

# FACT SHEET FOR HEALTHCARE PROVIDERS

Adaptive Biotechnologies Corporation  
T-Detect COVID Test

March 5, 2021

Coronavirus  
Disease 2019  
(COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the T-Detect COVID Test.

**You should not interpret the results of this test as an indication of immunity or protection from COVID-19.**

The T-Detect COVID Test is authorized as an aid identifying individuals with an adaptive T-cell immune response to SARS-CoV-2 in human venous whole blood using di-potassium ethylenediaminetetraacetic acid (K2 EDTA) as an anticoagulant.

**All individuals whose specimens are tested with this test will receive the Fact Sheet for Recipients: Adaptive Biotechnologies Corporation - T-Detect COVID Test.**

## What are the symptoms of COVID-19?

Many patients with COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, dyspnea), although some individuals experience only mild symptoms or no symptoms at all. The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that, when present, symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat, new loss of taste or smell, nausea or vomiting or diarrhea. Signs and symptoms may appear any time from 2 to 14 days after exposure to the virus, and the median time to symptom onset is approximately 5 days. For further information on the symptoms of COVID-19 please see the link provided in "*Where can I go for updates and more information?*" section.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States. Please check the CDC COVID-19 webpage (see link provided in "*Where can I go for updates and more information?*" section at the end of this document) or

**This test detects human SARS-CoV-2 rearranged T-cell receptor beta (TCR  $\beta$ ) gene sequences from human genomic DNA (gDNA) generated as part of the human adaptive immune response to the COVID-19 virus and is to be performed on only venous whole blood specimens using K2 EDTA as an anticoagulant.**

your local jurisdiction's website for the most up to date information.

## What do I need to know about COVID-19 testing?

Current information on COVID-19 for healthcare providers is available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "*Where can I go for updates and more information?*" section).

- The T-Detect COVID Test can be ordered by healthcare providers to test venous whole blood using K2 EDTA as an anticoagulant to aid in identifying individuals with an adaptive immune response to COVID-19, indicating recent or prior infection.
- The T-Detect COVID Test should not be used to diagnose or exclude acute infection and should not be used as the sole basis for treatment or patient management decisions. Direct testing for SARS-CoV-2 should be performed using a FDA approved, cleared, or authorized molecular or antigen test for SARS-CoV-2, if acute infection is suspected.
- The performance of the T-Detect COVID Test has not been established in individuals that have received a COVID-19 vaccine.
- The T-Detect COVID Test is authorized for use in laboratories designated by Adaptive Biotechnologies Corporation that includes the Adaptive Biotechnologies Lab located at 1551 Eastlake Ave E Ste 200, Seattle, Washington, which is also certified under the Clinical Laboratory Improvements Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meets requirements to perform high-complexity tests.
- Specimens should only be tested from individuals that are 15 days or more post-symptom onset.

**Report Adverse events**, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>) or by calling **1-800-FDA-1088**

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Specimens should be collected with appropriate infection control precautions. Current guidance is available at the CDC's website (see links provided in "Where can I go for updates and more information?" section).

When collecting and handling specimens from individuals suspected of being infected with COVID-19, appropriate personal protective equipment should be used as outlined in the CDC *Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)*. For additional information, refer to CDC *Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19)* (see links provided in "Where can I go for updates and more information?" section).

## **What does it mean if the specimen tests positive for an adaptive T-cell immune response against the virus that causes COVID-19?**

A positive test result with the T-Detect COVID Test indicates that an adaptive T-cell immune response to SARS-CoV-2 was detected, and the individual has potentially been exposed to COVID-19.

It may take several days after initial infection to prime and expand adaptive T cell immune responses, although the duration of time the adaptive T cell immune responses are present is not well characterized for SARS-CoV-2. If an adaptive T-cell immune response to SARS-CoV-2 was detected, it often indicates a past infection but does not exclude recently infected patients who are still contagious and may infect others with COVID-19.

The clinical significance of a positive *adaptive T-cell immune response to SARS-CoV-2* result for individuals that have received a COVID-19 vaccine is unknown.

