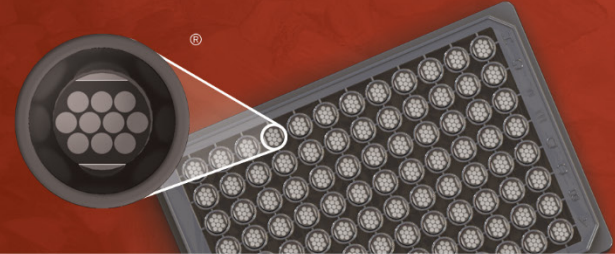


MSD™ Reference Standard 1



Ordering Information

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**For Research Use Only.
Not for use in diagnostic
procedures.**

Catalog Number	C00ADK-2
Contents	Reference Standard 1 (1 mL frozen liquid per vial)
Storage	≤-70 °C

Summary and Intended Use

Reference Standard 1 is a serum-based reagent for use as an assay calibrator in the V-PLEX® COVID-19 Serology Kits.

For assigned values for calibrators in MSD arbitrary units (AU/mL) and WHO international units (BAU/mL) refer to the V-PLEX COVID-19 Serology Kits product insert or Reference Standard 1 lot-specific certificate of analysis (COA).

Calibration

Reference Standard 1 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:

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

Lot numbers A00V004 and A0080270

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

Lot number A0080286

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

Storage and Handling

To maximize consistency in calibrator values across assay runs, the calibrator must be stored at the recommended temperature and handled according to the instructions provided herein. Stock calibrator is stable for 5 years from the date of manufacture when stored at ≤-70 °C. Thawed calibrator is stable through five freeze-thaw cycles. Excess diluted calibrator should be discarded after use.

We recommend a 7-point calibration curve with 4-fold serial dilution steps and a zero calibrator blank. Thaw the stock calibrator on ice, equilibrate to room temperature and then add to the assay diluent to make the calibrator curve solutions.

Refer to the assay-specific product insert for calibrator preparation and instruction for use.

The 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/Y² 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 samples and controls are determined from their ECL signals by backfitting to the calibration curve. Correcting for dilution then provides the final sample concentrations in AU/mL.

Safety

Reference Standard 1 contains human serum and is a biosafety level 2 (BSL-2) product. 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 lab coats when handling calibrators. 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 safety data sheet (SDS), which can be obtained from MSD Customer Service or at www.mesoscale.com.

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