Q&A | Monkeypox testing

1. What is Monkeypox?

A: Per the CDC website: "Monkeypox is a rare disease caused by infection with the monkeypox virus. Monkeypox virus 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 is not related to chickenpox."[1]

Test number:
[140230] Monkeypox (Orthopoxvirus), DNA, PCR

Turnaround time:
2 to 3 days turnaround time from the date of specimen pickup.

Collection of sample:
Vigorously swab or brush the base of the lesion with a sterile dry polyester, rayon or Dacron swab. Collect a second swab from the same lesion. Insert both swabs into the sterile plastic aliquot tube or sleeve and break off the end of the swabs, if required, to tightly close the sample. **Do not add any transport media to the sample.** Two swabs should be submitted to ensure adequate material is sampled.

2. What do the test results indicate?

A: The test is qualitative, and will indicate a detected, not detected, inconclusive, or equivocal result for the presence of DNA from non-variola orthopoxvirus species, of which monkeypox is one. Here is what these results indicate:

- **Detected:** A non-variola orthopoxvirus was detected. In addition to monkeypox, there are several viral species in the genus *Orthopoxvirus*. But since there are no current epidemiological concerns about those other viruses, a detected result is presumptive positive for monkeypox. Variola is the virus that causes smallpox. This test will not detect smallpox, hence "non-variola".
- **Not Detected:** This means that an orthopoxvirus was not detected, and the patient is therefore negative for monkeypox.
- **Equivocal:** This result can occur when the virus is detected at levels close to the limit of detection of the assay, and a definitive result cannot be determined. For any equivocal result, the CDC recommends that a new patient sample should be collected and tested.
- **Inconclusive:** This result can occur when the assay control criteria are not met and no virus is detected. The concern here is a poorly collected sample, and the CDC recommends that a new patient sample should be collected and tested.

3. If the result is detected, are we sure that it is monkeypox?

A: A detected result on this assay indicates a presumptive positive for monkeypox. Though this assay does screen for multiple orthopoxviruses, there is no current epidemiological evidence for those other viruses circulating currently.

4. Can this assay produce a quantitative result?

A: No. This assay is only qualitative, as defined above.

5. Do we offer this testing through our PSCs?

A: No. Samples must be collected by a clinician in office or at a hospital.

6. What about billing and reimbursement?

A: There has been an urgency from the CDC to have commercial labs launch this test due to public health concerns. Some of the information typically available at time of launch relating to billing and reimbursement is still in process. At the time of test launch, billing and reimbursement have not yet been determined. We will update you as soon as that information becomes available.

7. Did we develop this test internally?

A: No. We are running the FDA-cleared version of the test that we received from the CDC. However, we have made some adjustments to the assay in order to make it more high throughput.

Reference

1. Centers for Disease Control and Prevention. About Monkeypox. https://www.cdc.gov/poxvirus/monkeypox/about.html. Accessed July 1, 2022.

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labcorp