Public Health Ontario | Santé publique Ontario

COVID-19

If you are concerned that you may have been exposed to, or are experiencing symptoms of COVID-19, please contact Telehealth at (1-866-797-0000), your primary care provider, or your local public health unit.

Coronavirus Disease 2019 (COVID-19) Testing

There is in an increased global demand for viral nasopharyngeal swabs due to COVID-19. In an effort to ensure swabs are available where most needed, the Public Health Laboratory is limiting the volume of swabs supplied. We are also validating other swab types and will provide an update when available. Please be assured we are working diligently to address this issue. Please monitor your inventory closely and reorder only as required.

This document provides testing guidelines for the novel coronavirus 19 disease (COVID-19, formerly known as 2019-nCoV) associated with an outbreak of respiratory illness that originated in Wuhan, Hubei Province, China in late 2019. The causative agent for COVID-19 disease is SARS-CoV-2 virus. For the purpose of clear communication, PHO uses the term COVID-19 to refer to both the virus and the disease.

Who to test:

PHO Laboratory will accept specimens for COVID-19 testing from individuals meeting criteria for a person under investigation (PUI) or probable case for COVID-19 as outlined by the **Ministry of Health**.

Clinical presentations that do not fit case definition, but are considered at risk of COVID-19 by the assessing clinician will also be accepted for testing. PHO is not currently recommending routine testing of asymptomatic persons for COVID-19. If the clinician would like to further discuss the role for testing the PHO Microbiologists on-call are available and can be contacted through the PHO Laboratory's Customer Service Centre at **416-235-6556** / **1-877-604-4567** or the After-Hours Emergency Duty Officer at **416-605-3113**.

Mandatory data accompanying testing requests:

In order to expedite testing, as of February 10, 2020 PHO Laboratory pre-approval for COVID-19 testing is no longer required, provided that the following mandatory information is included on the specific **PHO COVID-19 Test Requisition**:

1. Whether the individual meets criteria for a person under investigation (yes/ no)
2. Travel history (country and dates)
3. Exposure history (contact of PUI, case or probable case (yes/no), and details of any exposure)
4. Clinical information (e.g. fever, cough, rhinorrhea, pneumonia) including symptom onset date
5. Specimen type
6. Patient setting

Specimen collection recommendations:

A) Patients not admitted to hospital (including those in ER)

- **A single upper respiratory tract specimen will be accepted for COVID-19 testing**. Upper respiratory tract specimens include a nasopharyngeal swab (NPS) **OR** viral throat swab collected in universal transport medium (UTM). **NPS is preferred** since information available to date suggests that a NPS has higher sensitivity than a throat swab for COVID-19 detection.

B) In-patients

For in-patients, it is recommended to collect a minimum of two specimens, from two different sites:

- Upper respiratory tract: submit both a NPS **AND** viral throat swab collected in UTM.
- Lower respiratory tract specimens: submit when possible.
- Sputum: collect if patient has a productive cough. Do not induce.

Note: As of March 2, 2020, the respiratory virus multiplex PCR (MRVP) will no longer be performed on all specimens submitted for COVID-19 testing. MRVP will only be performed by request for patients that meet PHO Laboratory's acceptance criteria for this testing (e.g. hospitalized, outbreaks, institutionalized). Refer to the **Respiratory Viruses Test Information Sheet** for more details and acceptance criteria.

Serology for COVID-19 is not available.

STAT testing requirements:

PHO's Laboratory is committed to prioritizing testing to assist health-care providers in making swift patient care decisions in an urgent or emergency circumstance ("STAT").

- STAT samples must be shipped separately from routine specimens to **the shipping and receiving dock at 661 University Ave., Toronto, Ontario**. For delivery instructions please see **Directions to 661 University Shipping Dock for Clinical Samples**
- STAT samples must be placed in a clearly marked package indicating 'STAT' and handled in accordance with the Canadian Biosafety Standards and shipped in accordance with the Transportation of Dangerous Goods Regulations.
- Failure to ship separately will delay testing, primarily due to delays in transportation, and will be processed as a routine sample.

Local public health unit notification:

The local public health unit must be contacted about all individuals being tested for COVID-19. For contact and information on your local health unit, please see the **Ministry of Health PHU Locator**.

