

# FACT SHEET FOR RECIPIENTS

Roche Diagnostics, Inc.  
Elecsys Anti-SARS-CoV-2 S

November 25, 2020

Coronavirus  
Disease 2019  
(COVID-19)

You are being given this Fact Sheet because your sample(s) is being tested or was tested for antibodies to the virus that causes Coronavirus Disease 2019 (COVID-19) using the Elecsys Anti-SARS-CoV-2 S.

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**You should not interpret the results of this test as an indication or degree of immunity or protection from reinfection.**

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This Fact Sheet contains information to help you understand the risks and benefits of using this test to evaluate your adaptive immune response to SARS-CoV-2, the virus that causes COVID-19. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider. You have the option to refuse use of this test. However, your doctor may be recommending this test because they believe it could help with your care.

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**For the most up to date information on COVID-19 please visit the CDC Coronavirus Disease 2019 (COVID-19) webpage:**  
<https://www.cdc.gov/COVID19>

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## What is COVID-19?

COVID-19 is caused by the SARS-CoV-2 virus which is a new virus in humans causing a contagious respiratory illness. COVID-19 can present with a mild to severe illness, although some people infected with COVID-19 may have no symptoms at all. Older adults and people of any age who have underlying medical conditions have a higher risk of severe illness from COVID-19. Serious outcomes of COVID-19 include hospitalization and death. The SARS-CoV-2 virus can be spread to others not just while one is sick, but even before a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.). A full list of

symptoms of COVID-19 can be found at the following link: <https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html>.

## How are people tested for COVID-19?

Two kinds of tests are currently available for COVID-19: diagnostic tests and antibody tests.

- A diagnostic test tells you if you have a current infection.
- An antibody test tells you if you had a previous infection

## What is the Elecsys Anti-SARS-CoV-2 S?

This test is an antibody test. It will help assess if you have antibodies to the virus that causes COVID-19. An antibody test may not be able to show if you have a current infection, because it can take 1-3 weeks after infection to make antibodies.

## What are the known and potential risks and benefits of the test?

Potential risks include:

- Possible discomfort or other complications that can happen during sample collection.
- Possible incorrect test result (see below for more information).

Potential benefits include:

- The results, along with other information, can help your healthcare provider make informed recommendations about your care.

## What does it mean if I have a positive test result?

If you have a positive test result, it is possible that you have or previously had COVID-19 and that you have developed an antibody response to the virus. Your healthcare provider will work with you to determine how best to care for you based on the test results along with other factors of your medical history, your symptoms, possible exposures, and geographic location of places

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- **Where can I go for updates and more information?** The most up-to-date information on COVID-19 is available at the CDC General webpage: <https://www.cdc.gov/COVID19>. In addition, please also contact your healthcare provider with any questions/concerns.
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you have recently traveled. There is also a chance that this test can give a positive result that is wrong (a false positive result). Even a high-performing antibody test when used in a population without many cases of COVID-19 infection may produce as many or more false results as true results because the likelihood of finding someone who has been infected is very small.

Your healthcare provider will work with you to determine the likelihood of false result.

***This test may give you a numerical result, but you should not interpret the number to mean that having any measurement of antibodies to SARS-CoV-2 will protect you from getting infected again or help reduce the severity or duration of a future COVID-19 infection. This topic is being studied, but the information is unknown. It is also not known how long antibodies to SARS-CoV-2 will remain present in the body after infection.***

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

## **What does it mean if I have a negative test result?**

A negative test result means that antibodies to the virus that causes COVID-19 were not found in your sample. However, it is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. Additionally, a negative result may occur if you are tested early in your illness and your body hasn't had time to produce antibodies to infection. This means that you could possibly still have COVID-19 even though the test is negative. If this is the case, your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you.

It is important that you work with your healthcare provider to help you understand the next steps you should take.

## **Is this test FDA-approved or cleared?**

No. This test is not yet approved or cleared by the United States FDA. When there are no FDA-approved or cleared tests available, and other criteria are met, FDA can make tests available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA for this test 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 for the detection and/or diagnosis of the virus that causes COVID-19. This EUA will remain in effect (meaning this test can be used) for the duration of the COVID-19 declaration justifying emergency of IVDs, unless it is terminated or revoked by FDA (after which the test may no longer be used).

