

Questions and Answers for Pharmacists: Publicly Funded COVID-19 PCR Testing Services in Ontario Pharmacies

February 9, 2024

This Questions and Answers document accompanies the most recent Executive Officer (EO) Notice on Publicly Funded COVID-19 PCR Testing services in Ontario Pharmacies.

These Qs and As and the accompanying <u>EO Notice</u> constitute a Ministry policy that pharmacy operators must comply with when submitting claims for payment to the Ministry respecting pharmacy services related to COVID-19 testing. Compliance with all Ministry policies is required under section 3.2 of the Health Network System (HNS) Subscription Agreement for Pharmacy Operators.

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General Questions

1. What are the publicly funded COVID-19 testing services available at participating pharmacies?

Type of Pharmacy Service	Type of COVID-19 Test		
Specimen collection in pharmacy	Laboratory based polymorous shair		
Specimen self-collected by patient	Laboratory-based polymerase chain reaction (PCR*) test		
OLIS Digital Self-Collection Kit (NEW)			
Specimen collection and performance of test in pharmacy	In-store point-of-care** polymerase chain reaction (PCR*) test		

^{*}Also known as lab-based molecular testing in this document.

2. Where can we find the locations of the participating pharmacies?

Participating pharmacies are included in the Ministry's pharmacy locations website: ontario.ca/covidtestinglocations. This website will continue to be updated as additional pharmacies are onboarded (as needed).

3. Is testing at pharmacies available by walk-in or appointment?

To minimize the need for individuals to wait for testing, pharmacy specimen collection and testing services must be provided by appointment only.

Individuals <u>do not</u> need an appointment to pick up PCR self-collection kits and/or drop off self-collected specimens for PCR testing.

4. Where can my pharmacy obtain supplies for performing in-store point-of-care PCR testing and pre-assembled kits for dispensing (digital) self-collection kits or lab-based PCR testing and?

Eligible pharmacies can order pre-assembled OLIS Digital Self-Collection Kits, other testing supplies, as well as materials needed for performing point-of-care PCR tests using ID NOWTM through the following website at no cost: PPE Supply Portal - Sign In (ontario.ca). Pharmacies must be approved by the Ministry to proceed with publicly funded COVID-19 testing and OLIS Digital Self Collection before test kits may be ordered. Please note that at this time, ID NOWTM (point-of-care PCR test) is only being offered in select pharmacies in Northern Ontario.

Pharmacies that belong to a banner or chain corporation or group purchasing organization may work through their corporate head office, who may centrally coordinate, order, and facilitate distribution of supplies. Independent pharmacies may order supplies directly from the above website.

^{**}Also known as rapid molecular testing in this document.

Patient Eligibility

5. Who is eligible for publicly funded COVID-19 testing services at pharmacies?

For the current eligibility criteria, please see the *Executive Officer Notice: Publicly Funded COVID-19 Testing Services in Ontario Pharmacies.*

Please note, persons using OLIS Digital Self-Collection must have a green and white Ontario health card in addition to currently eligibility criteria for publicly funded COVID-19 testing. Individuals without a green and white health card remain eligible for all other publicly funded testing services in pharmacies.

6. What role will pharmacies play in the in-store COVID-19 PCR testing and self-collection, including OLIS Digital Self-Collection?

Participating pharmacies will make COVID-19 Digital Self-Collection kits available for pick up at their location. Patients can drop-off their specimen to any participating pharmacy; however, it is recommended patients drop-off at same location they picked up their test. The drop-off location is the identified Health Information Custodian and ordering clinician for the lab test and is responsible for transporting the specimen to a provincially performing lab for testing.

Patients must register their kit online and upon completion of swabbing, must drop-off their specimen at a participating pharmacy within 24 hours.

Please note that a Patient Ineligibility Screening Fee cannot be billed for self-collected specimens for lab-based PCR tests dropped off at pharmacies by these individuals. If completion of the ordering clinician's section is required, use Self-Collection Kit (General) PIN.

In-Store COVID-19 PCR testing requires pharmacists to complete COVID-19 requisitions using the Ontario Laboratories Information System Mobile Order and Results Entry (OLIS-MORE) solution.

7. What is Self-Collected Lab-Based PCR COVID-19 Specimen Handling Fee (Other Organization)?

In some circumstances, patients may drop-off a self-collected sample prepared by another health care provider or organization (excluding pharmacies) and which has a requisition already filled out. The requisition must include the name and information of an ordering clinician.

At this time, most organizations and health care providers are no longer providing these kits patients.

8. Are publicly funded COVID-19 tests (and related pharmacy services) available for an individual who needs a negative COVID-19 test result for travelling out of the country?

No. Effective December 11, 2020, individuals requesting a COVID-19 test for international travel clearance are not eligible for a publicly funded COVID-19 test in Ontario, including related services at a participating pharmacy. Pharmacy staff can refer them to a private testing facility such as a travel clinic. Some pharmacies also offer privately funded COVID-19 tests. Please note that a Patient Ineligibility Screening Fee cannot be billed for individuals seeking a COVID-19 test for travel purposes.

NOTE: This does not apply to International Agriculture Workers seeking a test to return to their country of origin.

