

# FACT SHEET FOR RECIPIENTS

**ImmunoPass Rapid Test for COVID19 Neutralizing Antibodies**  
**Axim Biotech**

**September 14, 2020**

**CORONAVIRUS**  
**DISEASE 2019**  
(COVID-19)

You are being given this Fact Sheet because the convalescent plasma you may receive was evaluated for levels of neutralizing antibodies to SARS-CoV-2, the virus that causes COVID19. Neutralizing antibodies protect your cells from becoming infected by binding to a specific location on the virus so that it cannot infect your cells. Current thinking is that the higher the levels of neutralizing antibodies, the more beneficial the convalescent plasma treatment. Not all convalescent plasma has the same levels of neutralizing antibodies.

This Fact Sheet contains information to help you understand the risks and benefits of using this test to measure levels of neutralizing antibodies in the convalescent plasma you may receive. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider.

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**FOR THE MOST UP TO DATE INFORMATION ON COVID19 PLEASE VISIT THE CDC CORONAVIRUS DISEASE 2019 (COVID-19) WEBPAGE:**

[HTTPS://WWW.CDC.GOV/COVID19](https://www.cdc.gov/covid19)

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## WHAT IS COVID-19?

COVID-19 is caused by the SARS-CoV-2 virus. The virus, which can cause mild to severe respiratory illness has now spread globally, including the United States. The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that symptoms include cough, shortness of breath or difficulty breathing, fever, chills, muscle pain, headache, sore throat or new loss of taste or smell.

## HOW ARE PEOPLE TESTED FOR COVID-19?

Three 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
- A neutralizing antibody test measures levels of antibodies that protect against infection.

## WHAT IS THE IMMUNOPASS RAPID TEST FOR COVID19 NEUTRALIZING ANTIBODIES?

This test measures relative levels of antibodies in plasma or serum that prevent the virus from infecting your cells.

This test should be performed on convalescent plasma prior to infusion to determine if the plasma contains levels of neutralizing antibodies high enough to effectively neutralize SARS-CoV-2 after infusion.

## WHAT ARE THE KNOWN AND POTENTIAL RISKS AND BENEFITS OF THE TEST?

Potential risks include:

- There are no known risks to you, as a patient, to perform this test on a sample from a unit of plasma that may be infused into your blood to help you recover from COVID19.
- If the test incorrectly indicates the plasma intended for your infusion has high levels of neutralizing antibodies, you would still be infused with plasma from an individual who recovered from COVID19, so there may be protective elements in the plasma that were not measured by the test.

Potential benefits include:

- By performing this test on plasma you might receive, you and your healthcare provider will learn if it contains elevated levels of neutralizing antibodies which are

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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](https://www.cdc.gov/covid19)

In addition, please also contact your healthcare provider with any questions/concerns.

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Empowered SARS-CoV-2 Neutralizing Antibodies Test Kit  
Empowered Diagnostics, LLC

September 14, 2020

CORONAVIRUS  
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thought to prevent further infection of your cells by the virus. These types of antibodies may help you recover faster from COVID19.

## **WHAT DOES IT MEAN IF THE PLASMA HAS HIGH LEVELS OF NEUTRALIZING ANTIBODIES?**

Your healthcare provider will explain that when plasma with high levels of neutralizing antibodies is infused, the goal is to prevent SARS-CoV-2 from further infecting your cells such that you may recover more quickly.

## **WHAT DOES IT MEAN IF THE PLASMA HAS LOWER LEVELS OF NEUTRALIZING ANTIBODIES?**

You have the right to refuse infusion of plasma with low levels (or high levels) of neutralizing antibodies. If you consent to be infused with plasma containing low levels of neutralizing antibodies, it is not known if it will help eliminate SARS-CoV-2 from your body or if you will recover more quickly than if you do not consent to convalescent plasma infusion.

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**IT IS NOT KNOWN EXACTLY HOW LONG NEUTRALIZING ANTIBODIES TO SARS-COV-2 WILL REMAIN IN THE BODY AFTER INFUSION. CURRENT THINKING IS THAT THE MOST COMMON TYPE OF ANTIBODY, IGG, REMAINS IN CIRCULATION FROM 23-25 DAYS. INFUSION OF PLASMA DOES NOT AFFECT YOUR ABILITY TO MAKE YOUR OWN ANTIBODIES THAT NEUTRALIZE THE VIRUS.**

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## **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 AVAILABLE ALTERNATIVES?**

There are no approved available alternative tests. FDA has issued EUAs for other antibody tests that can be found at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policyframework/emergency-use-authorization#2019-ncov>.

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