

### Lab-Based COVID-19 Testing for Pharmacies

Thursday, December 2, 2021 9:30-10:30 am or Tuesday, December 7, 2021 4:00-5:00 pm

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#### **Objectives**

By the end of this session, you will understand:

- Changes in availability of lab-based COVID-19 testing in pharmacies
- How to assemble and handle kits for on-site collection or self-collection
- How to collect specimens for COVID-19 testing on site or at home
- How to complete the requisition form for COVID-19 testing
- How to safely package and transport specimens to the lab
- How to receive results and perform the appropriate follow-up actions

Note: This document is intended to provide general information only to pharmacies on specimen collection and handling for lab-based PCR COVID-19 tests. It is not intended to provide medical or legal advice. This document is up to date as of the time of presentation. As guidelines changes, participants are encouraged to visit the <u>Ministry of Health's COVID-19 website</u> regularly for updates to <u>COVID-19 symptoms</u> and <u>Public Health Ontario resources</u>.

#### **Expansion of lab-based PCR testing in pharmacies**

- Ontario publicly-funded COVID-19 testing is a voluntary program for pharmacies as part of the <u>Ontario Enhancing COVID-19 Winter Testing</u> news release on November 18, 2021.
- Select sites may be eligible to provide services at no cost to individuals meeting provincial criteria for lab-based PCR testing (see <u>COVID-19</u> <u>Provincial Testing and Clearance Guidance</u>) including:
  - Specimen collection on site, and/or
  - Handling of self-collected specimens for lab-based testing.
- Sites must be registered through the Ministry of Health program to provide services related to publicly-funded COVID-19 testing.

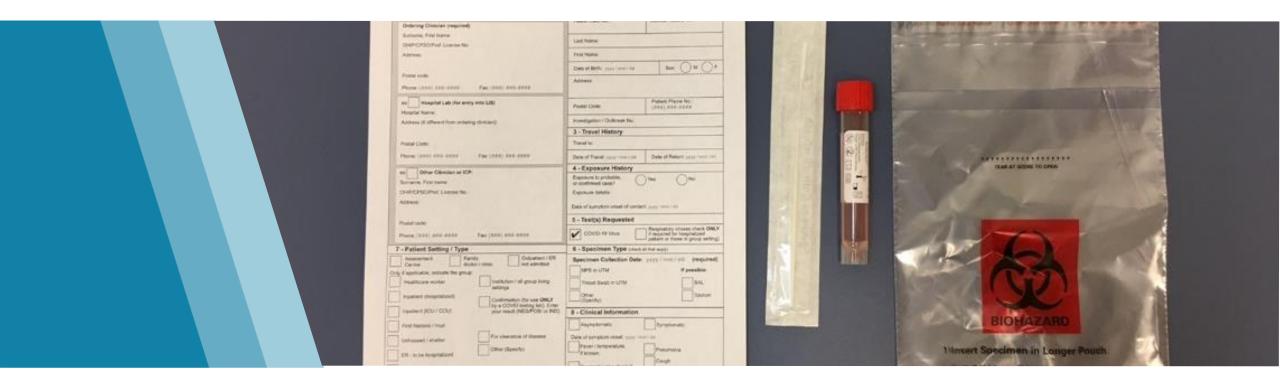
#### **General principles of lab-based COVID-19 testing**

- A specimen is collected from the patient and sent to the lab where polymerase chain reaction (PCR) testing occurs.
- PCR testing is highly sensitive when a good quality specimen is provided to the lab.
  - Proper specimen collection, labelling, packaging, and shipping are all essential steps for adequate testing.



• Responsibility of the pharmacist to ensure sample quality is maintained and results are correctly acted upon.

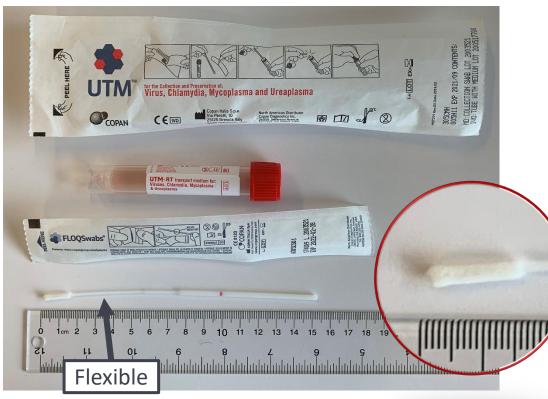
#### Test kit preparations for specimen collection



