FDA's emergency use authorization policy for COVID-19 diagnostic tests

Erin R. Conway | Monday, March 30, 2020

On March 16, 2020, the United States Food and Drug Administration issued updated guidance for clinical laboratories, commercial manufacturers, and Food and Drug Administration staff on its Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency. FDA issued the guidance to help accelerate the availability of diagnostic tests for novel coronavirus—"SARS-CoV-2"—and the disease it causes—"Coronavirus Disease 2019" (COVID-19)—developed by laboratories and commercial manufacturers during the public health emergency in order to achieve more rapid and widespread testing capacity in the United States.

This guidance describes FDA's temporary policy for accelerating the development of diagnostic tests for COVID-19 by laboratories certified under Clinical Laboratory Improvement Amendments (CLIA) that meet the CLIA regulatory requirements to perform high-complexity testing. Such labs may seek Emergency Use Authorization (EUA) from FDA to develop and perform diagnostic tests to detect the SARSCoV-2 virus (as initially set out in FDA's guidance of February 29, 2020).

FDA has made available an "accelerated" template that laboratories may use to facilitate the preparation, submission, and authorization of an EUA. The template is only applicable to CLIA certified high-complexity laboratories with experience developing and validating molecular diagnostics for viral pathogens. Further, the template is only applicable for the in vitro qualitative detection of RNA from the SARS-CoV-2 in respiratory samples, e.g., nasopharyngeal, sputum, and BAL specimens.

The template must be completed and submitted to FDA within 15 business days following completion of assay validation and FDA notification in accordance with the guidance. FDA does not intend to object to a laboratory's use of its subject SARS-CoV-2 test for specimen testing for a reasonable period of time after validation and while the laboratory is preparing its EUA request.

After receipt of the EUA request, the FDA will conduct a preliminary review to identify any problems with the performance data. If any problems are identified, FDA intends to work with the laboratory to address the problem (e.g., through labeling or bench testing). If a laboratory is notified that any problems are significant and cannot be addressed in a timely manner, or that FDA is otherwise not able to authorize the EUA, the laboratory is expected to stop testing and issue corrected test reports indicating prior results may not be accurate.

While awaiting FDA determination on the EUA request, FDA recommends that clinical laboratories obtain confirmation of the first five positive and the first five negative clinical specimens using an EUA-authorized assay, which may involve sending these ten specimens to another laboratory for confirmation. If any of these results cannot be confirmed, the laboratory should notify FDA at CDRH-EUA-Templates@FDA.HHS.GOV, and take other appropriate actions such as terminating testing patient specimens, and issuing a corrected test report that indicates the prior test result may not be valid.

If FDA issues an EUA to a clinical laboratory, the subject SARS-CoV-2 in vitro diagnostic test is temporarily authorized for use until further notice, the public health emergency is terminated or the EUA is revoked by the FDA.

FDA notes that most of the 21 CFR 820 Quality System Regulation (QSR) requirements can be waived for the duration of the EUA. However, laboratories performing these tests must follow comparable practices as much as possible and should consider previous compliance history when determining whether or not to waive certain QSR requirements for a specific product. Adverse events, as per 21 CFR Part 803, have to be reported for authorized devices.

The guidance also describes a policy for commercial manufacturers to more rapidly distribute their SARS-CoV-2 diagnostics to laboratories for specimen testing after validation while an EUA is being prepared for submission to FDA. FDA provides recommendations regarding validation of COVID-19 tests and stressed that it remains "critically important" to validate these tests to avoid false results.

McDonald Hopkins is also closely following progression of the CARES Act through Congress and will update these materials with any additional information from the Act that affects or touches on clinical testing considerations.

Erin R. Conway
Team member bio