

Attachment 4: Optional Lesion Samples to CDC for Resistance Testing

I. Guidance on Specimen Collection and Shipping

Specimen: volume or quantity	When it should be collected	How it should be stored	Shipment Address and Point of Contact	Additional details*
<p>Testing for viral resistance: At least two lesion swabs or crusts</p> <p>NOTE: Lesion samples collection will help monitor potential emergence of antiviral resistance. However, individual patient results cannot be made available for directly informing individual patient treatment decisions.</p>	<p>Any new lesions during tecovirimat treatment and after treatment completion.</p>	<p>Collect at least two lesion specimens concurrent with stage of disease. This may be a swab or crust. The swab may be dry or placed in viral transport media.</p> <p>Freeze (-20°C or lower) specimens within an hour after collection. Ship frozen samples with adequate amount of dry ice (about 10 lbs.). Frozen samples must be received at CDC within 60 days.</p> <p>Label specimen container with two patient identifiers (i.e., patient first and last name with another unique patient identifier such as date of birth, medical record number).</p>	<p>Specimens can be shipped as category B infectious substance, if tested positive by a nonvariola orthopoxvirus assay (See Packaging and Transporting Infectious Substances Smallpox CDC) to the following address:</p> <p>Centers for Disease Control and Prevention c/o Whitney Davidson RDSB/STATT Unit 47 1600 Clifton Road NE Atlanta, GA 30329 404.639.2933</p>	<p>Any transport media that does not contain inactivating agents can also be used.</p> <p>Complete CDC Form 50.34 electronically. Indicate Poxvirus Molecular Detection (CDC-10515) for the test order (code). Indicate in “Brief Clinical Summary” that patient was treated with tecovirimat and if available, start date of tecovirimat or tecovirimat treatment day# and HIV status. Include date of collection on the 50.34 form. Alternatively, the Global File Accessioning Template (GFAT) can be completed in place of 50.34 form. If using the GFAT, the file must be password protected and emailed to Poxviruslab@cdc.gov with wfd6@cdc.gov and kgv3@cdc.gov cc’d. Please include in a separate email the password and tracking info. GFAT file can be provided by CDC during a clinical consultation on a monkey patient or request it by email to Poxviruslab@cdc.gov.</p> <p>Please send notification via email (Whitni and Ninnie): wfd6@cdc.gov and kgv3@cdc.gov when specimens are shipped.</p> <p>The same baseline diagnostic lesions sent to CDC for confirmatory MPX PCR testing can also be used for resistance testing (as long as viable virus is cultured) for the pre-tecovirimat sensitivity testing.</p> <p>Please also include a shipping log detailing the patient specimens included (example shipping log provided on next page). If tecovirimat treatment decision is made before the specimens are shipped to CDC, please clearly label/indicate on the shipping log that the baseline swabs are from patients who will receive tecovirimat. If treatment decision is made after shipment to CDC, then notify via email (Whitni and Ninnie): wfd6@cdc.gov and kgv3@cdc.gov</p>

II. Example Shipping Log to Include with Lesion Specimen Samples sent to CDC

Shipping Log: Tecovirimat Lesion Specimen For Resistance Testing

Please complete and include this specimen shipping log with each sample that is sent to CDC, along with the completed Form 50.34.

Patient Name: _____ Hospital-Issued Patient ID: _____

Treating Physician Name: _____

Hospital Name/Address: _____

Has the patient been on tecovirimat treatment? Yes No

If yes: Tecovirimat Dose (mg) and Frequency: _____

Date of first dose of tecovirimat: _____ Duration of tecovirimat treatment (# days): _____

Location of lesion	Collection Date	Collection Time

For lesion specimens, please include 2 crusts or lesion swabs. The samples may be dry or placed in viral transport media.

Comments:

Samples frozen at -20°C? Yes No

Name of person preparing/shipping the specimen (please print): _____

Shipment preparer's contact information (phone #, email address): _____