### **Examples of different types of swab-based specimen collection kits**

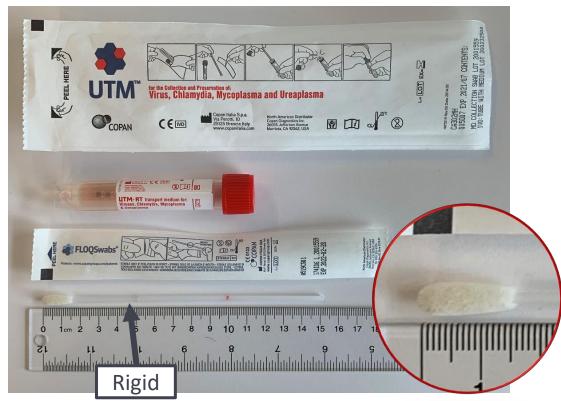
## A) Kit with nasopharyngeal (NP) swab and transport media tube

#### Uses: NP sampling



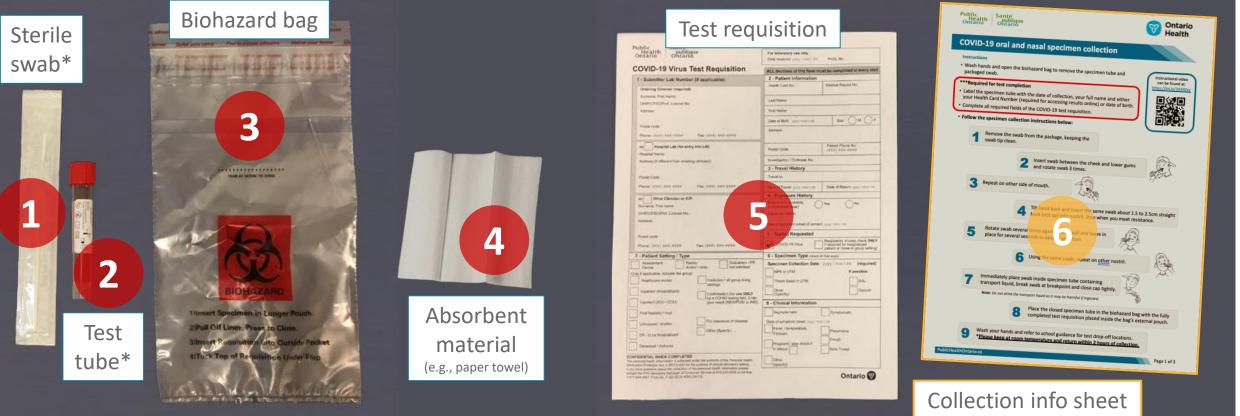
#### B) Kit with nasal or throat swab and transport media tube

#### Uses: combined oral-nasal or nasal sampling



#### **COVID-19 swab test kit components**

\*Note: To obtain the listed supplies, please submit your order via the following link: <u>https://ehealthontario.on.ca/en/health-care-</u> professionals/digital-health-services



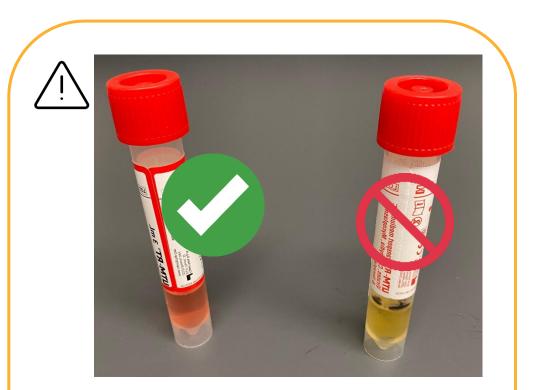
(self-collection kits only)

