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Section: Bacteriology Procedures	Subject Title: Monkeypox Procedure	
Prepared by QA Committee		
Issued by: Laboratory Manager	Revision Date:6/23/2022	
Approved by Laboratory Director: Microbiologist-in-Chief	Next Review Date:6/23/2024	

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Introduction

This procedure provides general guidance on how to handle specimens from patients with suspect or confirmed monkeypox.

Specimen Collection and Storage

- Recommended specimens varying on the patient's presenting signs/symptoms.
 - Throat swab/NP swab** and **serum** may be requested at the prodromal stage along with **lesion fluid/crust/scab**, **lesion swab** at the skin rash stage – all for **Monkeypox Virus Detection**.
- Please refer the list below for the acceptable specimen types:



Specimen Type	Minimum Volume	Comment
Serum	≥0.5mL	<ul style="list-style-type: none"> Red top Serum separator tube (SST) Centrifugation of serum tubes is not needed and should be avoided
Lesion fluid, crust material or scab	Not Applicable	<ul style="list-style-type: none"> Sterile 1.5-5.0mL tube/container with or without transport media
Swab of lesion	Not Applicable	
Nasopharyngeal and/or oropharyngeal swab	Not Applicable	
Cerebrospinal fluid (CSF) (if encephalitic)	≥0.5mL	
Urine (if severely ill)	50mL	
Tissues	Not Applicable	
Formalin-fixed, or paraffin embedded tissues	Entire blocks, or four to six 10 micron block sections	Sterile container (clearly label if formalin fixed)

- All specimens will be cleaned and placed in specimen transport bags then deliver to the lab
 - NOTE:** the pneumatic tube may be used, however skin samples are expected to arrive in Zip N' Fold bags.

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Tests Performed in SHS/UHN Department of Microbiology

The tests listed below are performed in SHS/UHN Department of Microbiology with the initial specimen processing to be completed following **safety precautions** as stated in specimen processing procedure below.

- a. Routine bacteriology
- b. Routine mycology
- c. HSV/VZV on **Aries**
- d. COVID-19 on **Aries/GeneXpert**
- e. Influenza/RSV on **Aries/GeneXpert**
- f. *C. difficile* toxin B detection on **Aries/GeneXpert**
- g. Serology testing on **Alinity**
- h. Virology testing on **cobas6800**
- i. PCR testing on **easyMag-Biorad** platform

Note: Other tests that impact patient care may be considered upon consultation with the microbiologist-on-call

Reagents/Materials/Media

1. Accel PREvention Wipes
2. Necessary suppliers for the tests performed in-house
3. Personal protective equipment:
 - Fit-tested N95 (choose fit tested model and size)
 - Disposable face shield
 - Disposable water resistant gown
 - disposable nitrile gloves



Specimen Processing

1. Specimens should be received as soon as they arrive in the laboratory.
NOTE: centrifugation of serum tubes is not needed and should be avoided.
2. **Don PPE** while handling specimens
3. Disinfect the bag and specimens with AccelPREvention Wipes

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NOTE: Page microbiologist-on-call through locating for any discrepancies between samples and requisition

4. Receive all orders in the LIS system and add in the RG3 alert “MPX-1”.
5. print the LIS labels including the media labels for the tests that will be performed in-house
6. Label all specimens with correct LIS label
7. Set up all in-house tests in BSC according to the appropriate protocol for the indicated test
8. Disinfect the BSC using Accel PREvention Wipes
9. Proceed with in-house tests as per usual protocols in the BSC
10. Discard all wastes from the samples under monkeypox investigation in biohazard bin prior to sending out for incineration.
11. Use the following test codes for monkeypox virus detection:
 - **MOPXX – Monkeypox Virus Detection (Other)**
 - **MOPXB – Monkeypox Virus Detection (Blood)**
12. Order **Virology Refer Out** using keypad for the 1st additional send-out PCR test (e.g. Enterovirus)
13. Order **Virology PCR** using keypad for the 2nd additional send-out PCR test
14. Place LIS sticker in the template below when sending out samples for Monkeypox
15. Keep the log sheet in the binder on the Virology Accessioning Bench

Monkeypox sendout			
LIS#	Date sent out	Date resulted	Tech Initial

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Specimen Transportation for Monkeypox Virus Detection

