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Ortho launches two COVID-19 Antibody tests

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Being 100% specificity-compliant, Ortho's VITROS® Anti-SARS-CoV-2 Total and IgG tests can help to identify, with great confidence, previously exposed individuals who have developed antibodies to SARS-CoV-2

With 6,287,771 confirmed cases worldwide and 379,941 deaths due to the novel coronavirus scourge —2,16,919 cases /5,815 deaths in India — healthcare professionals, researchers and government officials in the country and across the globe are racing against the clock to find solutions to better manage Covid-19 and save more lives and families…ICMR has asked states to conduct antibody tests on large scale.

Study results show that even with 97% specificity, there is a chance of getting 30 false positive results out of 1,000 and with 99.6%, 4 false positive results out of 1,000. Only with 100% specificity can one be fully confident that the antibody positive test result is a true positive, such as with the one developed and launched recently by Ortho Clinical Diagnostics.

Why 100% specificity is vital

Unlike many commercially available antibody test kits, Ortho's high-throughput, automated VITROS® Anti-SARS-CoV-2 antibody tests are highly reliable and have demonstrated 100% specificity in assay validation studies. The tests can help to identify with high accuracy a previously infected patient who can donate antibody-containing plasma to treat severe COVID-19 patients. This is important because any inaccurate test result could lead to a plasma therapy without antibodies to SARS-CoV-2, the active ingredients in the convalescent plasma therapy.

Both VITROS® Anti-SARS-CoV-2 antibody tests target the S1 subunit of the Spike (S) protein of SARS-CoV-2. The virus uses the S1 protein to bind to the angiotensin-converting enzyme 2 (ACE2) receptor to facilitate viral entry and infection. Antibodies that can bind to S1 and block S1-ACE2 interaction can inhibit viral infection, which are called neutralizing antibodies. The VITROS® Anti-SARS-CoV-2 antibody tests can detect neutralizing antibodies that bind to the S1 protein.

Ortho's 100% specificity-compliant antibody assay for Covid-19 testing — the VITROS® Immunodiagnostic Products Anti-SARS-CoV-2 Total and IgG Reagent Packs and Calibrators — have now been included in the updated list of approved

Rapid/ CLIA/ ELISA kits the Central Drugs Standard Control Organization (CDSCO), under the Ministry of Health and Family Welfare, GoI. (*No other company has 100% specificity).

New CDC guidelines

The recent guidelines from the Centre for Disease Control and Prevention (CDC) for Covid-19 antibody testing emphasizes on the serological methods/antibody testing towards monitoring and responding to the Covid-19 pandemic.

Antibodies most commonly become detectable 1-3 weeks after symptom onset, at which time evidence suggests that infectiousness is, possibly, greatly decreased and that some degree of immunity from future infection has developed.

Serologic assays for SARS-CoV-2 with very high specificity, now available, can play an important role in understanding the virus's epidemiology in the general population and identifying groups at higher risk for infection.

Recommended testing strategies

The utility of laboratory tests depends on the sensitivity and specificity of the assays. Also, the predictive values of a test should be considered because these values affect the overall outcome of testing.

o Positive predictive value is the probability that individuals with positive test results are truly antibody-positive.

o Negative predictive value is the probability that individuals with negative test results are truly antibody-negative.

o Positive and negative predictive values are determined by the percentage of truly antibody-positive individuals in the tested population (prevalence, pre-test probability) and the sensitivity and specificity of the test.

Example explains best

- In a high-prevalence setting, the positive predictive value increases — meaning it is more likely that persons who test positive are truly antibody-positive — compared to a situation where the test is performed in a population with low-prevalence.
- When a test is used in a low-prevalence population, the positive predictive value drops because there are more false-positive results, since the pre-test probability is low. And so on.

In the current pandemic, maximizing specificity, and thus positive predictive value, in a serologic algorithm is preferred in most instances, since the overall prevalence of antibodies in most populations is, possibly, low. Choosing a test with a very high specificity, perhaps 99.5% or greater, will yield a high positive predictive value in populations tested with prevalence >5%.

Ortho Clinical Diagnostics' VITROS® Anti-SARS-CoV-2 antibody test offers 100% specificity, providing high confidence to positive test results. These kits have received EUA from U.S.FDA and are CE marked too.

High throughput

o The VITROS® analyzers (i.e. instruments) from Ortho can run up to 150 of these critical tests/hour.

o The COVID-19 antibody tests can be run on all Ortho's flagship laboratory analyzers, the VITROS® XT 7600 Integrated System, the VITROS® 3600 Immunodiagnostic System and the VITROS® 5600 Integrated System. It will soon also be available on the VITROS® ECi/ECiQ Immunodiagnostic Systems.

Accuracy

o Ortho's testing demonstrated high clinical performance — critical to ensuring confidence in the results these tests deliver.

The VITROS® Systems that have already been installed in hospitals and laboratories in India and the neighboring SAARC countries are self-contained and do not require any external water source to run, offering labs placement flexibility.

Production plans

- A limited quantity of test kits will be available in India in the coming days.
- Ortho will be in full production mode in the coming weeks.
- It plans to manufacture several million SARS-CoV-2 antibody tests over the next month.