PublicHealthOntario.ca

### For sites assembling self-collection kits for distribution

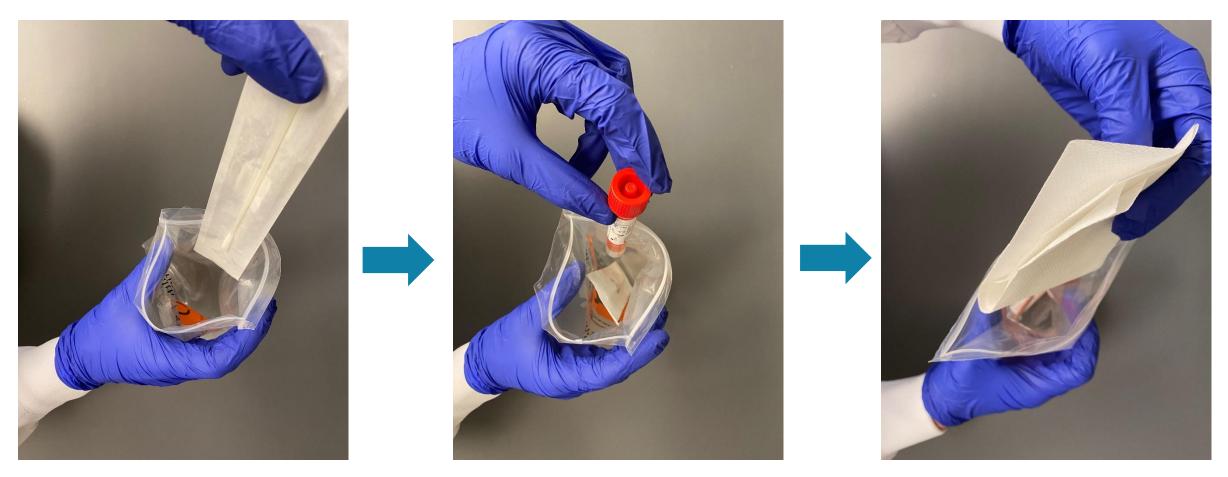
#### **Prior to assembling a self-collection kit:**

- Perform hand hygiene
  - Wearing gloves is recommended to limit potential cross-contamination.
- Select a clean area
  - Ideally separate from patient testing area.
- Check expiry dates on both the tube and the swab.
- Transport media in the tube should be clear and red, orange or pink.



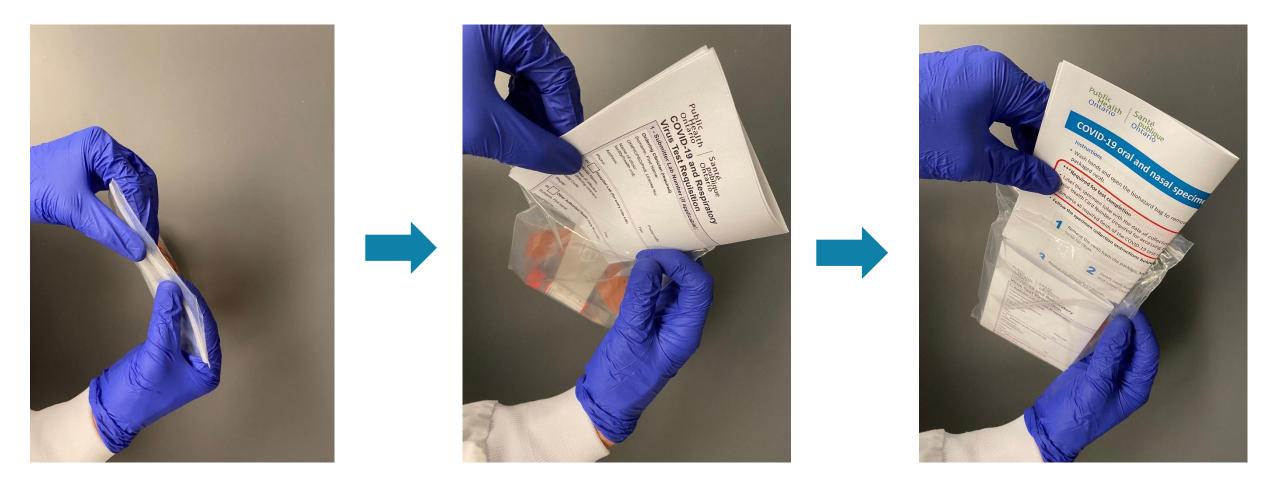
• Do NOT use a test tube if the transport media is bright yellow, green, or cloudy.

#### Assembling a self-collection kit: Main compartment



Place the sterile swab, test tube, and absorbent material in the main compartment of the biohazard bag.

#### Assembling a self-collection kit: External pouch



Add the collection info sheet and test requisition into the outer pouch of the bag for easier and safer access.

#### **Specimen collection for lab-based PCR testing**

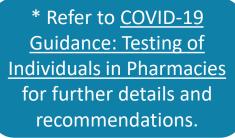


#### **Step 1: Collect the specimen**

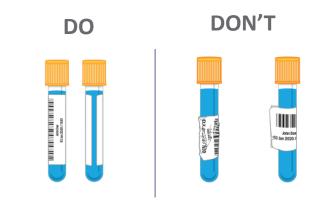
- Hand hygiene prior to handling testing kits.
- For on-site collection, follow recommended infection prevention and control (IPAC) measures.\*
- Always label the test tube with:
  - 1. Date of collection,
  - 2. Patient's full name,

#### AND

- 3. At least one additional unique identifier (e.g., Health Card number or date of birth)
- If using a sticker, affix the sticker to the tube longitudinally.

