EMERGENCY USE AUTHORIZATION (EUA) SUMMARY FOR THE LABCORP MONKEYPOX PCR TEST HOME COLLECTION KIT

For *In vitro* Diagnostic Use
Rx Only
For use under Emergency Use Authorization (EUA) only
For Use by Individuals 18 Years of Age and Older when Self-collected

Lesion swabs collected by individuals using the Labcorp Monkeypox PCR Test Home Collection Kit will be sent to laboratories that have been designated by Labcorp. Testing is limited to the Center for Esoteric Testing, Burlington, North Carolina, and laboratories designated by Labcorp and certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a and meet requirements to perform high complexity tests and test the specimens collected using the Labcorp Monkeypox PCR Test Home Collection Kit on CDC's Non-Variola Orthopoxvirus Real-time PCR Primer and Probe Set – EUA for the detection of non-variola *Orthopoxvirus* DNA.

INTENDED USE

The Labcorp Monkeypox PCR Test Home Collection Kit is intended for the collection of lesion swab specimens at home by individuals 18 years of age or older (self-collected) presenting with acute, generalized pustular or vesicular rash suspected of mpox when determined to be appropriate by a healthcare provider. The swab specimen is placed in media and transported to the laboratory for testing non-variola *Orthopoxvirus* DNA extracted from the specimens.

The lesion swab specimens collected using the Labcorp Monkeypox PCR Test Home Collection Kit are transported at ambient temperature in transport media for testing at an authorized laboratory. Non-variola *Orthopoxvirus* DNA from the lesion swab is maintained in the specimen packaging and is only for use in molecular diagnostic testing performed using CDC's Non-Variola Orthopoxvirus Real-time PCR Primer and Probe Set – EUA when used consistent with its authorization.

Testing is limited to the Center for Esoteric Testing, Burlington, North Carolina, and laboratories designated by Labcorp and certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests and that test the lesion swab specimens collected using the Labcorp Monkeypox PCR Test Home Collection Kit with CDC's Non-Variola Orthopoxvirus Real-time PCR Primer and Probe Set – EUA when used consistent with its authorization.

Results are provided to the ordering physician and are available to the patient in the Labcorp Patient portal at patient.labcorp.com.

The Labcorp Monkeypox PCR Test Home Collection Kit is not a substitute for visits to a healthcare provider. The information provided in this kit when combined with an authorized test should not be used to start, stop, or change any course of treatment unless advised by one's healthcare provider.

The Labcorp Monkeypox PCR Test Home Collection Kit is only for use under the Food and Drug Administration's Emergency Use Authorization.

SPECIAL CONDITIONS OF USE STATEMENTS

For *In vitro* Diagnostic Use
For Prescription Use Only
For Emergency Use Authorization (EUA) Only
For Use by Individuals 18 Years of Age and Older when Self-collected

The Labcorp Monkeypox PCR Test Home Collection Kit is only authorized for use in conjunction with CDC's Non-Variola Orthopoxvirus Real-time PCR Primer and Probe Set – EUA for the detection of non-variola Orthopoxvirus DNA for testing self-collected lesion swab specimens from any individuals, 18 years of age or older presenting with acute, generalized pustular or vesicular rash suspected of mpox when determined to be appropriate by a healthcare provider.

DEVICE DESCRIPTION

1) *Collection Kit Description*

The Labcorp Monkeypox PCR Test Home Collection Kit consists of a shipping box, pre-labeled return envelope, printed specimen collection and shipping instructions, specimen collection materials (swab and collection tube), a specimen biohazard bag containing an absorbent sheet, and a specimen confirmation form.

Table 1: Labcorp Monkeypox PCR Test Home Collection Kit Components

Name	Material Supplier	Catalog #
Instructions for Use	Labcorp	Not applicable
Shipping box	The Dot	17279
Return envelope-FedEx Pak UN 3373	FedEx	163034
Specimen biohazard bag with absorbent sheet	ASP Global	22130
Specimen Confirmation Form	Labcorp	Not applicable
UTM Viral Transport Medium, Swab, and Collection Tube (1 swab and 1 (3mL) tube)	Copan	3C059N

2) *Collection Kit Ordering and Processing*

The Labcorp Monkeypox PCR Test Home Collection Kit will be dispensed to patients when prescribed by their physician using the Labcorp provider interface to order diagnostic tests. Once the physician order is placed, Labcorp will mail the home collection kit to the patient, who will perform the sample collection and mail it back to Labcorp.