Pharmacy Eligibility

9. How can pharmacies participate?

Pharmacies interested in providing publicly funded services related to COVID-19 tests should contact the ministry at OPDPInfoBox@ontario.ca to be enrolled into the program. Enrollment is subject to consideration by the Ministry.

Upon approval of the Ministry, Pharmacies must onboard with OLIS-MORE for in-store COVID-19 PCR testing, or with the COVID-19 OLIS Digital Self-Collection solution.

Pharmacies can sign up at this link: <u>Mobile Order Requisition Form: Intake Form | Ontario Health (ehealthontario.on.ca).</u> (https://ehealthontario.on.ca/en/health-care-professionals/more?a=onboard)

Pharmacies must also onboard to Ontario Health's OLIS Digital Self-Collection solution to participate. More information on OLIS Digital Self Collection is available at: https://ehealthontario.on.ca/en/health-care-professionals/self-collection?a=onboard

10. What do I do before proceeding with providing publicly funded COVID-19 testing services and billing the Ministry of Health through the HNS?

Pharmacies MUST be registered as a participating pharmacy through the Ministry of Health to provide publicly funded COVID-19 testing services before claims can be submitted. Inappropriate claim submissions from non-registered pharmacies are subject to recovery.

Only participating pharmacies that have received confirmation of registration from the Ministry and comply with the requirements of the Ministry policy set out in this Executive Officer's Notice and in this Qs and As document will be able to receive payment for these services.

11. What training will be provided to pharmacists to provide COVID-19 testing services?

Pharmacists must be familiar with the procedure for specimen collection and handling for PCR testing (including lab-based and point-of-care PCR) and performing point-of-care PCR tests using ID NOWTM. Resources for pharmacist training include:

- Public Health Ontario's specimen collection instructions.
- Ontario Health's ID NOWTM COVID-19 Molecular Point-of-Care Testing Onboarding Package
- The Ministry of Health's PCR COVID-19 Testing Resource for Pharmacy document provided at registration (available on request)
- Best practices for lab-based PCR Testing through pharmacies webinars held in December 2021 and January 2022: <u>Webinar Recording</u> and <u>Webinar</u> <u>Presentation Deck.</u>
- Ontario Health's website for more information on OLIS-MORE, Digital Self-Collection (https://www.ontariohealth.ca/providing-health-care/clinical-resourceseducation/covid-19)
- Ontario College of Pharmacists (OCP) COVID-19 Testing in Community
 Pharmacies guidance document and other COVID-19 related information for
 pharmacy professionals developed by the Ontario College of Pharmacists (OCP)
 available on their website.

It is the professional responsibility of every pharmacist to ensure that he or she has the appropriate training on specimen collection and sufficient knowledge to competently collect and handle the specimen and conduct the PCR or rapid point-of-care molecular test.

12. Do pharmacists have the appropriate scope of practice to collect COVID-19 specimens from patients?

Pharmacists are performing specimen collection using a Public Health Ontario validated specimen collection method that is not a controlled act under the *Regulated Health Professions Act, 1991*, such as an anterior nasal swab or throat swab. The anterior nasal swab occurs within 1 centimeter of the nostrils.

Regulatory changes under the *Laboratory and Specimen Collection Centre Licensing Act* enable pharmacists to collect specimens for molecular testing (PCR lab-based and point-of-care PCR). Only Part A pharmacists can order the lab-based test and collect the specimen for the lab-based test, i.e., not pharmacy interns, students, (registered) pharmacy technicians, or pharmacists (Emergency Assignment or EA). Furthermore, under the provincial Publicly Funded COVID-19 Testing Services in Pharmacies program, Part A pharmacists must be the ordering clinicians in the COVID-19 test requisition forms. In addition, HNS claim submissions for COVID-19 testing services must identify a Part A pharmacist ID in the prescriber field.

Pharmacy interns, students, (registered) pharmacy technicians, or pharmacists (Emergency Assignment or EA) cannot be listed as the ordering clinicians on test requisition forms or make HNS claims submission as part of the publicly funded COVID-19 testing services program.

For any questions regarding scope of practice for pharmacists (EA), pharmacy interns, students or (registered) pharmacy technicians, please contact the Ontario College of Pharmacists.

13. When should individuals be screened for eligibility?

For in-store specimen collection for molecular testing (PCR lab-based and point-of-care PCR), screening should take place at the time of appointment booking and in-store at the time of the individual's appointment.

For self-collection for lab-based PCR testing, screening should take place at the time the self-collection kit is dispensed to an individual and when the individual drops off their self-collected specimen. Pre-requisites: along with meeting testing guideline requirements, they must have a green and white health card and the ability to register online.

Note: A Patient Ineligibility Screening Fee cannot be billed for individuals seeking a COVID-19 test for travel purposes. A Patient Ineligibility Screening Fee can only be billed when an individual is deemed ineligible for a pharmacy service related to a publicly funded COVID-19 test. Payment for screening eligible persons is incorporated into the fee paid for other pharmacy services related to publicly funded COVID-19 tests (i.e., specimen handling, specimen collection, and point-of-care testing). For more information, please see the most recent version of the *EO Notice: Publicly Funded COVID-19 Testing Services in Ontario Pharmacies* on the ministry's website.

