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FDA Continues to Accelerate Availability of COVID-19 Tests

by Cathy Burgess and Ben Wolf

To accelerate availability of diagnostic tests for SARS-CoV-2 (the virus that causes COVID-19), the Food and Drug Administration (FDA) continues to utilize its authority to permit diagnostic tests on the market via emergency use authorization (EUA). Most recently, on March 21, 2020, the FDA issued its first EUA for a point of care diagnostic that provides results to patients within hours, without the need to send samples to a laboratory. The Cepheid point of care test is indicated for the qualitative detection of nucleic acid from SARS-CoV-2. The EUA granted to the Cepheid Xpert Xpress SARS-CoV-2 test represents another milestone in the FDA's efforts to respond to the rapidly evolving coronavirus pandemic.

On March 16, in a revised version of its Policy for Diagnostics Testing in Laboratories Certified to Perform High-Complexity Testing Under CLIA Prior to Emergency Use Authorization for Coronavirus Disease-2019 During the Public Health Emergency, (the "Guidance," originally issued February 29), the FDA announced that it is permitting labs that are certified to perform high-complexity testing under Clinical Laboratory Improvement Amendments (CLIA) and comply with CLIA requirements to utilize validated nucleic acid or serological assay tests after notifying the FDA of completed validation. The FDA recommends that the lab submit an EUA request for nucleic-acid-based tests to the FDA within 15 business days after initial notification to the FDA.

Following the announcement of a public health emergency by the Secretary of Health and Human Services (HHS), the FDA first exercised its authority to bring diagnostics to the market on an emergency basis on February 4, 2020, when the FDA authorized an EUA for the Centers for Disease Control and Prevention's (CDC) 2019-nCoV Real-Time RT-PCR Diagnostic Panel for the presumptive qualitative detection of nucleic acid from the coronavirus in upper and lower respiratory specimens. The CDC granted other entities seeking an EUA a right of reference to the performance data contained in its request for an EUA.

In tandem with the issuance of the CDC EUA, the FDA stated in an FAQ that clinical laboratories were not required to apply for their own EUAs if the clinical laboratories: (1) are certified to perform high-complexity testing under CLIA; (2) purchase CDC-qualified lots of SARS-CoV-2 test kit reagents; and (3) follow the CDC protocol exactly. In the FAQs, the FDA further clarified that certain other extraction platforms and detection instruments can be substituted for those specified in the CDC EUA without additional validation or the FDA review (i.e., no bridging studies are needed). The FDA has also stated in the FAQs that if a lab's method is similar to the CDC's, but the differences are not identified in the FAQ as permitted variations, the lab may use bridging studies in lieu of complete revalidation.

If a lab opts to utilize its test before the FDA authorization of the EUA, the requestor must send the first five positive and first five negative clinical specimens tested to another lab for confirmatory testing that uses an EUA-authorized test. Test reports should indicate that "the test has been validated but the FDA's independent review of this validation is pending." If the FDA is ultimately unable to authorize the EUA, or if confirmatory testing provides contradictory results from those reached using the test under review, testing must stop and corrected test reports indicating that the test may not be valid must be issued. A list of labs that have notified the FDA that they have validated a COVID-19 test and have begun testing is provided in the FAQs.

Since the CDC EUA authorized on February 4, the FDA has authorized an additional 12 EUAs for diagnostic tests not covered by the CDC EUA.

The March 16 Guidance also provides for serology-based tests to be used without submitting an EUA, but test reports must include statements that: (1) the "test has not been reviewed by the FDA"; (2) "negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals"; (3) "Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status"; and (4) "Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E."

Companies manufacturing diagnostic tests may market diagnostic tests for SARS-CoV-2 in the same manner, and under the same limitations, as those tests developed by CLIA high-complexity labs except that: (1) the tests may be used at labs or by health care providers, while tests developed by CLIA high-complexity labs may only be used at the lab where the test was developed; and (2) nucleic-acid-based tests developed for commercial distribution need not be confirmed by labs using an EUA-authorized method. Lists of companies taking advantage of the policy for nucleic-acid- and serology-based tests can be found in the FAQs.

