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Section: Bacteriology Procedures	Subject Title: 2019 Novel Coronavirus Procedure	
Prepared by QA Committee		
Issued by: Laboratory Manager	Revision Date: 4/2/2020	
Approved by Laboratory Director:	Next Review Date: 5/1/2021	
Microbiologist-in-Chief		

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## INTRODUCTION

The SARS-CoV-2 is a new coronavirus similar to SARS-CoV causing COVID-19 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 SARS-CoV-2 (COVID-19) test sample, the following steps will be taken:

A. Notification to Laboratory

Infection control shall:

- 1. Call the Ministry of Health designated line for reporting: 1-866-212-2272 (there is an after hours emergency line on the voicemail)
- 2. Inform TPH liaisons during business hours (Erika or Olivia) or call 311 after hours

No notification to laboratory is required.

## B. <u>Test order by Ward</u>

## EPR and CERNER:

- i. For all patients with suspect COVID-19:
  - order the 2019-novel coronavirus COVID-19 Detection order set found under: "All Laboratory/Microbiology/2019 Novel Coronavirus (COVID-19) Detection".
  - this will automatically ask for an NP swab and throat swab for COVID-19
    - COVID-19 testing will automatically include
      - multiplex respiratory virus detection
      - avian influenza testing
      - influenza A, B RSV in house testing

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- 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 COVID-19 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 COVID-19 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 COVID-19
    - COVID-19 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
- **all** laboratory specimens from patients with suspect or confirmed COVID-19, regardless as to whether they are being sent for COVID-19 testing or other testing, should be handled as follows:
  - Place specimen in two sealed clean biosafety bags
  - Label with "suspect COVID-19" or "confirmed COVID-19" on the outside of the second bag
  - Transport by porters (do not use the pneumatic tube system)

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## SPECIMEN PROCESSING

*Biosafety Alert* - <u>All</u> specimens from a R/O COVID-19 patient 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

Please view the following video for visual reminders of how to don and doff for COVID-19 and RG 3\_4 samples. A written summary is provided below.

## Donning & Doffing Instructional Video

	DONNING	DOFFING	
1.	Remove all unnecessary layers of clothing and	1. Remove gloves	
2. 3.	jewelry. Ensure hair is tied back Perform hand hygiene (rub hand for 15-20 second or until completely dry)	<ul> <li>Grasp outer edge near wrist and per rolling the glove inside out</li> <li>Reach under the second glove and paway discarding directly into trash.</li> </ul>	peel
4.		<ol> <li>Remove gown starting at the neck, the contaminated side of the gown is pulled</li> </ol>	outer
5.	Put on "fit tested" N95 respirator. Pinch nose piece. Perform seal check	forward and turned inward, rolled off th and discarded into trash	
6.	Put on face shield. Ensure strap is on the	3. perform hand hygiene	
7.	crown of your head Put on gloves taking care not to rip or puncture gloves. Ensure they fit over the	4. Remove face shield by <b>only</b> touching the of the strap which is considered clean. I into waste receptacle	
	gown. Place a second set of gloves overtop.	<ol> <li>Remove N95 respiratory. Grasp bottom top strap from the back of your head an forward off head falling away from fac</li> </ol>	id pull
		<ul><li>Discard into waste receptacle</li><li>6. Perform hand hygiene.</li></ul>	

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

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Laboratory Order entry

A. COVID-19 Requests:

Please phone ward (not infection control) if we don't receive all specimens.

- i. Add in RG3 alert into LIS and laboratory signage Refer to Suspect Risk Group 3&4 Biosafety Manual *If you are not able to add the flag, please forward to a senior or charge for entry as soon as possible.*
- ii. Process in house for respiratory viral detection
  - Order in house respiratory viral detection from the LIS keypad.
- iii. All orders will come in as COVID-19 which will automatically trigger VREF (Virology Referred-Out).
- iv. Request "SARS-CoV-2" in VREF and on the PHOL requisition
- v. PHOL forms will have the requested clinical/epidemiologic information on the form.
- vi. Email ICPs samples have been received in lab and forwarded to PHOL.
- vii. Prepare and freeze 3 aliquots
- B. Respiratory Sample requests:

If lower respiratory tests are ordered for C&S and mycology in addition to COVID-19: (BAL, Sputum, TS for GAS, ETT etc)

- process using <u>enhanced Level 2 practices</u> ("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
- disinfect the outsides of all items using Virox wipes
- remove from hood and incubate following usual incubation parameters

# C. Stool samples

- Remove sample from biosafety bag in a Class II A2 BSC
- Clean sample with Virox wipes
- Process routinely
- D. All other samples
  - As any other samples is removed from its biohazard bag, wipe the outside of the samples with a virox wipe/

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## Send out Procedure to Public Health Ontario Laboratory (PHOL)

A. Sending Specimens to PHOL

Batch send all specimens to PHOL through KJV following Category B TDG practices (available 24/7) at the following times:

- 6am
- 10am
- 4pm

Ensure the outside of the box is marked with "STAT" to alert PHOL to the urgent specimens.

Refer to Send Out Manual for KJV procedure

B. Reporting results from PHOL

PHOL will provide written reports.

See Post-Analytical Refer-out Test Results Reporting Procedure QPCMI18001

Enter the COVID-19 result in the NCOV order Enter the viral flu/RSV and multiplex results in the VREF order

PHOL results will be available 8 hours after each run.

PHOL Run time	Expected faxed results time
8:00am	4:00-4:30pm
12:00pm	8:00-8:30pm
6:00pm	2:00-2:30am

Any COVID-19 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.

• enter the results from written report is received.

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- $\circ\;$  use canned test comment below for negative results based on PHOL's negative reports.
- notify (email) infection control

## }NCV

#### 2019-novel coronavirus (COVID-19) Detection:

"COVID-19 virus RdRp gene: NOT detected COVID-19 virus Envelope gene: NOT detected INTERPRETATION: COVID-19 virus NOT detected by real-time PCR NOTE: This real-time PCR assay has been validated at Public Health Ontario Laboratories and the National Microbiology Laboratory for clinical use. It has not been cleared or approved by Health Canada. This test includes two targets: RNA dependent RNA polymerase (RdRp) gene and Envelope gene(E). Detection of two gene targets is required for laboratory confirmation of COVID-19 (2019 novel coronavirus disease) virus by real-time PCR. Results should be interpeted in the context of the clinical history and other pathologic findings. Copy of result sent to MOH. [ADD IN As resulted from PHOL ...usual phrase]"

## References

https://www.cdc.gov/

https://www.who.int/csr/don/12-january-2020-novel-coronavirus-china/en/

https://www.publichealthontario.ca/en/laboratory-services/test-information-index/wuhan-novelcoronavirus

https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/biosafetydirectives-advisories-notifications/novel-coronavirus-january-27.html

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#### **Record of Edited Revisions**

## Manual Section Name: Application Login Information

Page Number / Item	Date of Revision	Signature of Approval
Addition of sample collection and transport section. Removed "Pre" EPR and Cerner information (all now Live)	January 27, 2020	Dr. T. Mazzulli
Expanded notifications made by IPAC.	Est	D. T. M11
Procedure updated to reflect current updated practices Donning and Doffing instructions added	February 28, 2020	Dr. T. Mazzulli
Updated all procedures	March 4, 2020	Dr. T. Mazzulli

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