FDA FACT SHEET

SEROLOGICAL TESTING FOR ANTIBODIES TO SARS-CoV-2 INFECTION

Serological tests detect antibodies present in the blood when the body is responding or has responded to a specific infection, like COVID-19. They detect the body’s immune response to the infection caused by the virus rather than detecting the virus itself.

Experience with other viruses suggests that individuals whose blood contains antibodies associated with SARS-CoV-2 infection—provided they are recovered and not currently infected with the virus—may be able to resume work and other daily activities in society. They may also be eligible to serve as potential donors of convalescent plasma.

The positive (or negative) predictive value of a serological test – or the number of actual antibody positive (or negative) results divided by the total number of positive (or negative) results the test provides – is dependent on the prevalence of antibody-positive individuals in a given population and the sensitivity and specificity of the test. Because prevalence has such an impact on the predictive value of a test, a test’s performance and usefulness may vary with local conditions. For example, the predictive value of a serological test may be higher in a region with widespread infection than it would be in an area with only a small number of cases. To minimize the number of false positive results, serological tests must be well-designed to specifically identify antibodies against SARS-CoV-2 and must not “cross-react,” or provide positive results when encountering antibodies against other respiratory viruses.

Following the requisite declaration to support issuance of Emergency Use Authorizations (EUA) for diagnostic tests, the FDA began issuing Emergency Use Authorizations for COVID-19 tests, including SARS-CoV-2 serological tests. In addition, on March 16, 2020, the FDA announced in a guidance document that we do not intend to object to commercial manufacturers developing and distributing, and laboratories developing and using serological tests in laboratories or by health care workers at the point of care that have not been reviewed by the FDA where the test developers notify the FDA that they conducted their own validation and include disclaimers about the limitations of the results generated by their tests, as outlined in the guidance document. As stated in the guidance, this policy does not apply to at-home testing, including at-home specimen collection because of the added challenges in assuring test accuracy these pose. The FDA issued this policy with a goal of providing laboratories and providers with early access to serological tests, so laboratories and health care providers could determine if particular tests warranted being used.

The FDA is also working with the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and the Biomedical Advanced Research and Development Authority (BARDA) to establish a capability at NIH to assess the performance of serological tests. The approach represents a balanced attempt to provide a reasonable understanding of the potential performance of a significant number of tests within a short time period. Performance results from this collaboration are intended to inform other efforts, including FDA review in support of an EUA as needed.

Emergency Use Authorization (EUA)

The FDA encourages developers to submit EUA requests for their devices, as an EUA will provide laboratories and providers with assurance that FDA has reviewed a test. The FDA’s goal is to make the process for EUA submission as streamlined and efficient as possible. The FDA is working on a new template for serology tests that
detect SARS-CoV-2 antibodies that laboratories and manufacturers can choose to use to facilitate the preparation and submission of an EUA request for such tests and will make that available for download from FDA.gov once completed.

Laboratories and manufacturers can reference the currently available template for molecular assays as a starting point for basic information (e.g., measurand, identifying information, Intended Use, etc.) and can reach out to CDRH-EUA-Templates@FDA.HHS.GOV with questions. The FDA will work collaboratively with the laboratory or manufacturer to address any concerns or safety considerations raised during the FDA’s EUA review and will contact the laboratory or manufacturer regarding a final determination. The FDA has already issued EUAs for SARS-CoV-2 serological tests and has engaged with more than 100 serological test developers through its pre-EUA process.

For more information:

- FAQs on Diagnostic Testing for SARS-CoV-2

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