

## 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

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