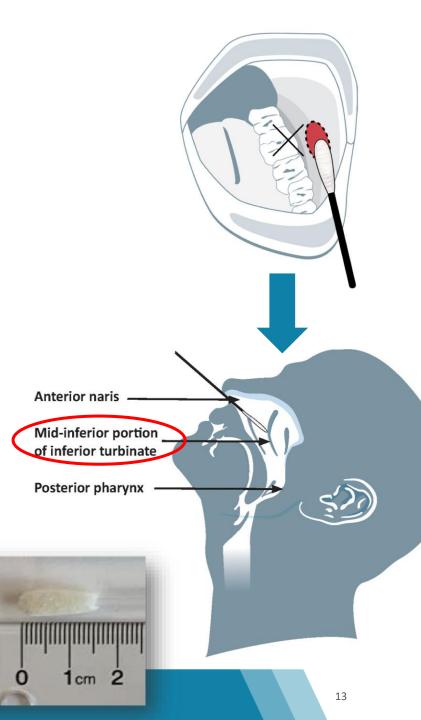






## Preferred specimen collection type: Combined oral and nasal sampling

- Combined oral and nasal sampling is another <u>preferred</u> specimen type for patients **NOT at risk** of severe disease.
  - Risks of **severe COVID-19 infection** include: age > 50, obesity, immunosuppression, or cardiovascular/lung/metabolic/kidney/liver disease.
- Combined oral-nasal sampling provides adequate accuracy (~95%) compared to NP sampling in most settings.
- Collection can be performed by any individual.
  - Step 1 (oral collection): can be taken from both cheeks (+/- the posterior tongue) or throat.
  - Step 2 (nasal collection): insert all of the soft tip end into one nostril (i.e. up to 2.5 cm), rotate the swab 5-10 times against the inside wall of the nose, then remove and repeat into the other nostril.

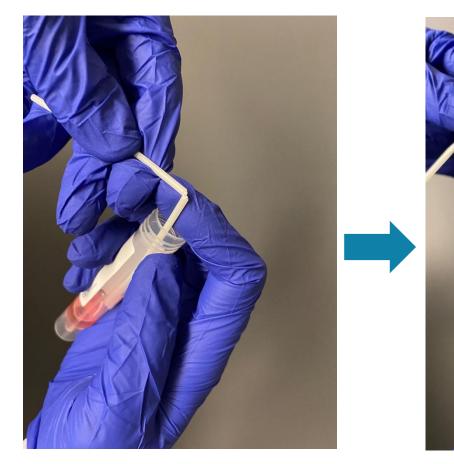


## Specimen collection type NOT preferred: Nasal sampling

- Nasal sampling is <u>not</u> a preferred specimen type.
- Combining this method with oral sampling is <u>preferred</u> as sensitivity is lower (~85%) using nasal sampling alone compared to combined oral-nasal sampling (~90-95%).
  - See earlier slide on combined oral and nasal sampling for further instructions.

\*Note: inserting the swab up to shorter distances (e.g., anterior nares) is **discouraged**, especially if not combined with oral sampling.

#### **Step 2: Place collected specimen swab in test tube**



Once the sample is collected, break the swab handle at the breakpoint before closing the cap tightly.



- Do NOT fold the swab instead of breaking it at the breakpoint.
  - If the swab is folded instead of broken, the test tube cap may not close properly and cause leakage.
  - It can also be a safety risk when opening the tube in the lab.

#### **Step 3: Place test tube in the biohazard specimen bag**





Confirm the test tube cap is closed tightly and properly to avoid leakage.

Leaking specimens will be **rejected** by the laboratory.



Name Jane Doe Hospital No Room Age/DOB 16/05 May 10 sex F

Confirm the test tube is properly labelled.

Unlabelled tubes will be **rejected** by the laboratory.

# Step 4: Add absorbent material inside the main compartment of the biohazard bag next to the test tube

SPECIMEN BAG







Do NOT process the specimen further if leakage is found.

• Leaking specimens will be **rejected** by the laboratory.

## Step 5: Insert *COVID-19 Virus Test Requisition* sheet into the external pouch of the biohazard bag



 $! \setminus$  Confirm ALL required fields are filled in the requisition.