I. Shipping Condition

Sample Type	Shipping Condition (Time between collection and shipping)	
	Within 72 hours (≤ 72 hrs)	More than 72 hours (> 72 hrs)
Lesion fluid, crust material or scab	2-8°C (Ice Pack)	$\leq -70^\circ\text{C}$ (Dry Ice)
Swab of lesion	2-8°C (Ice Pack)	$\leq -70^\circ\text{C}$ (Dry Ice)
Nasopharyngeal and/or throat swab	2-8°C (Ice Pack)	$\leq -70^\circ\text{C}$ (Dry Ice)
Serum	2-8°C (Ice Pack)	$\leq -70^\circ\text{C}$ (Dry Ice)
Cerebrospinal fluid (CSF)	2-8°C (Ice Pack)	$\leq -70^\circ\text{C}$ (Dry Ice)
Urine	2-8°C (Ice Pack)	$\leq -70^\circ\text{C}$ (Dry Ice)
Tissues	2-8°C (Ice Pack)	$\leq -70^\circ\text{C}$ (Dry Ice)
Formalin-fixed, or paraffin embedded tissues	Room Temperature	

II. Shipping Documents/Transportation Preparation

1. Print PHOL requisition using **MIC10** format from LIS
 - The following information must be provided on PHOL requisition
 - 1.1. Patient identifiers
 - 1.2. Number of specimens being sent
 - 1.3. Indicate Monkeypox Virus Detection as the requested test
 - 1.4. Include clinical information from order entry. (Symptoms and onset, Risk factors/exposures, travel history, VZV vaccination history etc)



2. Arrange for transportation to PHOL using Category B shipment protocols (as directed by Temporary Certificate TU0886).
 - 2.2. Ship specimens at 6am each weekday to PHOL
 - 2.3. When ready to ship, contact KJV for transportation

3. Email ICP of submitting hospital that the specimen was received and has been sent to PHOL for Monkeypox Virus Detection with the associated specimen LIS number.

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Phrases for deferring non-monkeypox tests

For tests that can be deferred:

“This test has been deferred for biosafety reasons until monkeypox is ruled out. Please contact the microbiologist-on-call with any questions.”

For tests that can't be deferred and need to be cancelled:

“This test was CANCELLED for biosafety reasons given that monkeypox is being rule out. Please contact the microbiologist-on-call with any questions.”

For tests that are cancelled after positive monkeypox results:

“This test was CANCELLED for biosafety reasons given positive monkeypox test results. Please contact the microbiologist-on-call with any questions.”

For tests set up late due to initial deferral:

“Testing was delayed until monkeypox was ruled out which may reduce the sensitivity of this test. Please take this into consideration when interpreting this result. Please contact the microbiologist-on-call with any questions.”

Monkeypox Testing Logarithms in PHOL

1. Samples requesting monkeypox testing will be screened at PHOL for Orthopoxvirus.
2. Orthopox negative and invalid results from PHOL lab will be final report.
3. Orthopox positive and indeterminate specimens will be reported as preliminary results and the specimen will be forward to the National Microbiology Laboratory (NML) in Winnipeg for confirmatory testing.

Orthopox Result In PHOL	Report status from PHOL	Report status from NML
Negative	Final	N/A
Invalid	Final	N/A
Positive	Preliminary	Final
Indeterminate	Preliminary	Final

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Resulting from PHOL Report

1. Negative Result – Result in the **VSEND** test comment :
 - 1.1. Press “**F8**” to open Test Comment Window
 - 1.2. Select **Y >MOP** from VSEC-1 of 1 window
 - 1.3. Select **1 }-MOP**
 - 1.4. **Finalize** the report

Key	Text
W	}REFV
0	>MOHT
B	}NVIR
M	}MUL-
G	}FLU
H	}OSND
P	}PHL#
1	}PHLV
2	}PHLR
E	}NML
3	}HSC
4	}HSCR
5	}HHS
6	}HHSR
7	}BELL
8	>VPCR
9	>VHEM
F	}FLU
A	}+FLA
V	}+VIR
N	}NEGC
C	}hh6-
D	}hh7-
R	}RRV-
U	}UNAB
Y	>MOP