14. Can a pharmacy technician or other pharmacy staff do the pre-screening?

Pre-screening could potentially be completed by another pharmacy staff member. However, the pharmacist will be responsible for ensuring that the information collected is accurate and complete. Documentation requirements must be met before a claim for payment is submitted.

Please note: Only pharmacists can order the laboratory test using the test requisition form and collect the specimen, i.e., not pharmacy interns, students, (registered) pharmacy technicians, or pharmacists (Emergency Assignment or EA).

15. How many specimens can a pharmacy collect per day?

There are currently no daily limits on a pharmacy's specimen collection or point-of-care testing services or limits on ordering testing supplies.

Only one (1) fee can be claimed per day for an eligible individual. However, in the event that a self-collected specimen received from the individual is not viable (i.e., does not pass the in-pharmacy specimen quality control check), a second pharmacy service can be provided and billed on the same day.

16. Can pharmacists provide publicly funded COVID-19 testing services outside of the pharmacy (e.g., set up a pop-up testing clinic at a school)?

Specimen handling and in-store specimen collection, as well as point-of-care PCR testing, must take place within the premises of the pharmacy. Pharmacy premises include the pharmacy's physical space, facilities, and premises (including the building and areas surrounding the pharmacy). Pharmacies may choose to offer publicly funded COVID-19 testing services in the outside surroundings of a pharmacy where appropriate.

17. Can pharmacies employ other healthcare providers (e.g., registered nurses) to provide specimen collection services and point-of-care testing services?

With respect to specimen collection for lab-based PCR COVID-19 only persons listed in subsection 31(1) of Ontario Regulation 45/22 under the Laboratory and Specimen Collection Centre Licensing Act (LSCCLA) may collect specimens, such as pharmacists and nurses.

With respect to specimen collection for point-of-care PCR COVID-19 tests, any healthcare provider may collect specimens.

However, regardless of what type of molecular test the specimen collection is for (PCR lab-based and rapid point-of-care) the healthcare provider collecting the specimen must use a method of collection within their scope of practice.

With respect to performing point-of-care COVID-19 tests (i.e., testing the collected specimen), any healthcare provider may perform the test in accordance with the device's manufacturer's label and instructions for use.

Should it be necessary that a pharmacy retain the services of other healthcare providers to conduct pharmacy services related to publicly funded COVID-19 tests, the pharmacy must comply with all terms and conditions in the Ministry's Executive Officer Notice and this Questions and Answers document ("Ministry Policies"). For clarity, all terms and conditions in Ministry Policies respecting pharmacy services related to publicly funded COVID-19 provided by a pharmacist, intern, registered pharmacy student, pharmacy technician, or Emergency Assignment pharmacists apply equally to the other healthcare providers that have been retained by the pharmacy to provide the services.

In addition, a Part A pharmacist must be the ordering clinicians in all requisition forms for lab-based COVID-19 tests and must be identified in the prescriber field on the claim through the HNS for all testing-related pharmacy services provided by other health care professionals. **Exception**: For PCR self-collection kits provided by other organizations, a prescribing physician (i.e., not the pharmacist) can be the ordering clinician on the requisition form. Pharmacists must ensure to use the correct corresponding PIN for these tests.

Infection Prevention and Control Measures

18. What protocols or requirements must be in place before a pharmacy can collect and handle specimens for PCR COVID-19 tests?

Like licensed specimen collection centres, pharmacies must implement and follow infection and prevention control measures to help protect their staff, patients, and customers against COVID-19. For more information, please review the COVID-19 Guidance Personal Protective Equipment (PPE) (gov.on.ca) Pharmacies must also read Ontario College of Pharmacists' (OCP) COVID-19 Testing in Community Pharmacies guidance document available on <a href="Meleritation-testing-testin

19. What PPE is required to provide publicly funded COVID-19 testing services?

Personal protective equipment (PPE) is intended to protect the wearer by reducing the person's risk of exposure to the virus. All individuals who will be participating in the specimen collection process must wear appropriate PPE for their activities. For the individual collecting specimens, this means PPE for Droplet/Contact Precautions which include:

- Surgical/procedure mask (medical mask);
- Eye protection (i.e., face shields, goggles);
- o Gloves; and
- o Gown.

PPE (gowns and gloves) should be changed between patients and disposed of properly after use. Eye protection may be reused after it has been properly cleaned and disinfected.

20. What should pharmacists do to inform customers that these testing-related services are taking place at a pharmacy?

Pharmacies are to post signage indicating that the pharmacy location provides services related to COVID-19 testing to eligible individuals, including both symptomatic and asymptomatic individuals, if applicable, and should provide specific direction for individuals seeking COVID-19 testing. For more information on signage requirements, please review the COVID-19 Guidance Personal Protective Equipment (PPE) (gov.on.ca)

21. Does specimen collection need to be conducted in a separate area?

Pharmacies must ensure that there is sufficient space that is dedicated for specimen collection. This space should be designed to minimize contact between the specimen collection area and the rest of the commercial area through the use of plexiglass barriers or other physical barriers/markers (e.g., private rooms). The specimen collection area must also be separate from areas for medication dispensing and flu/vaccine shot clinics occurring concurrently, to minimize congregation of people in the store. If the space for COVID-19 specimen collection is being used for other activities (e.g., counselling, flu shots), the area must be cleaned and disinfected between each use.