*Uncontrolled print copy. Valid only on day of print: 16 March 2020.

Specimen Collection and Handling

Specimen Requirements

Test Requested	Required Requisition(s)	Specimen Type	Minimum Volume	Collection Kit
COVID-19		Upper respiratory	Nasopharyngeal	**Virus Respiratory Kit order # 390082**

	Coronavirus Disease 2019 (COVID-19) Test Requisition	tract: Nasopharyngeal swab (NPS)	swab in 1 ml universal transport media (UTM)	
COVID-19	Coronavirus Disease 2019 (COVID-19) Test Requisition	Viral throat swab (see Submission and Collection Notes below)	Swab in 1 ml universal transport media (UTM)	Virus Culture Kit order #390081
COVID-19	Coronavirus Disease 2019 (COVID-19) Test Requisition	Lower respiratory tract (when possible): sputum, BAL, bronch wash, pleural fluid, lung tissue (see Submission and Collection Notes below)	1.0 ml	Tuberculosis Kit order#: 390042

Submission and Collection Notes

1

Respiratory Tract Specimens:

A) Patients not admitted to hospital (including those in ER)

- **A single upper respiratory tract specimen will be accepted for COVID-19 testing**. Upper respiratory tract specimens include a nasopharyngeal swab (NPS) **OR** viral throat swab collected in universal transport medium (UTM). **NPS is preferred** since information available to date suggests that a NPS has higher sensitivity than a throat swab for COVID-19 detection.

B) In-patients

For in-patients, it is recommended to collect a minimum of two specimens, from two different sites:

- Upper respiratory tract: submit NPS **AND** viral throat swab collected UTM.
- Lower respiratory tract specimens: submit when possible.
- Sputum: collect if patient has a productive cough. Do not induce.

2

Complete all fields of the COVID-19 Test Requisition.

1. Whether the individual meets criteria for a person under investigation (yes/ no)
2. Travel history (country and dates)
3. Exposure history (contact of PUI, case or probable case (yes/no), and details of any exposure)
4. Clinical information (e.g. fever, cough, rhinorrhea, pneumonia) including symptom onset date
5. Specimen type
6. Patient setting

Preparation Prior to Transport

Place specimen in biohazard bag and seal. Specimens should be stored at 2-8°C following collection and shipped to PHO Laboratory on ice packs. If transport of specimen to testing laboratory will be delayed more than 72 hours, specimens should be frozen at -80°C and shipped on dry ice.

Package and ship primary clinical specimens to the local PHO Laboratory in accordance with the Transportation of Dangerous Goods Regulations.

Special Instructions

For respiratory specimens follow the instructions found in the **Virus – Respiratory Kit Instruction Sheet**.

For sputum, BAL, pleural fluid and lung tissue, see **Tuberculosis Kit N-0042**.

For viral throat swab use **Virus Culture Kit N0081**.

Requisitions and Kit Ordering

New

TEST REQUISITION

Coronavirus Disease 2019 (COVID-19) Test Requisition

Requires completion of mandatory information for COVID-19 testing as outlined above, along with submitter (physician) and patient information, and the tests requested.

238 KB | Updated 2 March 2020

FORM OR TOOL

Requisition for Specimen Containers and Supplies

Please note that specimen containers and supplies are supplied to submitters exclusively for samples that are to be tested by PHO.

232 KB | Updated 28 Sep 2017

Test Frequency and Turnaround Time (TAT)

Testing for COVID-19 is performed at PHO Laboratory Toronto as required. NOTE: Turnaround time will vary according to geographical location and proximity to PHO Laboratory Toronto.

Laboratory confirmation of COVID-19 occurs at PHO Laboratory. Additional testing is conducted at the National Microbiology Laboratory (NML) in Winnipeg when required.

The current test for COVID-19 at PHO Laboratory takes less than 24 hours to complete from the time testing begins.

Reporting

Final results of COVID-19 testing from PHO Laboratory are reported to the ordering health- care provider as indicated on the requisition.

As a disease of public health significance, all positive results will be reported to the local public health unit. As an interim measure we will also be reporting all negative results to the local public health unit.

