Update: May 4, 2020

There are many questions surrounding the utility of antibody tests, and if done right these tests can have big implications for the ability to reopen the economy while still keeping people safe. However, due to growing reports of high levels of false positives and false negatives from practitioners deploying antibody testing, ***the AANP is strongly recommending that NDs advise all patients that the accuracy of antibody testing remains questionable, and should in no way change behavior in terms of social distancing and adherence to public health guidelines.*** The potential for inaccurate results should be weighed alongside the cost to the patient of administering the test.

Date: April 17, 2020

AANP COVID Task Force and Scientific Affairs Committee – Statement on COVID-19 Antibody Testing:

As the United States and the rest of the world work tirelessly to get ahead of the COVID-19 Pandemic and restore some normalcy to our lives, wide-spread testing of the population is a key step. This includes rapid, accurate *diagnostic testing* of active disease, as well as post-infection *antibody testing* to determine who has already had the infection and may have some level of immunity.

Recently, we have seen commercial laboratories rolling out antibody testing which we hope and expect will be useful for NDs and other healthcare providers to support their communities. However, the AANP COVID-19 Task Force, in conjunction with AANP's Scientific Affairs Committee, would like to offer some words of caution around some of these tests.

In this quickly evolving testing climate, it is important that providers understand the different kinds of tests available, and recognize the risks associated with tests that have yet to be sufficiently validated.

The vast majority of antibody tests being offered have not yet received FDA approval, which labs are typically acknowledging on their websites. Commercially available antibody tests should be viewed as insufficiently validated until standardized controls and performance characteristics are more broadly available. While we are not discouraging testing, it is important that all providers educate themselves on currently available testing options and the ramifications of non-validated results. Further, as the public demands these tests, providers should educate their patients about test validity and implications for susceptibility.

Potential Areas of Concern To Understand with Antibody (Currently available IgG/IgM) Tests:

1. It is as of yet unknown if these tests are able to offer sensitivity and specificity in a commonly acceptable range.
    a. False negatives might occur in patients who have yet to mount an antibody response or in those who might not do so despite viral exposure.

    b. There could be cross-reactivity with other coronaviruses that are not SARS-CoV-2, which could result in false positives potentially putting a person into a false sense of security.
2. There is not yet clarity that having detectable antibodies confers immunity. Thus, we don't know if having antibodies prevents recurrence.
3. It is also possible to have positive antibodies and continue to shed the virus for several weeks. Thus, we don't yet have clarity that having antibodies prevents community spread.

What NDs should look for to determine antibody test validity:

- There are variations in methodologies among these antibody tests that you should understand as clinicians. Ask the laboratory about their testing methodology and the specificity/sensitivity of their test for SARS-CoV-2 (vs. other coronaviruses).
- Ask the laboratory to provide details on how they have validated their particular test and how many subjects they validated with diagnostically confirmed exposure.
- Confirm with the lab that positive test results are being reported to the appropriate health authority.

Further, companies offering serological testing are required by the FDA to inform providers and patients about the following:

- The test has **not been reviewed by the FDA.**
- **Negative results do not rule out SARS-CoV-2 infection,** particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic test should be considered to rule out infection in those individuals.
- Results from **antibody testing should not 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.
- More information about the current utility of serological testing can be found here as labs submit data to the FDA.

Clinicians utilizing IgG/IgM tests may want to educate patients about these distinctions and their ramifications for the patient's treatment protocols. Until further information is available, test results should not change adherence to public health guidelines for social distancing and/or sheltering in place.

Note: The Natural Medicine Journal has released a podcast on 4/13/20 interviewing Dr. Heather Zwickey which discusses the use of antibody testing (Link Here)