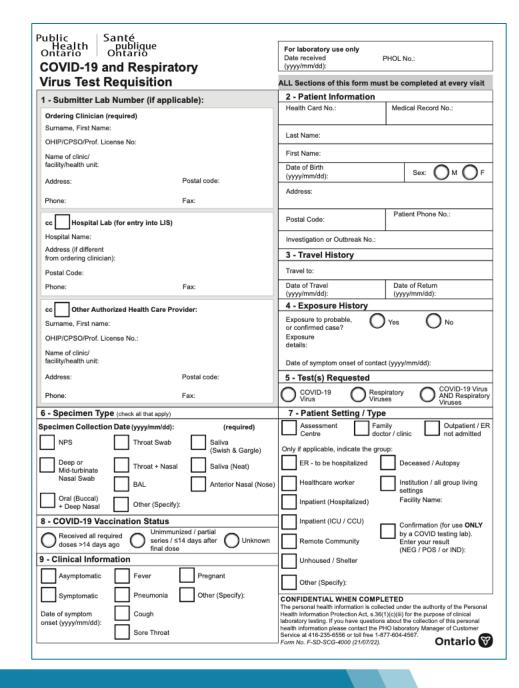
• Requisitions with missing information will be **rejected** by the laboratory.

#### **Completion and verification of the requisition**



## **COVID-19 and respiratory virus test requisition form**

Make sure to use the most current version of Public Health Ontario's COVID-19 test requisition available at: <u>https://www.publichealthontario.ca/-</u> <u>/media/documents/lab/2019-ncov-</u> <u>test-requisition.pdf?la=en</u>



#### **Section 1: Submitter information**

- Ordering clinician should be a qualified health care provider (e.g., registered pharmacist).
- Fax numbers require registration and authorization through PHO's Customer Service Centre.
  - Non-validated fax numbers will result in report delivery by Canada Post.
- If your site is associated with a hospital laboratory, please fill in the **'cc Hospital Lab'** subsection.
- If results will be forwarded to an additional health care provider (e.g. primary care provider), please fill in the 'cc Other Authorized Health Care Provider' subsection.

- Submitter Lab Number (if applicable):		
Ordering Clinician (required)		
Surname, First Name:		
OHIP/CPSO/Prof. License No:		
Name of clinic/ facility/health unit:		
Address:	Postal code:	
Phone:	Fax:	
cc Hospital Lab (for entry into LIS)		
Hospital Name:		
Address (if different from ordering clinician):		
Postal Code:		
Phone:	Fax:	
cc Other Authorized Health Care Provider:		
Surname, First name:		
OHIP/CPSO/Prof. License No.:		
Name of clinic/ facility/health unit:		
Address:	Postal code:	
Phone:	Fax:	

#### **Section 2: Patient information**

- Provide full patient details including name, date of birth, address, postal code, phone number, and Health Card number (if available).
  - Middle names may be entered in the 'first name' section.
  - Important to use the patient's current address and postal code for contact tracing (may differ from permanent address)
  - Information should match the information on the patient's Health Card (if available)



Confirm the information on the <u>requisition</u> matches the <u>label</u> on the test tube.

Mismatched information will be **rejected** by the laboratory.

Medical Record No.:
Sex: OM OF
Patient Phone No.:
estigation number mber if applicable lual being tested.

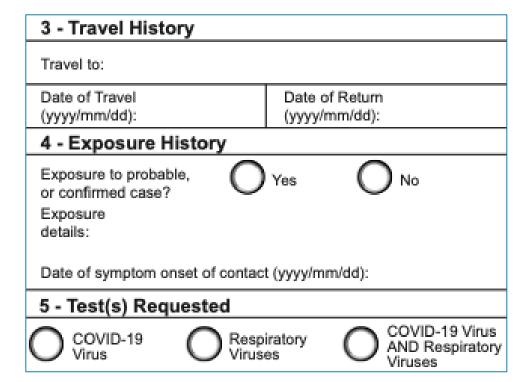
#### **Details on outbreak numbers versus investigation numbers**

Number Identification	Outbreak Number	Investigation Number (e.g., screen testing)
Number provided by	Public Health Unit	Ontario Health and Public Health Ontario
Number format	XXXX-YYYY-##### XXXX - PHU code YYYY – Year when outbreak was declared ##### – sequential number for this episode	LTS-#### (Long-Term Care STAFF) LTR-#### (Long-Term Care RESIDENT) RHS-#### (Retirement Home STAFF) RHR-#### (Retirement Home RESIDENT) EDU-ZZZZ-P-#### (Education PUPIL) Other numbers as assigned for the facility
Used for	Outbreaks only, as directed by the PHU	Screen testing for routine activities
Validity of number	For the duration of the active outbreak Do not re-use number after outbreak is over	Ongoing, can be used repeatedly for the purpose of screen testing
Tests ordered	COVID-19 on all patients Respiratory viruses if required by PHU* *Up to 4 symptomatic patients per outbreak	COVID-19 on all patients

For a list of investigation number, contact OH or your local LHIN.

