Health Care Alert: New NIH Process for Evaluation of Antibody Tests May Offer Increased Confidence, Protection for Providers

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CLIENT ALERT | 4.20.2020

On April 18, 2020, the U.S. Food and Drug Administration (FDA) published an official statement confirming that the National Institutes of Health (NIH) will soon begin conducting performance evaluations for serological, or antibody-based, diagnostic tests for COVID-19. This new evaluation process is ***not*** intended to replace FDA's current guidance, but instead may "complement and inform" FDA's determination of whether to issue an Emergency Use Authorization (EUA) for a particular test.

By way of background, serological tests rely on the presence of antibodies in the blood to detect SARS-CoV-2, the virus that causes COVID-19. As a result, they are prone to false negatives in the early days of infection, when the body has not yet had a chance to build up significant levels of antibodies.

In guidance issued last month, FDA invited developers of serological diagnostic tests to submit EUA requests for review, but indicated that it will not object to the use or marketing of such tests without an EUA where (1) the tests are validated by the developer in accordance with FDA recommendations; (2) notification of the developer's validation is provided to FDA; and (3) the tests' labeling complies with certain requirements.

Currently, therefore, an EUA may not be necessary to mitigate the risk of regulatory enforcement against a test developer or the health care providers with whom the developer contracts; however, because an EUA provides evidence of specific FDA review, it could help protect a developer or provider in a subsequent negligence action. Similarly, an evaluation by NIH is intended to "[support] greater confidence in test performance," potentially laying the foundation for a provider to show that it has met the applicable standard of care.

If you have questions about the FDA's statement, its guidance on serological tests, or the implications of contracting with a testing provider, please contact Jonathan Ishee, Mairi Mull, or your regular Vorys attorney.

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Vorys COVID-19 Task Force

Vorys attorneys and professionals are counseling our clients in the myriad issues related to the coronavirus (COVID-19) outbreak. We have also established a comprehensive Coronavirus Task Force, which includes attorneys with deep experience in the niche disciplines that we have been and expect to continue receiving questions regarding coronavirus. Learn more and see the latest updates from the task force at vorys.com/coronavirus.