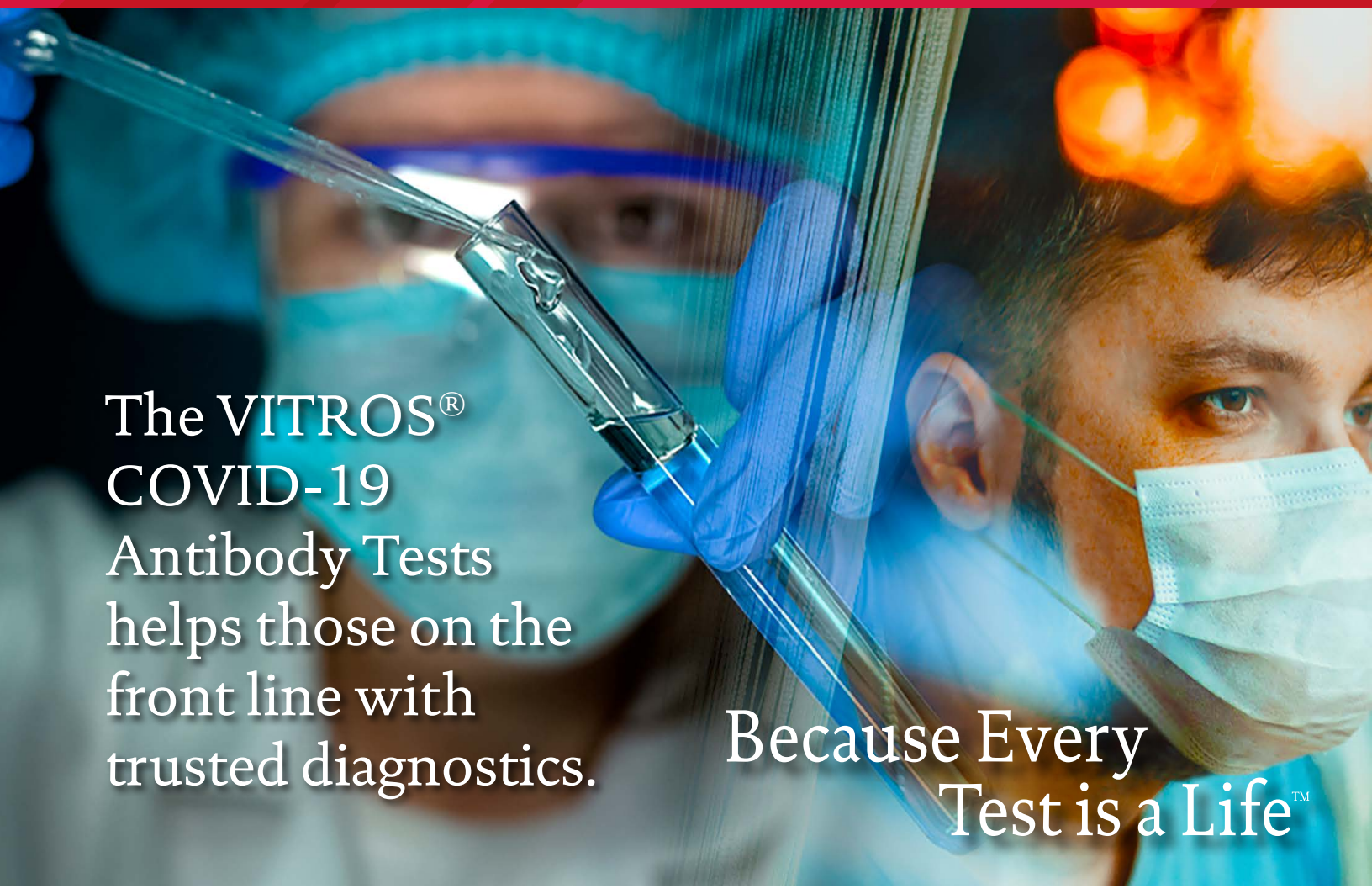


1. What testing options are available for diagnosing COVID-19 and how do they work?

There are two main types of COVID-19 testing today: (1) molecular diagnostics and (2) serology antibody testing. Since these tests have utility during different phases of infection, both are useful in understanding scope and spread of the outbreak.

