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Sharon Young
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Device:	Allplex HSV-1&2/VZV/MPXV Assay
EUA Number:	EUA250001
Company:	Seegene USA, Inc.
Indication:	This test is authorized for the simultaneous qualitative detection and differentiation of viral nucleic acid from monkeypox virus (MPXV clade I/II and MPXV clade II)[1], herpes simplex virus type 1 (HSV-1), herpes simplex virus type 2 (HSV-2), and varicella-zoster virus (VZV) in human lesion swab specimens (i.e., swabs of acute pustular or vesicular rash) from individuals suspected of viral infection consistent with mpox[2] by their healthcare provider. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratories:	Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

Dear Sharon Young:

This letter is in response to your[3] request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of your product,[4] pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

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[1] 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 letter 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.

[2] 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.

[3] For ease of reference, this letter will use the term "you" and related terms to refer to Seegene USA, Inc.

[4] For ease of reference, this letter will use the term "your product" to refer to the Allplex HSV-1&2/VZV/MPXV Assay used for the indication identified above.

On August 9, 2022, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency, or a significant potential for a public health emergency, that affects or has a significant potential to affect national security or the health and security of United States citizens living abroad that involves monkeypox virus.[5] Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on September 7, 2022 that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus*, subject to the terms of any authorization issued under Section 564(a) of the Act.[6]

FDA considered the totality of scientific information available in authorizing the emergency use of your product for the indication above. A summary of the performance information FDA relied upon is contained in the "Allplex HSV-1&2/VZV/MPXV Assay Instructions for Use." Viral infections caused by MPXV, HSV-1, HSV-2, and VZV can have similar clinical presentation and diagnostic considerations. Thus, to differentially detect monkeypox virus, information from a test that detects and differentiates the virus that causes mpox and HSV-1, HSV-2 and VZV viruses is needed. There is an FDA-cleared test for the qualitative detection of non-variola *Orthopoxvirus*, that includes monkeypox virus, but this is not an adequate and available alternative to your product.[7]

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of your product, described in the Scope of Authorization of this letter (Section II), subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of your product meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. The monkeypox virus can cause a serious or life-threatening disease or condition, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in diagnosing infection with the monkeypox virus, through the simultaneous qualitative detection and differentiation of monkeypox virus (MPXV clade I/II and MPXV clade II), herpes simplex virus type 1 (HSV-1), herpes simplex virus type 2 (HSV-2), and varicella-zoster virus (VZV) DNA, and that the known

[5] 87 FR 50090 (August 15, 2022)
[6] 87 FR 56074 (September 13, 2022)
[7] To date, the FDA-cleared CDC Non-variola *Orthopoxvirus* Real-time PCR Primer and Probe Set (Product Code: PBK; DEN070001, K181205, K221658, K221834, K222558) is the only test available in the United States with FDA clearance for the detection of non-variola *Orthopoxvirus* DNA, including vaccinia, cowpox, monkeypox and ectromelia viruses at varying concentrations. Available information indicates that timely detection of mpox cases in the United States requires wide availability of diagnostic testing to control the spread of this contagious infection and there is currently a need for additional diagnostic testing for monkeypox virus in the United States.

and potential benefits of your product when used for diagnosing infection with the monkeypox virus, outweigh the known and potential risks of your product; and

3. There is no adequate, approved, and available alternative to the emergency use of your product.[8]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the indication above.

Authorized Product Details

Your product is a multiplex real-time polymerase chain reaction (PCR) in vitro diagnostic test (IVD) intended for the simultaneous qualitative detection and differentiation of viral nucleic acid from monkeypox virus (MPXV clade I/II and MPXV clade II), herpes simplex virus type 1 (HSV-1), herpes simplex virus type 2 (HSV-2), and varicella-zoster virus (VZV) in 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. Symptoms due to MPXV clade I/II, MPXV clade II, HSV-1, HSV-2, and VZV infection can be similar.

Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

The device is not intended for use with cerebrospinal fluid or for prenatal screening.

The assay detects and differentiates the presence of MPXV clade I/II, MPXV clade II, HSV-1, HSV-2, and VZV viral nucleic acid targets. Clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results are indicative of the presence of MPXV clade I/II and/or MPXV clade II, HSV-1, HSV-2, or VZV nucleic acid but do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Negative results obtained with this device do not preclude MPXV clade I/II, MPXV clade II, HSV-1, HSV-2, or VZV infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

Your product, is to be used with the Seegene STARlet System (or other authorized system as may be requested under Condition O. below) which automates nucleic acid extraction and PCR plate setup, and the Bio-Rad CFX Opus 96 Dx instrument (or other authorized real-time PCR instrument as may be requested under Condition O. below) for detection and differentiation of the monkeypox virus (MPXV clade I/II and MPXV clade II), HSV-1, HSV-2, and/or VZV nucleic acid targeted sequences using real-time PCR assays, as described in the authorized labeling (described below). The Allplex HSV-1&2/VZV/MPXV Assay includes the materials (or

[8] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

other authorized materials as may be requested under Condition O. below) described in the authorized labeling (described below).

