INTRODUCTION

The 2019 novel coronavirus is a coronavirus genetically distinct from the two newer human coronaviruses MERS-CoV and SARS-CoV causing respiratory illness in human. Due to the ease of human to human transmission, it is essential to have a diagnostic laboratory specimen management protocol that protects employees working with these related specimens as well as facilitating swift result transmission to practitioners and transparent communication with Public Health authorities.

SPECIMEN COLLECTION

Upon identifying the need for a 2019-novel coronavirus (2019-nCoV) test sample, the following steps will be taken:

A. Notification to Laboratory
   i. Ward to contact infection control to initial testing process
   ii. Infection control to confirm with MOHLTC/PHOL/TPH that testing is approved:
      1. Email PHOL and SH Micro Lab with travel, clinical history and expected specimens: Erik.Kristjanson@oahpp.ca, Romy.Olsha@oahpp.ca, jonathan.gubbay@oahpp.ca, MicrobiologySpecialQueries-MBX@sinaiahealthsystem.ca, Susan.Poutanen@sinaiahealthsystem.ca, Tony.Mazzulli@sinaiahealthsystem.ca, jennie.johnstone@sinaiahealthsystem.ca, and cc Infection Control Medical Physicians and Manager
         • If PHOL does not respond to the email, contact PHOL customer service at 416-235-6556/1-877-604-4567 or After-Hours Emergency Duty Officer at 416-605-3113 to obtain approval and make arrangements if after-hours testing is desired; then email update SHS Micro lab that approval has been received
         • If SHS Micro does not respond to the email, call the microbiologist-on-call through locating.
      2. Call the Ministry of Health designated line for reporting: 1-866-212-2272 (there is an after hours emergency line on the voicemail)
      3. Inform TPH liaisons during business hours (Erika or Olivia) or call 311 after hours
iii. infection control to send microbiologyspecialqueries email, all medical microbiologists, laboratory director and manager email notification of incoming specimens and confirmation that PHOL has confirmed that they will test the specimens.
   • if received after-hours, microbiologist-on-call to contact the lab to confirm the email has been forwarded to senior-on-duty

B. Test order by Ward

EPR and CERNER:

i. For all patients with suspect 2019-nCoV:
   - this will automatically ask for an NP swab and throat swab for 2019-nCoV
     o 2019-nCoV testing will automatically include multiplex respiratory virus detection and avian influenza testing
   - All required clinical/epidemiologic information requested will need to be entered in order to complete the order

ii. If the patient has pneumonia:
   - in addition to ordering the 2019-novel coronavirus 2019-nCoV Detection order set, the option of ordering C. pneumoniae and Mycoplasma on the same NP swab is available to select on the same NP swab
   - this will direct the user to order 2019-nCoV testing on lower respiratory samples if they are being collected

iii. For patient with pneumonia from whom lower respiratory samples are being collected
   - Order BAL or sputum C&S, fungal, AFB, Legionella cultures as deemed clinically indicated
   - Add on 2019-nCOV
     o 2019- nCoV testing will automatically include multiplex respiratory virus detection and avian influenza testing

C. Sample Collection & Transport

- specimens to be collected following usual protocol using PPE as directed by infection control
- specimens to be placed into a biosafety bag followed by a clean second biosafety bag marked in anyway to identify it as a 2019-nCoV sample.
SPECIMEN PROCESSING

_Biosafety Alert_ - All specimens are to be handled using enhanced Level 2 practice (“Level 2.5”). All specimens shall be handed in the BSC within the Level 2.5 room with the following PPE:

- a water impermeable gown
- gloves
- N95 mask
- Rounded faceshield

Remove everything from the BSC and wipe down all surfaces with Virox when finished processing specimens.

_Laboratory Order entry_

A. 2019-nCov Requests:

i. Add in RG3 alert into LIS and laboratory signage
   Refer to Suspect Risk Group 3&4 Biosafety Manual

ii. Do NOT order in house viral detection / respiratory viral detection

iii. All orders will come in as 2019-nCoV which will automatically trigger VREF (Virology Referred-Out).


v. PHOL forms will have the requested clinical/epidemiologic information on the form.

vi. Remove/cancel VREF on throat swab as PHOL will not complete multiplex respiratory testing on throat swabs

B. C&S and Mycology Requests:

If lower respiratory tests are ordered for C&S and mycology in addition to 2019-nCoV:

- process using _enhanced Level 2 practices_ (“Level 2.5”)
- open all centrifuged or cytospun canisters in the BSC in the “Level 2.5” lab
- methanol fix all slides in the BSC in the “Level 2.5” lab
- tape all agar plates and label and disinfect the outsides of using Virox wipes
- place in separate rack with RG3 label and incubate following usual incubation parameters
Send out Procedure to Public Health Ontario Laboratory (PHOL)

A. Sending Specimens to PHOL

Send all specimens to PHOL as they are received through KJV following Category B TDG practices (available 24/7)
*Refer to Send Out Manual for KJV procedure*

Call PHOL customer service to inform them that specimens are being sent

Laboratory Customer Service Hours
Monday to Friday, 7:30 a.m. to 7 p.m.
Saturday, 8 a.m. to 3:45 p.m.
Tel.: 416-235-6556
Toll Free: 1-877-604-4567

After Hours contact the After Hours Duty Officer at 416-605-3113
For after-hours specimen drop off information see link: [Directions to Shipping Dock](#)

B. Reporting results from PHOL

PHOL will provide verbal report and written reports.
*See Post-Analytical Refer-out Test Results Reporting Procedure QPCMI18001*

Enter the 2019-nCoV result in the NCOV order
Enter the viral flu/RSV and multiplex results in the VREF order

All verbal POSITIVE results should be entered and reported in real-time as they are received.
- immediately notify ward, infection control, microbiologist-on-call and laboratory director and manager with verbal results.
- request a faxed report to be sure the report reflects the final report result based on PHOL’s report. An isolate will be generated when OLIS build is complete.

All negative results should be reported in real-time as they are received.
- immediately notify ward and infection control and microbiologist-on-call
- entering the results can be deferred until the next day shift once the written report is received
o use canned test comment below for negative results based on PHOL’s negative reports.

}NCV

2019-novel coronavirus (2019-nCoV) Detection:
"Coronavirus RDRP protein gene: NOT detected
Interpretation: Coronavirus RNA NOT detected by PCR
NOTE: This is an end-point PCR and Sanger sequencing-based assay. It has not been verified for the detection of novel coronavirus linked to Wuhan, China. Results should be interpreted in the context of the clinical history and other pathological findings. The coronavirus RNA-dependent RNA polymerase (RDRP) protein gene PCR and sequencing detects gene sequences in coronaviruses. Specimen has been forwarded to the National Microbiology Laboratory (NML) for repeat testing. as reported by the Public Health Laboratory (PHL), 661 University Ave., Suite 1701, Toronto, Ont., M5G 1M1. PHL Specimen No. ____________

References

https://www.cdc.gov/


Record of Edited Revisions

Manual Section Name: Application Login Information

<table>
<thead>
<tr>
<th>Page Number / Item</th>
<th>Date of Revision</th>
<th>Signature of Approval</th>
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<tbody>
<tr>
<td>Addition of sample collection and transport section. Removed “Pre” EPR and Cerner information (all now Live) Expanded notifications made by IPAC.</td>
<td>January 27, 2020</td>
<td>Dr. T. Mazzulli</td>
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