MedStar Family Choice

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Novel Coronavirus (COVID-19) Antibody Testing
May 4, 2020

Last week CMS indicated that Medicare and Medicaid would begin to cover COVID-19 antibody testing. As of this writing, the Maryland Department of Health has not yet provided specific guidance regarding Maryland Medicaid coverage for antibody testing. Therefore, antibody testing is currently **not a covered benefit** for MedStar Family Choice members.

MedStar Family Choice has been working closely with the MedStar Health clinical leadership team on this topic. MedStar Health and MedStar Family Choice are following the recommendations from the World Health Organization (WHO) and the Infectious Disease Society of America. This current body of evidence states that antibody tests are best used for determining community prevalence. This type of testing should not be used to determine individual immunity or active infection.

MedStar Family Choice has attached a COVID-19 Rapid antibody Testing FAQ for our provider network. Additional information regarding antibody testing can be found in this document. MedStar Health is actively monitoring the current national and international data related to this topic. Additional guidance will be communicated as it becomes available.

We fully anticipate obtaining specific direction from the Maryland Department of Health regarding coverage of antibody testing. In the event MDH determines antibody testing to be a covered benefit, MFC plans to require prior authorization for the testing with criteria that will conform to the MedStar Health guidelines. Until that time, COVID-19 antibody testing remains a noncovered benefit.

MedStar Health

Updated: 04.29.20

COVID-19

COVID-19: Rapid Antibody Testing
FAQ for Providers

What you need to know:

Medstar Health is actively monitoring current data and national and international recommendations on the accuracy and utility of COVID-19 rapid antibody tests as the demand for the test increases within our community. Based on the current evidence, MedStar is following recommendations from organizations such as the World Health Organization and the Infectious Disease Society of America and does not recommend rapid antibody testing at this time for diagnostic decisions or assessments of immunity. While the tests can help us better understand the level of SARS-CoV-2 (the virus that causes COVID-19) exposure in the community (prevalence), they are not useful in guiding clinical decisions (i.e. whether a patient is immune or has an active infection). The following document has been developed to assist MedStar Health providers navigate frequently asked questions regarding antibody testing.

Q: What is a rapid antibody test, and should patients get one?

A: The rapid antibody tests look for IgG, IgM, or IgA antibodies in the blood produced in response to SARS-CoV-2. We are still learning more information about the best use of these tests. Currently, not enough is known about COVID-19 to confirm whether the presence of antibodies confers immunity. Right now, the current tests on the market do not help us provide any information about current infection status, one's risk of getting the virus in the future and can provide false information about whether someone was infected in the past. Because of this, MedStar Health does not recommend routine rapid antibody testing at this time.

Q: What are some of the specific issues related to the tests?

A: The sensitivity and specificity of the tests are relatively low and can cross-react with related viruses. For example, tests may falsely detect antibodies to other coronaviruses, including those that cause common colds; or they may not be sensitive enough to detect COVID-19 (SARS-CoV-2) antibodies when they are present, producing false negatives.

We also need more information on how the test results should be interpreted including: 1) titer cut-offs; 2) which antibodies can be detected and 3) what the presence of antibodies represents at this point (e.g. whether it confers immunity).

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Q: Why did the FDA allow use of rapid antibody testing for COVID-19 if the test accuracy is still unknown?

A: The rapid tests have been approved through the FDA's Emergency Use Authorization (EUA) pathway. This is a special consideration for medical products that *may be effective* to prevent, diagnose, or treat a life-threatening disease or condition. Medical products approved through this pathway have a lower level of evidence of effectiveness than what the FDA normally uses for product approvals, as such, these are NOT yet considered FDA-approved tests.

Q: Can a rapid antibody test be used to diagnosis COVID-19?

A: A "regular" COVID-19 test (or a molecular test) looks for viral RNA to diagnose an **active** infection. We currently perform this test with a nasopharyngeal swab or a nasal swab. Rapid antibody tests look for evidence of present or **past** infection by detecting antibodies produced by the immune system following exposure to a virus. By the time antibodies to the virus are produced and detectable in the bloodstream, someone may already have recovered from the virus and may no longer be infectious. Because the antibody test is a lagging indicator of infection, the Food and Drug Administration (FDA) recommends against using it as the sole means of diagnosing COVID-19.

Q: Does a positive antibody test mean that someone is immune?

A: No. The antibody response in infected patients remains largely unknown, and there are different antibody tests with variable performance. According to the World Health Organization (WHO) there is currently not enough evidence to suggest that people who have recovered from COVID-19 and have antibodies are protected from a second COVID-19 infection.

Q: What commercial antibody tests are available?

A: There are a variety of different antibody tests out there, ranging from fingerstick tests to more comprehensive enzyme-linked immunosorbent assay (ELISA) serum tests that require a blood draw. Most rapid tests are done by fingerstick and are not very specific for SARS-CoV-2. Both LabCorp and Quest, among others, offer ELISA testing to detect IgG, IgM, and IgA components and rapid testing. Tests vary in whether they target nucleoprotein (N protein) or spike protein (S protein), are combination (IgG/IgM) or single targets or are semi-quantitative or qualitative. Select studies have shown IgG tests to have the lowest number of false negatives and false positives, but not at a level of confidence to use for determination of immunity. Findings from a LabCorp pilot testing site can be found here: https://allcarefamilymed.com/covid19-antibody-test.

MedStar Health is committing to using the ELISA serum (blood draw) test for IgG antibodies with the DiaSorin analyzer. The DiaSorin test has 98% specificity with more rigorous testing

than with other devices, making it one of the best tests currently available. We emphasize that although the DiaSorin test is very good at detecting SARS-CoV-2 IgG antibodies, results are not being used to determine immunity or active infection, only prevalence in the community (number of people with past infection).

Q: LabCorp and Quest offer at-home (direct-to-consumer) testing. Can someone use this to go back to work?

A: LabCorp and Quest use finger stick testing, which can give false positive and false negative results. Antibody tests alone cannot determine if someone has recovered from COVID-19 or has an active COVID-19 infection, and thus can't help in determining if the person is safe to return to work. Both Quest and LabCorp provide these disclaimers on their websites.

Q: Are there other good sources to consult for this?

A: Yes, listed below are three resources that provide additional information on the current evidence base of antibody testing:

- FactCheck.org Q&A on COVID-19 Antibody Tests: https://www.factcheck.org/2020/04/qa-on-covid-19-antibody-tests/
- Infectious Diseases Society of America - IDSA COVID-19 Antibody Testing Primer: https://www.idsociety.org/globalassets/idsa/public-health/covid-19/idsa-covid-19-antibody-testing-primer.pdf
- WHO "Immunity passports" in the context of COVID-19: https://www.who.int/news-room/commentaries/detail/immunity-passports-in-the-context-of-covid-19