660U-2	K15660U-4	K15661U-2	K15661U-4
V-PLEX COVID-19 Coronavirus Panel 1 Kit	K15362U-2	K15362U-4	K15363U-2	K15363U-4	K15364U-2	K15364U-4
V-PLEX COVID-19 Coronavirus Panel 2 Kit	K15369U-2	K15369U-4	K15370U-2	K15370U-4	K15371U-2	K15371U-4
V-PLEX COVID-19 Coronavirus Panel 3 Kit	K15399U-2	K15399U-4	K15400U-2	K15400U-4	K15401U-2	K15401U-4

Kit Name	IgG		IgM		IgA	
	5-Plate Kit	25-Plate Kit	5-Plate Kit	25-Plate Kit	5-Plate Kit	25-Plate Kit
Multiplex Kits on the MULTI-SPOT 96-Well, 10-Spot plate						
V-PLEX COVID-19 Respiratory Panel 2 Kit	K15372U-2	K15372U-4	K15373U-2	K15373U-4	K15374U-2	K15374U-4
V-PLEX COVID-19 Respiratory Panel 3 Kit	K15403U-2	K15403U-4	K15404U-2	K15404U-4	K15405U-2	K15405U-4
V-PLEX Respiratory Panel 1 Kit	K15365U-2	K15365U-4	K15366U-2	K15366U-4	K15367U-2	K15367U-4
V-PLEX Respiratory Panel 4 Kit	K15707U-2	K15707U-4	-	-	-	-
V-PLEX Respiratory Panel 7 Kit	K15735U-2	K15735U-4	-	-	K15736U-2	K15736U-4

Plate Diagram