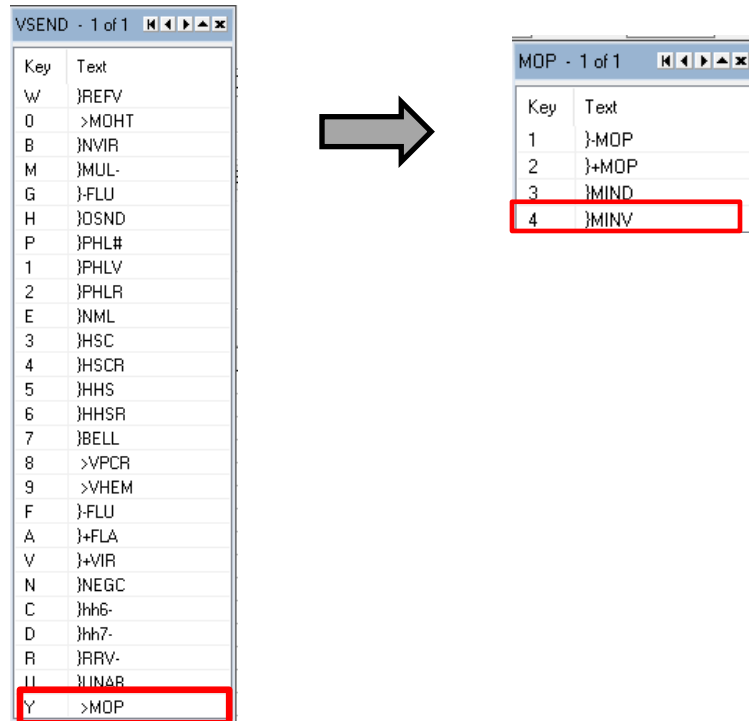


Key	Text
1	}-MOP
2	}+MOP
3	}MIND
4	}MINV

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2. **Invalid Result** – Result in the VSEND test comment :

- 2.1. Press “**F8**” to open Test Comment Window
- 2.2. Select **Y >MOP** from VSEC-1 of 1 window
- 2.3. Select **4 }MINV**
- 2.4. **Finalize** the report

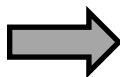


3. **Positive Result** -Result in the VSEND test comment.

- 3.1. Press “**F8**” to open Test Comment Window
- 3.2. Select **Y >MOP** from VSEC-1 of 1 window
- 3.3. Select **2 }+MOP**
- 3.4. **Interim** the report
- 3.5. **Ensure** to set significant status with Red check mark in LIS by right clicking mouse

VSEND - 1 of 1

Key	Text
W)REFV
0	>MOHT
B)NVIR
M)MUL-
G)FLU
H)OSND
P)PHL#
1)PHLV
2)PHLR
E)NML
3)HSC
4)HSCR
5)HHS
6)HHSR
7)BELL
8	>VPCR
9	>VHEM
F)FLU
A)FLA
V)VIR
N)NEGC
C)hh6-
D)hh7-
R)RRV-
U)UNAB
Y	>MOP



MOP - 1 of 1

Key	Text
1)MOP
2)MOP
3)MIND
4)MINV

M	+	C	S	Date
M			I	2022.05.27

Test Comments

Add Test

Cancel Test

Delete Test

Set Prelim Status

Set Interim Status

Set Final Status

Set Review Status

Mark for Review

Clear Interim Status

Restore Status

Set Significant Status



M	+	C	S
M	✓		I

4. Indeterminate Result -Result in VSEND test comment.

- 4.1.Press “F8” to open Test Comment Window
- 4.2.Select **Y >MOP** from VSEC-1 of 1 window

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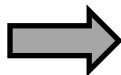
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4.3. Select **3 }MIND**

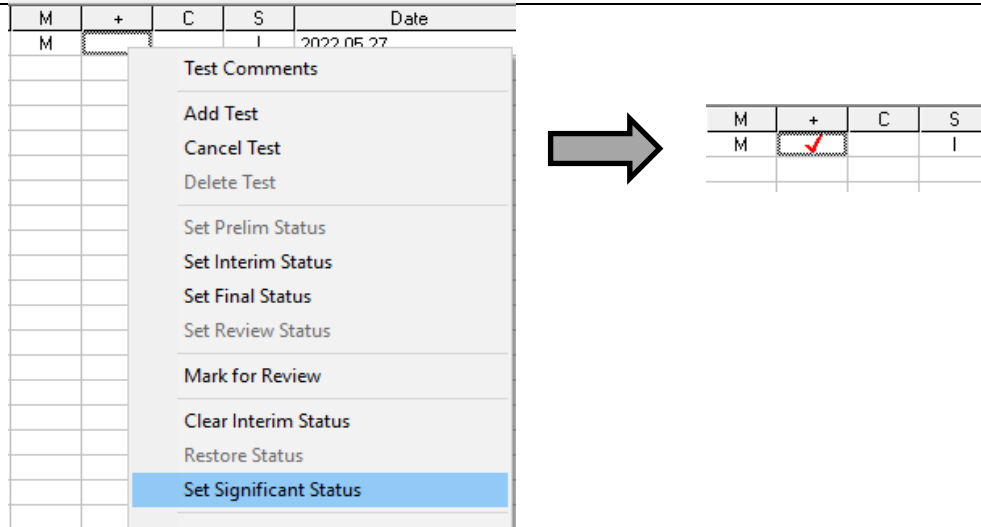
4.4. **Interim** the report

4.5. **Ensure** to set significant status with Red check mark in LIS by right clicking mouse

