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.

There is no U.S. Food and Drug Administration (FDA) approved product available to treat COVID-19. 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?
There are no 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 PATIENTS

Aptima® SARS-CoV-2 assay – Hologic, Inc. **May 14, 2020**

Coronavirus Disease 2019 (COVID-19)

You are being given this Fact Sheet because your sample(s) was tested for the Coronavirus Disease 2019 (COVID-19) using the Aptima SARS-CoV-2 assay.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for the diagnosis of 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.

- **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**

What is COVID-19?
COVID-19 is caused by the SARS-CoV-2 virus. The virus, which can cause mild to severe respiratory illness, was first identified in Wuhan, China, and 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.

What is the Aptima SARS-CoV-2 assay?
The test is designed to detect the virus that causes COVID-19 in respiratory specimens, for example nasal or oral swabs.

Why was my sample tested?
You were tested because your healthcare provider believes you may have been exposed to the virus that causes COVID-19 based on your signs and symptoms (e.g., fever, cough, difficulty breathing), and/or because:

- You live in or have recently traveled to a place where transmission of COVID-19 is known to occur, and/or
- You have been in close contact with an individual suspected of or confirmed to have COVID-19.

Testing of the samples will help find out if you may have COVID-19.

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.
- The results of this test may help limit the spread of COVID-19 to your family and others in your community.

What does it mean if I have a positive test result?
If you have a positive test result, it is very likely that you have COVID-19. Therefore, it is also likely that you may be placed in isolation to avoid spreading the virus to others. There is a very small chance that this test can

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give a positive result that is wrong (a false positive result). Your healthcare provider will work with you to determine how best to care for you based on the test results along with medical history, and your symptoms.

What does it mean if I have a negative test result?
A negative test result means that the virus that causes COVID-19 was not found in your sample. For COVID-19, a negative test result for a sample collected while a person has symptoms usually means that COVID-19 did not cause your recent illness.

However, it is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. 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).

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FACT SHEET FOR PATIENTS

BD SARS-CoV-2 Reagents for BD MAX™ System – BD **April 8, 2020**

Coronavirus Disease 2019 (COVID-19)

You are being given this Fact Sheet because your sample(s) was tested for the Coronavirus Disease 2019 (COVID-19) using the BD SARS-CoV-2 Reagents for BD MAX™ System.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for the diagnosis of 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.

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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, was first identified in Wuhan, China, and has now spread globally, including the United States. There is limited information available to characterize the spectrum of clinical illness associated with COVID-19 but it likely spreads to others when a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.).

What is the BD SARS-CoV-2 Reagents for BD MAX™ System?
The test is designed to detect the virus that causes COVID-19 in respiratory specimens, for example nasal or oral swabs.

Why was my sample tested?
You were tested because your healthcare provider believes you may have been exposed to the virus that causes COVID-19 based on your signs and symptoms (e.g., fever, cough, difficulty breathing), and/or because:

- You live in or have recently traveled to a place where transmission of COVID-19 is known to occur, and/or
- You have been in close contact with an individual suspected of or confirmed to have COVID-19.

Testing of the samples will help find out if you may have COVID-19.

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.
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FACT SHEET FOR PATIENTS

Xpert® Xpress SARS-CoV-2– Cepheid **March 20, 2020**

Coronavirus Disease 2019 (COVID-19)

You are being given this Fact Sheet because your sample(s) was tested for the Coronavirus Disease 2019 (COVID-19) using the Xpert Xpress SARS-CoV-2 test.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for the diagnosis of 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.

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What is COVID-19?
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What is the Xpert Xpress SARS-CoV-2 test?
The test is designed to detect the virus that causes COVID-19 in respiratory specimens, for example nasal or oral swabs.

Why was my sample tested?
You were tested because your healthcare provider believes you may have been exposed to the virus that causes COVID-19 based on your signs and symptoms (e.g., fever, cough, difficulty breathing), and/or because:

- You live in or have recently traveled to a place where transmission of COVID-19 is known to occur, and/or
- You have been in close contact with an individual suspected of or confirmed to have COVID-19.

Testing of the samples will help find out if you may have COVID-19.

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

Potential risks include:

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