Coronavirus (COVID-19): Understanding Serology Tests – For Customers

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Dear Valued Customer,

Supporting those on the front lines of the COVID-19 pandemic is a role we take very seriously. Thank you for all you're doing to continue to provide quality patient care during this unprecedented time.

Patient testing is a key component of care, and you've probably heard about new tests for COVID-19 or SARS-CoV-2 in the market. There are three types being developed to test for COVID-19 or SARS-CoV-2: molecular, viral antigen and host antibody tests. **Given the very limited availability of highly-accurate molecular tests**, there has been a lot of news about blood tests; the blood tests are a type of host antibody testing and a subset of "serology" testing.

Understanding Serology Tests

Background: Currently, molecular tests are being reviewed by the U.S. Food and Drug Administration (FDA) through the Emergency Use Authorization (EUA) process. The FDA has also provided guidance regarding the development and distribution of serology tests without an EUA – more specifically, serology tests that identify antibodies (like IgM and IgG) to SARS-CoV-2 from clinical specimens. **The FDA has made it clear that these antibody serology tests can't be used as the sole basis for diagnosis of SARS-CoV-2.**

An antibody serology test measures the presence of antibodies in the blood when the body is responding to a specific infection. It can take 2-10+ days for the antibodies to show up in the bloodstream after exposure to the virus. An antibody serology test **doesn't directly test the virus itself like molecular tests do**. Rather, it measures the patient's immunological response to the viral infection.

As part of its guidance, the FDA published an updated policy for antibody serology testing. A few callouts from this policy include:

- This test hasn't been reviewed by the FDA.
- Negative results don't rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
- Results from antibody testing shouldn't be used as the sole basis to diagnose or exclude SARS-CoV-2 infection, or to inform infection status.
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.

The FDA also shared a list of manufacturers that intend to make and distribute serology tests.

Our Recommendation:

We encourage you to read through the latest FDA policy to make the most informed decision about how your practice or facility might use these tests.

Thank you for your partnership. Thank you for your trust and patience. And thank you for taking care of our communities during the best of times and hardest of times.

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