Finally, under the March 16 Guidance, states or territories may take sole responsibility to regulate SARS-CoV-2 tests developed by CLIA-certified labs regulated by the state or territory. This extends the enforcement discretion that the FDA afforded the New York State Department of Health (NYSDOH) on March 12 and the President's subsequent Memorandum on Expanding State-Approved Diagnostic Tests directing the FDA to extend the enforcement discretion to all states and territories. The FDA would not review an EUA request – authorization for the use of the tests would be under state law and using procedures developed by the state. However, the FDA does expect the tests to be validated. The FDA is requesting that states or territories notify it when they decide to self-regulate tests developed by CLIA-certified labs regulated by the state or territory. The FDA is also requesting that labs alert the FDA when they begin testing and what their testing capacity is. A list of states opting to self-regulate SARS-CoV-2 diagnostic tests can be found in the FAQs.

The FDA has made numerous attempts to expedite the introduction of diagnostic tests to the market. For instance, the FDA indicated that it completed its review of the first two commercial test EUAs within 24 hours of receiving the requests and allowed some of these tests to be shipped before receipt of the EUAs. The FDA also held a virtual town hall on March 6 to discuss a prior iteration of the policy, released February 29, and to field questions from diagnostic test developers. The FDA has indicated that it will work collaboratively with any requestor to address any potential concerns or safety considerations raised during the review of the EUA request. In addition, the FDA has established a 24-hour toll-free line, 1-888-INFO-FDA, to assist test developers.

To date, there have been no EUAs issued for diagnostic tests intended for home use. On March 20, the FDA issued a statement, FDA Alerts Consumers About Unauthorized Fraudulent COVID-19 Test Kits, addressing the marketing of diagnostic test kits marketed for use in the home. The FDA indicates that the marketing of diagnostic test kits without appropriate FDA oversight can pose serious health risks by causing some patients to delay or forgo appropriate treatment. The FDA further

states that enforcement action, similar to the joint action it took with the Federal Trade Commission (FTC) on March 9, will be taken against those illegally marketing SARS-CoV-2 diagnostic tests. Further actions including seizures and injunctions may also be considered.

While the FDA has extended considerable leeway to labs and manufacturers in the marketing and use of diagnostic tests for SARS-CoV-2, we expect the FDA to take decisive action against any entity putting patient or caregiver health at risk for personal gain.

Implications of the Policy for Commercial Manufacturers

The global COVID-19 pandemic requires a massive and coordinated response. Accelerating market access for tests developed by commercial manufacturers will greatly expand availability of tests. We note, however, that because the FDA is not undertaking a full review of these tests, and is waiving quality system regulation (QSR) requirements for manufacturers during the duration of the EUA, issues related to design flaws or manufacturing issues may not be readily apparent.

Moreover, with its recent announcements on postponing inspections (Alston & Bird advisories on the topic can be found here and here), the FDA will not have its usual means of ensuring that manufacturers are meeting their regulatory obligations. While the FDA may request documents in lieu of inspection, if a test is shown to be ineffective, the FDA could conduct a for-cause inspection and/or take enforcement action.

Background on EUAs

EUAs are authorized and regulated under Section 564 of the Federal Food, Drug, and Cosmetic Act (FFDCA). EUAs can be authorized if an emergency is declared by at least one of four federal entities, including HHS, the parent agency of the FDA, and the Secretary of HHS has determined that: (1) the "biological, chemical, radiological, or nuclear agent or agents [BCRNAs] … can cause a serious or life-threatening disease or condition"; (2) the available evidence suggests that "it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing" either "such disease or condition; or a serious or life-threatening disease or condition caused by a product authorized under [the FFDCA] for diagnosing, treating, or preventing such a disease or condition caused by such an agent"; (3) the benefits of the product outweigh the risks, taking into account the threat from the BRCNA; and (4) "that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition."

Conclusion

In the past week, the FDA's efforts to address the shortage of diagnostic tests has accelerated considerably. The FDA is now moving quickly, under what it describes as an "unprecedented policy," to allow a much broader set of diagnostic tests onto the market for emergency use. At the same time, the FDA has started taking enforcement action against bad actors that are attempting to market fraudulent test kits. These recent developments suggest that the FDA will continue to adapt and respond to meet the needs of health care providers and patients to address the demands resulting from the coronavirus pandemic.

Alston & Bird has formed a multidisciplinary task force to advise clients on the business and legal implications of the coronavirus (COVID-19). You can view all our work on the coronavirus across industries and subscribe to our future webinars and advisories.

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