FDA authorizes first T cell-based test to detect prior SARS-CoV-2

March 10 2021

(HealthDay)—The T-Detect COVID Test, a T cell-based test that helps

to identify individuals with recent or prior severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection, was granted emergency use authorization, the U.S. Food and Drug Administration announced Friday.

The next-generation sequencing-based test analyzes DNA sequences to identify those with an adaptive T cell immune response to SARS-CoV-2. As opposed to antibody tests, which have been the primary detection method to determine prior SARS-CoV-2 infection, T cell responses appear earlier and last longer in the blood, according to a company press release. The FDA notes that the test will be especially useful for people who may have had symptoms of SARS-CoV-2 or who believe they were exposed but did not test positive with a molecular or antigen diagnostic test.

A positive test result signaling that an individual has recently or previously been infected with SARS-CoV-2 could help to address potential long-term effects of the virus. The FDA notes that negative results do not preclude acute or current SARS-CoV-2 infection, and the test results should be used in combination with clinical examination, patient medical history, and other findings.

The T-Detect COVID Test is indicated for use at least 15 days after symptom onset. Patients can order the test online after answering eligibility questions through a secure portal. Virtual providers authorize the prescription, and patients can have their blood drawn by a mobile phlebotomist or at a Labcorp patient service center.

It is currently unknown how long the T cell immune response remains in individuals after infection and what level of protection a T cell immune response provides. "Information and scientific data that deepen our understanding of SARS-CoV-2 remain important keys to get ahead of this global pandemic," Jeff Shuren, M.D., J.D., director of the FDA

Center for Devices and Radiological Health, said in an agency news release.

The T-Detect COVID Test was developed by Adaptive Biotechnologies.

More information: More Information