Home Collection Kit Use: The specimen collection and shipping instructions are included

in the kit to direct users on how to collect a lesion swab specimen appropriately, place it in the specimen collection tube, properly package the specimen and mail it back to the laboratory using the pre-labeled FedEx return envelope. Specimens should be returned on the same day as they were collected.

3) *Collection Kit Stability*

The specimen collection tube and specimen collection swab included in the Labcorp Monkeypox PCR Test Home Collection Kit are manufactured by third party. The expiration date assigned to the Labcorp Monkeypox PCR Test Home Collection Kit will be determined by LabCorp based on the expiration date assigned by the manufacturer of the specimen collection tube and the swab.

4) *Specimen Stability, Transport and Storage*

Specimens collected using the Labcorp Monkeypox PCR Test Home Collection Kit are brought to the FedEx drop box on the same day it is collected before the last Express pickup Monday-Thursday (no weekends). Specimens are delivered to Labcorp at ambient temperature.

5) *Inspection of Specimens*

Prior to acceptance for testing with the Non-Variola Orthopoxvirus Real-time PCR Primer and Probe Set – EUA, samples received at the clinical laboratory must be subjected to the following accessioning procedure:

a) The FedEx package is opened, and the kit box is removed. The kit box is opened and the biohazard specimen bag containing the sample is removed.

b) Any potential issues with the specimen that would prevent it from being accessioned are identified. Issues include but are not limited to:

- No swab included with the collection tube.
- Collection tube leaked, resulting in no sample for testing.
- Missing specimen labelling/identification on the collection tube as well as the specimen confirmation form (SCF).

Lesion swab specimens collected using the Labcorp Monkeypox PCR Test Home Collection Kit are tested with CDC's Non-Variola Orthopoxvirus Real-time PCR Primer and Probe Set – EUA consistent with its authorization. Refer to EUA230054 EUA Summary for details.

The test report will then be electronically delivered to the ordering healthcare provider and are available to the patient in the Labcorp Patient portal at patient.labcorp.com.

PERFORMANCE EVALUATION

1) Shipping Stability Study (Summer and Winter Excursion)

The shipping stability of lesion swab samples when using the Labcorp Monkeypox PCR Test Home Collection Kit was demonstrated by performing a summer and winter temperature excursion stability study to confirm that signal degradation at high and low temperatures would not occur during shipping. Twenty contrived low positive samples (2x LoD of the authorized test) and 10 contrived high positive samples (10x LoD) were created by

diluting Vaccinia virus (ATCC-1566) into pooled patient specimens negative for *Orthopoxvirus* DNA. This study simulated shipping conditions by cycling the specimens through the following temperature excursion:

Summer Shipping Excursion Profile

Temperature	Cycle Period	Cycle Period Hours	Total Time Hours
40°C	1	8	8
22°C	2	4	12
40°C	3	2	14
35°C	4	36	50
40°C	5	6	56
35°C	6	16	72
22°C	7	72	144

Winter Shipping Excursion Profile

Temperature	Cycle Period	Cycle Period Hours	Total Time Hours
-10°C	1	8	8
18°C	2	4	12
-10°C	3	2	14
10°C	4	36	50
-10°C	5	6	56
10°C	6	16	72
22°C	7	72	144

Summer Shipping Excursion Results Summary

Contrived Samples	T-0 hr		T=144 hr		
	Pos/Total	Mean Ct	Pos/Total	Mean Ct	Delta Ct
2X LoD	20/20 (100%)	33.96	19/20 (95%)	35.82	1.86
10X LoD	10/10 (100%)	31.04	10/10 (100%)	32.87	1.83

Winter Shipping Excursion Results Summary

Contrived Samples	T-0 hr		T=144 hr		
	Pos/Total	Mean Ct	Pos/Total	Mean Ct	Delta Ct
2X LoD	20/20 (100%)	34.51	20/20 (100%)	35.60	1.09
10X LoD	10/10 (100%)	31.36	10/10 (100%)	33.06	1.70

Specimens were tested at each timepoint with the Non-Variola Orthopoxvirus Real-time PCR Primer and Probe Set – EUA. The Ct values at each timepoint were compared to the Ct values at time zero. All specimens remained positive at 72 hours after cycling in and out of high temperatures. Additionally, Ct values demonstrated less than 2 Ct difference between time 0 and 72 hours, indicating acceptable specimen stability under simulated shipping conditions.

