FDA authorizes first COVID-19 at-home test collection kits

The U.S. Food and Drug Administration authorized the first diagnostic test with a home collection option for COVID-19. Specifically, the FDA re-issued the emergency use authorization (EUA) for the Laboratory Corporation of America (LabCorp) COVID-19 RT-PCR Test to permit testing of samples self-collected by patients at home using LabCorp's Pixel by LabCorp COVID-19 Test home collection kit.

"Throughout this pandemic we have been facilitating test development to ensure patients access to accurate diagnostics, which includes supporting the development of reliable and accurate at-home sample collection options," said FDA Commissioner Stephen M. Hahn, M.D. "The FDA's around-the-clock work since this outbreak began has resulted in the authorization of more than 50 diagnostic tests and engagement with over 350 test developers. Specifically, for tests that include home sample collection, we worked with LabCorp to ensure the data demonstrated from at-home patient sample collection is as safe and accurate as sample collection at a doctor's office, hospital or other testing site. With this action, there is now a convenient and reliable option for patient sample collection from the comfort and safety of their home."

This reissued EUA for LabCorp's molecular test permits testing of a sample collected from the patient's nose using a designated self-collection kit that contains nasal swabs and saline. Once patients self-swab to collect their nasal sample, they mail their sample, in an insulated package, to a LabCorp lab for testing. LabCorp intends to make the Pixel by LabCorp COVID-19 Test home collection kits available to consumers in most states, with a doctor's order, in the coming weeks.

The LabCorp home self-collection kit includes a specific Q-tip-style cotton swab for patients to use to collect their sample. Due to concerns with sterility and cross-reactivity due to inherent genetic material in cotton swabs, other cotton swabs should not be used with this test at the present time. The FDA continues to work with test developers to determine whether or not Q-tip-style cotton swab can be used safely and effectively with other tests.

This authorization only applies to the LabCorp COVID-19 RT-PCR Test for at-home collection of nasal swab specimens using the Pixel by LabCorp COVID-19 home collection kit. It is important to note that this is not a general authorization for at-home collection of patient samples using other collection swabs, media, or tests, or for tests fully conducted at home.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation’s food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.