

| TODIO                                      |   |
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| TOPIC                                      | DESCRIPTION   |
| Test Name                                  | Non-variola Orthopoxvirus Molecular Detection                               |
| Other Name (s)                             | mpox Testing, mpox PCR  |
| Analyte(s)                                 | Non-variola Orthopoxvirus   |
| Test Code                                  | 9778  |
| Lab location                               | Jacksonville, Miami, Tampa  |
| Department                                 | BT  |
| Prior Authorization                        | Requires prior approval from Regional Epidemiology and notification         |
|  | to the testing lab. Contact local County Health Department to start         |
|  | the process for approval.   |
| Required Forms                             | DH1847 – Add test requested in additional information                       |
| Specimen Sources<br>Collection Media       | Swabbed lesion material is required for persons with an active lesion       |
|  | or rash.  |
|  | Acceptable samples are: dry swabs, swabs in viral transport media           |
|  |   |
|  | (VTM) [except for Clade I/Congo Basin Monkeypox virus].                     |
|  |   |
|  | <b>NOTE</b> : Any "universal" media will result in sample rejection. Please |
|  | contact a BT Coordinator with questions.                                    |
|  |   |
|  | Collect duplicate lesion swabs. Preliminary testing will occur at the       |
|  | Bureau of Public Health Labs. If positive, characterization testing may     |
|  | be carried out at the CDC.  |
| Minimum Volume                             | Viral transport media: 0.3 mL   |
|  |   |
| Supplemental Information- Special Specimen | Swabs should be nylon, dacron, or polyester. <u>Do not use cotton or</u>    |
| Preparation                                | rayon swabs. Do not use swabs with metal shafts.                            |
| Storage Conditions                         | For dry swabs:  |
|  | Freeze (-20°C or lower) or refrigerate (2-8°C) specimens promptly           |
|  | after collection. Store frozen samples for up to 60 days. Freezing is       |
|  | strongly recommended. However, if there is no freezer available,            |
|  | refrigerate samples (2-8°C) and store for up to 7 days. It is strongly      |
|  | recommended to send samples within 7 days of collection.                    |
|  |   |
|  | For swabs in viral transport media:   |
|  | Freeze (-20°C or lower) or refrigerate (2-8°C) specimens promptly           |
|  | after collection. Store frozen samples for up to 30 days. Freezing is       |
|  | strongly recommended. However, if there is no freezer available,            |
|  | refrigerate samples (2-8°C) and store for up to 7 days.                     |
| Specimen Labeling                          | Specimen must be labeled with at least two unique patient                   |
|  | identifiers, Ex: Name and DOB. Information on the specimen must             |
|  | match the requisition.  |
| Packaging and Shipping Instructions        | Preferred: Ship frozen using dry ice (-20°C or lower)                       |
|  | Acceptable: Ship refrigerated with ice packs (2-8°C)                        |
| Test Methodology                           | PCR   |
| Turnaround Time                            | 48 hours after received at testing facility                                 |
| Result Indicator                           | Detected/Not detected   |
|  | ·   |
| Unsatisfactory Specimen                    | Any transport media not specifically designated "viral transport            |
|  | media". "Universal" media designed for bacterial preservation will          |
|  | result in sample rejection. Please refer to the product sheet and/or        |
|  | reach out to a BT Coordinator for more information.                         |
| Interferences and Limitations              | Cotton and rayon swabs and swabs in media designed for bacterial            |
|  | preservation and/or transport may cause PCR inhibition and should           |
|  | not be used. Commonly misleading and unacceptable media                     |
|  | includes "Universal Viral Transport Media" and "Universal                   |
|  | Transport Media".   |
|  |   |
|  | Specimens with insufficient human DNA will be resulted as                   |
|  | inconclusive.   |
|  |   |
| Additional Information & Notes             | Collection and submission requirements adapted from CDC Test                |
|  | Order CDC-10515 (Poxvirus Molecular Detection).                             |
| Poforonco Pongo                            | N/A   |
| Reference Range                            |   |
| Reference Lab                              | CDC   |