

COBAS MPXV**Roche Molecular Systems, Inc.**

November 15, 2022

For the most up to date monkeypox virus information, including symptoms, please visit:

<https://www.cdc.gov/poxvirus/monkeypox/response/2022/index.html>

Your sample(s) was tested for monkeypox virus using the cobas MPXV assay.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for the diagnosis of monkeypox. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider.

WHAT IS MONKEYPOX?

Monkeypox is a disease is caused by the Monkeypox virus.

WHAT IS THE COBAS MPXV ASSAY?

The test is designed to determine if you likely have monkeypox, in the following clinical specimens: human lesion swab specimens (i.e., swabs of acute pustular or vesicular rash).

WHY WAS MY SPECIMEN TESTED?

Testing of your specimen(s) will help find out if you may have monkeypox.

WHAT ARE THE KNOWN AND POTENTIAL RISK AND BENEFITS OF THE TEST?

Potential risks include:

- Possible discomfort or other complications that can happen during specimen 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 monkeypox to your family, intimate partners, and others you come into close contact with.

WHAT DOES A POSITIVE TEST RESULT MEAN?

If you have a positive test result, it is very likely that you have monkeypox. Depending on the severity of your illness, your personal medical history, and other factors, your doctor may discuss treatment options with you. You will most likely be asked to isolate at home for the duration of the illness to avoid spreading the virus to others. You should follow CDC guidance to reduce the potential transmission of disease and discuss with your doctor if any other actions should be taken (e.g., vaccination of your close contacts to reduce the risk of them developing the disease).

There is a smaller possibility that this test can give a positive result that is wrong (a false positive result) particularly when used in a population without many cases of monkeypox. In that case it is possible that a different disease process is responsible for your symptoms. Your healthcare provider will work with you to determine how best to care for you based on the test results along with your symptoms and medical history.

Antiviral treatment may reduce the intensity and duration of your infection, and preventive options (vaccines or antiviral medications) can reduce the risk of infection for other people who were exposed to monkeypox but have not yet developed symptoms of illness. Please see CDC guidance (<https://www.cdc.gov/poxvirus/monkeypox/index.html>), sections on Treatment and Vaccines for more information.

WHAT DOES A NEGATIVE TEST RESULT MEAN?

A negative test result means that the virus that causes monkeypox was not found in your specimen.

However, it is possible for this test to give a negative result that is incorrect (false negative) in some people with monkeypox. You might test negative if the specimen was collected too early or too late during your infection, or from a body site other than where the virus was present. You could also be exposed to monkeypox after your sample was collected and then have become infected.

This means that you could possibly still have monkeypox even though the test result is negative. If your test is negative but your symptoms and other information (such as your medical history, possible exposures, and geographical location of places you have recently traveled) continue to suggest monkeypox infection, your healthcare provider will consider the test result together with all of this information in deciding how to care for you and whether the testing should be repeated.

New developments may shed additional light on how monkeypox is best prevented, diagnosed, and treated. It is important that you work with your healthcare provider to help you understand the next steps you should take based on the most up-to-date scientific knowledge.

WHAT IS AN EUA?

This test has been issued an Emergency Use Authorization (EUA) by the U.S. FDA. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternative tests. 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 laboratory tests for the diagnosis of infection with the monkeypox virus. This EUA will remain in effect (meaning this test can be used) for the duration of the monkeypox declaration justifying the emergency use of in vitro diagnostics, unless the declaration is terminated or authorization is revoked sooner. An EUA is NOT an FDA-approval or clearance.

WHAT ARE THE APPROVED AVAILABLE ALTERNATIVES?

Any tests that have received full marketing status (e.g., cleared, approved), as opposed to an EUA, by FDA can be found by searching the medical device databases here:

[https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-](https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases)

[assistance/medical-device-databases](https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases). As of the date of this fact sheet, there is only one cleared test.¹ A cleared or approved test should be used instead of a test made available under an EUA, when appropriate and available. Any tests that are issued an EUA by FDA can be found at:

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

¹ There is an FDA-cleared diagnostic test for non-variola orthopoxviruses, including monkeypox virus, which the Centers for Disease Control and Prevention (CDC) developed.