***At this time, it is unknown how long the T-cell immune response persists following infection and if any protection may be conferred by the presence of a T-cell immune response.***

***Incorrect assumptions of immunity may lead to premature discontinuation of physical distancing***

***requirements and increase the risk of infection for individuals, their households and the public.***

***Regardless of the test result, individuals should continue to follow CDC guidelines to reduce the risk of infection, including social distancing and wearing masks.***

False positive results may occur due to cross-reactivity with other microorganisms or other possible causes.

The T-Detect COVID Test has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, risks include an increased risk of infection to the patient or other individuals by exposure to persons with active COVID-19. If a recent infection is suspected a false positive result may lead to a recommendation for isolation of the patient, monitoring of household or other close contacts for symptoms, additional testing, patient isolation that might limit contact with family or friends and may increase contact with other potentially COVID-19-infected patients, limits in the ability to work, or other unintended adverse effects.

Laboratory test results should always be considered in the context of clinical observations and epidemiological data in making patient management decisions.

All laboratories using this test must follow the standard testing and reporting guidelines according to their appropriate public health authorities.

## **What does it mean if the specimen tests negative for an adaptive T-cell immune response against virus that causes COVID-19?**

A negative test result with this test means that an adaptive T-cell immune response were not present in the specimen above the limit of detection. ***However, patients tested early after infection may not have a detectable adaptive T-cell immune response despite active infection; in addition, it is not certain that all infected patients will develop a detectable adaptive T-cell immune response to SARS-CoV-2 infection. A negative result should not be used to rule out infection. Direct testing of SARS-CoV-2 should be***

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***performed using a molecular or antigen SARS-CoV-2 assay, if acute infection is suspected.***

The sensitivity of the T-Detect COVID Test is unknown.

The clinical significance of a negative *adaptive T-cell immune response to SARS-CoV-2 result* for individuals that have received a COVID-19 vaccine is unknown.

Risks to a patient of a false negative result include: restriction of activities potentially deemed acceptable for patients with evidence of an antibody response to SARS-CoV-2, lack of monitoring of infected individuals and their household or other close contacts for symptoms resulting in increased risk of spread of COVID-19 within the community, or other unintended adverse events

The performance of this test was established based on the evaluation of a limited number of clinical specimens. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

## **What is an EUA?**

The United States FDA has made this test available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics (IVDs) for the detection and/or diagnosis of the virus that causes COVID-19.

An IVD made available under an EUA has not undergone the same type of review as an FDA-approved or cleared IVD. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that this IVD may be effective at diagnosing recent or prior infection with SARSCoV-2 by identifying individuals with an adaptive immune response

to the virus that causes COVID-19.

The EUA for this test is in effect for the duration of the COVID-19 declaration justifying emergency use of IVDs, unless terminated or revoked (after which the test may no longer be used).

## **What are the approved available alternatives?**

There are no approved available alternative tests. FDA has issued EUAs for other tests that can be found at: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

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## Where can I go for updates and more information?

### **CDC webpages:**

**General:** <https://www.cdc.gov/COVID19>

**Symptoms:**

<https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html>

**Healthcare Professionals:**

<https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html>

**Information for Laboratories:** <https://www.cdc.gov/coronavirus/2019-nCoV/guidance-laboratories.html>

**Laboratory Biosafety:** <https://www.cdc.gov/coronavirus/2019-nCoV/lab-biosafety-guidelines.html>

**Isolation Precautions in Healthcare Settings:**

<https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html>

**Specimen Collection:** <https://www.cdc.gov/coronavirus/2019-nCoV/guidelines-clinical-specimens.html>

**Infection Control:** <https://www.cdc.gov/coronavirus/2019-ncov/infection-control/index.html>

### **FDA webpages:**

**General:** [www.fda.gov/novelcoronavirus](http://www.fda.gov/novelcoronavirus)

**EUAs:**(includes links to patient fact sheet and manufacturer's instructions) <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>

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