## Sections 3, 4, and 5: Travel history, exposure history, and test(s) requested

- Provide any recent international travel history, or exposure to a probable or confirmed case of COVID-19.
- Include the date of symptom onset for probable or confirmed cases if available.
- Select **'COVID-19 Virus'** in the 'Test(s) Requested' section.
- Testing for respiratory viruses other than COVID-19 is not indicated in the community
  - Testing for other respiratory viruses is currently reserved for paediatric populations seen in the emergency department, hospitalized patients, outbreak-associated patients, or patients in institutions with acute respiratory illness.



### Sections 6, 7, 8, and 9: Specimen type, patient setting/type, COVID-19 vaccination status, and clinical information

- Provide as many details as possible regarding each of the required sections below.
- Do not forget to fill the
   "Specimen Collection
   Date" subsection
   (highlighted yellow
   here) once the
   specimen has
   been collected.

6 - Specimen Type (check all that apply)	7 - Patient Setting / Type
Specimen Collection Date (yyyy/mm/dd): (required)	Assessment Family Outpatient / ER Centre Octor / clinic Outpatient / ER
NPS Throat Swab Saliva (Swish & Gargle)	Only if applicable, indicate the group:
Deep or Mid-turbinate Throat + Nasal Saliva (Neat)	ER - to be hospitalized Deceased / Autopsy
Nasal Swab BAL Anterior Nasal (Nose)	Healthcare worker Institution / all group living settings
Oral (Buccal) + Deep Nasal Other (Specify):	Inpatient (Hospitalized) Facility Name:
8 - COVID-19 Vaccination Status	Inpatient (ICU / CCU) Confirmation (for use ONLY
O Received all required doses >14 days ago O Unimmunized / partial series / \$14 days after final dose O Unknown	Remote Community by a COVID testing lab). Enter your result (NEG / POS / or IND):
9 - Clinical Information	Unhoused / Shelter
Asymptomatic Fever Pregnant	Other (Specify):
Symptomatic Pneumonia Other (Specify):	
Date of symptom Cough onset (yyyy/mm/dd):	
Sore Throat	

#### Test packaging, storage and transport



#### **Storage requirements and expected transport timelines**

- Specimens self-collected at home should be kept at **room temperature** and transported to drop-off site ideally within 2 hours.
- Specimens collected on site should be kept **refrigerated (2-8**°C) and ideally transported same day to the lab.

Specimens should not be stored in refrigerators with vaccines, medications, unused supplies, or any food products to limit cross-contamination.

- If no dedicated refrigerator available, specimens may be stored in clean rigid outer container (e.g., Styrofoam cooler box) with an ice pack.
- If expected duration of storage or shipment is greater than 72 hours, specimens should be kept **frozen (-20 to -70**°C) if a freezer is available.

#### Packaging of specimens for ground transportation to the lab

The following packaging instructions are:

- Valid for the duration of the exemption period from the *Temporary Certificate TU-0764* (consult with Transport Canada for expiry date);
- Valid for ground transportation between two points within Canada only;
- Suggested guidelines only.

Always refer to the latest edition of the *Transportation of Dangerous Goods Regulations* (TDGR) and requirements listed in the <u>Temporary</u> <u>Certificate TU-0764.</u>

#### Additional supplies for ground transportation to the lab

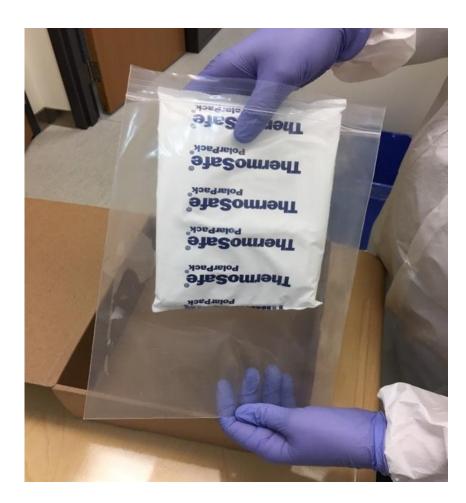


# Step 1: Place sealed biohazard bags containing specimens into sealable plastic bag and place in outer rigid packaging



Each outer rigid packaging should have a maximum of 800 test samples (4 L total volume).