22. What are the requirements for improving ventilation/filtration at participating pharmacies?

Pharmacies providing testing services for symptomatic persons are to optimize ventilation within the pharmacy to maximize airflow. This may include increasing outdoor air ventilation (minimize recirculation), increasing HVAC filter efficiency and re-directing air flow from AC units and fans at head level. Pharmacies should refer to PHO's Resource on Heating, Ventilation and Air Conditioning (HVAC) Systems in Buildings and COVID-19.

OLIS Digital Self Collection Information

23. How do I prepare an OLIS Digital Self-Collection kit?

COVID-19 self-collection kits are specific to digital self-collection and **come pre-assembled** with the following components:

- 1 x Resealable biohazard specimen bag
- 1 x Absorbent pad
- 1 x Nasal/oral swab (iClean swab)
- 1 x Digital barcoded specimen tube (Copan media)
- 1 x Patient instructions on digitally registering document

More information about the COVID-19 self-collection kit can be found in the Ministry of Health's PCR COVID-19 Testing Resource for Pharmacy document provided to pharmacies via O365.

24. Do individuals need to pick up a PCR self-collection kit and drop it off at the same pharmacy?

It is recommended that patients drop off self-collection kits (including OLIS Digital Self Collection Kits) at the same pharmacy where they were pick up. However, in circumstances where this is not possible, individuals may pick up a PCR self-collection kit (including OLIS Digital Self-Collection Kit) and drop off the self-collected specimen at a different participating pharmacy. However, pharmacies cannot bill a Specimen Handling Fee unless a self-collected specimen is dropped off at their pharmacy and is made ready for transportation to the designated processing laboratory. Pharmacies are encouraged to follow up with individuals after dispensing PCR self-collection kits to have them drop off their self-collected specimens at the same pharmacy.

25. Do individuals need to make an appointment to pick up a PCR self-collection kit or drop off a self-collected specimen at a pharmacy?

Appointments are required for in-store services, such as specimen collection or In-store point-of-care PCR testing. Walk-ins are permitted for self-collection testing services, including OLIS Digital Self-Collection pick-up and drop-off.

26. What do I need to do when I receive a self-collected specimen?

Drop-off locations must validate the specimen collection time to ensure it is within acceptable testing time frame. They must also ensure the specimen is labelled and

legible with the required patient identification information. The specimen tube must be sealed properly and in a biohazard bag to prevent leaking. For OLIS Digital Self-Collection kits, the pharmacy must also confirm the patient completed the registration and QR code is scanned to link the kit with drop-off location, ordering clinician and performing lab. If a specimen does not meet the specimen quality control check checks conducted by the pharmacist, the specimen must be rejected, and the individual must be asked to be retested (either in store or by using another PCR self-collection kit).

Patient screening is not required for self-collected specimens received from other organizations if the ordering clinician section of the test requisition form is already completed.

Part A pharmacists must serve as the ordering clinician for the lab-based PCR test and, if applicable, add their name and licence number to the test requisition form. For more information, please review the Ministry of Health's PCR COVID-19 Testing Resource for Pharmacy document provided via O365 (available on request).

For more information, please review the Ministry of Health's PCR COVID-19 Testing Resource for Pharmacy document provided via O365 (previously ONEMail).

In-Store Point-of-Care PCR Testing Information

27. What is ID NOW™?

The ID NOW[™] is a point-of-care PCR. It detects COVID-19 faster than a lab-based PCR molecular test. It takes about 15 minutes or less to receive results.

28. How can my pharmacy enroll to provide Point-of-Care PCR testing using ID NOWTM?

Pharmacies interested in providing point-of-care PCR tests using ID NOWTM should contact the ministry at OPDPInfoBox@ontario.ca to be enrolled into the program. Please note that at this time, ID NOWTM (point-of-care PCR test) is only being offered in select pharmacies in Northern Ontario.

29. How can pharmacies order ID NOW™ equipment and supplies?

Currently, only select pharmacies located in Northern Ontario are eligible to perform **point-of-care PCR tests** using ID NOWTM. Once a pharmacy has received written confirmation from the ministry to provide in-store **point-of-care PCR testing**, an order can be made for the ID NOWTM equipment and supplies through the <u>eHealth portal</u>. A step-by-step guide can be found in Appendix F of Ontario Health's ID NOWTM COVID-19 Molecular Point-of-Care Testing Onboarding Package.

30. How can pharmacies order supplies for the ID NOW™ device quality control checks?

Device quality control (QC) tests are a key component of ongoing best practices for ID NOWTM COVID-19 molecular point-of-care testing. Pharmacists must complete quality

control checks for all point-of-care devices when a new person is training to perform testing, when a new shipment is received, when there is a change in lot number, after the device is moved, and after the device software is updated.