## **What are the approved 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?** The most up-to-date information on COVID-19 is available at the CDC General webpage: <https://www.cdc.gov/COVID19>. In addition, please also contact your healthcare provider with any questions/concerns.
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## **FACT SHEET FOR PATIENTS AND PARENTS/CAREGIVERS**

### **EMERGENCY USE AUTHORIZATION (EUA) OF COVID-19 CONVALESCENT PLASMA FOR TREATMENT OF COVID-19 IN HOSPITALIZED PATIENTS**

You are being given COVID-19 convalescent plasma to treat COVID-19. This fact sheet contains information to help you understand the risks and benefits of taking the COVID-19 convalescent plasma you have received or may receive.

Transfusion of COVID-19 convalescent plasma may benefit patients hospitalized with COVID-19.

Read this Fact Sheet for information about COVID-19 convalescent plasma. Talk to your health care provider if you have questions. It is your choice to accept treatment with COVID-19 convalescent plasma or stop it at any time.

#### **WHAT IS COVID-19?**

You have been diagnosed with disease caused by the SARS-CoV-2 virus also known as coronavirus disease 2019 (COVID-19). This type of coronavirus has not been seen before. This new virus has caused a worldwide pandemic with many patients developing severe respiratory illness and other serious complications. You can get COVID-19 through contact with another person who has the virus.

#### **WHAT ARE THE SYMPTOMS OF COVID-19?**

Common symptoms are fever, cough, and shortness of breath, which may appear 2-14 days after exposure. COVID-19 illnesses have ranged from very mild (including some with no reported symptoms) to severe, including illness resulting in death. While information so far suggests that most COVID-19 illness is mild, serious illness can occur and may cause some of your other medical conditions to become worse. Older people and people of all ages with severe chronic medical conditions like heart disease, lung disease, and diabetes, for example, seem to be at higher risk of being hospitalized for COVID-19.

#### **WHAT IS COVID-19 CONVALESCENT PLASMA?**

The blood from people who recover from COVID-19 contains substances called antibodies, which are capable of fighting the virus that causes the illness. For some other diseases caused by respiratory viruses, giving people the liquid portion of blood that contains these antibodies, called plasma, obtained from those who have recovered from the virus, may lead to more rapid improvement of the disease. Patients with COVID-19 may improve faster if they receive plasma from those who have recovered from COVID-19, because it may have the ability to fight the virus that causes COVID-19.

#### **HOW IS COVID-19 CONVALESCENT PLASMA GIVEN?**

You will be given plasma, the liquid portion of the blood, from a person who has recovered from COVID-19. It will be given into one of your veins, using a sterile single use needle, and will be given over the course of up to about one to two hours. Approximately 200 mL (a little less than 8 ounces) of plasma will be given in an initial infusion. Additional infusions of plasma may occur throughout your hospital stay if the treating physician determines that additional treatments are clinically justified.

#### **WHAT ARE THE POSSIBLE BENEFITS OF GETTING COVID-19 CONVALESCENT PLASMA?**

This treatment might be effective in improving the likelihood of you recovering from the disease.

## **WHAT ARE THE COMMON AND/OR POSSIBLE SIDE EFFECTS (RISKS) OF COVID-19 CONVALESCENT PLASMA?**

Transfusion carries the risk of adverse reactions such as allergic reactions, transfusion-associated circulatory overload, or lung damage with profound breathing difficulty, cardiac (heart) rhythm irregularities, and blood clotting.

As with receipt of any blood product, there is a risk of transfusion-transmitted infection including HIV, hepatitis B, and hepatitis C. The risk of these infections is very low, because only screened blood is used for transfusion.

You may have other side effects that are not known at this time and may include serious injury or pain, disability, or death. There is also a chance that confidentiality of your private information could be lost; however, procedures are in place to minimize this risk.

## **WHO SHOULD NOT GET COVID-19 CONVALESCENT PLASMA?**

Discuss with your health care provider if previously you had any reactions to plasma products or other blood products.

