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FDA Issues New COVID-19 EUA Requirements After HHS Restores Agency's LDT Oversight Role

by Elizabeth Orr

A controversial Trump-era policy that blocked the US FDA from regulating laboratory-developed tests was binned by the Health and Human Services secretary on 15 November. As a result, the FDA will once again require emergency use authorizations or other clearances for new COVID-19 tests.

The US Department of Health and Human Services (HHS) has withdrawn a controversial 2020 dictate that blocked the Food and Drug Administration from regulating laboratory-developed tests (LDTs), allowing the agency to impose new requirements on submissions for COVID-19 diagnostics.

The FDA's *revised policy for COVID-19 tests*, issued on 15 November, says new diagnostics should get an OK from the agency in the form of a cleared emergency use authorization (EUA) or other marketing clearance before being distributed for clinical use. The new policy prioritizes EUAs for specific categories of tests that the FDA believes could pose a higher risk to the public.

Prioritized EUA categories include:

- Tests performed at home or at the point of care that are manufactured in high volume;
- High-volume lab tests that use techniques like specimen pooling or testing for multiple respiratory viruses to expand test capacity;
- High-volume antibody tests that can measure the amount of antibodies or neutralizing antibodies in patient samples; and

- Tests supported by a government stakeholder, such as the Biomedical Advanced Research and Development Authority or the National Institutes of Health's Rapid Acceleration of Diagnostics.

Further, the agency will prioritize tests where the sponsor says they have sufficient instrument and kit production capacity, or sufficient assay and collection kit production capacity for home-based tests.

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"High volume" means the manufacturer plans to make at least 500,000 tests per week within three months of authorization, the document explains.

"The FDA remains committed to helping to increase the availability of tests that will have the biggest impact on the nation's ongoing COVID-19 testing needs, such as at-home and point-of-care diagnostic tests that can be produced in high volumes," said FDA device center director Jeff Shuren. "By focusing our review on these types of tests, and helping to ensure that available tests have appropriate oversight, we can better respond to the pandemic as the nation's testing needs continue to evolve."

In addition to the new policy, the agency also issued an *umbrella EUA* for molecular LDTs that are used for serial testing in settings like workplaces or schools. The new document will help those tests reach users more efficiently, the FDA said.

Manufacturers of tests outside the high-priority categories should "consider pursuing marketing authorization through traditional device review pathways such as 510(k) notification or de novo classification," the FDA said.

LDT Oversight Boomerangs Back To 2019

LDT regulation has long been a hot-button issue. While the tests have traditionally been regulated by the Centers for Medicare and Medicaid Services (CMS) under the Clinical Laboratory Improvement Amendments (CLIA), stakeholders including the FDA have pressed for additional agency authority as a way to better ensure test quality and safety.

At the start of the COVID-19 pandemic, the agency asked developers of COVID-19 LDTs to submit EUAs. But HHS shut that down in August 2020, when it issued a memorandum stating the FDA had acted beyond its authority in requesting the applications, and that no EUA would be required for LDTs going forward. (Also see "*Override: HHS Revokes FDA's LDT Policies*" - Medtech Insight, 20 Aug, 2020.)

Withdrawing the Trump-era policy represents a reversion to the pre-2020 status quo. Additionally, HHS secretary Xavier Becerra said, giving some LDT oversight back to the FDA will help ensure COVID-19 tests are accurate and reliable. Test accuracy has been a persistent problem throughout the pandemic; most recently, the FDA categorized a recall of Ellume's EUA-cleared home test as high-risk class I because the diagnostic can give false positives. (Also see "*Recall Of Millions Of Ellume COVID-19 Tests High-Risk Class I, FDA Says*" - Medtech Insight, 10 Nov, 2021.)

"By withdrawing the policy, HHS is helping to ensure that COVID-19 tests work as intended. Effective today, HHS no longer has a policy on LDTs that is separate from FDA's longstanding approach in this area," Becerra said.

The reversal follows months of pressure from Capitol Hill. In May, a group of House Democrats sent a *letter* asking Becerra to allow the FDA to review LDTs once again. And the Verifying Accurate, Leading-edge IVCT Development (VALID) Act, introduced in Congress in June, would create a new regulatory pathway that would include both LDTs and *in vitro* diagnostics. (Also see "*Patient Advocacy Groups Pressure US Lawmakers To Pass VALID Act For Diagnostics Regulation*" - Medtech Insight, 2 Jul, 2021.)