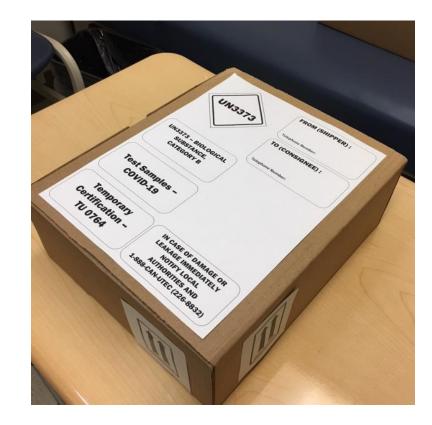
#### **Step 2: Place ice pack in outer packaging**



- Ice packs should placed in the outer rigid packaging to preserve specimen during transport.
- Ensure the ice pack is placed in a sealable plastic bag to prevent wetness due to condensation.
- The ice pack should be of appropriate size and placed in the box in a way to limit movement of the pack during transport (otherwise it may hit and damage the sample tubes).
- Couriers are not required to use refrigerated trucks for shipping as long as specimens are transported with an ice pack.

#### **Step 3: Print PDF of labels and tape on sealed cardboard box**





#### Step 4: Complete the address (To/From)

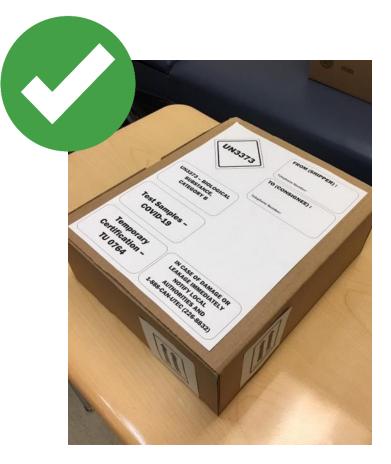


Complete the address and telephone number for both labels:

- From (shipper)
- To (consignee)

#### Package is ready to be transported!





### **Unacceptable packaging**

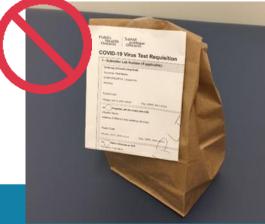
#### Do not use:

- Grocery bags Envelopes
- Garbage bags File folders
- Paper bagsGloves

#### **Risks**:

- Samples could get lost/delayed
- Risk to public if sample leaks
- Risk of fine by Transport Canada





#### **Arranging for transportation**

- Pharmacies must arrange their own appropriate courier services (private, shared, or self-courier) to the receiving lab.
- Courier services should ideally be timed for same-day transport of specimens and drop off to the receiving lab.
- Transportation should be to the closest PHO location offering COVID-19 testing (not all PHO locations offer COVID-19 testing).

#### **PHO Laboratory Sites Offering COVID-19 Testing**

Public Health Unit	Testing Lab	Public Health Unit	Testing Lab
<ul> <li>Brant County Health Unit</li> <li>Hamilton Public Health Services</li> <li>Region of Waterloo, Public Health</li> </ul>	<b>PHO Hamilton</b> 250 Fennell Ave. W Hamilton, Ontario L8N 3R5	<ul> <li>Eastern Ontario Health Unit</li> <li>Leeds, Grenville and Lanark District Health Unit</li> <li>Ottawa Public Health</li> </ul>	<b>PHO Ottawa</b> 2380 St. Laurent Bld. Ottawa, Ontario K1G 6C4
<ul> <li>Haliburton, Kawartha, Pine Ridge District Health Unit</li> <li>Hastings and Prince Edward Counties Health Unit</li> <li>Kingston, Frontenac and Lennox &amp;</li> </ul>	<b>PHO Kingston</b> 181 Barrie Street Kingston, Ontario K7L 4V8	<ul> <li>Renfrew County and District Health Unit</li> <li>Northwestern Health Unit</li> <li>Thunder Bay District Health Unit</li> </ul>	PHO Thunder Bay 336 South Syndicate Ave. Thunder Bay, Ontario P7E 1E3
<ul> <li>Addington Health Unit</li> <li>Peterborough Public Health</li> <li>Chatham-Kent Health Unit</li> <li>Grey Bruce Health Unit</li> </ul>	<b>PHO London</b> Unit 102,	<ul> <li>Algoma Public Health Unit</li> <li>North Bay Parry Sound District Health Unit</li> <li>Porcupine Health Unit</li> <li>Sudbury and District Health Unit</li> </ul>	PHO Timmins 67 Wilson Avenue Timmins, Ontario P4N 2S5
<ul> <li>Huron Perth Health Unit</li> <li>Lambton Health Unit</li> <li>Middlesex-London Health Unit</li> <li>Niagara Region Public Health Department</li> <li>Wellington-Dufferin-Guelph Health Unit</li> <li>Windsor-Essex County Health Unit</li> </ul>	1200 Commissioners Rd. E. London, Ontario N5Z 4R3	<ul> <li>Timiskaming Health Unit</li> <li>Durham Region Health Department</li> <li>Halton Region Health Department</li> <li>Peel Public Health</li> <li>Simcoe Muskoka District Health Unit</li> <li>Toronto Public Health</li> <li>York Region Public Health Services</li> </ul>	<b>PHO Toronto</b> 661 University Avenue Toronto, Ontario M5G 1M1