## **WHAT IF I AM PREGNANT OR BREASTFEEDING?**

The safety and effectiveness of COVID-19 convalescent plasma in pregnancy and nursing mothers has not been evaluated. If you are pregnant or breastfeeding, please talk with your health care provider to decide if you should receive COVID-19 convalescent plasma.

## **HOW DO I REPORT SIDE EFFECTS?**

After receiving COVID-19 convalescent plasma, if you are experiencing any side effects that are bothersome, serious, or that do not go away, please contact your health care provider. When you are reporting a side effect, you should identify that you received COVID-19 convalescent plasma.

## **ARE THERE OTHER ALTERNATIVES TO COVID-19 CONVALESCENT PLASMA?**

As of the date of this fact sheet, one drug has been approved by FDA for the treatment of certain hospitalized patients with COVID-19

([https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2020/214787Orig1s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/214787Orig1s000lbl.pdf)). There are no other drugs or other therapeutics approved by the FDA to prevent or treat COVID-19 infection. Like convalescent plasma, FDA may allow for the emergency use of other medicines to treat people in the hospital with COVID-19.

In addition, your health care provider may talk to you about clinical trials you may be eligible for. It is your choice to be treated or not to be treated with COVID-19 convalescent plasma. You can decide not to get it or stop it at any time. Whether you decide to take COVID-19 convalescent plasma or not, it will not change your standard medical care. You may be given other available treatments that may include oxygen, fluids, and medications depending on your condition and determined by your doctor.

## **HOW CAN I LEARN MORE?**

1. Ask your health care provider
2. Contact your local or state public health department

## **WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?**

The United States FDA has made COVID-19 convalescent plasma available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

COVID-19 convalescent plasma has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that it is reasonable to believe that known and potential benefits of the product, when used to treat COVID-19, outweigh the known and potential risks of the product. All of these criteria must be met to allow for the authorized product to be used in the treatment of patients during the COVID-19 pandemic.

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

# FACT SHEET FOR HEALTHCARE PROVIDERS

Roche Diagnostics, Inc.  
Elecsys Anti-SARS-CoV-2 S

November 25, 2020

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 Elecsys Anti-SARS-CoV-2 S.

**You should not interpret the results of this test as an indication or degree of immunity or protection from reinfection.**

The Elecsys Anti-SARS-CoV-2 S is authorized for the detection of antibodies to SARS-CoV-2 in human serum and plasma (lithium heparin, dipotassium EDTA, tripotassium EDTA, and sodium citrate).

**All individuals whose specimens are tested with this test will receive the Fact Sheet for Recipients: Roche Diagnostics, Inc. – Elecsys Anti-SARS-CoV-2 S.**

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

**This test detects human SARS-CoV-2 antibodies that are generated as part of the human adaptive immune response to the COVID-19 virus and is to be performed on only serum and plasma (lithium heparin, dipotassium EDTA, tripotassium EDTA, and sodium citrate) specimens.**

## 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 Elecsys Anti-SARS-CoV-2 S can be ordered by healthcare providers to test serum and plasma (lithium heparin, dipotassium EDTA, tripotassium EDTA, and sodium citrate) to detect if there has been an adaptive immune response to COVID-19, indicating recent or prior infection.
- The Elecsys Anti-SARS-CoV-2 S 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 if acute infection is suspected.
- The Elecsys Anti-SARS-CoV-2 S provides a qualitative and semi-quantitative result. The clinical applicability of a semi-quantitative result is currently unknown and cannot be interpreted as an indication or degree of immunity or protection from reinfection. Because semi-quantitative SARS-CoV-2 antibody assays are not standardized, and the performance characteristics of each semi-quantitative SARS-CoV-2 antibody test is uniquely established, results from different semi-quantitative SARS-CoV-2 antibody assays are not comparable.
- The Elecsys Anti-SARS-CoV-2 S is authorized for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high or moderate complexity tests.

**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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- Please refer to the Elecsys Anti-SARS-CoV-2 S instructions for use for additional information.

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 antibodies against the virus that causes COVID-19?**

A positive test result with the SARS-CoV-2 antibody test indicates that antibodies to SARS-CoV-2 were detected, and the individual has potentially been exposed to COVID-19.

Antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection. Individuals may have detectable virus present for several weeks following seroconversion. If antibodies are present, it often indicates a past infection but does not exclude recently infected patients who are still contagious.

***This test may give a numerical result, but you should not interpret the number to mean that having any measurement of antibodies to SARS-CoV-2 will protect the individual tested from getting infected again or help reduce the severity or duration of a future COVID-19 infection. This topic is being studied, but the information is unknown. It is also not known how long antibodies to SARS-CoV-2 will remain present in the body after infection.***

***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 from pre-existing antibodies or other possible causes.

The Elecsys Anti-SARS-CoV-2 S has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, risks to the patient include the following: risk of infection 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, 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.

***Due to the risk of false positive results, confirmation of positive results should be considered – using a second, different antibody assay that detects the same type of antibodies.***

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 antibodies against virus that causes COVID-19?**

A negative test result with this test means that SARS-CoV-2 specific antibodies were not present in the specimen above the limit of detection. ***However, patients tested early after infection may not have detectable antibodies despite active infection; in addition, it is not certain that all infected patients will develop a detectable antibody response to SARS-CoV-2 infection. A negative result should not***

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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*be used to rule out infection. Direct testing of SARS-CoV-2 should be performed if acute infection is suspected.*

The absolute sensitivity of the Elecsys Anti-SARS-CoV-2 S 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.

## 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 SARS-CoV-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>.

## 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>

### Roche Diagnostics GmbH

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Roche HCP Support: 1-866-987-6243

US Customer Technical Support: 1-800-428-2336

[diagnostics.roche.com](http://diagnostics.roche.com)

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



## FACT SHEET FOR HEALTH CARE PROVIDERS

### EMERGENCY USE AUTHORIZATION (EUA) OF COVID-19 CONVALESCENT PLASMA FOR TREATMENT OF COVID-19 IN HOSPITALIZED PATIENTS

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product COVID-19 convalescent plasma to treat hospitalized patients with COVID-19.

#### INSTRUCTIONS FOR HEALTH CARE PROVIDERS

The information in this Fact Sheet is the minimum information necessary to inform you of the significant known and potential risks and benefits of the emergency use of COVID-19 convalescent plasma.

As the health care provider administering COVID-19 convalescent plasma, you must provide recipients with the **Fact Sheet for Patients/Caregivers** and must communicate the following information to the recipients:

1. FDA has authorized emergency use of COVID-19 convalescent plasma, which is not an FDA-approved biological product
2. The patient or caregiver has the option to accept or refuse administration of COVID-19 convalescent plasma
3. The significant known and potential risks and benefits of COVID-19 convalescent plasma and the extent to which such risks and benefits are unknown
4. Information on available alternative treatments and the risks and benefits of those alternatives.

If providing this information will delay the administration of COVID-19 convalescent plasma to a degree that would endanger the lives of patients, the information must be provided to the patients as soon as practicable after convalescent plasma is administered.

For information on clinical trials that are testing the use of COVID-19 convalescent plasma for COVID-19, please see [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

#### INTENDED USE

The EUA for COVID-19 convalescent plasma authorizes the use of COVID-19 convalescent plasma for the treatment of hospitalized patients with COVID-19. This EUA is based on historical evidence using convalescent plasma in prior outbreaks of respiratory viruses, certain preclinical evidence, results from small clinical trials of convalescent plasma conducted during the current outbreak, and data obtained from the ongoing National Expanded Access Treatment Protocol (EAP) sponsored by the Mayo Clinic.

Data suggest that use of COVID-19 convalescent plasma with high antibody titer may be effective in reducing mortality in hospitalized patients with COVID-19. Units containing anti-SARS-CoV-2 antibodies but not qualified as high titer by a test described below are considered “COVID-19 Convalescent Plasma of Low Titer” and are authorized for use (see Product Description). Health care providers can decide whether to use these units based on an individualized determination of potential benefit:risk. FDA will continue to evaluate this authorization based on additional data that become available. Current evidence also suggests that benefit is most likely in patients treated early in the course of the disease.

