FDA Authorizes First Diagnostic Test Using At-Home Collection of Saliva Specimens

Today, the U.S. Food and Drug Administration authorized the first diagnostic test with the option of using home-collected saliva samples for COVID-19 testing. Specifically, the FDA issued an emergency use authorization (EUA) to Rutgers Clinical Genomics Laboratory for their COVID-19 laboratory developed test (LDT), which had been previously added to the high complexity molecular-based LDT "umbrella" EUA, to permit testing of samples self-collected by patients at home using the Spectrum Solutions LLC SDNA-1000 Saliva Collection Device. This announcement builds on last month's EUA for the first diagnostic test with a home-collection option, which uses a sample collected from the patient's nose with a nasal swab and saline.

"Authorizing additional diagnostic tests with the option of at-home sample collection will continue to increase patient access to testing for COVID-19. This provides an additional option for the easy, safe and convenient collection of samples required for testing without traveling to a doctor's office, hospital or testing site," said FDA Commissioner Stephen M. Hahn, M.D. "We will continue to work around the clock to support the development of accurate and reliable tests, as we have done throughout this pandemic. The FDA has authorized more than 80 COVID-19 tests and adding more options for at-home sample collection is an important advancement in diagnostic testing during this public health emergency."

Today's EUA for Rutgers Clinical Genomics Laboratory's molecular test permits testing of a saliva sample collected

from the patient using a designated self-collection kit. Once patients collect their saliva sample, they return it to the Rutgers Clinical Genomics Laboratory in a sealed package for testing.

The Rutgers Clinical Genomics Laboratory test is currently the only authorized COVID-19 diagnostic test that uses saliva samples to test for SARS-CoV-2, the strain of coronavirus that causes COVID-19. The test remains prescription only.

Today’s authorization is limited to testing performed at the Rutgers Clinical Genomics Laboratory using their molecular LDT COVID-19 authorized test for saliva specimens collected using the Spectrum Solutions LLC SDNA-1000 Saliva Collection Device. It is important to note that this is not a general authorization for at-home collection of patient samples using other collection methods, saliva collection devices, or tests, or for tests fully conducted at home.