The following supplies are needed to conduct **ID NOW**TM **device quality control checks:**

- Positive and Negative Control Swabs from the test kit box (procured from Abbott)
- External positive COVID-19 swab (procured from Microbix)
- Printer Labels (procured from Abbott)

To procure the supplies needed to conduct the routine device quality control checks and supply fees:

- a) Contact Abbott: Email: andrew.mckinley@abbott.com
- b) Contact Microbix: Email: shane.niyamuddin@microbix.com

QC for 1.0 Test Kits

Every time QC is performed for 1.0 test kits, test using the following 3 swabs (each using the 'Run QC Test' option):

- Positive Control Swab (flu-based) from the test kit box from Abbott;
- Negative Control Swab from the test kit box from Abbott (or any dry sterile swab);
 and,
- External positive COVID-19 swab from Microbix.*

QC for 2.0 Test Kits

Unlike 1.0 test kits, the 2.0 test kits come with true COVID-19 positive control swab. Therefore, the QC test should use the following 2 swabs (each using the 'Run QC Test' option):

- Positive Control Swab from the test kit box from Abbott or Microbix; and,
- Negative Control Swab from the test kit box (or any dry sterile swab)

Please note that 1.0 positive control swabs will not work with ID NOW analyzers with 2.0 software (Vers: 7.0.0.20).

Supplier	Code	Description	Quote	
Abbott	190080	ID NOW™ COVID-19 1.0 Controls	\$250.00	
		(24 swabs)		
	192080	ID NOW™ COVID-19 2.0 Controls	\$250.00	
		(24 swabs)		
Microbix	RED-S-19-	REDx™ FLOQ® SARS-CoV-2	\$49.00 per swab	
	01C	Swab Positive Control (1 swab)		
Abbott	26333	Universal Printer Labels 59MM	\$12.00	

31. What training is provided for pharmacists to conduct point-of-care PCR testing using ID NOWTM?

Pharmacies conducting **point-of-care PCR testing** using ID NOW™ must ensure that best practices are in place. Appendix G of Ontario Health's ID NOW™ COVID-19 Molecular Point-of-Care Testing Onboarding Package provides best practices for providing this type of test as well as information on Abbott training sessions available. All relevant staff must complete training following the Best Practices guidance. Operators must also complete the Abbott and online results reporting training session in person or via video prior to commencing testing on specimens. Other staff involved may wish to participate.

Similarly, Ontario Health will provide online training to pharmacies on using OLIS-MORE for results entry upon enrollment in the testing services program.

32. What are the accepted specimen collection (swabbing) methods for ID NOW™?

A combined nasal and oral swab, throat swab, or nasal swab are accepted specimen collection methods for ID NOWTM. The combined swabbing of the throat AND both nares is the preferred alternative method. Nasal/nares/nostrils specimens are acceptable but have a lower sensitivity. Throat specimens are also acceptable but have a lower sensitivity.

33. Where can I find information about how to prepare to use ID NOW™?

Ontario Health's ID NOWTM COVID-19 Molecular Point-of-Care Testing Onboarding Package shared with pharmacies by the Ministry of Health via O365 (previously ONEMail) provides a step-by-step guide on what to do to prepare your pharmacy to use ID NOWTM.

34. When is additional testing using laboratory-based PCR tests required?

As per the updated <u>COVID-19 Provincial Testing Guidance</u>, confirmatory testing of rapid point-of-care test results is no longer required. Any rapid point-of-care molecular test result is considered final as per the <u>COVID-19 Provincial Testing Guidance</u>.

35. What accuracy verification is necessary for the ID NOW™ COVID-19 assay?

All ID NOWTM assays must undergo routine device quality control checks when a new person is training to perform testing, when a new shipment is received, when there is a change in lot number, after the device is moved, and after the device software is updated. Pharmacies must also document when quality control checks are being done.

- For sites performing more than 24 tests/day (1 kit box), perform control swabs at the beginning of the day before patient testing begins.
- For sites performing less than 24 tests/day (1 kit box), perform control swab each time a new kit box is opened or at least weekly, whichever is more frequent. Be sure to rotate device quality control checks on each device.

Every time quality control is performed, test the following swabs:

- Positive Control Swab from the test kit box (using the 'Run QC Test' option)
- Negative Control Swab from the test kit box (using the 'Run QC Test' option)
- External positive COVID-19 swab (using the 'Run Test' option)

Pharmacists should investigate failed device quality control checks and stop new specimen testing until the cause of the failure has been identified and corrected. Please review Ontario Health's ID NOW™ COVID-19 Molecular Point-of-Care Testing Onboarding Package shared with pharmacies by the Ministry of Health via O365 (previously ONEMail) for more information and instructions on how to conduct accuracy verifications.

Note: Pharmacies are eligible for reimbursement for one (1) fee claim per quality control kit box (containing control swabs) used for device quality control checks and verification based on manufacturer recommendations. For more information, please see the most recent version of the *EO Notice: Publicly Funded COVID-19 Testing Services in Ontario Pharmacies* on the ministry's website.

36. What are the requirements to report ID \mathbf{NOW}^{TM} test results?

Pharmacists are required to report all ID NOWTM test results to the Ontario Laboratory Information System (OLIS) on the same day that the test was conducted using Ontario Health's, Ontario Laboratories Information System-Mobile Order Result Entry (OLIS-MORE) platform. This is a web-based application to enable electronic COVID-19 test requisition capture and results submission directly to OLIS. For more information on OLIS-MORE, please review Ontario Health's ID NOWTM COVID-19 Molecular Point-of-Care Testing Onboarding Package or contact ac.labautomation@ontariohealth.ca.