**Given that the clinical evidence supporting this EUA was not obtained from prospective, well-controlled randomized clinical trials (RCTs), additional RCTs are needed. Convalescent plasma should not be considered a new standard of care for the treatment of patients with COVID-19. Ongoing clinical trials of convalescent plasma should not be amended based on the issuance of the EUA. Providers are encouraged to enroll patients in those ongoing clinical trials.**

## **PRODUCT DESCRIPTION**

COVID-19 convalescent plasma is human plasma collected by FDA registered blood establishments from individuals whose plasma contains anti-SARS-CoV-2 antibodies, and who meet all donor eligibility requirements (21 CFR 630.10 and 21 CFR 630.15) and are qualified. Convalescent plasma is qualified and labeled as having high titer anti-SARS-CoV-2 antibodies based on testing accepted by FDA under this EUA.

Units containing anti-SARS-CoV-2 antibodies but not qualified as High Titer COVID-19 Convalescent Plasma are considered Low Titer COVID-19 Convalescent Plasma and must be labeled accordingly. These units are authorized for use. Health care providers can decide whether to use the units based on an individualized assessment of benefit:risk. FDA will continue to evaluate this authorized use based on additional data that become available.

## **DOSAGE, ADMINISTRATION, AND STORAGE OF COVID-19 CONVALESCENT PLASMA**

### **Dosage**

Health care providers will administer COVID-19 convalescent plasma according to standard hospital procedures and institutional medical and nursing practices.

Clinical dosing may first consider starting with one convalescent plasma unit (about 200 mL), with administration of additional convalescent plasma units based on the prescribing physician’s medical judgment and the patient’s clinical response.

Patients with impaired cardiac function and heart failure may require a smaller volume or more prolonged transfusion times.

## **Administration**

Administer COVID-19 convalescent plasma infusion through a peripheral or central venous catheter according to standard institutional medical and nursing practices for the administration of plasma (<http://www.aabb.org/tm/coi/Documents/coi1017.pdf>).

## **Storage**

COVID-19 convalescent plasma, may be stored frozen at -18°C or colder, and has an expiration date one year from the date of collection. Once thawed, it can be refrigerated for up to 5 days prior to patient transfusion.

## **DRUG INTERACTIONS**

COVID-19 convalescent plasma may be contraindicated in patients with a history of severe allergic reactions or anaphylaxis to plasma transfusion.

## **SIDE EFFECTS, RISKS, BENEFITS, AND RISK-BENEFIT ASSESSMENT**

### **Side Effects**

Known side effects and hazards associated with plasma transfusion include transfusion-transmitted infections (e.g. HIV, hepatitis B, hepatitis C), allergic reactions, anaphylactic reactions, febrile nonhemolytic reactions, transfusion-related acute lung injury (TRALI), transfusion-associated cardiac overload (TACO), and hemolytic reactions. Hypothermia, metabolic complications, and posttransfusion purpura have also been described. Additional information on risks of plasma can be found in the AABB Circular of Information (<http://www.aabb.org/tm/coi/Documents/coi1017.pdf>).

### **Risks**

A theoretical risk of administration of convalescent plasma is the phenomenon of antibody-dependent enhancement of infection (ADE). ADE has been described in other viral infections, such as dengue, and involves an enhancement of disease in the presence of certain antibodies. For coronaviruses, several mechanisms of ADE have been proposed, including the theoretical concern that antibodies to one type of coronavirus could enhance infection to another strain. Preparations with high titers of antibody against the same virus strain are thought to be less likely to cause ADE.

Another theoretical risk is that antibody administration may attenuate the immune response and make patients more susceptible to re-infection.

### **Benefits**

COVID-19 is a serious and potentially fatal or life-threatening human disease. The potential benefits of COVID-19 convalescent plasma therapy could include improvement in symptoms, reduced need for supplemental oxygen and mechanical ventilation, and reduced mortality. Support for the safety and effectiveness of COVID-19 convalescent plasma is derived from past human experience with convalescent plasma, evidence of preclinical safety and efficacy in animal models, published studies on the safety and efficacy of COVID-19 convalescent plasma in COVID-19 patients including from the National Expanded Access Treatment Protocol sponsored by the Mayo Clinic (EAP). A report of adverse events in the initial population of

20,000 subjects in the EAP found low overall rates of serious adverse events. Analysis of over 35,000 transfused patients in the EAP study found a dose-response between antibody level and reduction in mortality. Available evidence suggests that COVID-19 convalescent plasma with high antibody titer may be effective in reducing mortality in hospitalized patients with COVID-19. Units containing anti-SARS-CoV-2 antibodies but not qualified as high titer by a test found acceptable for this purpose by FDA (see Product Description) are considered Low Titer COVID-19 Convalescent Plasma and are authorized for use. Health care providers can decide whether to use the units based on an individualized assessment of patient benefit:risk.