#### **Result Communication and Follow-up Actions**



#### **Receiving test reports from the laboratory**

- Pharmacies must be registered with the lab before requisition forms and specimens are processed.
- Test reports are faxed to the authorized submitter listed on the test requisition.
- Pharmacies must ensure that their fax system is private, secure, available after hours, and adequately maintained (e.g., sufficient paper at hand).
- Turnaround times for test results vary based on test volumes across the provincial laboratory network.
- If a Health Card number was provided on the requisition, results will also be available for patients through the <u>COVID-19 Test Result Viewer</u> portal.

### **Communicating results to the patient**

• Pharmacies are responsible for communicating test results where appropriate:

Test result	Interpretation	Follow-Up Actions
Positive	COVID-19 infection detected	<ul> <li>Inform patient</li> <li>Direct patient to self-isolate and seek medical advice if feeling unwell</li> <li>Lab will notify public health unit</li> <li>Public health unit will contact patient for contact tracing</li> </ul>
Negative	No evidence of COVID-19 infection	<ul> <li>Inform patients that have no health card number on their requisition as they will be unable to access their results online</li> </ul>
Indeterminate	Either a low level of virus present or a non-specific signal when there is no virus present	<ul> <li>Inform patient</li> <li>Direct patient to have another specimen collected as soon as possible to avoid further delays</li> </ul>
Cancelled or rejected	Testing not performed due to poor quality specimen (e.g., leaking, incomplete information)	<ul> <li>Inform patient</li> <li>Direct patient to have another specimen collected as soon as possible to avoid further delays</li> </ul>

#### **Key Contacts**

- To obtain COVID-19 swab kits, please submit your order via the following Ontario Health link: <u>https://ehealthontario.on.ca/en/health-care-</u> professionals/digital-health-services
- For ordering providers Public Health Ontario Customer Service Centre: <u>CustomerServiceCentre@oahpp.ca</u>
- For any other issues or questions not related to testing or results: <u>OPDPinfobox@ontario.ca</u>

#### Resources

- Ontario Ministry of Health. COVID-19 Guidance: Testing of Individuals in Pharmacies, version 2 [Internet]. Toronto, ON: Queen's Printer for Ontario; 2021 [cited 2021 Nov 29]. Available from: <u>https://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/docs/2019 guidance asym</u> <u>ptomatic testing pharmacies.pdf</u>
- Ontario Agency for Health Protection and Promotion (Public Health Ontario). Coronavirus disease 2019 (COVID-19) – PCR [Internet]. Toronto, ON: Queen's Printer for Ontario; 2021 [cited 2021 Nov 29]. Available from: <u>https://www.publichealthontario.ca/en/laboratory- services/test-informationindex/covid-19</u>
- Ontario Agency for Health Protection and Promotion (Public Health Ontario). COVID-19 PCR collection kits [Internet]. Toronto, ON: Queen's Printer for Ontario; 2021 [cited 2021 Nov 29]. Available from: <u>https://www.publichealthontario.ca/en/laboratory-services/covid-19-pcr-collection-kits</u>
- Transport Canada. Temporary certificates [Internet]. Ottawa, ON: Government of Canada; 2020 [modified 2021 Jan 22; cited 2021 Nov 29]. Available from: <u>https://tc.canada.ca/en/dangerous-goods/temporary-certificates</u>
- Ontario Ministry of Health. COVID-19 (coronavirus) in Ontario [Internet]. Toronto, ON: Queen's Printer for Ontario; 2021 [cited Nov 29]. Available from: <u>https://covid-19.ontario.ca/index.html</u>



#### For More Information About This Presentation, Contact:

CustomerServiceCentre@oahpp.ca

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