ALLPLEX HSV-1&2/VZV/MPXV ASSAY

Seegene USA, Inc.

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All individuals whose specimens are tested with this product will receive the Fact Sheet for Patients for the product.

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the Allplex HSV-1&2/VZV/MPXV Assay.

WHERE CAN I GO FOR GENERAL INFORMATION ON MONKEYPOX, HERPES SIMPLEX VIRUS, AND VARICELLA-ZOSTER VIRUS?

For general information on mpox[1], herpes, chickenpox and shingles, including the symptoms of these infections, infection control precautions, and other information please check the CDC Mpox, HSV, and VZV webpages (see links 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.

WHAT DO I NEED TO KNOW ABOUT MPOX TESTING WITH THIS PRODUCT?

- The Allplex HSV-1&2/VZV/MPXV Assay can be **used to test human lesion swab specimens (i.e., swabs of acute pustular or vesicular rash)** from individuals suspected of viral infection consistent with mpox by their healthcare provider.
- The Allplex HSV-1&2/VZV/MPXV Assay should be ordered for the detection and differentiation of viral nucleic acid from monkeypox virus (MPXV clade I/II and MPXV clade II)[2], herpes simplex virus type 1 (HSV-1), herpes simplex virus type 2 (HSV-2), and varicella-zoster virus (VZV) by a healthcare provider.
- The Allplex HSV-1&2/VZV/MPXV 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 high complexity tests.

Specimens should be collected with appropriate infection control precautions. When collecting and handling specimens from individuals suspected of being infected with monkeypox virus, appropriate personal protective equipment should be used as outlined on the CDC *Infection Prevention and Control of Monkeypox in Healthcare Settings* webpage. For additional information, refer to the CDC *Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings (2007)* (see links provided in "*Where can I go for updates and more information?*" section at the end of this document).

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[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 cause by the monkeypox virus. Refer to: https://www.who.int/news/item/28-11-2022-who-recommends-new-name-for-monkeypox-disease.

[2] On August 12, 2022, following a meeting convened by the World Health Organization (WHO) monkeypox virus variants were renamed to align with current best practices under the International Classification of Diseases and the WHO Family of International Health Related Classifications (WHO-FIC). This Fact Sheet will refer to the former Congo Basin (Central African) clade as clade one (I) and the former West African clade as clade two (II). Refer to: https://www.who.int/news/item/12-08-2022-monkeypox--experts-give-virus-variants-new-names.

WHAT DOES IT MEAN IF THE SPECIMEN TESTS POSITIVE FOR THE VIRUS THAT CAUSES MPOX OR HERPES SIMPLEX VIRUS, OR VARICELLA-ZOSTER VIRUS?

A positive test result for mpox, herpes or chickenpox/shingles indicates that DNA from either monkeypox virus (MPXV clade I/II and MPXV clade II), HSV-1, HSV-2 or VZV were detected, and therefore the patient is infected with the virus and presumed to be contagious. A positive test result for any of these viruses does not preclude the possibility of another infectious pathogen (e.g., a bacterial infection or co-infection with other viruses) contributing to the patient's symptoms. Healthcare providers should always consider laboratory test results in the context of clinical observations and epidemiological data (such as local prevalence rates and current outbreak/epicenter locations) in determining individual diagnosis and patient management decisions and should follow current CDC guidelines.

The monkeypox virus clade II has been the most identified member of the *Orthopoxvirus* genus known to be circulating among humans in the US at this time. A positive result for the MPXV clade I/II target most likely represents the presence of monkeypox virus clade II, although there is a small possibility that this result could represent the presence of monkeypox virus clade I. If clinical concern for such an infection exists, healthcare providers should contact the CDC and their local public health authorities for guidance.

The Allplex HSV-1&2/VZV/MPXV Assay has been designed to minimize the likelihood of false positive test results. However, it is still possible that this test can give a false positive result. In the event of a false positive result, risks to patients could include the following: 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 potential patients with mpox, limits in the ability to work, delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of treatment or therapy, negative impact on mental health and/or interpersonal relationships, or other unintended adverse effects.

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 THE VIRUS THAT CAUSES MPOX OR HERPES SIMPLEX VIRUS, AND VARICELLA-ZOSTER VIRUS?

