Coronavirus Disease 2019 (COVID-19) Testing

INTERPATH LABORATORY

Effective May 19, 2020, Interpath Laboratory is offering in-house testing for antibodies against SARS-CoV-2, the etiologic agent of coronavirus disease 2019 (COVID-19). The Interpath Laboratory "Anti-SARS-CoV-2 Ab (IgM + IgG)" test (#2870) is a total antibody test, detecting IgM + IgG antibodies, as is currently recommended by the U.S. Centers for Disease Control and Prevention (CDC).

Recent studies[1,2,3] have shown some utility for antibody tests as supplements (not stand-alone) to the NAATs in diagnosing late acute (active) COVID-19. However, due to the highly variable performance (e.g., sensitivity, specificity) of the multitude of assays that have been developed, we have chosen a test that has been granted emergency use authorization (EUA) designation by the U.S. Food and Drug administration (FDA).

In addition, we continue to offer "SARS-CoV-2 by PCR" (test #2785), a nucleic acid amplification test (NAAT) which remains the recommended test type for diagnosis of acute (active) COVID-19. Even as testing capacity continues to increase, we recommend that clinicians continue to work closely with local and state public health officials and follow CDC guidelines to determine prioritization of patients to be tested (https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html).

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Evaluation Criteria for COVID-19 Laboratory Testing

Per CDC guidance, "Clinicians considering testing of persons with possible COVID-19 should continue to work with their local and state health departments to coordinate testing." Though testing capacity is increasing, it is still recommended that you prioritize your patients to determine who should get testing first. For recommended priority levels (High and Regular Priority), please see: https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html.

Outside of the above-mentioned priority levels, the CDC recommends: "Clinicians should use their judgment to determine if a patient has signs and symptoms compatible with COVID-19 and whether the patient should be tested... Other considerations that may guide testing are epidemiologic factors such as known exposure to an individual who has tested positive for SARS-CoV-2, and the occurrence of local community transmission or transmission within a specific setting/facility (e.g., nursing homes) of COVID-19." In other words, outside of the priorities listed by the CDC, clinicians, in close consultation with their local and/or state public health authorities, may decide to test asymptomatic individuals who are contacts of confirmed positive patients or may have otherwise been exposed to the SARS-CoV-2 virus.

SARS-CoV-2 by PCR (test #2785)

The recommended tests for diagnosis of COVID-19 continues to be those that detect the nucleic acid (RNA) of the SARS-CoV-2 virus. This type of test is typically called a nucleic acid amplification test (NAAT). There is still not enough data available to determine the real-time (and real-life) accuracy of this test for SARS-CoV-2. However, similar NAAT tests to detect the presence of viral nucleic acid generally demonstrate sensitivities >90% (<10% false negative rate) and specificities >95% (<5% false positive rates). These numbers will likely hold true for specimens taken from severely symptomatic patients. However, it is also likely true that specimens taken from mildly symptomatic or asymptomatic individuals will yield lower sensitivities (60-90%), though specificities will remain high.

Federal guidelines were released on April 16, 2020, on opening up businesses across America from an epidemiologic and phased approach (https://www.whitehouse.gov/openingamerica/). As part of this plan, states are responsible for increasing testing capacity to a level where symptomatic patients can be screened, contacts of confirmed positive patients can be traced and screened and established sentinel surveillance sites (e.g., businesses that serve individuals at high risk of developing severe disease) can be screened for asymptomatic cases. To date, NAATs for SARS-CoV-2 are the only tests that can reliably detect acute (active) COVID-19 cases.

Anti-SARS-CoV-2 Ab (IgM + IgG) (test #2870)

Over the past several weeks, there has been an extraordinary amount of work directed towards the development and utilization of assays that detect antibodies against SARS-CoV-2. However, much is still unknown about the accuracy of these tests and how results could be used (by individual healthcare providers or public health authorities).

How antibody tests could be used:

- Public health officials will certainly utilize antibody testing to determine the epidemiological characteristics (e.g., percent prevalence) of the COVID-19 pandemic within their jurisdictions. These data will assist county, state and federal agencies in making decisions regarding stay-at-home, social distancing and other public health policies.
- Recent studies have shown that antibody testing may be useful as a supplemental lab diagnostic to the NAATs, particularly in patients in the mid to late stages of COVID-19 illness[1,2,3]. If used for this purpose, the CDC recommends the use of a total antibody (IgM + IgG) test (https://www.cdc.gov/coronavirus/2019-ncov/lab/testing-laboratories.html#For-All-Laboratories:-Serology). Given the large number of antibody tests that have been quickly developed and the highly variable nature of how they perform, we have chosen a test that has been given emergency use authorization (EUA) designation by the U.S. Food and Drug Administration (FDA).

How antibody tests should NOT be used:

- Antibody test results should not be used as the sole determinant of acute (active) COVID-19 infection status.
- Each antibody test is developed to detect antibodies against a specific viral antigen(s). Though a positive result will likely indicate exposure to SARS-CoV-2, It is still unknown which antibodies are protective (against re-infection) and at what levels. We continue to recommend adherence to local and state policies and CDC guidance on when individuals can return from quarantine or home isolation (https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html).

References

1. Xiang F, *et al*. Clin Infect Dis. 2020 Apr 19. pii: ciaa461. doi: 10.1093/cid/ciaa461.
2. Yong G, *et al.* J Med Virol. 2020 Apr 22. doi: 10.1002/jmv.25919.
3. Yongchen Z, *et al*. Emerg Microbes Infect. 2020 Apr 20:1-14. doi: 10.1080/22221751.2020.1756699.