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Commissioner

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Dear Colleague,

I am certain that many of you are getting frequent questions related to COVID19 testing and/or are in the position to interpret the results of COVID19 tests. Please consider the following information as you advise colleagues, treat patients and inform policy decisions at your respective places of work.

COVID19 tests designed to evaluate individual persons for active infection rely on molecular and antigen testing methods that detect the presence of the virus in specimens collected from the respiratory tract. These types of tests are acceptable for the purpose of case detection, public health action, clinical evaluation of individual patients and informing infection prevention/control practices. Many tests have received Emergency Use Authorization (EUA) from the Food and Drug Administration (FDA) and a complete list of such tests can be found at: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd>. Most of these tests are designed to be performed in a laboratory setting but a small number of them (those noted with a "w" in the authorized setting column on the linked website) are called Point of Care (POC) tests, designed to be performed in patient settings such as urgent care centers, doctor's offices and Emergency Departments.

In addition to diagnostic tests, serologic tests (e.g., IgG, IgA, IgM) have been developed in an effort to determine if patients have previously been infected by SARS-CoV-2 (the virus that causes COVID19). Currently, these tests may be useful to determine the prevalence of COVID19 in a population or to identify individual patients who **may** be candidates to donate plasma for therapeutic purposes. There is, of course, also great interest in identifying individuals who may be immune to SARS-CoV-2 due to previous infection. However, due to the lack of current evidence that detection of SARS-CoV-2 antibody on any serologic test is indicative of durable immunity, and that false positives can occur with any of these serologic tests, they **should not** be used for this purpose at this time. Additionally, serologic tests do not have a role in diagnosing acute infection in symptomatic individuals since antibody responses to infection may take days to weeks to be detectable. A negative serologic test does not rule out active infection and a positive serologic test may reflect prior infection with a human coronavirus other than SARS-CoV-2. A positive test is not indicative of immunity and should not be used for return-to-work decisions.

Further complicating the implementation and utility of serologic tests is the fact that there are many such tests that are being marketed which have not been completely validated nor reviewed by the FDA. Additionally, some manufacturers and distributors are claiming, falsely, that their tests have been approved by the FDA. As of April 27, 2020, seven serology assays have received FDA EUA (please refer to <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd>), and all seven must be performed in a moderate or high complexity laboratory setting (i.e. none of them are approved for POC use). We strongly urge healthcare providers,

laboratories, businesses, and local health departments to avoid using and/or relying on the results of unvalidated serologic tests that have not been granted EUA from FDA.

As our understanding of test methods and the pathophysiology of SARS-CoV-2 infection evolves, our guidance may change, and updates will be provided to laboratories and healthcare providers as necessary.

Sincerely,

Thomas J. Kirn MD PhD
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