- Molecular diagnostics (rRT-PCR), is the current gold standard for diagnosing suspected cases of COVID-19. rRT-PCR is a nucleic acid amplification test that detect unique sequences of the virus that causes COVID-19 in respiratory specimens through nasopharyngeal swabs. These tests have sensitivity in the range of 55-85% due to collection errors, test timing after symptom onset and others[1].

- Serology antibody testing, measured with a blood sample, detects antibodies developed by the immune system in response to a pathogen, in this case a virus.

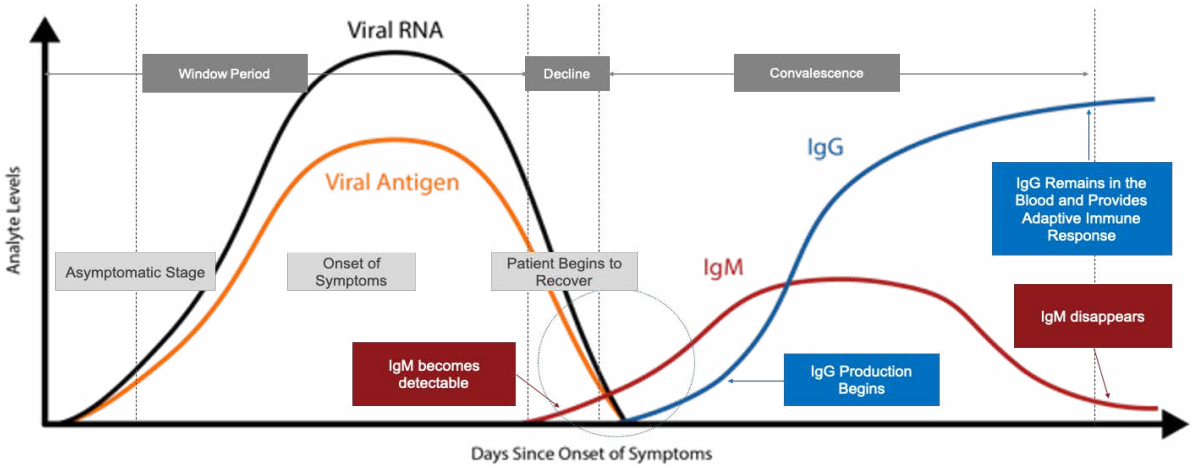
2. How soon can antibodies for COVID-19 be detected?

The availability of antibody seroconversion data for SARS-CoV-2 has not yet been established, but new data is rapidly emerging as new research is made available.

In general, the IgM antibody is a valuable diagnostic marker for infectious disease because it is usually the first immunoglobulin made following antigen exposure and is relatively short-lived[2].

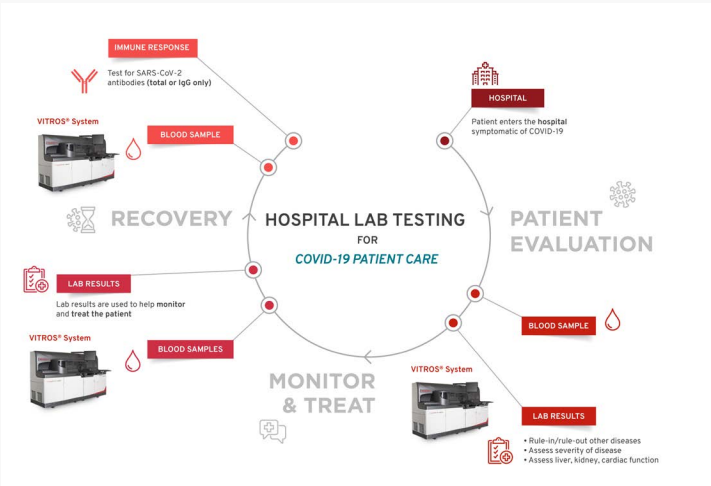
The IgG antibody is the most abundant class of antibody, consisting of approximately 80% of all antibodies in serum. IgG antibodies are produced slowly upon primary exposure to an antigen and then produced rapidly under secondary or subsequent exposure as a part of an "adaptive" immune response, becoming the major antibody present. The ability of the immune system to "adapt" to the foreign substance and create memory against the same antigen is known as immunological memory. This memory allows the body to more quickly and efficiently react to the pathogen in the future[2].

