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FAQ about Testing in the Time of COVID-19

A great deal of our public attention and private conversations are currently focused on testing for COVID-19. We are encouraged by public health and government officials to get tested and that we need increased testing to understand the pandemic to more safely open our society. Unfortunately, many of the messages are short sound bites and are thus confusing. Even the knowledgeable reader/listener must furiously dig for details because some public proclamations can be misleading. This document is an attempt to clarify some of the critical issues around COVID-19 testing to help you determine whether testing is indicated for you, your family, and/or your employees (if you are an employer).

What are the different types of tests and how are they used?

Currently there are two major types of tests, each with a particular purpose. **Antigen** testing (Ag) seeks to identify an active infection by looking for the virus itself (or some of the proteins known to make up the virus), and a positive Ag test is an indication of current or active infection.

Some patients with the virus and/or a positive Ag test have active symptoms (fever, cough, shortness of breath, chills, headache, muscle pain, sore throat, shaking chills, or new loss of taste or smell, vomiting or diarrhea) while others have NO symptoms (asymptomatic). In both situations, a patient may test positive and is considered contagious for the disease. A negative test in a symptomatic patient does NOT guarantee they do not have the disease as there can be problems with the specimen collection or lab error.

Antibody tests (Ab) seek to determine if a patient had a **prior** infection, not an active infection. Antibodies are of two types: a short lived one which may appear in blood as early as 3 days after the onset of symptoms, and one that persists for a longer period but is not detectable until 14 days after the onset of symptoms.

How are the tests performed?

Antigen testing is commonly referred to as a "swab" test. Currently the most widely used swab test for COVID-19 is a nasopharyngeal (way back in your nose to absorb some mucous in that area) swab, but other types may gain use as research proves their quality.

Antibody tests, commonly referred to as either blood or serum tests (serum is the fluid portion of blood left when all of the cells are removed) is the source. The blood can be obtained typically by removing a tube of blood from the arm or for some tests, a finger stick.

Are the tests Food and Drug Administration (FDA) approved?

As of this writing NO tests (either antigen or antibody) have FDA "approval". There are a very limited number of tests among the myriad being marketed which have "authorization" from the FDA (a much lower level of evaluation) under a rule known as Emergency Use Authorization (EUA).

Therefore, you should ensure that the provider of your test (either antigen or antibody) has at least achieved EUA before taking the test.

Who should have an Antigen test?

Criteria for who should be tested has changed many times over the past two months. There is often some variation between federal, state and local guidelines, though for the most part they are consistent. A consistent recommendation had been only SYMPTOMATIC persons should take an Ag test but even this criterion is in the process of changing. Current criteria include:

High Priority

- Health care workers, workers in congregate living settings (i.e. nursing homes) and first responders with symptoms; or
- Residents in long-term care facilities or other congregate living centers including prisons and shelters, who have symptoms; or
- Persons identified through public health cluster and selected contact investigation

Priority

- Persons **with** symptoms of potential COVID-19 infection, including fever, cough, shortness of breath, chills, muscle pain, new loss of taste or smell, vomiting or diarrhea and/or sore throat; or
- Persons **without** symptoms who are prioritized by health departments or clinicians, for any reason, including but not limited to: public health monitoring, surveillance, or screening of other asymptomatic individuals according to state and local plans

What does a positive Antigen test mean?

A positive Ag test means the person tested has the virus, has an active infection, and, in most cases, should be considered actively contagious to others. As such, they should be in isolation. There is some evidence that late in the disease, Ag can remain present in some patients but they are not contagious. However, at the present time this area remains poorly understood. Anyone who tests positive to an Antigen test should follow the advice of their physician or health care advisor regarding ending their isolation.

Who should have an Antibody test?

At present the only group for whom this is recommended is for those patients who have recovered from an Antigen test proven illness with COVID-19 and who are participating in donation of plasma. Plasma donation remains an experimental treatment for those who are seriously ill with COVID-19.

At present, there are no national, state or local guidelines recommending antibody testing for any group. This is recognized as an area for a great deal more research.

What does a positive Antibody test mean?

Unfortunately, the answer to this question is unclear. A positive Ab test is presumed by many to indicate a person has developed resistance and is thus immune to a repeat COVID-19 infection due to a prior infection. This has NOT been proven with COVID-19. While there are many types of viral infections for which a patient may produce antibodies either after contracting or being vaccinated against the disease, (i.e. measles, chicken pox) this statement does not apply to

every type of viral infection; hence the doubt and the controversy. More time and more research are necessary to understand the meaning of a positive antibody test with COVID 19.

Another concern is that if, in fact, the presence of antibody does ultimately provide immunity, it is unclear how long the immunity might last; is it one year? Three years? Lifetime (doubtful)?

The Public has a great deal of curiosity about antibody testing and many want to "know my status". However, if tested, a positive test should NOT be a license to take increased risks with one's own health or that of others. A positive test should NOT be used to discontinue or reduce social distancing, hand washing or use of masks. Until we know more about antibody testing, the behavior of both the positive antibody group and the negative antibody group should remain the same as it has been since the beginning of this disease process. As noted above, at present we do NOT know if a positive antibody test provides any protection.

Should I be tested with either an Ag or Ab Test?

If you have symptoms of COVID-19, the answer is yes, you should be tested with an Ag test, and isolate while awaiting the results. For a positive test, isolation should continue until all three of the following criteria are met:

- It has been at least 10 days since the onset of symptoms; AND
- It has been at least 72 hours without fever (while not taking medication to reduce fever); AND
- Respiratory symptoms (cough and shortness of breath are improving)

A negative test should be interpreted by your health care provider, since false negatives can occur. A negative test alone, in the face of symptoms should follow the same return to life guidelines as for the positive test results.

Regarding antibody testing, there is no basis for a medical recommendation for this test at this time. Patients are curious and fearful and often "just want to know". This type of testing lacks any defined medical benefit (which should be the objective of medically based testing).

I have read/heard the arguments against antibody testing, but want it done anyway.

If medically indicated (please note above, there is currently no medical indication), it may be a covered service by most insurance carriers. However, given there is no medical indication it is not clear if carriers will pay for all or part of the test. They may determine this is 100% patient responsibility. As such there may be a cost for the test and any associated medical evaluation.

Best practices are to find a reputable medical office to provide the test. All tests authorized under EUA are considered moderately complex and testing must usually be done in a licensed laboratory. Expect results to take about 48 hours.

Should I test my employees with either an antigen or antibody test?

No. Antigen testing for the presence of the virus is merely a snapshot of a moment in time. A negative test today does not ensure the person will remain negative tomorrow, or in one or two weeks. In fact, VERY early in the course of the disease it is possible a person is "incubating" (in the process of developing the infection after an exposure) but the virus is not detectable by testing. Except in certain unique situations, it is also not practical to test employees repeatedly.

Antibody testing is likewise NOT recommended in settings such as employer groups. In the future, it is possible this recommendation could change and thus ongoing attention to the matter is recommended.

I still have several questions regarding my business, my family or my personal risk related to COVID-19. Where can I get more answers?

The Center for Disease Control and local metropolitan health districts are the primary up-to-date sources for more information. Individuals may wish to consult with their personal physician or health advisor. If none is available, please visit our website at www.texasmedclinic.com to schedule a visit time and meet with a physician expert.

Employers may wish to obtain consulting services from an expert who can evaluate the details of their unique business. Please contact our Director of Business Development and Marketing, Leah Martinez at lmartinez@texasmedclinic.com or 210-349-5577, Ext 8734 for more details and to learn about options and pricing.