SARS-CoV-2 Total Assay*

Atellica IM Analyzer and
ADVIA Centaur XP/XPT
Immunoassay System

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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.

For use outside the U.S.

**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.*

SIEMENS Healthineers

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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 Siemens Healthineers SARS-CoV-2 Total (COV2T) assay is for in vitro diagnostic use in the qualitative detection of total antibodies (including IgG and IgM) to SARS-CoV-2 in human serum and plasma (EDTA and lithium heparin) using the Atellica® IM Analyzer, ADVIA Centaur® XP and ADVIA Centaur® XPT Immunoassay Systems.

This assay is intended as an aid in the diagnosis of patients with suspected SARS-CoV-2 infection and as an aid in identifying patients with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection.

Cross-reactivity was determined in accordance with CLSI Document EP07-ed3.[3] The assay was evaluated for potential cross-reactivity in specimens with other viral and microbial antibodies and other disease states. Out of the specimens tested, none were found to cross react with the COV2T assay.

COV2T 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

System	Sample Types	Sample Volume	Calibration Interval	Cutoff (Index)	Measuring Interval (Index)	Onboard Stability	Clinical Specificity	Time to First Result
Atellica IM Analyzer	Serum, plasma (EDTA, lithium heparin)	50 µL	Lot: 28 days Pack: 14 days	<1.0 nonreactive ≥1.0 reactive	0.05–10.0	28 days	99.82%	10 min
ADVIA Centaur XP/XPT Systems	Serum, plasma (EDTA, lithium heparin)	50 µL	14 days	<1.0 nonreactive ≥1.0 reactive	0.05–10.0	28 days	99.81%	18 min

Clinical Sensitivity

System	Samples Tested	Days Post PCR Positive	Number Tested	Reactive	Nonreactive	Clinical Sensitivity	95% Confidence Interval
Atellica IM Analyzer	250	0–6	89	54	35	60.67%	49.75%–70.87%
		7–13	119	116	3	97.48%	92.81%–99.48%
		≥14	42	42	0	100.00%	91.59%–100.00%
ADVIA Centaur XP/XPT Systems	262	0–6	95	58	37	61.05%	50.50%–70.89%
		7–13	120	117	3	97.50%	92.87%–99.48%
		≥14	47	47	0	100.00%	92.45%–100.00%

Atellica IM COV2T Assay Ordering Information

Catalog No.	Contents	Quantity
11206711	1 Atellica IM COV2T ReadyPack® primary reagent pack 1 vial Atellica IM COV2T CAL low calibrator (CAL L), 1.0 mL per vial 1 vial Atellica IM COV2T CAL high calibrator (CAL H), 1.0mL per vial	100 tests
11206923	5 Atellica IM COV2T ReadyPack primary reagent packs, 2 vials Atellica IM COV2T CAL low calibrator (CAL L), 1.0 mL per vial 2 vials Atellica IM COV2T CAL high calibrator (CAL H), 1.0 mL per vial	500 tests
11206712	Atellica IM QC Kit: 2 vials x 2.0 mL negative control, 2 vials x 2.0 mL positive control	1 set with 4 vials total

ADVIA Centaur COV2T Assay Ordering Information

Catalog No.	Contents	Quantity
11206710	1 ReadyPack primary reagent pack 1 vial of ADVIA Centaur COV2T low calibrator (CAL L), 1.0 mL per vial 1 vial of ADVIA Centaur COV2T high calibrator (CAL H), 1.0 mL per vial ADVIA Centaur COV2T master curve card ADVIA Centaur COV2T calibrator assigned value sheet and bar-code labels	100 tests
11206922	5 ReadyPack primary reagent packs 2 vials of ADVIA Centaur COV2T low calibrator (CAL L), 1.0 mL per vial 2 vials of ADVIA Centaur COV2T high calibrator (CAL H), 1.0 mL per vial ADVIA Centaur COV2T master curve card ADVIA Centaur COV2T calibrator assigned value sheet and bar-code labels	500 tests
11206713	ADVIA Centaur QC Kit: 2 vials x 2.0 mL negative control, 2 vials x 2.0 mL positive control	1 set with 4 vials total

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.

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/ciaa344.
2. https://www.cdc.gov/coronavirus/2019-ncov/lab/testing-laboratories.html#For-All-Laboratories:-Serology. Accessed April 29, 2020.
3. Clinical and Laboratory Standards Institute. Interference Testing in Clinical Chemistry; Approved Guideline—Third Edition. Wayne, PA: Clinical and Laboratory Standards Institute; 2018. CLSI Document EP07-ed.

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