Estimate of general biomarker levels during the typical time-course of COVID-19/SARS-CoV-2 infection[3].



3. What are the clinical applications for antibody testing?

Serology tests play a critical role in managing the COVID-19 pandemic. They can determine whether individuals exposed to the virus have developed an immune response. Antibody tests can identify individuals with resolved infections, including those that were mild or asymptomatic, in order to understand the prevalence of the COVID-19 disease within a population.



4. What is the importance of specificity for antibody testing as it relates to COVID-19?

While both sensitivity and specificity are important, a COVID-19 antibody test needs to be accurate so that antibodies to other diseases like the common cold cannot be mistaken for antibodies to COVID-19. High specificity (100%) helps ensure the lowest possible risks of "false-positives"—that the test will not become reactive to any other antibody.

The ability to more accurately assess those with antibodies helps inform public health decisions by allowing for accurate surveillance of the disease prevalence within a population. In addition, understanding how long antibodies to SARS-CoV-2 remain in the body help researchers determine the relationship between immune response and immunity to the virus.

The VITROS COVID-19 assays target the Spike (S1) protein of the SARS-CoV-2 virus. During assay development, Ortho examined the use of multiple proteins for the VITROS Anti-SARS-CoV-2 assays. S1 was chosen due to its higher uniqueness compared to other virus proteins (Nucleocapsid Protein, S2 protein), and its superior performance in comparison with all other viral proteins as tested in Ortho's R&D studies.

5. What is the importance of sensitivity and how does it relate to positive percent agreement for COVID-19?

The sensitivity of a clinical test refers to the ability of the test to correctly identify those patients with the disease, necessary to contain the disease and prevent it's spread.

For US FDA EUA filing, FDA required comparisons to PCR since there is no other equivalent method to compare or confirm the accuracy of the VITROS® assay. PCR detects viral RNA, since RNA appears earlier than antibody, not all PCR positive samples contain detectable antibody. In the absence of a perfect reference standard, the performance of a test evaluated against an imperfect reference standard is expressed as positive percent agreement (PPA).

6. What is the difference between tests operating under FDA Emergency Use Notification (EUN) and those which have received FDA Emergency Use Authorization (EUA)?

- Emergency Use Notification is an FDA policy that allows manufacturers who have validated their test and provided notification to the FDA via email to begin distribution. These manufacturers then have 10 business days to submit an application for Emergency Use Authorization. If the FDA fails to authorize the EUA, the product must be pulled from the market. Under EUN, tests can only be run by labs licensed by CLIA to analyze high complexity tests.

- Once a manufacturer submits their application for Emergency Use Authorization, the FDA will then review the data for the claims submitted and, if approved, will issue an EUA number and post it on their website. Under EUA, tests can be run by moderate or high complexity CLIA labs.

Ortho Clinical Diagnostics was the first manufacturer to receive FDA Emergency Use Authorization for both COVID-19 Total & IgG Antibody Tests. You can view more information on FDA testing by clicking here.

7. How do I decide which antibody test is right for my lab?

Every hospital is responding to the unique needs of the communities they serve. Both of Ortho's COVID-19 Antibody tests have demonstrated excellent assay performance, so whether you choose one or both assays, we recommend basing your decision on your unique goals and strategy to address the pandemic in your community. Below are the key differentiators for Ortho's COVID Total and IgG Antibody Tests:

The Total Antibody test detects all (IgG, IgM, IgA and other isotypes) antibodies to the virus, including those that present during acute infection and those that present later in the immune response cycle, however the test does not differentiate between these antibodies. The Total Antibody test can help inform patient management decisions by aiding in the diagnosis of acute or recent infection in patients suspected of COVID-19.

