Mpox specimen collection guidelines
Mpox Virus DNA, Qualitative, Real-Time PCR—for test code 12084

Quest specimen requirements and acceptable supplies for mpox Virus DNA, Qualitative Real-Time PCR (test code 12084)

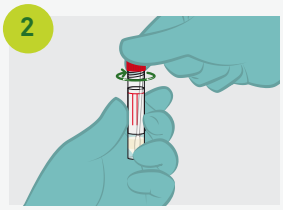
This guide is intended to describe the collection swabs and media to be used for lesion swab specimens for mpox virus molecular PCR testing. Quest Diagnostics supplies specimen collection kits for this assay. Please contact your Quest supplies ordering line or sales representative for more information. This guide provides additional information on supplies that are not provided by Quest but acceptable to send samples for testing. Please refer to the information below. Other resources include the **Quest Test Directory** or the **FAQ document**.

Collection instructions

1

Remove 1 swab from its package. Do not touch the tip of the swab or the length of the swab that will be submerged in liquid with your hands. Only 1 swab per lesion is required for testing.

2

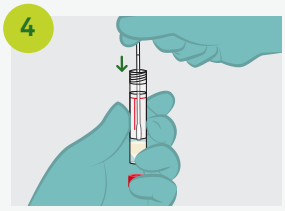


Unscrew the top of the collection tube. Hold the swab in 1 hand and the collection tube in the other.

3

Do not clean the lesion with alcohol or any other disinfectant prior to swabbing. Swab a pustule/lesion vigorously without unroofing or lancing the lesion, applying firm enough pressure so that the swab shaft, if plastic, may bend slightly. This may result in discomfort but is necessary to obtain adequate DNA. Swipe the swab back and forth on the lesion surface at least 2 to 3 times. Then rotate and repeat on the other side of the swab.

4



Insert the swab into the viral transport medium without touching the outside of the collection tube, and break off the end of the swab, if required.

5

Screw the top of the collection tube back on **tightly**. Leaking specimens will be rejected and not tested.

Note: No additional confirmatory testing is required at the Centers for Disease Control and Prevention (CDC); therefore, a duplicate swab from the same lesion is not needed. If clinically indicated, consider submitting additional swabs when multiple lesions with different stages are present. Multiple specimens collected from a single patient should be submitted separately. If a result for each specimen is desired, each should be accompanied by a separate requisition and transported in its own sealed bag. If multiple specimens/tubes are on 1 requisition, a single tube will be tested and reported; other tubes will be considered duplicate specimens.

Acceptable swabs:

- Flocked swabs are preferred, but not required
- Lesion swabs are recommended. If a lesion swab is unavailable and you use a nasopharyngeal (NP) swab for lesions, please ensure adequate specimen collection due to the small surface area of the NP swab
- Swab specimens should be collected using only swabs with a synthetic tip, such as rayon, nylon, or Dacron®, and an aluminum or plastic shaft. Calcium alginate swabs are unacceptable, and cotton swabs with wooden shafts are not recommended

Note: Supplies ordered through Quest Diagnostics should only be used for collection for Quest Diagnostics testing.

Unacceptable swabs:

- Foam swabs
- Dry swabs
- Cotton swabs or swabs appearing similar to Q-tips
- Swab submissions in glass transport tubes
- 3D-printed swabs
- Calcium alginate swabs or swabs with wooden shafts are unacceptable as they may contain substances that inactivate some viruses and inhibit polymerase chain reaction (PCR) testing. (See **https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html**)

Acceptable media:

- 3 ml of media is preferred; minimum 0.5 ml
- Universal transport media (UTM) or equivalent

The products described below are equivalent products. They are manufactured in identical fashion with all raw materials being utilized in all products being equivalent and at the same ratios and would be accepted.