2) *Clinical Validation and Usability Studies for the Labcorp Monkeypox PCR Test Home Collection Kit*

a) Usability study:

A usability study was conducted to confirm that patients could follow the

instructions included in the Labcorp Monkeypox PCR Test Home Collection Kit to appropriately collect, package, and ship a lesion swab specimen to a Labcorp laboratory for testing. The study was completed in simulated home setting at two U.S. clinical sites.

After providing informed consent, lay user participants were provided a Labcorp Monkeypox PCR Test Home Collection Kit, which included the instructions for use, shipping box, pre-labeled return envelope, collection and shipping directions, specimen collection materials (swab and collection tube), a specimen biohazard bag containing an absorbent sheet, and a specimen confirmation form. After confirming all contents of the kit were present, the participant performed the specimen collection procedure in a private room with a table and chair that simulated a home environment and packed the shipping box with the specimen following the instructions for use. Specimens were then shipped to a Labcorp laboratory at room temperature by the study staff on the date of collection on behalf of the participant. Participants were also asked to fill out a questionnaire that assessed their ability to understand the different steps in the instructions for use/ ease of sample collection.

A total of 55 individuals consented to participate in the study. These lay user participants included individuals representing varying education levels and age ranges of 18 to 65 years old. Of the 55 individuals, 54 followed the sample collection instructions correctly. Of these 55 individuals, 39 collected a specimen that was acceptable for testing according to pre-determined acceptance criteria. Health care provider (HCP)-collected samples were also collected from the same lesions for these individuals. The self-collected and HCP-collected specimens were tested with the Non-Variola Orthopoxvirus Real-time PCR Primer and Probe Set – EUA for the detection of non-variola *Orthopoxvirus* DNA.

b) Clinical Validation Study:

The above human usability study included a total of 39 specimens (self-collected and matched HCP-collected lesion swab specimens) that were acceptable for testing with the Non-Variola Orthopoxvirus Real-time PCR Primer and Probe Set – EUA for the detection of non-variola *Orthopoxvirus* DNA. These specimens were used to compare the results generated from the intended lay user self-collected lesion swabs to the results generated from HCP-collected lesion swabs, where the same lesion was sampled for each subject.

Based on the testing of these 39 specimens sets, all internal specimen adequacy control results (39/39), and five out of six *Orthopoxvirus* DNA positive (VAC1) results were concordant between HCP-collected and self-collected specimens, resulting in an overall positive percent agreement of 83.3% and negative percent agreement of 100.0% between HCP-collected and self-collected specimens. The average difference in the internal specimen adequacy control and VAC1 gene Ct values between the self-collected and HCP-collected specimens was less than one Ct. These data support that intended users can successfully self-collect lesion swab specimens in a simulated home setting using the Labcorp Monkeypox PCR Home Collection Test Kit.

Warnings:

a. For in vitro diagnostic use
b. For use under Emergency Use Authorization only.
c. For Prescription Use only.
d. For Use by individuals 18 years of age and older.
e. Do not use reagents past their expiration date.
f. This product has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA;
g. This product has been authorized only for the collection and maintenance of lesion swab specimens as an aid in detection of nucleic acid from non-variola *Orthopoxvirus*, including monkeypox virus, not for any other viruses or pathogens; and
h. 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.

EUA REVISION HISTORY:

Date	Summary of Updates
March 22, 2024	Original authorization
July 18, 2024	Add the specimen accessioning SOP titled "Accessioning of Mpox Specimens Collected with Labcorp Home Collection Kits", correct collection kit components, and correct a typographical error in the Instructions For Use.