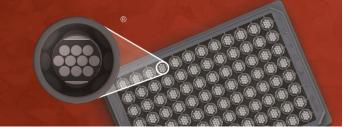
MSD® Reference Standard 2



Ordering Information

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Scientific Support

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

Catalog Number	C00AUB-2
Contents	Reference Standard 2 (1 mL frozen liquid per vial)
Storage	≤-70 °C

Summary and Intended Use

MESO SCALE DISCOVERY® Reference Standard 2 is a serum-based reagent for use as an assay calibrator in V-PLEX® COVID-19 Serology and V-PLEX Respiratory Panel Kits. Assigned values are provided for measurement of IgG and IgA antibodies to different antigens in the V-PLEX Kits. For the assigned values in arbitrary units (AU/mL) for Reference Standard 2, please refer to the V-PLEX COVID-19 Serology Kits product insert or Reference Standard 2 lot-specific certificate of analysis (COA).

Calibration

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

WHO/NIBSC Units (BAU/mL) = MSD Units (AU/mL) x conversion factor

Lot number A0080403

	IgG			lgA		
Antigen	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	1,270	11.4	0.00901	227	14.1	0.0619

Table 1: IgG and IgA concentrations in Reference Standard 2 lot A0080403 for SARS-CoV-2 Nucleocapsid and Spike antigens.

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 10 years from the date of manufacture when stored at \leq -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.

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 $1/Y^2$ 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 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 2 contains human serum and is a biosafety level 2 (BSL-2) product. Samples 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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