Key	Text
W	}REFV
0	>MOHT
B	}NVIR
M	}MUL-
G	}FLU
H	}OSND
P	}PHL#
1	}PHLV
2	}PHLR
E	}NML
3	}HSC
4	}HSCR
5	}HHS
6	}HHSR
7	}BELL
8	>VPCR
9	>VHEM
F	}FLU
A	}+FLA
V	}+VIR
N	}NEGC
C	}hh6-
D	}hh7-
R	}RRV-
U	}UNAB
Y	>MOP



Key	Text
1	}MOP
2	}+MOP
3	}MIND
4	}MINV



Updating Result from NML Report

Once NML reports are received in the lab, **update** any preliminary **POSITIVE** and **INDETERMINATE** results previously reported by PHOL by **adding** NML final result.

1. Press “F8” to open Test Comment Window
2. Type **UPDATED REPORT** and press “F6” to add the date
3. Update the result according to NML report
4. **Finalize** the report
5. See below for the positive report

UPDATED REPORT 2022.06.10
Probe PCR Assay Pathogen: Monkeypox
-qPCR Assay Result: POSITIVE
 * * * * *

as reported by the National Microbiology Laboratory,
1015 Arlington, Winnipeg, MB.

NML Lab#:

PHL Lab#:

* * * * *

Previously reported as:

Orthopoxvirus PCR: DETECTED



Interpretation: Preliminary detection of Orthopoxvirus
by real-time PCR.

Note: Monkeypox virus is the only virus belonging to the
Orthopoxvirus genus recently detected in Canada.

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Specimen will be forwarded to the National Microbiology Laboratory for confirmatory testing. This test was performed using a Canadian Laboratory Response Network protocol, developed for environmental testing. This assay is currently undergoing validation for testing clinical specimens.

**as reported by the Public Health Laboratory (PHL),
661 University Ave., Suite 1701, Toronto, Ont., M5G 1M1.
PHL Specimen No.**

Result Communication

1. Communicate any verbal results (positive/negative/invalid/indeterminate) according to the isolate notification table in the internal manual
2. Result in LIS only when hard copies are received from PHOL or NML.
3. Communicate the new result received from NML according to the isolate notification table in the internal manual **IF** there is a **change** from the previous PHL report (e.g. initially reported as Indeterminate and then reported by NML as negative (or positive)).
4. Remove RG3 “MPX-1” alert in the LIS if **ALL** monkeypox results are NEGATIVE; verbal reports are sufficient to remove the RG3 alert. Do not remove alert if there are monkeypox results still pending.
5. All results will be notified to the Medical Officer of Health by Public Health Ontario.



Troubleshooting

1. Follow up any monkeypox orders that have not been reported after 48 hours of receipt in PHOL.
 - 1.1. Call PHOL customer service if no monkeypox report available in MSH Microbiology Lab
 - 1.2. If PHOL customer service does not have the results, make sure to ask them to investigate the delay with the PHOL lab technologist.
2. Page microbiologist-on-call through locating for any other situation not included in this procedure

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Reference

1. PHOL: <https://www.publichealthontario.ca/en/Laboratory-Services/Test-Information-Index/Monkeypox-Virus>
2. NML: <https://cnphi.canada.ca/gts/reference-diagnostic-test/5030?labId=1021>
3. CDC: <https://www.cdc.gov/poxvirus/monkeypox/lab-personnel/lab-procedures.html>
4. Rimoin et al. PNAS 2010: <https://www.pnas.org/doi/pdf/10.1073/pnas.1005769107>

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Record of Edited Revisions

Manual Section Name: Standard Operation Procedure Template

Page Number / Item	Date of Revision	Signature of Approval
New	May 27, 2022	Dr T Mazzulli

Full document review included in all updates. Bi-annual review conducted when no revision had been made within 2 years.

Page Number / Item	Date of Revision	Edited by:
Added in-house testing platform Ensure to set significant status for positive result	June 01, 2022	Qin Liu
Updated Transport Canada requirement TU0886 Updated PHOL process Updated BSC information, ensure to use BSC with PPE (no need for 2.5) Updated disposal information, follow routine RG3/4 procedure and send for incineration (no need to autoclave inhouse) Removed responsibility of microbiologist to notify ID	June 8, 2022	Wayne Chiu
Update Resulting from PHOL report Update result communication: Only result in LIS when hard copies received from PHOL Add the updated result from NML report Add the trouble shooting for any orders with no results after 48 hours receipt in PHOL	June 10, 2022	Qin Liu
Added monkeypox test codes Deleted the actual resulting words	June 17, 2022	Qin Liu
Multiple updates re microbiologist approval, transport, pneumatic tube ok, sendout frequency	June 23, 2022	Wayne Chiu

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