COVID-19 Update: FDA announces policies to increase availability of coronavirus testing

March 19, 2020

The Food and Drug Administration (FDA) announced a policy shift on March 16, 2020, to allow state health departments to approve COVID-19 (coronavirus) diagnostic tests without FDA involvement during the current public health emergency. Given the global magnitude of the COVID-19 pandemic, there is a greater need for testing capacity than is currently available. The FDA's unprecedented policy change is intended to aid in rapidly expanding the availability of COVID-19 diagnostic tests.

The new state approval process applies to labs certified under Clinical Laboratory Improvement Amendments (CLIA) that meet the requirements to perform high complexity testing. States that elect to use the FDA's grant of state power must notify the FDA of their intentions. As of March 18, 2020, Ohio had not publicly indicated an intention to take responsibility for approving COVID-19 diagnostic tests.

The FDA guidance also includes a policy, first unveiled on February 29, 2020, for accelerating the development and performance of diagnostic tests for CLIA labs, which can be utilized by labs in states that have not opted to exercise oversight over COVID-19 tests. However, that option still involves FDA oversight and requires an Emergency Use Authorization (EUA) submission to the FDA within 15 business days of the test's validation and an initial notification to the FDA. Similarly, under the latest

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FDA guidance, commercial manufacturers may also opt into an accelerated process, whereby the commercial manufacturer may distribute validated COVID-19 diagnostic test kits to clinical laboratories or health care workers for point-of-care testing while an EUA is being prepared for submission to the FDA. This is permissible as long as such submission takes place within 15 business days of the test's validation and initial notification to the FDA.

The FDA believes that by increasing flexibility, these policies will help address urgent public health concerns by expanding the number and variety of diagnostic tests for COVID-19, as well as available testing capabilities in reference and commercial laboratories and health care settings.