Pharmacists are required to report all positive ID NOWTM test results to their local public health unit, as well as negative results when they are associated with an outbreak investigation or outbreak (if disclosed by the patient), which will usually be associated with an investigation or outbreak number generated by public health. Pharmacists must contact the public health unit to arrange the communication of positive results.

37. What are the specimen storage requirements for ID NOW™?

Swab specimens should be tested immediately after collection to ensure that only freshly collected specimens are tested for maximum accuracy. If not feasible, specimens can be stored at room temperature (15-30 °C) for up to 1 hour prior to testing. If a specimen will be held for longer than 1 hour, it must be refrigerated at 2-8 °C (or on ice packs) and tested within 24 hours from the time of sample collection.

Specimens should not be tested if stored for more than 24 hours after collection.

Swab specimens may be stored in a sterile 10 mL specimen collection tube that is dry, empty, and uncoated. The swab should NOT be put into a vial or other transport media or any other fluid, as this will dilute the quantity of virus on the swab and may yield

erroneous results. Pharmacists must ensure that the swab fits securely within the tube by trimming or breaking the shaft handle, then tightly closing the cap.

Mobile Order Result Entry (OLIS-MORE) platform

38. What is the OLIS-MORE platform?

The Ontario Laboratories Information System-Mobile Orders and Results Entry (OLIS-MORE) system is a scalable and strategic solution to digitally support ordering COVID-19 lab tests and to submit rapid, point-of-care test results into the Ontario Laboratories Information System (OLIS). With OLIS-MORE, pharmacies will now be able to submit COVID-19 requisition order forms digitally and directly to the OLIS, allowing integrated testing labs to receive the orders digitally and eliminating the manual data entry effort required with manual paper-based processes.

OLIS-MORE also allows for rapid point of care sites using ID NOW™ to directly submit testing results into OLIS. The Ministry requires all pharmacies to be onboarded into the OLIS-MORE platform as a mandatory requirement to participate in the Publicly Funded COVID-19 Testing Services program. An overview of the onboarding process is outlined in the Ministry of Health's PCR COVID-19 Testing Resource for Pharmacy document provided via O365 (previously ONEMail).

39. Is it mandatory for pharmacies to onboard into the OLIS-MORE platform as a requirement to participate in the program?

Yes, it is mandatory for pharmacies to transition lab requisition requests from paper-based forms to electronic submission via the OLIS-MORE platform. All pharmacies are required to be onboarded into the OLIS-MORE platform as a mandatory requirement to participate in the program. Pharmacies must express commitment to enroll in OLIS-MORE by completing a Client Information Form (CIF) available here: https://ehealthontario.on.ca/en/health-care-professionals/more?a=onboard.

Pharmacies must enroll in OLIS- MORE in order to be eligible to continue participating in the publicly funded COVID-19 testing services program. Paper requisitions will no longer be accepted at a future date.

40. How do pharmacies onboard onto the OLIS-MORE platform?

To begin the OLIS-MORE onboarding process at your pharmacy, please complete the online Client Information Form using this link: https://ehealthontario.on.ca/en/health-care-professionals/more?a=onboard. Commitment to OLIS-MORE adoption would be represented by way of completing an OH Client Information Form.

Pharmacies that undergo the OLIS-MORE onboarding process should also request access to a provincial clinical viewer, which would provide them access to OLIS data.

41. How do I complete the Requisition Form in the OLIS-MORE platform?

Pharmacies utilizing OLIS-MORE can complete laboratory requisition forms digitally. The following link provides an overview on OLIS-MORE:

https://www.ontariohealth.ca/providing-health-care/clinical-resources-education/covid-19/mobile-orders-and-results-entry

42. Where can I find additional information about the OLIS-MORE platform?

For questions, please send an email to <u>ac.labautomation@ontariohealth.ca</u>.

43. What actions should I take if my Pharmacy has new ownership, name change or Pharmacist has changed?

All Pharmacies that are digitally submitting to OLIS-MORE or OLIS Digital Self-Collection must inform Ontario Health of any changes that impact their accreditation number and/or Pharmacist responsible for testing. Any changes to this information will prevent you from submitting digitally. Please contact: ac.labautomation@ontariohealth.ca.

All pharmacies must inform the Ministry of Health of any changes that impact their accreditation number or changes to the testing services provided by emailing: OPDPInfoBox@ontario.ca.

Specimen Transportation for Lab-Based PCR Testing

44. What does the Transportation Fee include?

The Transportation Fee provides reimbursement for the actual shipping costs incurred including shipping materials (e.g., Styrofoam coolers, ice packs, etc.) for transporting the COVID-19 swab specimens (in-store collection and/or self collection only) from the pharmacy to the designated laboratory. Pharmacies must only submit claim amounts equal to their actual daily transportation costs, up to \$140 per day. If your transportation costs are less than \$140 per day, you must submit your actual costs and CANNOT submit \$140.