The IgG Antibody test detects only the IgG antibody which becomes present weeks after infection. This assay can help with viral tracking and surveillance in addition to supporting back to work objectives by helping to identify an adaptive immune response in recent or prior infections.

8. Do I need to have a VITROS® analyzer in order to run the VITROS® Total and IgG Antibody Tests?

Yes, VITROS® Anti-SARS-CoV-2 Total and IgG Assays are designed to run on all Microwell enabled systems in addition to VITROS Automation Solutions.

- VITROS Automation Solutions
- VITROS XT 7600 Integrated System
- VITROS 5600 Integrated System
- VITROS XT 3600 Immunodiagnostic System
- VITROS ECiQ Immunodiagnostic System*

*Pending Availability

9. Where can I get more information on Ortho's COVID-19 Antibody Testing?

To find additional information on Ortho's COVID-19 Antibody Tests, you can visit our website here or you can view IFU information by clicking on the following links:

VITROS® Anti-SARS-CoV-2 Total

VITROS Anti-SARS-CoV-2 Total Instructions For Use

Fact Sheet for Healthcare Providers

Fact Sheet for Patients

VITROS® Anti-SARS-CoV-2 IgG

VITROS Anti-SARS-CoV-2 IgG Instructions For Use

Fact sheet for Healthcare Providers

Fact Sheet for Patients

Questions from laboratories, healthcare providers, government, or media regarding the COVID-19 antibody test can contact us direcly by providing your information here.

VITROS® Anti-SARS-CoV-2 Total and VITROS® Anti-SARS-CoV-2 IgG Assays

- Ortho Clinical Diagnostics ("Ortho") has received Emergency Use Authorization from the FDA for both VITROS® Total and IgG Immunodiagnostic Products Anti-SARS-CoV-2 Reagent Pack and Calibrators
- Ortho's antibody tests are serology (blood-based) tests that detects antibodies to SARS-CoV-2. The tests will identify patients who have contracted COVID-19 and developed an immune response.
- Both of Ortho's COVID-19 antibody tests demonstrated 100% specificity and are among the first to receive Emergency Use Authorization by the FDA. Ortho's COVID-19 antibody tests are run on VITROS analyzers which are random-access high-throughput, fully-automated instruments.
- Ortho's Total Antibody test can be used to aid in the diagnosis of patients with suspected SARS-CoV-2 infection. Ortho's IgG Antibody Test for COVID-19 is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection.
- For the Hospital Labs, Reference Labs, Public Health labs, Blood Centers and Medical Professionals looking to better understand the COVID-19 disease progression, Ortho's total antibody test for COVID-19 aids in evaluating acquired immunity in patients. These may also help provide robust data that will help inform in guiding us all on what is the best protocol to apply this new tool in the coronavirus pandemic and how it can ultimately support decisions for getting people back to work.

1. "IFCC Information Guide on COVID-19 - Monday 4 May Updates." IFCC, 4 May 2020, www.ifcc.org/ifcc-news/2020-03-26-ifcc-information-guide-on-covid-19/.
2. "Principles of Immunology." BC Centre for Disease Control, Chapter 2, Appendix F Immunization, Sept. 2009
3. TheNativeAntigenCompany.com: Data from Liu et al. and Li et al

EUA Disclaimer:
The VITROS Anti-SARS-CoV-2 Total and IgG tests have not been FDA cleared or approved. They have been authorized by the FDA under an emergency use authorization and testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate or high complexity tests. The VITROS Antibody tests have been authorized only for the detection of either Total or IgG antibodies from SARS-CoV-2, not for any other viruses or pathogens, and results should not be used as the sole basis for diagnosis. These tests are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests 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.

Fact sheet for Healthcare Providers and Patients available at www.orthoclinicaldiagnostics.com