ALLPLEX HSV-1&2/VZV/MPXV ASSAY

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For the most up to date mpox information, including symptoms, please visit:
https://www.cdc.gov/monkeypox/index.html

For information on Herpes, including symptoms, please visit:
https://www.cdc.gov/herpes/about/index.html

For information on Chickenpox and Shingles, including symptoms, please visit:
https://www.cdc.gov/chickenpox/about/
https://www.cdc.gov/shingles/

Your sample(s) was tested for the virus that causes mpox using the Allplex HSV-1&2/VZV/MPXV Assay.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for the diagnosis of mpox,[1] herpes, chickenpox and shingles. 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 MPOX?

Mpox is a disease caused by a virus.

WHAT IS HERPES, CHICKENPOX AND SHINGLES?

Herpes, chickenpox and shingles are diseases caused by specific viruses that can result in a similar blister-like rash as mpox.

WHAT IS THE ALLPLEX HSV-1&2/VZV/MPXV ASSAY?

The test is designed to determine if you likely have mpox, herpes, chickenpox or shingles 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 mpox, herpes, chickenpox or shingles.

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.

[1] On November 28, 2022, following a series of consultations with global experts, the World Health Organization (WHO) began using a new preferred term “mpox” as a synonym for monkeypox, the disease caused by the monkeypox virus. Refer to: https://www.who.int/news/item/28-11-2022-who-recommends-new-name-for-monkeypox-disease.

- The results of this test may help limit the spread of these diseases to your family, intimate partners, and others you come into close contact with.

WHAT DOES A POSITIVE MPOX TEST RESULT MEAN?

If you have a positive test result, it is very likely that you have mpox. 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 mpox. 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 mpox but have not yet developed symptoms of illness. Please see CDC guidance (https://www.cdc.gov/monkeypox/hcp/vaccine-considerations/index.html), sections on Treatment and Vaccines for more information.

WHAT DOES A POSITIVE TEST RESULT FOR HERPES SIMPLEX VIRUS AND/OR VARICELLA-ZOSTER VIRUS MEAN?

If you have a positive test result for the presence of herpes simplex virus or varicella-zoster virus, it is very likely that you either have herpes, chickenpox or shingles. If you have a positive result for any of these viruses, your healthcare provider will determine the best way to care for you based on the test results along with other factors in your medical history. There is a very small chance that this test can 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, medical history, and your symptoms.

WHAT DOES IT MEAN IF I HAVE A POSITIVE TEST RESULT FOR MPOX AND HERPES SIMPLEX VIRUS AND/OR VARICELLA-ZOSTER VIRUS?

It is possible for an individual to be infected with herpes simplex virus, varicella-zoster virus, and/or monkeypox virus at the same time. Your healthcare provider will work with you to determine how best to care for you based on these test results, your medical history, and your symptoms.

WHAT DOES A NEGATIVE TEST RESULT MEAN?

If your test result was negative for monkeypox, herpes simplex and varicella-zoster viruses then those viruses 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 mpox, herpes, chickenpox or shingles. 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 these viruses after your sample was collected and then have become infected.

This means that you could possibly still have mpox, herpes, chickenpox or shingles 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 mpox, herpes, chickenpox or shingles, 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 mpox 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 mpox 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-assistance/medical-device-databases. As of the date of this fact sheet, there is only one cleared test.[2] 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.

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