Your product requires control materials (or other authorized control materials as may be requested under Condition O. below) that are described in the authorized labeling. Your product also requires the use of additional authorized materials and authorized ancillary reagents that are not included with your product and are described in the authorized labeling.

The labeling entitled "Allplex HSV-1&2/VZV/MPXV Assay Instructions for Use" (available at https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/monkeypox-emergency-use-authorizations-medical-devices), and the following fact sheets pertaining to the emergency use, are required to be made available as set forth in the Conditions of Authorization (Section IV), and are collectively referred to as "authorized labeling":

- Fact Sheet for Healthcare Providers: Seegene USA, Inc. – Allplex HSV-1&2/VZV/MPXV Assay
- Fact Sheet for Patients: Seegene USA, Inc. – Allplex HSV-1&2/VZV/MPXV Assay

The above described product, when accompanied by the authorized labeling provided as set forth in the Conditions of Authorization (Section IV), is authorized to be distributed to and used by authorized laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of your product, when used consistent with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of your product.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that your product may be effective in diagnosing infection with the monkeypox virus, when used consistent with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that your product (as described in the Scope of Authorization of this letter (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of your product under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) of the Act described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1) of the Act, your product is authorized for the indication above.

III. Waiver of Certain Requirements

I am waiving the following requirements for your product during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality management system requirements under 21 CFR Part 820, which incorporates by reference ISO 13485:2016, with respect to the design, manufacture, packaging, labeling, storage, and distribution of your product, but excluding those parts of 21 CFR Part 820 which incorporates by reference ISO 13485:2016 that relate to acceptance activities, nonconforming product, statistical techniques, and complaint files, including, but not limited to: ISO 13485:2016 Clauses 7.5.8, 8.2.2, 8.2.6, 8.3 and 21 CFR 820.35.

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

Seegene USA, Inc. (You) and Authorized Distributor(s)[9]

A. Your product must comply with the following labeling requirements pursuant to FDA regulations: the intended use statement (21 CFR 809.10(a)(2), (b)(2)); adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5), (7), and (8)); appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4); and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

B. Your product must comply with those parts of 21 CFR Part 820, which incorporates by reference ISO 13485:2016, that relate to acceptance activities, nonconforming product, statistical techniques, and complaint files, including, but not limited to: ISO 13485:2016 Clauses 7.5.8, 8.2.2, 8.2.6, 8.3 and 21 CFR 820.35.

C. You and authorized distributor(s) must make your product available with the authorized labeling to authorized laboratories.

D. You and authorized distributor(s) must make available on your website(s) the authorized labeling.

E. You and authorized distributor(s) must include a physical copy of the authorized "Allplex HSV-1&2/VZV/MPXV Assay Instructions for Use" with each shipped product to authorized laboratories and must make the authorized "Allplex HSV-1&2/VZV/MPXV Assay Instructions for Use," electronically available.

F. You and authorized distributor(s) must inform authorized laboratories and relevant

[9] "Authorized Distributor(s)" are identified by you, Seegene USA, Inc., in your EUA submission as an entity allowed to distribute your product.

public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and authorized labeling.

G. Through a process of inventory control, you and authorized distributor(s) must maintain records of the authorized laboratories to which your product is distributed and the number of your product distributed.

H. You and authorized distributor(s) must collect information on the performance of your product. You must report any significant deviations from the established performance characteristics of your product of which you become aware to the Division of Microbiology (DMD)/Office of Health Technology 7 (OHT7): Office of In Vitro Diagnostics /Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) (via email: CDRH-EUA-Reporting@fda.hhs.gov).

I. You and authorized distributor(s) are authorized to make available additional information relating to the emergency use of your product that is consistent with, and does not exceed, the terms of this letter of authorization.

Seegene USA, Inc. (You)

J. You must register and list consistent with 21 CFR Part 807 within one month of this letter.

K. You must notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).

L. You must have a signed agreement with each authorized distributor that distribution of the authorized product must be consistent with this Letter of Authorization.

M. If requested by FDA, you must submit associated documents and records related to your quality management system for FDA review within 48 hours of the request.

N. You must provide authorized distributor(s) with a copy of this EUA and communicate to authorized distributor(s) any subsequent amendments that might be made to this EUA and its authorized accompanying materials (e.g., Fact Sheets).

