Position Statement on Antibody Testing for COVID-19 (SARS-2-CoV)

SARS-2-CoV antibody tests have flooded the market and everyone wants to know ***"Can we use antibody testing to safely gauge an individual's immunity to COVID-19?"***

The IDSA and WHO have published statements regarding the current lack of evidence to support using serologic tests to gauge immunity to COVID on an individual level. **Antibody tests should not be used to diagnose COVID in a patient with new infectious respiratory symptoms. It is not a replacement for the PCR-based COVID test.** Antibody testing may ultimately have a broader public health utility in determining the overall proportion of the population who may have been infected with COVID-19 and help inform a vaccination strategy. However, we do not support individual patient testing at this time.

The caveats to using antibody tests as "immunity passports" on an individual level include:

1) We do not know if a positive antibody test means a patient had COVID-19 infection for the following reasons:
    a. False-positives are likely to occur in areas with a low community prevalence of disease.
    b. False-positives may occur if there is cross-reactivity between the SARS-2-CoV antibodies and other "common-cold" coronavirus antibodies.
2) We do not know if a negative antibody test means that a patient did not have COVID-19 infection for the following reasons:
    a. False-negative antibody tests may occur if the tests are performed too early in the disease course.
    b. False-negative antibody tests may occur if the patient had a mild infection or did not mount a big immune response.
3) We do not yet know the duration of immunity following COVID-19 infection, or if it provides any protection at all against future infection. Therefore, it is not clear at this time if a true positive antibody test means an individual is immune to recurrent COVID-19 infection.

For all these reasons, we would not recommend routine antibody screening for individual patient care at this time. If performed, results should not be used to guide clinical decision-making or patient counseling regarding risk of acquiring COVID-19. If a positive antibody is detected, it should be made clear to patients that they could still be at risk of infection, and that they should still engage in frequent handwashing, wear a face mask while out in public, and maintain social distancing. Further research is needed to determine the utility of SARS-2-CoV antibody testing at this time.

To learn more about research opportunities that involve antibody testing or plasma donation for patients with confirmed or suspected COVID, please contact Dr. Chris Woods or Dr. Liz Petzold by using the email DukeMESSIStudy@duke.edu, or call 919-452-1605. The MESSI research study will follow patients with suspected or confirmed COVID infection for up to 1 month and will perform viral, serologic (antibody) and genetic studies.

References:

1) "Immunity passports" in the context of COVID-19 – WHO Statement
2) IDSA COVID-19 Antibody Testing Primer
3) https://dicon.medicine.duke.edu/sites/dicon.medicine.duke.edu/files/dicon_covid-19_faq_serology_4-30-2020.pdf

Frequently Asked Questions Regarding Antibody Testing for COVID-19

Is Duke planning to offer an antibody test? If so, when?

Yes, Duke is planning on offering an antibody test. At this time, the laboratory is validating the test for use. Part of the validation is to establish how the test can be used. Duke will not offer the test unless we can clearly define its clinical utility. Currently medical and professional societies are not recommending antibody testing in the care of the individual patient. Rather, they are being supported as epidemiological tools.

What are the clinical circumstances that should prompt an antibody test?

At this time, there are no well-defined clinical circumstances that should prompt an antibody test. We do not recommend routine antibody screening for individual patient care. If performed, results should not be used to guide clinical decision-making or patient counseling regarding risk of acquiring COVID-19. We recommend that patients with new infectious symptoms concerning for COVID be tested using a PCR-based method as opposed to using an antibody test.

Should patients consider other commercial avenues for testing?

For the reasons mentioned above, we would not recommend that patients pursue commercially available antibody tests.

What are the pros and cons to getting a test?

Pros: If an antibody test is collected as part of a research study, it may contribute to a better scientific understanding of the accuracy of antibody tests in identifying patients who were infected with SARS-2-CoV and utility of antibody testing for population health that may potentially inform future vaccination strategies.

Cons:

1) Antibody tests do not replace PCR-based COVID tests in terms of diagnosing active COVID infection. They do not directly detect COVID virus, but rather, act as an indirect way to check if a patient may have been exposed to COVID.
2) We do not know if a positive antibody test means a patient had COVID-19 infection for the following reasons:
    - False-positives are likely to occur in areas with a low community prevalence of disease.
    - False-positives may occur if there is cross-reactivity between the SARS-2-CoV antibodies and other “common-cold” coronavirus antibodies.
3) We do not know if a negative antibody test means that a patient did not have COVID-19 infection for the following reasons:
    - False-negative antibody tests may occur if the tests are performed too early in the disease course.
    - False-negative antibody tests may occur if the patient had a mild infection or did not mount a big immune response.
4) We do not yet know the duration of immunity following COVID-19 infection, or if it provides any protection at all against future infection. Therefore, it is not clear at this time if a true positive antibody test means an individual is immune to recurrent COVID-19 infection.

Does a positive antibody test confirm exposure?

We do not know if a positive antibody test means a patient had COVID-19 infection for the following reasons:

1) False-positives are likely to occur in areas with a low community prevalence of disease.
2) False-positives may occur if there is cross-reactivity between the SARS-2-CoV antibodies and other "common-cold" coronavirus antibodies.

Does a positive antibody test predict immunity?

We don't know many things about the antibody test's ability to predict immunity including:

- We do not know if a positive antibody test means a patient had COVID (see false-positives above).
- We do not know the duration of immunity following COVID-19 infection, or if it provides any protection at all against future infection.

Therefore, it is not clear at this time if a true positive antibody test means an individual is immune to recurrent COVID-19 infection.

How will antibody tests be used in the re-opening of the health system, the university, the city, or the state?

At this time, antibody tests are not being used as a guide to the safe-reopening of the health system, university, city, or state. We continue to recommend social distancing measures, universal masking, increased hand hygiene, cough/respiratory etiquette, avoiding going out into public or around others when ill, and increase cleaning of high-touch surfaces to help reduce the spread of COVID. Duke Health has worked hard with infectious diseases and infection prevention experts to prepare for re-opening the health system safely for our patients, visitors, and team members.

Will a positive antibody test obviate the need for masking?

Because we cannot rely on an antibody test to predict immunity, patients with positive COVID antibody tests will still be required to wear personal protective equipment. This means that antibody-positive individuals will still be required to wear face masks in public and healthcare workers/team members who provide direct patient care to COVID-positive patients will still be required to follow special airborne contact isolation precautions.

What are the false positive and negative rates with the available testing?

The false-positive and false-negative rates of antibody tests are not currently known. Further study is needed to determine this.