- Copan UTM 330C
- BD universal viral transport (UVT) 220220
- Cepheid XPert Sample Collection Kit for Viruses F-100
- Fischer Universal Transport Medium 23001718
- Hardy-HealthLink UTM 330CHL
- Quest VCM transports 220223
- Quidel/Diagnostics Hybrids 330C.DHI

All other non-equivalent media (ie, CITOSWAB MEDIUM, GTM, Ruhof, etc) have NOT been validated.

Unacceptable media (not inclusive):

- Saline
- Phosphate buffered saline (PBS)
- Amies
- Aptima

Acceptable specimens:

Lesion swabs (ie, swabs of acute pustular or vesicular rash), including mucosal (oral, anogenital) collected in appropriate healthcare settings, such as hospitals and physician offices. Swabs of lesions cannot be collected at Quest's patient service centers (PSCs).

Unacceptable specimens:

- Swabs from non-lesion sources, eg, nasopharyngeal, nares, throat, or saliva, are not accepted unless a lesion is present
- Any tubes that lack proper labeling
- Any leaking tubes

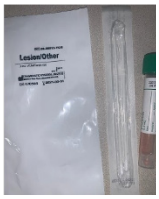
Specimen stability:

Room temperature: Unacceptable

Refrigerated: 7 days

Frozen: 30 days

Ship frozen (preferred) or refrigerated (acceptable)

Acceptable specimen kits for Mpox Virus DNA, Qualitative, Real-Time PCR for test code 12084	
VCM (Diagnostic Hybrids 330C.DHI)[1] • Lesion swab kit ordering information: • PeopleSoft item #: 142060 • PeopleSoft product ID #: S68 (mpox specific) or S03 • Quanum product ID #: S68 (mpox specific) or S03 • Ordered by the EA (each) *Note: both swabs in supply kit S03 are the same; only 1 is necessary for specimen collection.*	  
Not supplied by Quest but acceptable media kits for Mpox Virus DNA, Qualitative, Real-Time PCR for test code 12084	
UTM (Copan)[2] Collection kit-306C UTM medium 3 mL-330C or 3U044n Flocked swab-519CS501	 or 
UVT (BD)[3] Collection kit-220528 UTM medium 3 mL-220220 (1 mL-220244) Flocked swab-220250	
Cepheid® Xpert® sample collection kit for viruses[4] F-100	 F-100
Hardy Diagnostics Healthlink UTM[5] Hardy: 3C038NHL 3 mL Hardy: 3C011NHL 1 mL Hardy: 330CHL: 3 mL UTM Hardy: 302CHL 3 mL (2 with plastic applicator)	 Hardy: 3C038NHL

References

1. Quest website. Accessed August 3, 2022. https://www.questdiagnostics.com/healthcare-professionals/test-directory/specimen-handling/specimen-collection-transport-guide
2. Copan website. Accessed August 3, 2022. https://www.copanusa.com/vendor-part-numbers-for-covid-19-products/
3. BD website. Accessed August 3, 2022. https://www.bd.com/en-us/products-and-solutions/products/product-families/bd-universal-viral-transport-system#bd-tabs-605d5120cc-item-fa06f3d158-tab
4. Cepheid website. Accessed August 3, 2022. https://mms.mckesson.com/product/1087731/Cepheid-SWABF-100
5. Hardy Diagnostics website. Accessed August 3, 2022. https://hardydiagnostics.com/healthlink-utm/

This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an Emergency Use Authorization (EUA) for use by the authorized laboratories.

This product has been authorized only for the detection of nucleic acid from MPXV or other NVO, not for any other viruses or pathogens.

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 mpox 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 assay should only be used to test specimens with low/moderate risk of smallpox. If the specimen is categorized as a high risk for smallpox, only variola testing labs should process specimens. Please call the CDC Emergency Operators Center (1.770.488.7100).

Personnel who collect specimens should use personal protective equipment in accordance with CDC guidance.

Infection Prevention and Control of Mpox in Healthcare Settings https://www.cdc.gov/poxvirus/mpox/clinicians/infection-control-healthcare.html

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