Platelia SARS-CoV-2 Total Ab Assay

Immunoassay to test for total anti-nucleocapsid antibodies (IgM, IgA, IgG) to coronavirus SARS-CoV-2

**Total Antibody Solution for COVID-19**

**Platelia SARS-CoV-2 Total Ab Assay**

**Total Antibody Detection in One Test**

The Platelia SARS-CoV-2 Total Ab assay detects total anti-nucleocapsid antibodies IgM, IgA and IgG against coronavirus SARS-CoV-2, the virus associated with COVID-19. This serological assay enables clinicians to identify individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection, and complements Bio-Rad’s extensive portfolio of COVID-19 solutions.

**Identify Immune Response to SARS-CoV-2**

The Platelia SARS-CoV-2 Total Ab assay detects total antibodies against SARS-CoV-2 to help identify people who may have been infected with the SARS-CoV-2 virus or have recovered from COVID-19 infection.

**Total Antibody Detection**

The Total Ab immunoassay format is based on the detection of total antibodies – IgM, IgA and IgG – against the nucleocapsid protein (N) of SARS-CoV-2, all in just one test.

The antibodies IgM and IgA are detectable in the case of acute SARS-CoV-2 infection while IgG is detectable in the recovery phase or post infection. Combining the results from these phases delivers a Total Antibody positive result.

**Antibody Detection Over the Course of Viral Infection**

![Antibody Detection Over the Course of Viral Infection](image)

Disclaimer: This serological profile represents well-known infections associated with other viruses. At this time, it is unknown how long SARS-CoV-2 antibodies persist following infection.
Why Target the Nucleocapsid Protein?

The Nucleocapsid protein (N-protein) is the most abundant coronavirus SARS-CoV-2 protein and is a significant marker for serological testing assays. Studies in 2020 show that anti-nucleocapsid antibodies (IgM and IgG) can be produced at higher levels and detected very early in the acute infection in comparison to anti-spike antibodies.\(^5\,^6\)

In addition, ELISA detection of anti-nucleocapsid antibodies is associated with higher sensitivity by comparison to anti-spike antibody detection.\(^1\,^4\)

The Value of Total Ab Detection Including IgA

Following SARS-CoV-2 infection, IgA and IgM are produced first, while IgG antibodies are detectable later. In a study by Guo et al., 2020, the median time to detect IgM and IgA antibodies was 5 days and to detect IgG was 14 days after symptom onset. The data suggests that IgA detection is associated with better sensitivity, by comparison to notably, IgM detection alone.

"IgA antibodies could be valuable diagnostic markers that show strong signals early after onset of mild COVID-19 associated symptoms."
– Dahike et al., 2020
Testing on the System of Your Choice
The Platelia SARS-CoV-2 Total Ab is designed as an open mode protocol, and is recommended for use on the EVOLIS System and manual platform system (PR4100/PW41/IPS). However, the assay can easily be run on other validated automated and manual systems.

Secure Processing
Full results traceability and high safety standards for reliable sample processing.

Automated, High-Throughput EVOLIS Immunoassay System
Automated, high-throughput processing, and validated for Platelia SARS-CoV-2 Total Ab assay testing.

A Complete COVID-19 Offer
We make the tools. You'll win the fight.
Diagnosis | Confirmation | Antibody Detection | Therapies
As a leader and contributor in the fight against COVID-19, Bio-Rad offers this Total Antibody assay to complement our other SARS-CoV-2 testing and research solutions which include:
- Real-Time PCR instruments and reagents
- SARS-CoV-2 standards
- Droplet Digital PCR instruments and reagents
- SARS-CoV-2 ddPCR kit (FDA EUA)
Platelia SARS-CoV-2 Total Ab Assay Performance

Performance You Expect

Confidence in results that are true negative or true positive is what clinicians and the world seek. In clinical tests, the Bio-Rad Platelia SARS-CoV-2 Total Ab test demonstrated >99% specificity for SARS-CoV-2 while showing no cross-reactivity to non-SARS coronaviruses or other medical conditions. In a study of PCR-positive patients, the assay detected antibodies in 100% of patients that were collected and tested between 9 and 22 days after onset of symptoms.

High Specificity
>99%
Testing of 600 specimens
(Blood donors and hospitalized patients)

No Cross-Reactivity
Testing of 168 specimens
(Specimens positive for the 4 most common coronaviruses, EBV, CMV, RSV, flu vaccine and upwards of 25 other medical conditions)

High Sensitivity
Overall sensitivity: 98%
≤8 days: 92%
>8 days: 100%
Testing* of 50 patients

*Post onset of symptoms

Comparison of Platelia SARS-CoV-2 Total Ab Assay and Concurrent Assays

Longitudinal case study of one positive patient

With Total Antibody detection, the Platelia SARS-CoV-2 Total Ab assay is associated with earlier detection of seroconversion and consistent detection of the patient’s adaptive immune response over time. With one result, the Platelia SARS-CoV-2 Total Ab assay reliably detects patients that have been exposed to SARS-CoV-2.

Distribution of Negative Test Ratios

500 negative blood donor specimens screened with the SARS-CoV-2 Total Ab assay (specificity: 99.6%)

When negative specimens are tested with the Platelia SARS-CoV-2 Total Ab assay, strongly negative values are obtained. The high discrimination between negative and positive values is associated with accuracy and reliability of the results.
Platelia SARS-CoV-2 Total Ab Assay

The Platelia SARS-CoV-2 Total Ab assay uses a 1-step antigen capture format requiring 90 minutes incubation time. The kit features 96-well breakable testing strips with ready-to-use reagents and visual control of sample dilution and reagent addition.

Sandwich ELISA Procedure

The Platelia SARS-CoV-2 Total Ab assay uses a sandwich format to "capture" the target nucleocapsid antibodies – IgM, IgA, or IgG – between two complementary proteins.

FDA Emergency Use Authorization

This test has been authorized by the FDA under an EUA for use by authorized laboratories. The test has not been FDA cleared or approved. The test has been authorized only for the presence of total antibodies against SARS-CoV-2, not for any other viruses or pathogens. The 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

4. Okba, NMA et al. (2020). Severe Acute Respiratory Syndrome Coronavirus 2 – Specific Antibody Responses in Coronavirus Disease Patients. Emerging Infectious Diseases, 26(7), 1478-1488. Advance online publication. https://dx.doi.org/10.3201/eid2607.200841

Ordering Information

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