### **Risk-Benefit Assessment**

Based on the totality of scientific evidence available at this time, the known and potential benefits of COVID-19 convalescent plasma outweigh the known and potential risks.

## **USE IN SPECIFIC POPULATIONS**

### **Pediatric**

Safety and effectiveness of COVID-19 convalescent plasma in the pediatric population has not been evaluated. The decision to treat patients <18 years of age with COVID-19 convalescent plasma should be based on an individualized assessment of risk and benefit.

### **Geriatric**

In the National Expanded Access Treatment Protocol sponsored by the Mayo Clinic, 69,811 patients were treated as of August 20, 2020. Preliminary analyses of the first 20,000 patients indicated that 5,423 (27.1%) were 60-69 years of age, 4,114 (20.6%) were 70-79 years of age, and 2,568 (12.8%) were 80 years of age or older. Although adverse event rates in the geriatric subgroup have not yet been provided, the rates in the overall population for the individual events of mortality within 4 hours, TACO, TRALI, severe allergic transfusion reaction, thrombotic/thromboembolic complication, sustained hypotension, and cardiac events were  $\leq$  0.37%.

### **Pregnancy**

Safety and effectiveness of COVID-19 convalescent plasma in pregnancy has not been evaluated. It should be used during pregnancy only if the potential benefit justifies the potential risk for the mother and the fetus.

### **Nursing Mothers**

It is not known whether or not transfused anti-SARS-CoV-2 antibodies are excreted in human milk. The safety and effectiveness of COVID-19 convalescent plasma in nursing mothers has not been evaluated. The decision to treat nursing mothers with COVID-19 convalescent plasma should be based on an individualized assessment of risk and benefit.

## **REPORTING ADVERSE EVENTS**

Health care providers must maintain records and conduct a thorough investigation of adverse reactions after transfusion of convalescent plasma, and must report fatalities related to transfusion, as required under 21 CFR 606.170.

As a health care provider, you must comply with the mandatory requirements of the EUA.

### **FDA-APPROVED ALTERNATIVES**

As of the date of this fact sheet, one drug has been approved by FDA for the treatment of certain hospitalized patients with COVID-19

([https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2020/214787Orig1s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/214787Orig1s000lbl.pdf)), but it is not considered an adequate alternative for the treatment of hospitalized patients with COVID-19.

There are no other drugs or other therapeutics approved by the FDA to prevent or treat COVID-19 infection. There are EUAs for other COVID-19 treatments (visit

<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs>).

The health care provider should visit <https://clinicaltrials.gov/> to determine whether the patient may be eligible for enrollment in a clinical trial.

### **COUNTERMEASURES INJURY COMPENSATION PROGRAM**

The Countermeasures Injury Compensation Program (CICP) is a federal program created to help pay for related costs of medical care and other specific expenses for eligible people seriously injured by the administration or use of certain medical countermeasures. Medical countermeasures may include vaccines, medications, devices, or other items used to prevent, diagnose, or treat the public during a current, or potential future, public health emergency or a security threat. For more information about CICP, visit <http://www.hrsa.gov/cicp/> or call: 1-855-266-2427.

### **AUTHORITY FOR ISSUANCE OF THE EUA**

The Secretary of the U.S. Department of Health and Human Services (HHS) has declared a public health emergency that justifies the emergency use of drugs and biological products during the COVID-19 pandemic. In response, the FDA has issued an EUA for the unapproved product, COVID-19 convalescent plasma, for the treatment of hospitalized patients with COVID-19. FDA issued this EUA requested by ASPR and based on their submitted data and other available data about COVID-19 convalescent plasma.

