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FDA authorizes adaptive Biotechnologies T-Detect COVID test

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Novel technology that assesses the T cell immune response to COVID-19



The U.S. Food and Drug Administration on March 5th 2021 issued an emergency use authorization (EUA) for the T-Detect COVID Test developed by Adaptive Biotechnologies. The T-Detect COVID Test is a next-generation sequencing-based (NGS) test to aid in identifying individuals with an adaptive T cell immune response to SARS-CoV-2, indicating recent or prior infection with SARS-CoV-2.

Jeff Shuren, M.D., J.D., director of FDA's Center for Devices and Radiological Health, "The T-Detect COVID Test is a novel technology that assesses the T cell immune response to COVID-19. Information and scientific data that deepen our understanding of SARS-CoV-2 remain important keys to get ahead of this global pandemic."

The test analyzes DNA (deoxyribonucleic acid) sequences from T cells (white blood cells) to aid in identifying individuals with an adaptive T cell immune response to SARS-CoV-2, indicating recent or previous SARS-CoV-2 infection. A positive test result indicates recent or prior infection with SARS-CoV-2, while a negative test result indicates that a patient is unlikely to have been infected with SARS-CoV-2. Negative results do not preclude acute or current SARS-CoV-2 infection. All results from the test should be used in combination with a clinical examination, patient medical history and other findings. The T-Detect COVID Test should not be used to diagnose current SARS-CoV-2 infection.

A T cell response may be detected in blood several days after initial infection; however, it is unknown how long the T cell immune response remains following infection and what level of protection may be provided by the presence of a T cell immune response. The T-Detect COVID test will be a useful tool to help determine if a person previously had COVID-19. This is especially important for people who may have exhibited symptoms previously or believe they have been exposed but have not tested positive for COVID-19 using a molecular or antigen diagnostic test.

The test is indicated for use by qualified healthcare professionals on samples from individuals who are 15 days or more post-symptom onset. Testing is currently limited to laboratories designated by Adaptive Biotechnologies Corporation that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and meet the requirements to perform high complexity tests.