SARS-CoV-2 IgG

DIAGNOSTICS

Abbott partners in the COVID-19 crisis by quickly bringing an assay for the specific detection of SARS-CoV-2 IgG antibody. The test is designed by trusted and leading Abbott scientists and manufactured in volumes required to support the urgent needs of ongoing patient care.

INTENDED USE[1,2]

The SARS-CoV-2 IgG assay is a chemiluminescent microparticle immunoassay (CMIA) intended for the qualitative detection of IgG antibodies to SARS-CoV-2 in human serum, serum separator tube and plasma (ACD, CPD, CPDA-1, dipotassium EDTA, tripotassium EDTA, lithium heparin, lithium heparin separator tube, sodium citrate, sodium heparin). The SARS-CoV-2 IgG assay is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. The SARS-CoV-2 IgG assay should not be used to diagnose acute SARS-CoV-2 infection. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, 42 U.S.C. § 263a, to perform moderate or high complexity tests.

Results are for the detection of SARS CoV-2 antibodies. IgG antibodies to SARS-CoV-2 are generally detectable in the blood several days after initial infection, although the duration of time antibodies are present post-infection is not well characterized. Individuals may have detectable virus present for several weeks following seroconversion.

Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

The sensitivity of SARS-CoV-2 IgG early after infection is unknown. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.

False-positive results for SARS-CoV-2 IgG assay may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

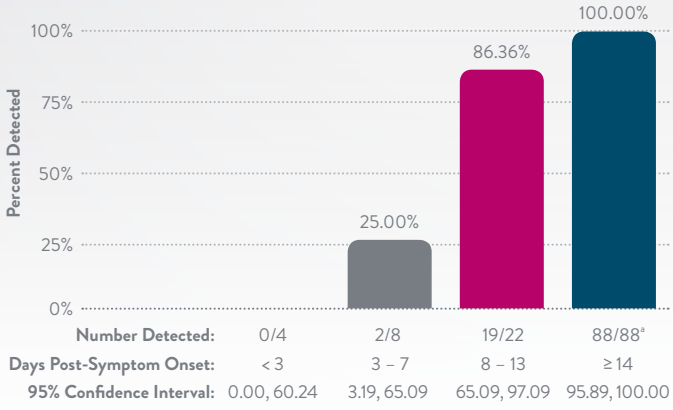
The SARS-CoV-2 IgG assay is only for use under the Food and Drug Administration's Emergency Use Authorization.

See reverse for important safety information.

CLINICAL PERFORMANCE[1,2]

PERCENTAGE OF POSITIVE PATIENTS DETECTED BY TIME POST-SYMPTOM ONSET

Excluding Immunocompromised Specimens
Instrument: ARCHITECT *i*2000SR



NEGATIVE AGREEMENT BY CATEGORY

CATEGORY	N	POSITIVE	NEGATIVE	NPA (95%)
Pre-COVID-19 Outbreak	997	4	993	99.60% (98.98, 99.89)
Other Respiratory Illness	73	0	73	100.00% (95.07, 100.00)
Total	**1,070**	**4**	**1,066**	**99.63% (99.05, 99.90)**

The positive agreement between the ARCHITECT *i*2000SR and the Alinity i was 100% and the negative agreement was 99.00%.

[a]Five specimens from 1 immunocompromised patient were excluded from the study. Refer to the LIMITATIONS OF THE PROCEDURE section of the package insert for further information. When the results from these specimens were included, the PPA at ≥ 14 days post-symptom onset was 96.77% (95% CI: 90.86, 99.33).

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SPECIFICATIONS

	ARCHITECT SARS-CoV-2 IgG[1,3]	Alinity SARS-CoV-2 IgG[2,4]
Methodology	Qualitative 2-step chemiluminescent microparticle immunoassay (CMIA)	
Time to First Result	29 minutes	
Throughput	Up to 200 tests/hour on *i*2000SR Up to 100 tests/hour on *i*1000SR	Up to 200 tests/hour
Result Interpretation Index (Sample/Calibration)	< 1.4 – Negative ≥ 1.4 – Positive	
Precision (Within-Laboratory)	Positive Panel: 1.9% CV	Positive Panel: 1.7% CV
Specimen Volume	Priority: 75 µL; Routine: 150 µL 25 µL for each additional test	
Specimen Type	Human serum, serum separator tube, and human plasma (ACD, CPD, CPDA-1, dipotassium EDTA, tripotassium EDTA, lithium heparin, lithium heparin separator tube, sodium citrate, sodium heparin)	
Specimen Storage	Room temperature (15 to 30°C) – 2 days maximum storage time 2 to 8°C – 7 days maximum storage time	
Reagent Storage	Opened/Unopened: 2 to 8°C – until expiration Onboard: System Temperature – 7 days maximum storage time	

ORDERING INFORMATION

	PRODUCT NAME	CONFIGURATION	LIST NUMBER
ARCHITECT	SARS-CoV-2 IgG Reagent Kit	100 Test Kits	06R86-20
		500 Test Kits	06R86-30
	SARS-CoV-2 IgG Calibrator Kit	1 Vial x 1 Level	06R86-01
	SARS-CoV-2 IgG Control Kit	1 Vial Each, Positive and Negative	06R86-10
Alinity i	SARS-CoV-2 IgG Reagent Kit	200 (100 x 2) Test Kits	06R90-20
		1,000 (500 x 2) Test Kits	06R90-30
	SARS-CoV-2 IgG Calibrator Kit	1 Vial x 1 Level	06R90-01
	SARS-CoV-2 IgG Control Kit	1 Vial Each, Positive and Negative	06R90-10

ARCHITECT and Alinity i SARS-CoV-2 IgG instructions for use, e-Assay files, and fact sheets are available on www.corelaboratory.abbott

IMPORTANT SAFETY INFORMATION[1,2]

- For *In Vitro* Diagnostic Use Only.
- Instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from these instructions.
- For laboratory professional use only.

For use under an Emergency Use Authorization (EUA) Only:

- Prescription Use Only.
- This test has not been FDA cleared or approved.
- This test has been authorized by FDA under EUA for use by authorized laboratories.
- This test has been authorized only for the detection of IgG 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.

REFERENCES
1. Abbott ARCHITECT SARS-CoV-2 IgG Instructions for Use. H14806R01.
2. Abbott Alinity i SARS-CoV-2 IgG Instructions for Use. H14814R01.
3. ARCHITECT Systems Operations Manual. 96211-118.
4. Alinity Systems Operations Manual. 80000071-105.

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