SARS-CoV-2 (COVID-19) Serology at Multicare FAQ, 4.29.20

What COVID-19 serologic test will Multicare offer?

We will offer a qualitative SARS-CoV-2 IgG assay developed by Abbott Laboratories.

Who can order the test?

The test must be ordered by an appropriately licensed health care provider.
We will not accept self-referrals.

What are the indications for serological testing for SARS-CoV-2 (COVID-19)?

At this time the clinical indications are limited:

1. It could be useful in assisting a retrospective diagnosis of infection with SARS-CoV-2 if such information assists in management or further workup (for example in patients with unexplained strokes, hypercoagulable events, or other unusual COVID-19 manifestations).

2. This test could be used for a serological survey of groups to assist in understanding the epidemiology of this virus or to inform employers about potential gaps in protection of their employees. Looking ahead to the possibility of more COVID-19 cases in the summer and fall, antibody testing may help us determine whether a prior infection provides immunity against future infections.

Serological testing is NOT indicated for diagnosis of acute infection.

How soon after the onset of acute infection should a SARS-CoV-2 test be performed?

No sooner than 14 days after onset of symptomatic infection. Earlier testing decreases the sensitivity of this test.

How are the results reported?

Our current test is a qualitative assay for IgG. The results are either "positive" or "negative" based on a manufacturer-indicated cutoff.

What is the significance of a negative result?

A negative result indicates any of the following:

1. A person has not been infected with SARS-CoV-2.
2. SARS-CoV-2 infection is present but a detectable level of antibody level has not yet formed.
3. SARS-COV-2 infection was present but a detectible level of antibody was not formed or is no longer present.

A negative result does not rule out current or past infection with SARS-CoV-2.

What is the significance of a positive result?

A positive result indicates any of the following:

1. Previous or current infection with SARS-CoV-2.
2. A false positive result (see specificity below).

Does a positive result mean that a patient is immune to SARS-CoV-2?

At this time it is not known if a positive result correlates with immunity to future infection with SARS-CoV-2.

Should a patient with a positive serology result get a PCR test?

Not necessarily, providers should decide who needs a swab for COVID 19 PCR on a case to case basis.

How long do antibodies against SARS-CoV-2 last?

At this time we do not know how long the antibodies versus SARS-CoV-2 last.

How sensitive is the serological test?

In patients recovering from an acute SARS-CoV-2 infection, the sensitivity depends on how long ago the patient was infected. Limited data suggests 100% sensitivity 14 days after the onset of acute PCR positive SARS-CoV-2 infection. False negatives will occur if the test is ordered less than 14 days from the onset of an acute PCR positive SARS-CoV-2 infection.

How sensitive is the serological test in asymptomatic patients or patients without a PCR documented SARS-CoV-2 infection?

The sensitivity of the test in people with asymptomatic infections or patients without a PCR documented SARS-CoV-2 infection is unknown.

How specific is the test? Does it cross-react with other human coronaviruses?

The specificity appears to be high (99.6-99.8%) but studies of this are limited.
Cross-reactivity with other human coronaviruses cannot be completely ruled out and is currently an area of active study.
The cause or causes of false positives are unknown at this time.

What is the test's positive predictive value?

Positive predictive value is the probability that someone with a positive test was infected with SARS-CoV-2.
Positive predictive value depends on the prevalence of the disease in the population and the specificity of the test. Since the prevalence of SARS-CoV-2 infection in our population is currently unknown, the positive predictive value is unknown.
Below is a table of possible positive predictive values based on possible prevalence levels and a 99.6% specificity.

Prevalence	Positive predictive value
1%	71%
2%	83%
3%	88%
4%	91%
5%	93%

How will this test perform in immunocompromised patients?

We do not know. Immunocompromised patients may have undetectable levels of antibodies, or

have a delayed antibody response.

What will the turnaround time be, how many tests can we run per day?

The turnaround time will probably be within 24 hours, but that will depend on the volume of tests we receive. Initially we will be able to run ~600 tests per day.

Is there a role for point-of-care serology testing in COVID-19?

Due to poor performance characteristics there is no clinical role for point-of-care serology testing at this time, but this may change as assays improve. Current point-of-care testing may have a role in epidemiologic studies or contract tracing.

Will Multicare offer IgM testing, quantitative antibody testing, or other COVID-19 serology tests in the future?

Multicare will be active in providing any clinically relevant new assays as such assays are developed.

Is this test FDA approved?

This test is authorized under an FDA Emergency Use Authorization (EUA) that make available diagnostic tests to respond to public health emergencies. The FDA issued an EUA for this test because the potential benefits of testing outweigh the potential risks of releasing a test without the stringent and extensive process that usually occurs with FDA approval. Our in-house PCR testing is also offered under EUA.

If it is not FDA approved, how do we know it is an effective test?

This assay was extensively studied at the University of Washington prior to the issue of the EUA. The University of Washington was in an excellent position to evaluate the performance of the assay because of the high number of SARS-CoV-2 cases in Washington state.

The UW studies showed excellent laboratory performance characteristics as did studies performed at Abbott Laboratories. We repeated these studies with samples from Multicare patients and found similar performance characteristics.

With that being said, there are many studies that have yet to be done (viral neutralization studies, population studies) that will be necessary to fully determine what serologic testing means to an individual patient.

Are there any limits to testing that is authorized by EUA?

Yes there are many limits on how EUA tests can be performed, marketed, and used. Please see the link below if you are interested in the limitations of the EUA.
Under the EUA, health care provider and patient fact sheets should be made available to providers and patients. Here are links to the specific EUA for our assay and the fact sheets.

Abbott serology EUA:
https://www.fda.gov/media/137384/download
Health care provider fact sheet:
https://www.fda.gov/media/137381/download

Patient fact sheet:

https://www.fda.gov/media/137382/download

Are there documents I can look to for more information about serologic testing?

There are many up to date documents about issues surrounding serologic testing.

Johns Hopkins and the Center for Health Security have produced an excellent summary: https://www.centerforhealthsecurity.org/our-work/publications/developing-a-national-strategy-for-serology-antibody-testing-in-the-US

The Infectious Diseases Society of America (IDSA) has an excellent antibody testing primer: https://www.idsociety.org/news--publications-new/articles/2020/emphasizing-need-for-more-information-idsa-releases-antibody-testing-primer2/