

Monkeypox Dx™

Integrity Laboratories announces completion of Monkeypox Dx™ genetic-level PCR test validation

OVERVIEW – Monkeypox

Monkeypox is a rare disease caused by infection with the monkeypox virus. Monkeypox belongs to the Orthopoxvirus genus in the family Poxviridae. The Orthopoxvirus genus also includes variola virus (which causes smallpox), vaccinia virus (used in the smallpox vaccine), and cowpox virus.

Monkeypox was first discovered in 1958 when two outbreaks of a pox-like disease occurred in colonies of monkeys kept for research. Despite being named “monkeypox,” the source of the disease remains unknown. However, African rodents and non-human primates (like monkeys) may harbor the virus and infect people.

The first human case of monkeypox was recorded in 1970. Since then, monkeypox has been reported in people in several other central and western African countries. Prior to the 2022 outbreak, nearly all monkeypox cases in people outside of Africa were linked to international travel to countries where the disease commonly occurs, or through imported animals.

Monkeypox is a rare disease caused by infection with the monkeypox virus. Monkeypox virus is part of the same family of viruses as smallpox. Monkeypox symptoms are similar to smallpox symptoms, but milder; and monkeypox is rarely fatal. Monkeypox is not related to chickenpox.

Symptoms of monkeypox can include:

- Fever
- Headache
- Muscle aches and backache
- Swollen lymph nodes
- Chills
- Exhaustion
- A rash that can look like pimples or blisters that appears on the face, inside the mouth, and on other parts of the body, like the hands, feet, chest, genitals, or anus.

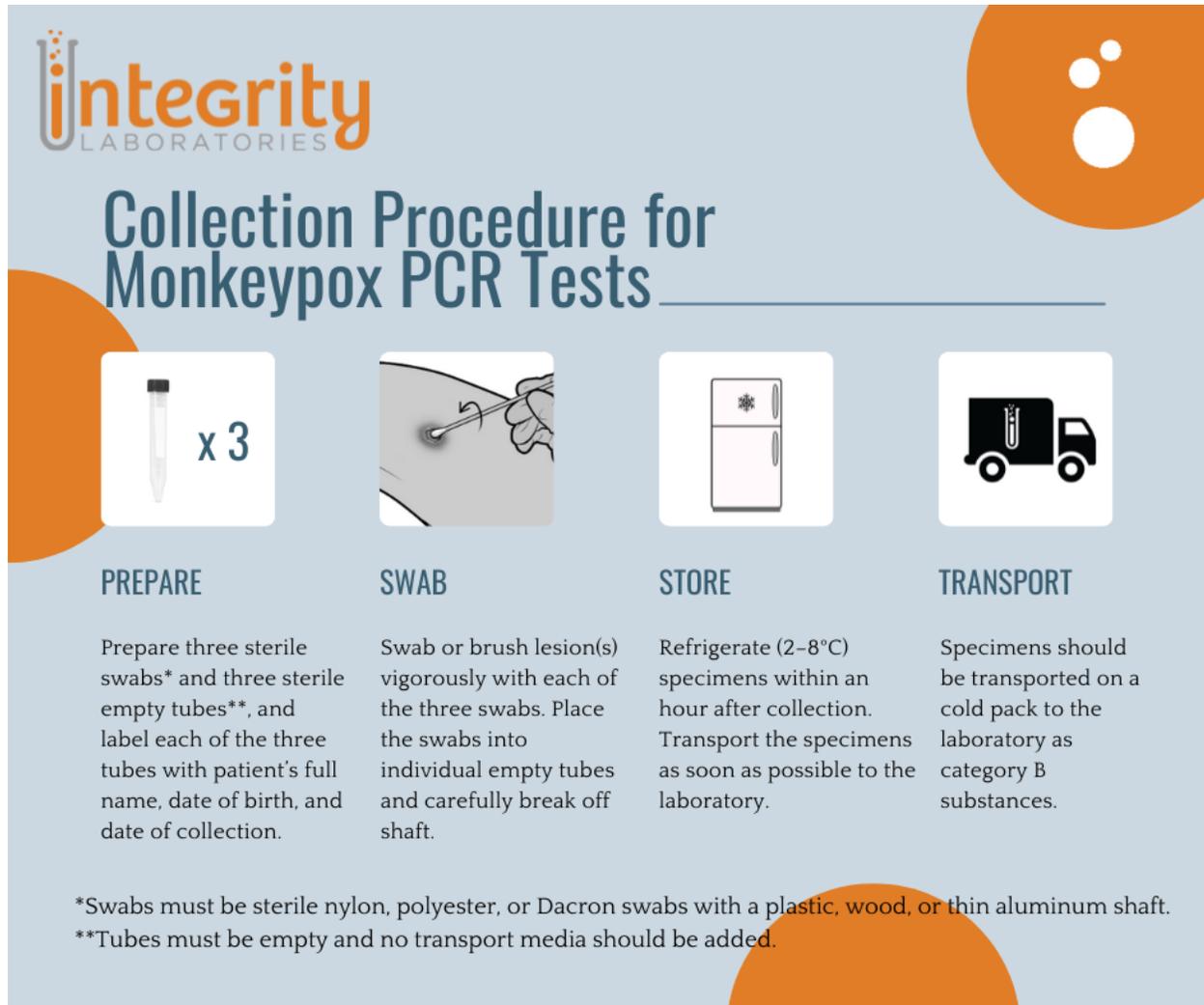
The rash goes through different stages before healing completely. This process can take several weeks. Sometimes people get a rash first, followed by other symptoms. Others only experience a rash.

<https://www.cdc.gov/poxvirus/monkeypox/about.html>

TEST VALIDATION

Integrity Laboratories has successfully completed validation of Monkeypox Dx™ Test for detection of Monkeypox virus causing monkeypox through an Integrity Laboratories, LLC developed LDT (Laboratory Developed Test). The sensitivity (LoD) for detection of the Monkeypox virus by our LDT is 10cp/uL with 100% specificity.

COLLECTION PROCESS – PLEASE READ CAREFULLY



The infographic features the Integrity Laboratories logo at the top left. The title 'Collection Procedure for Monkeypox PCR Tests' is centered in a large, dark blue font. Below the title are four columns, each with an icon and a heading: 1. 'PREPARE' with an icon of a test tube and 'x 3'. 2. 'SWAB' with an icon of a hand swabbing a lesion. 3. 'STORE' with an icon of a refrigerator. 4. 'TRANSPORT' with an icon of a cold pack carrier. Each column contains detailed instructions. At the bottom, there are two footnotes: '*Swabs must be sterile nylon, polyester, or Dacron swabs with a plastic, wood, or thin aluminum shaft.' and '**Tubes must be empty and no transport media should be added.'

Collection Procedure for Monkeypox PCR Tests

PREPARE	SWAB	STORE	TRANSPORT
Prepare three sterile swabs* and three sterile empty tubes**, and label each of the three tubes with patient's full name, date of birth, and date of collection.	Swab or brush lesion(s) vigorously with each of the three swabs. Place the swabs into individual empty tubes and carefully break off shaft.	Refrigerate (2-8°C) specimens within an hour after collection. Transport the specimens as soon as possible to the laboratory.	Specimens should be transported on a cold pack to the laboratory as category B substances.

*Swabs must be sterile nylon, polyester, or Dacron swabs with a plastic, wood, or thin aluminum shaft.
**Tubes must be empty and no transport media should be added.

AVAILABILITY

Monkeypox Dx™ is available immediately through Integrity Laboratories in Knoxville, TN.

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