

SARS-CoV-2 Total Antibody Assay*

Dimension Vista and
Dimension EXL Analyzers

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The COVID-19 pandemic has profoundly disrupted the world and tools that can help address the full spectrum of challenges to help secure communities and combat this pandemic are needed. Testing large numbers of individuals for immune response/antibody status against the SARS-CoV-2 virus is likely to be critical for re-opening society, as well as for managing the potential threat of a second wave of infections and for vaccine assessment.

*This test has not been FDA cleared or approved. This test has been authorized by FDA under an EUA for use by authorized laboratories. This test has been authorized only for detecting the presence of antibodies against SARS-CoV-2, not for any other viruses or pathogens. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner. Product availability may vary by country and is subject to regulatory requirements.

SARS-CoV-2 Total Antibody Assay

Clinical Utility

The presence of antibodies to SARS-CoV-2 indicates that the patient, whether symptomatic or asymptomatic, had an immune response to the virus. Total antibody tests detect both IgG and IgM in the blood to provide a clearer disease-state picture. These assays are more sensitive than the use of IgG or IgM alone for early detection of an immune response.¹ The U.S. Centers for Disease Control and Prevention (CDC) states that testing for total immunoglobulin may increase sensitivity for identifying people who have been recently infected.² These assays play an important role throughout the patient care pathway and are vital for the management and surveillance of the virus.

The Dimension® EXL™ and Dimension Vista® SARS-CoV-2 Total antibody assay is for in vitro diagnostic use in the qualitative detection of total antibodies (including IgG and IgM) to SARS-CoV-2 virus in human serum and plasma (EDTA, lithium heparin) using the Dimension® EXL™ integrated chemistry system with LOCI® Module and the Dimension Vista® System.

SARS-CoV-2 Total Antibody Assay Benefits

- Simplified identification of immune response with a total assay versus IgG or IgM only assay.
- Smart selection of the S1RBD antigen to detect antibodies that block the virus entry into cells.
- Reliable and rapid SARS-CoV-2 antibody testing on a large scale for both reference labs and acute care settings.

Assay Characteristics

Item	Description
Time to First Result	16 minutes
Sample Type	Serum and plasma (EDTA and lithium heparin)
Sample Volume	10 µL
Calibration Interval	7 days
Reagent On-board Stability	14 days
Measuring interval	0–2000 QUAL units reported as positive or negative
Clinical Specificity (Negative Percent Agreement)	Dimension Vista: 99.80%; Dimension EXL: 99.87%
Cut Off	1000 QUAL units. ≥1000 is positive, <1000 is negative

Dimension EXL Clinical Sensitivity (Positive Percent Agreement)

Days Post PCR Positive	Number Tested	Positive	Negative	Positive Percent Agreement	95% Confidence Interval
0–6	96	66	30	68.75%	59.65%–77.15%
7–13	38	37	1	97.37%	94.72%–99.53%
≥14	72	72	0	100.00%	95.83%–100.00%

Dimension Vista Clinical Sensitivity (Positive Percent Agreement)

Days Post PCR Positive	Number Tested	Positive	Negative	Positive Percent Agreement	95% Confidence Interval
0–6	96	64	32	66.67%	57.32%–75.29%
7–13	38	37	1	97.37%	94.72%–99.53%
≥14	72	72	0	100.00%	95.83%–100.00%

SARS-CoV-2 Total Antibody Assay Ordering Information

Product Name	Product Description	Siemens Material Number (SMN)/ Catalogue Number
Dimension Vista COV2T Assay	• 1 Flex Reagent Cartridge Test Carton (240 tests/carton, 4 flex/ctn 60 tests/Flex, 2 well sets)	11417414/K7414
Dimension EXL CV2T Assay	• 1 Flex Reagent Cartridge Test Carton (320 tests/carton, 8 flex/ctn, 40 tests /Flex, 2 well sets)	11417412/RF812
DV/DM COV2T/CV2T CAL	• COV2T/CV2T Low and High Calibrators (3 sets/6 vials, 3 of Level 1/A and 3 of level 2/B, 1.0 mL/vial)	11417413/KC813
DV/DM COV2T/CV2T POS/NEG CTRL	• 6 x 1.0 mL negative quality control • 6 x 1.0 mL positive quality control	11417415/KC815

At Siemens Healthineers, our purpose is to enable healthcare providers to increase value by empowering them on their journey toward expanding precision medicine, transforming care delivery, and improving patient experience, all made possible by digitalizing healthcare.

An estimated 5 million patients globally benefit every day from our innovative technologies and services in the areas of diagnostic and therapeutic imaging, laboratory diagnostics, and molecular medicine, as well as digital health and enterprise services.

We are a leading medical technology company with over 120 years of experience and 18,000 patents globally. Through the dedication of more than 50,000 colleagues in 75 countries, we will continue to innovate and shape the future of healthcare.

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Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

References:

1. Zhao J, et al. Antibody responses to SARS-CoV-2 in patients of novel coronavirus disease 2019. *Clinical Infectious Diseases*. 2020 Mar 28. doi: 10.1093/cid/cia344.
2. <https://www.cdc.gov/coronavirus/2019-ncov/lab/testing-laboratories.html#For-All-Laboratories:-Serology>. Accessed April 29, 2020.

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