Although limited scientific information is available, based on the totality of the scientific evidence available to date, it is reasonable to believe that COVID-19 convalescent plasma may be effective for the treatment of COVID-19 in hospitalized patients as specified in this Fact Sheet. You may be contacted and asked to provide information to help with the assessment of the use of the product during this emergency.

This EUA for COVID-19 convalescent plasma will end when the Secretary determines that the circumstances justifying the EUA no longer exist, if additional data were to become available to no longer support the product's use under an EUA, or when there is a change in the approval status of the product such that an EUA is no longer needed.

# FACT SHEET FOR HEALTHCARE PROVIDERS

Ortho-Clinical Diagnostics, Inc.

VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Reagent Pack

Updated: October 23, 2020

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 VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Reagent Pack assay.

**You should not interpret the results of this test as an indication or degree of immunity or protection from reinfection.**

The VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Reagent Pack assay is authorized for the detection of antibodies to SARS-CoV-2 in human serum.

**All individuals whose specimens are tested with this test will receive the Fact Sheet for Recipients: Ortho-Clinical Diagnostics, Inc. - VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Reagent Pack assay.**

## 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 IgG antibodies that are generated as part of the human adaptive immune response to the COVID-19 virus and is to be performed on only using human serum.**

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 VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Reagent Pack assay can be ordered by healthcare providers to test serum to detect if there has been an adaptive immune response to COVID-19, indicating recent or prior infection.
- The VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Reagent Pack assay 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 if acute infection is suspected.
- The VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Reagent Pack assay is authorized for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate or high complexity tests.
- Please refer to the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Reagent Pack assay instructions for use for additional information.

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).

**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**

# FACT SHEET FOR HEALTHCARE PROVIDERS

Ortho-Clinical Diagnostics, Inc.

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Updated: October 23, 2020

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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 antibodies against the virus that causes COVID-19?**

A positive test result with the SARS-CoV-2 antibody test indicates that antibodies to SARS-CoV-2 were detected, and the individual has potentially been exposed to COVID-19.

Antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection. Individuals may have detectable virus present for several weeks following seroconversion. If IgG antibodies are present, it often indicates a past infection but does not exclude recently infected patients who are still contagious.

***It is unknown how long antibodies to SARS-CoV-2 will remain present in the body after infection and it is not known if they confer immunity to infection.***

***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 from pre-existing antibodies or other possible causes.

The VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Reagent Pack assay has been designed to minimize the likelihood of false positive test results.

However, in the event of a false positive result, risks to the patient include the following: risk of infection 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, 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.

***Due to the risk of false positive results, confirmation of positive results should be considered – using a second, different antibody assay that detects the same type of antibodies.***

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 antibodies against virus that causes COVID-19?**

A negative test result with this test means that SARS-CoV-2 specific antibodies were not present in the specimen above the limit of detection. ***However, patients tested early after infection may not have detectable antibodies despite active infection; in addition, it is not certain that all infected patients will develop a detectable antibody 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 performed if acute infection is suspected.***

The absolute sensitivity of the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Reagent Pack assay 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

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# FACT SHEET FOR HEALTHCARE PROVIDERS

Ortho-Clinical Diagnostics, Inc.

VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Reagent Pack

Updated: October 23, 2020

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symptoms resulting in increased risk of spread of COVID-19 within the community, or other unintended adverse events

## 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>

## 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>

### Ortho-Clinical Diagnostics, Inc.:

100 Indigo Creek Drive  
Rochester, NY 14626

**Contact email:**

[OrthoCOVID19Test@orthoclinicaldiagnostics.com](mailto:OrthoCOVID19Test@orthoclinicaldiagnostics.com)

**Website:**

<https://www.orthoclinicaldiagnostics.com/>

**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**



# FACT SHEET FOR RECIPIENTS

Ortho-Clinical Diagnostics, Inc.

VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Reagent Pack

Updated: October 23, 2020

Coronavirus  
Disease 2019  
(COVID-19)

You are being given this Fact Sheet because your sample(s) is being tested or was tested for antibodies to the virus that causes Coronavirus Disease 2019 (COVID-19) using the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Reagent Pack assay.