45. The courier that I use for transporting the specimens invoices the pharmacy weekly. How should I submit the claim for transportation costs?

Pharmacies should submit the claim for the Transportation Fee on the same day as the transportation. However, the HNS can process online transactions for publicly funded services on any of the most recent seven calendar days, including the current date. This means that a claim for the Transportation Fee PIN could be submitted today for a service date in the past (as long as it is within the past 7 days). For example, if the current date is December 1, a claim with a transaction date of November 24 will be rejected (i.e., response code "A1 – Claim too old"); whereas a transaction date of November 25 will be accepted.

Note: Paper-based claims are not eligible for any of the COVID-19 PINs including the Transportation Fee PIN. The pharmacy can only submit the Transportation Fee PIN up to 7 days from the service date electronically through the HNS.

Regardless of invoice scheduling, pharmacies should be able to calculate the transportation cost on the days that shipping occurs. Invoices should be itemized to account for daily transportation.

46. Can I make more than one delivery to the designated laboratory per day?

A pharmacy may choose to make more than one specimen delivery per day; however, the Transportation Fee PIN may only be submitted once per day with the actual transportation cost per day, not *exceeding* a total of \$140.

47. What are the storage and shipping requirements for COVID-19 Specimens in Ontario?

Specimens must not be stored with publicly funded vaccines. In addition, they should not be stored with drugs or medications that require refrigeration, nor with any food. If there is no separate refrigerator to store specimens prior to shipping, pharmacy staff may store specimens in a rigid outer shipping container (e.g., a Styrofoam cooler box) with an ice pack to maintain the optimal temperature.

In most cases, collected specimens must be shipped to the lab the same day they are collected to ensure specimen integrity and a timely public health response in the case of a positive COVID-19 result. Table 2 (below) outlines the recommended storage and shipping requirements to preserve the integrity of the specimens collected.

Pharmacists must not batch samples together for transport if these will cause delays.

Table 2. Storage and Shipping Requirements

Specimen type	Temperature for storage until shipment	Expected duration of shipment	Recommended shipment temperature	Shipment Category
Anterior Nasal swab	2–8 °C	≤ 72 hours	2–8 °C (ice pack)	Package and ship clinical specimens in accordance with the Transportation of
		> 72 hours	−70 °C (dry ice)	Dangerous Goods Regulations.

Couriers are not required to use refrigerated trucks for shipping as long as specimens are transported in a cooler with an ice pack. While specimens should be maintained at 2-8°C following specimen collection (i.e., in the pharmacy), pharmacies are not required to ensure that this exact temperature is maintained during shipping. To keep specimens cool, they should be transported in a rigid container (e.g., Styrofoam cooler) with an ice

pack. If specimens will not be shipped within 72 hours, specimens will be required to be frozen and kept frozen during transport.

Specimens should be packaged and shipped in accordance with applicable law, including the Transportation of Dangerous Goods Regulations under the *Transportation of Dangerous Goods Act, 1992* (Canada). For more information, please visit <u>Transport Canada's Transportation of Dangerous Goods Guidelines</u> or connect with a transportation of dangerous goods training provider.

48. What are the preparations required prior to transport?

The following is a list of useful tips for preparing specimens for transport:

- Place COVID-19 specimens for lab-based PCR testing in sealed biohazard specimen bags and include the requisition in the outer pouches. The requisition should not be in contact with the collection tube.
- Place the individual biohazard bags together in sealed large plastic bags, along with some absorbent material (e.g., paper towels).
- Place the large plastic bags into a rigid outer shipping container (such as a Styrofoam cooler) with one ice pack.
- Address and label the container with "UN3373" and "COVID-19 specimens."

Please review the Specimen Collection, Handling and Labelling section of the Ministry's PCR COVID-19 Testing Resource for Pharmacy Document provided via O365 (previously ONEMail) for more detailed information on how to prepare specimens for transportation.

49. Where should specimens be dropped off?

<u>Pharmacies enrolled in Testing Program prior to November 2021 or currently ship to In-Common Laboratories (ICL):</u>

Pharmacies that are arranging their own courier services whether private, shared, or self-courier services, need to have documentation to support any billing for transport services. The current location for specimen collection drop-off is*:

In-Common Laboratories 57 Gervais Drive North York, ON, M3C 1Z2

Email: info@iclabs.ca; Customer Service: 416-422-3000 or 1-888-285-7817

Deliveries can be made between 7 am to 10 pm seven days per week (these hours may be expanded in time).

^{*} Subject to changes, updates will be communicated via O365 (previously ONEMail).

The fax number must be verified with the testing laboratory through a fax authorization process, and this process must be repeated for any new fax numbers. To support this process, pharmacies should send a list of all ordering clinicians/pharmacists, their phone numbers and fax numbers to the Ontario Health Provincial Diagnostic Network Operations Centre (PDNOC) at COVID-19.diagnostics@ontariohealth.ca.

