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HHS Withdraws Policy Concerning Laboratory Developed Tests | FDA Updates Certain COVID-19 Test Policies and Review Prioritization

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As the COVID-19 pandemic progressed, the U.S. Food and Drug Administration (FDA) sought to provide timely guidance to the relevant stakeholders to support continuity and response efforts. Notwithstanding, on August 19, 2020, the U.S. Department of Health and Human Services (HHS), under the Trump Administration, issued a policy that rescinded FDA guidance and other informal issuances concerning premarket review of laboratory developed tests (LDT), including premarket approval (PMA) or clearance (510(k)), and emergency use authorization (EUA). Such policies were intended to expedite the availability of COVID-19 tests. Although the FDA after notice-and-comment rulemaking could still require premarket review of LDTs, HHS's policy directing the FDA not to require premarket review for LDTs limited the FDA's ability to address certain problematic or poorly performing COVID-19 tests.

On November 15, 2021, HHS, under the Biden Administration, withdrew the policy in an effort to help ensure the accuracy and reliability of COVID-19 tests. On that same day, the FDA reissued the *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)* and took several other actions (listed below) to increase access to accurate and reliable COVID-19 tests, including tests that can be performed at the point of care (POC), such as at a hospital, emergency room, or doctor's office; or at home:

- → Issued a new Umbrella EUA for SARS-CoV-2 Molecular Diagnostic Tests developed by laboratories for Serial Testing
- → Reissued the EUA for Molecular Diagnostic Tests for SARS-CoV-2 Developed And Performed By Laboratories Certified Under CLIA To Perform High Complexity Tests

- → Revised the Enforcement Policy for Viral Transport Media During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (Revised) to update references to the *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency*.
- → Updated the FAQs on Testing for SARS-CoV-2

The *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)* is a reissued FDA policy document regarding diagnostic and serology tests for COVID-19, including FDA policies and recommendations regarding distribution, offering, and review prioritization of tests; modifications to EUA-authorized diagnostic COVID-19 tests; and State authorization of high-complexity CLIA-certified laboratories. For COVID-19 tests being offered prior to or without authorization, the FDA generally expects submission of an EUA request in accordance with its guidance. For tests with pending EUA requests, the FDA generally intends to review the EUA requests (EUA requests submitted prior to February 1, 2021, require certain affirmative actions by the test developer). If the FDA does not subsequently authorize the test, it expects developers to cease marketing the test within 15 calendar days of being notified through email. For newly offered tests, including LDTs, the FDA now generally expects the test to have an EUA or traditional marketing authorization such as a granted De Novo or cleared 510(k) prior to clinical use.

The FDA will now generally focus its review on certain EUA requests for (1) at-home and POC diagnostic tests; (2) certain high-volume, laboratory-based molecular diagnostic tests; (3) certain laboratory-based and POC high volume serology tests; and (4) tests for which the request is from or supported by a U.S. government stakeholder. For those tests not within the FDA's focus of review, developers may still pursue marketing authorization through traditional device review pathways such as 510(k) notification or De Novo classification.