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**You should not interpret the results of this test as an indication or degree of immunity or protection from reinfection.**

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This Fact Sheet contains information to help you understand the risks and benefits of using this test to evaluate your adaptive immune response to SARS-CoV-2, the virus that causes COVID-19. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider. You have the option to refuse use of this test. However, your doctor may be recommending this test because they believe it could help with your care.

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**For the most up to date information on COVID-19 please visit the CDC Coronavirus Disease 2019 (COVID-19) webpage:**  
<https://www.cdc.gov/COVID19>

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## What is COVID-19?

COVID-19 is caused by the SARS-CoV-2 virus which is a new virus in humans causing a contagious respiratory illness. COVID-19 can present with a mild to severe illness, although some people infected with COVID-19 may have no symptoms at all. Older adults and people of any age who have underlying medical conditions have a higher risk of severe illness from COVID-19. Serious outcomes of COVID-19 include hospitalization and death. The SARS-CoV-2 virus can be spread to others not just while one is sick, but even before a person shows signs or symptoms of being sick (e.g., fever,

coughing, difficulty breathing, etc.). A full list of symptoms of COVID-19 can be found at the following link: <https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html>.

## How are people tested for COVID-19?

Two kinds of tests are currently available for COVID-19: diagnostic tests and antibody tests.

- A diagnostic test tells you if you have a current infection.
- An antibody test tells you if you had a previous infection

## What is the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Reagent Pack assay?

This test is an antibody test. It will help assess if you have antibodies to the virus that causes COVID-19. An antibody test may not be able to show if you have a current infection, because it can take 1-3 weeks after infection to make antibodies.

## What are the known and potential risks and benefits of the test?

Potential risks include:

- Possible discomfort or other complications that can happen during sample collection.
- Possible incorrect test result (see below for more information).

Potential benefits include:

- The results, along with other information, can help your healthcare provider make informed recommendations about your care.

## What does it mean if I have a positive test result?

If you have a positive test result, it is possible that you have or previously had COVID-19 and that you have developed an antibody response to the virus. Your healthcare provider will work with you to determine how best to care for you based on the test results along with

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- **Where can I go for updates and more information?** The most up-to-date information on COVID-19 is available at the CDC General webpage: <https://www.cdc.gov/COVID19>. In addition, please also contact your healthcare provider with any questions/concerns.
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# FACT SHEET FOR RECIPIENTS

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other factors of your medical history, your symptoms, possible exposures, and geographic location of places you have recently traveled. There is also a chance that this test can give a positive result that is wrong (a false positive result). Even a high-performing antibody test when used in a population without many cases of COVID-19 infection may produce as many or more false results as true results because the likelihood of finding someone who has been infected is very small.

Your healthcare provider will work with you to determine the likelihood of false result.

***It is not known how long antibodies to SARS-CoV-2 will remain present in the body after infection. It is not known whether having antibodies to SARS-CoV-2 will protect you from getting infected again or help reduce the severity or duration of a future COVID-19 infection. Regardless of your test result, you should continue to follow CDC guidelines to reduce the risk of infection, including social distancing and wearing masks.***

## **What does it mean if I have a negative test result?**

A negative test result means that the antibodies to the virus that causes COVID-19 were not found in your sample. However, it is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. Additionally, a negative result may occur if you are tested early in your illness and your body hasn't had time to produce antibodies to infection. This means that you could possibly still have COVID-19 even though the test is negative. If this is the case, your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you.

It is important that you work with your healthcare provider to help you understand the next steps you should take.

## **Is this test FDA-approved or cleared?**

No. This test is not yet approved or cleared by the United States FDA. When there are no FDA-approved or cleared tests available, and other criteria are met, FDA can make tests available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA for this test 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 for the detection and/or diagnosis of the virus that causes COVID-19. This EUA will remain in effect (meaning this test can be used) for the duration of the COVID-19 declaration justifying emergency of IVDs, unless it is terminated or revoked by FDA (after which the test may no longer be used).

## **What are the approved 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?** The most up-to-date information on COVID-19 is available at the CDC General webpage: <https://www.cdc.gov/COVID19>. In addition, please also contact your healthcare provider with any questions/concerns.
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