O. You may request modifications to this EUA for your product, including to the Scope of Authorization (Section II in this letter) or to the authorized labeling, including requests to make available additional authorized labeling specific to an authorized distributor. Such additional labeling may use another name for the product but otherwise must be consistent with the authorized labeling, and not exceed the terms of authorization of this letter. Any request for modification to this EUA should be submitted to DMD/OHT7/OPEQ/CDRH and require appropriate authorization from FDA.

P. You must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that the tests released for distribution have the clinical and analytical performance claimed in the authorized labeling.

Q. If requested by FDA, you must submit lot release procedures to FDA within 48 hours of the request, including sampling protocols, testing protocols, and acceptance criteria, that you use to release lots of your product for distribution in the U.S.

R. You must evaluate the analytical limit of detection and assess traceability of your product with any FDA-recommended reference material(s) if requested by FDA.[10] After submission to and concurrence with the data by FDA, you must update your labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7/OPEQ/CDRH.

S. You must have a process in place to track adverse events and report to FDA pursuant to 21 CFR Part 803.

T. You must evaluate the impact of monkeypox viral mutations on your product's performance. Such evaluations must occur on an ongoing basis and must include any additional data analysis that is requested by FDA in response to any performance concerns you or FDA identify during routine evaluation. Additionally, if requested by FDA, you must submit records of these evaluations for FDA review within 48 hours of the request. If your evaluation identifies viral mutations that affect the stated expected performance of your device, you must notify FDA immediately (via email: CDRH-EUA-Reporting@fda.hhs.gov).

U. If requested by FDA, you must update your labeling within 7 calendar days to include any additional labeling risk mitigations identified by FDA regarding the impact of viral mutations on test performance. Such updates will be made in consultation with, and require concurrence of, DMD/OHT7/OPEQ/CDRH.

V. You must further evaluate the clinical performance of your product using fresh natural clinical specimens in an FDA agreed upon post authorization clinical evaluation study. After submission to and concurrence with the data by FDA, you must update the authorized labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7/OPEQ/CDRH.

W. If requested by FDA, you must submit records within 48 hours of the request of the instrument qualification procedures performed to verify that the RUO instruments authorized with your product are capable of performing the Allplex HSV-1&2/VZV/MPXV Assay with sufficient accuracy at authorized laboratories, as stated in the authorized labeling.

[10] Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material. FDA may request, for example, that you perform this study in the event that we receive reports of adverse events concerning your product.

X. You must submit to DMD/OHT7/OPEQ/CDRH within 3 months of the date of this letter your plan and anticipated timeline to establish and maintain a quality management system that is appropriate for your product's design and manufacture, and that meets the requirements of 21 CFR Part 820.

Authorized Laboratories

Y. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.

Z. Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

AA. Authorized laboratories using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

BB. Authorized laboratories using your product must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.

CC. Authorized laboratories must have a process in place to track adverse events and report to you (Customer Support: support.seegeneusa@seegene.com) and to FDA pursuant to 21 CFR Part 803.

DD. All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling your product, and use your product in accordance with the authorized labeling.

Seegene USA, Inc. (You), Authorized Distributor(s) and Authorized Laboratories

EE. You, authorized distributor(s), and authorized laboratories must collect information on the performance of your product and must report any significant deviations from the established performance characteristics of your product of which they become aware to DMD/OHT7/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) In addition, authorized distributor(s) and authorized laboratories report to you (via email: support.seegeneusa@seegene.com).

FF. You, authorized distributor(s), and authorized laboratories using your product must ensure that any records associated with this EUA, are maintained until otherwise notified by FDA. Such records must be made available to FDA for inspection upon request.

Conditions Related to Printed Materials, Advertising and Promotion

GG. All descriptive printed matter, advertising and promotional materials relating to the use of your product shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and meet the requirements set forth in section 502(a), (q)(1), and (r) of the Act, as applicable, and FDA implementing regulations.

HH. No descriptive printed matter, advertising or promotional materials relating to the use of your product may represent or suggest that this test is safe or effective for the detection of monkeypox virus or other non-variola orthopoxviruses.

II. All descriptive printed matter, advertising and promotional materials relating to the use of your product shall clearly and conspicuously state that:

- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by the authorized laboratories;

- This product has been authorized only for the detection and differentiation of nucleic acid from monkeypox virus, herpes simplex virus type 1, herpes simplex virus type 2, and varicella-zoster virus, not for any other viruses or pathogens; and

- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus*, under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

The emergency use of your product as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus*, is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

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Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and Radiological Health
Food and Drug Administration

Enclosure