A negative test result for this test means that monkeypox virus (MPXV clade I/II and MPXV clade II), HSV-1, HSV-2 and VZV DNA was not present in the specimen above the limit of detection. However, a negative result does not rule out infection with these viruses and should not be used as the sole basis for treatment or patient management decisions. It is possible for a test to miss infection with the monkeypox virus (MPXV clade I/II and MPXV clade II), HSV-1, HSV-2 or VZV if testing a person occurs too early or too late during their illness, or if the specimen is not collected from a site carrying adequate concentration of virus. Inadequate or improper specimen collection and handling may yield false negative results via the Allplex HSV-1&2/VZV/MPXV Assay.

When diagnostic testing is negative, the possibility of a false negative result should be considered in the context of an individual's recent exposures and the presence of clinical signs and symptoms consistent with mpox, herpes, chickenpox or shingles. The possibility of a false negative result should especially be considered if the individual's recent exposures or clinical presentation indicate that mpox, herpes, chickenpox or shingles is likely, and diagnostic tests for

other causes of illness (e.g., other illnesses with similar symptoms) are negative. Special consideration should be given to patients who are immunocompromised, pregnant, very young, or otherwise at increased risk of severe or complicated disease.

If mpox, herpes, chickenpox or shingles is still suspected based on exposure history together with other clinical findings, re-testing with an alternative method should be considered by healthcare providers, in consultation with public health authorities for nationally notifiable diseases (mpox and chickenpox). Additional testing may be helpful to ensure testing was not conducted too early and that an adequate specimen was collected from the appropriate anatomical site(s).

Risks to a patient of a false negative test result include delayed or lack of supportive treatment, lack of monitoring of infected individuals and their household or other close contacts for symptoms resulting in increased risk of spread of the disease within the community, or other unintended adverse events.

The performance of this test was established based on the evaluation of a limited number of clinical specimens. For mpox, new epidemiological, microbiological, and clinical information may emerge over time requiring updates to best practices in testing, prevention, and treatment of this virus.

WHAT DOES IT MEAN IF THE SPECIMEN TESTS POSITIVE FOR MONKEYPOX VIRUS AND ALSO POSITIVE FOR VARICELLA-ZOSTER VIRUS OR ONE OR BOTH OF THE HERPES SIMPLEX VIRUSES? IS CO-INFECTION POSSIBLE?

While co-infection with all four viruses is exceedingly rare, it is possible for an individual to be infected with HSV-1, HSV-2, VZV, and/or monkeypox virus (MPXV clade I/II and MPXV clade II) simultaneously. A positive test result for the viruses that cause mpox, herpes, chickenpox or shingles indicates that nucleic acid from these viruses were detected, the patient may be co-infected, and is presumed to be contagious. Laboratory test results should always be considered in the context of clinical findings and observations and epidemiological data in making a final diagnosis. Patient management decisions should be made with a healthcare provider and follow current CDC guidelines.

WHAT IS AN EUA?

The U.S. 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 mpox, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus*.

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 in diagnosing mpox.

The EUA for this test is in effect for the duration of the mpox declaration justifying emergency use of IVDs, unless the declaration is terminated or authorization is revoked sooner.

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.[3] A cleared or approved test should be used instead of a test made available under an EUA, when appropriate and available. 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 DO I REPORT ADVERSE EVENTS?

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**

WHERE CAN I GO FOR UPDATES AND MORE INFORMATION?

CDC WEBPAGES:

Mpox Home Page: https://www.cdc.gov/monkeypox/index.html

Herpes Home Page: https://www.cdc.gov/herpes/about/index.html

Varicella-zoster Virus (VZV – Chickenpox) Home Page: https://www.cdc.gov/chickenpox/about/

Varicella-zoster Virus (VZV – Shingles) Home Page: https://www.cdc.gov/shingles/

Isolation Precautions in Healthcare Settings: https://www.cdc.gov/infection-control/hcp/isolation-precautions/

FDA WEBPAGES:

General: https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/fda-monkeypox-response

EUAs: (includes links to patient fact sheet and manufacturer's instructions) https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/monkeypox-emergency-use-authorizations-medical-devices

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