2020 Health Alert #11:
Current Status of SARS-CoV-2 Serologic Testing

April 22, 2020

Dear Colleague,

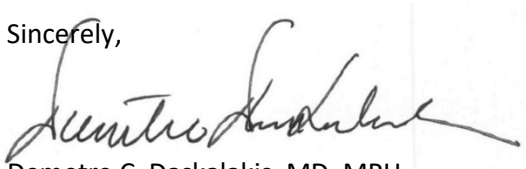
Although there is interest in identifying individuals who may be immune to SARS-CoV-2 due to previous infection, significant voids remain in our scientific understanding of the pathophysiology of SARS-CoV-2 which make interpreting serologic assays challenging for clinical and public health practice. Given the current lack of evidence that detection of SARS-CoV-2 antibody on any serologic test is indicative of durable immunity, it **should not** be used for that purpose.

Serologic tests should not be used to diagnose acute or prior SARS-CoV-2 infection, nor should they be used to determine immune status to SARS-CoV-2. They may produce false negative or false positive results, the consequences of which include providing patients incorrect guidance on preventive interventions like physical distancing or protective equipment. 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 serology would, therefore, not exclude SARS-CoV-2 infection in a patient with recent exposure to the virus. Cross-reactivity of antibody to other common coronavirus proteins may also occur, so a positive serology may either reflect infection with SARS-CoV-2 or past infection with other human coronaviruses.

Dr. Jennifer Rakeman, Director of the NYC Public Health Laboratory, recently sent a letter to NYC health care providers cautioning against using unvalidated serology test kits that are currently being marketed. The New York City Health Department cautions health care providers and clinical laboratories from assuming that any of the SARS-CoV-2 serology test kits now being marketed, some advertising falsely that they have been approved by the Food and Drug Administration (FDA), are reliable enough for use in routine clinical practice. As of April 14, 2020, only three serology assays have received FDA Emergency Use Authorization (EUA), and all three tests must be performed in a moderate or high complexity setting. The "Instructions for Use" documents for all three tests include disclaimer information regarding possible and demonstrated cross reactivity with common human coronavirus antibodies. Other tests may be coming online soon that do not cross react with commonly circulating coronaviruses. **Availability of such tests without cross reactivity would not change guidance on how to interpret a positive or negative antibody result as a test to prove or disprove immunity to SARS-CoV-2.**

The development of reliable serologic assays that accurately assess prior infection with SARS‑CoV-2 will be essential in the future for epidemiologic studies, ongoing surveillance, vaccine studies, and potentially for risk assessment of health care workers. The NYC Health Department recommendations on the reliability of available serology assays for SARS-CoV-2 infection may change as more data become available, at which time further guidance will be issued.

Sincerely,



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