Test Methods

Testing for COVID-19 is done by real-time PCR using protocols validated by PHO Laboratory and the NML. Targets include the RdRp (RNA-dependent RNA polymerase) gene and E (envelope) gene.

Specimens with a single real-time PCR target detected or any target that is indeterminate will be tested by PCR and Sanger sequencing for the COVID-19 virus RdRp gene.

Laboratory confirmation of COVID-19 at PHO Laboratory consists of:

- Detection of two genomic targets by real-time PCR

OR

- Detection of a single target, or one or both targets is/are indeterminate AND detection of COVID-19 virus by sequencing.

PHO Laboratory testing is considered INCONCLUSIVE if:

- A single target is detected by real-time PCR

OR

- One or both targets is/are indeterminate by real-time PCR

AND

- COVID-19 is not detected by sequencing.

Specimens will be sent to NML for further testing if required.

Details about the real-time PCR used at PHO for COVID-19 testing are available at: **Diagnostic detection of COVID-19 by real-time RT-PCR**.

The following publication contains additional technical information on the RdRp gene PCR and sequencing: **Assays for laboratory confirmation of novel human coronavirus (hCoV-EMC) infections**.

PHO Laboratory has adapted this protocol to be specific for COVID-19 virus detection.

Serology for COVID-19 is not currently available.

Algorithm

PHO Testing Algorithm for COVID-19 (as of February 07, 2020)

A. Testing for COVID-19

- Testing for COVID-19 is done by real-time RT-PCR using protocols validated by PHO Laboratory and the NML. Targets include the RdRp (RNA-dependent RNA polymerase) gene and E (envelope) gene.
- Detection of two genomic targets by real-time PCR is sufficient for laboratory confirmation.
- Specimens with a single real-time PCR target detected or any target indeterminate will undergo PCR and Sanger sequencing of the COVID-19 virus RdRp gene for confirmation.
- Specimens will be sent to National Microbiology Laboratory (NML), Winnipeg for further testing if required.

B. Testing for other respiratory viruses:

- Testing for other **respiratory viruses** by multiplex respiratory virus PCR (MRVP) can be ordered if patients meet PHO Laboratory's acceptance criteria for this testing (e.g. hospitalized, outbreaks, institutionalized). Refer to the **Respiratory Viruses Test Information Sheet** for more details and acceptance criteria.
  ***Cross-reaction with COVID-19 does not occur based on in-house laboratory data and available sequence data.**

- Testing for **avian influenza** can be ordered if patients meet criteria for this testing. See the **Avian Influenza Test Information Sheet** for more details.

Note: Testing for other respiratory viruses and avian influenza must be ordered on the laboratory requisition if required.

Additional tests to be considered:

Testing for bacterial causes of community-acquired pneumonia:

Patients with pneumonia/parenchymal lung involvement should also be tested for bacterial causes of community acquired pneumonia (CAP). Recommended testing available at PHO Laboratory includes:

i. ***Mycoplasma pneumoniae/Chlamydophila pneumoniae duplex PCR:***

- Should be ordered on the same NP or throat swab submitted for COVID-19 testing.

ii. Legionella testing:

- ***Legionella PCR:*** can be ordered on the same lower respiratory tract specimens submitted for COVID-19 testing (e.g. sputum, BAL, bronchial wash, aspirates, lung tissue).
- ***Legionella urinary antigen testing*** (minimum urine volume 2 ml).

NB. If a person under investigation is worsening or not improving, testing should be repeated, even if previous tests were positive for another pathogen.

Labstracts

LAB-SD-139, New Test Requisition and Approval Process for COVID-19 Testing at Public Health Ontario

*Uncontrolled print copy. Valid only on day of print: 16 March 2020.

Related Information

Coronavirus Disease 2019 (COVID-19)

External Resources

The 2019 Novel Coronavirus (COVID-19) - Ministry of Health

Coronavirus disease (COVID-19) outbreak - World Health Organization [China]

Coronavirus Disease 2019 (COVID-19) - Centers for Disease Control and Prevention (USA)

Novel Coronavirus from Wuhan, China (2019-nCoV). Biosafety Advisory - Public Health Agency of Canada

Contact Laboratory Customer Service

Laboratory Services

customerservicecentre@oahpp.ca

Updated 2 March 2020