Pharmacies enrolled after November 2021:

Pharmacies that are arranging their own courier services whether private, shared, or self-courier services, need to have documentation to support any billing for transport services. The current location for specimen collection drop-off is the closest PHO (Public Health Ontario) laboratory to your pharmacy location that performs COVID-19 testing. Please refer to Appendix 3: List of PHO Laboratories and Corresponding Public Health Unit of the Ministry's PCR COVID-19 Testing Resource for Pharmacy Document provided via O365 (previously ONEMail). The PHO processing laboratory will contact you directly **via fax/efax** to confirm your onboarding process.

Contact Information for PHO:

PHO Laboratory Customer Service Centre: 416-235-6556 or 1-877-604-4567 (toll-free) Email: customerservicecentre@oahpp.ca

Hours:

M-F 07:30 to 19:00 Sat 08:00 to 17:00 Sun 09:00 to 17:00

<u>Pharmacists must ensure that specimens collected for privately funded testing are not shipped to a PHO laboratory for processing.</u>

50. What courier service should I use? Can I drop off the specimens myself?

Pharmacies must arrange their own appropriate courier services to the receiving laboratory. Pharmacies may choose to drop off the specimens themselves so long as they are packaged and shipped in accordance with applicable law, including the Transportation of Dangerous Goods Regulations under the *Transportation of Dangerous Goods Act, 1992* (Canada). Failure to comply with the TDG Act and TDG Regulations may lead to fines and/or imprisonment. For more information, please visit Transport-transportation of Dangerous Goods Guidelines or connect with a transportation of dangerous goods training provider.

Billing

51. How do pharmacists bill for services related to publicly funded COVID-19 testing services in pharmacies?

For billing instructions, please see the most recent *Executive Officer Notice: Publicly Funded COVID-19 Testing Services in Ontario Pharmacies* posted on the Ministry's website.

52. How are claims submitted through the HNS?

HNS claims for pharmacy services related to publicly funded COVID-19 testing services must contain the appropriate PINs when an eligible person receives the service at the pharmacy. Please see the most recent *Executive Officer Notice: Publicly Funded COVID-19 Testing Services in Ontario Pharmacies* posted on the Ministry's website.

Pharmacists must ensure the patient's correct date of birth, Ontario health card number and name (as it appears on the health card) are entered accurately as part of the HNS claim submission. For individuals **without** a health card number, use the proxy ID # 79999 999 93. Please refer to the corresponding <u>EO Notice</u> for further details.

53. What is the procedure to submit the claim to the HNS?

The claim submission follows the normal process for submitting claims on the HNS.

54. How does the ministry pay a participating pharmacy for publicly funded COVID-19 testing services?

The payment is paid through the Ministry's HNS to the accredited pharmacy that has a billing account with the Ministry.

55. Can I submit manual (paper) claims?

Paper claims will not be accepted. Claims must be submitted online to the HNS only.

56. When does the pharmacist submit the claim?

Claims must be billed using the service date (i.e., the date on which the COVID-19 testing service was completed, or transportation of specimen occurred).

Documentation and Record Keeping

57.I am having trouble putting the claim through the HNS. Who should I contact?

If pharmacies have any questions or concerns related to billing issues, please contact the ODB Help Desk at 1-800-668-6641.

For other inquiries related to COVID-19 testing in pharmacies, please send an email to: PublicDrugPrgrms.moh@ontario.ca

Restrictions

58. How many tests can pharmacies provide to an individual per day?

Pharmacies can only provide one type of pharmacy service for one type of test per individual per day. For example, if an eligible individual is seeking a lab-based PCR test, then the pharmacy may collect the individual's specimen at the pharmacy or receive the specimen collected by the individual at home using a self-collection kit, but not both, and the pharmacy cannot perform a **point-of-care PCR test** at the pharmacy for the individual on the same day. Similarly, if an eligible individual is seeking a **point-of-care PCR test** at the pharmacy, then the pharmacy cannot provide that individual with any services relating to a lab-based PCR test on the same day.

However, if a self-collected specimen received from the individual is not viable (i.e. not pass the in-pharmacy specimen quality control check check), a second specimen collection service for a lab-based PCR test can be provided and billed on the same day.

59.I work in a hospital in-patient pharmacy. Can I submit claims for reimbursement?

No. The cost of COVID-19 testing services from hospital in-patient pharmacies must be covered through the hospital's budget.

60. Can publicly funded resources be used for privately funded COVID-19 testing?

No. Publicly funded resources (e.g., swab kits, PPE, ID NOWTM supplies, etc.) CANNOT be used for privately funded COVID-19 testing. Please refer to the <u>COVID-19</u> <u>Guidance: Considerations for Privately-Initiated Testing</u> on the Ministry's website for further details. Claims for private COVID-19 testing CANNOT be submitted for reimbursement through the HNS with the COVID-19 PINs. Inappropriate claim submissions for private COVID-19 testing are subject to recovery.

61. When can I bill a Patient Ineligibility Screening Fee?

A Patient Ineligibility Screening Fee can only be used when a patient is screened as **ineligible** for a pharmacy service related to a publicly funded test. Patients seeking a COVID-19 test for travel purposes are not eligible and a Patient Ineligibility Screening Fee cannot be billed for these patients. The Patient Ineligibility Screening Fee PIN cannot be used if a patient is eligible for a test and/or is provided with a pharmacy service related to a publicly funded COVID-19 test.

Note: payment for screening **eligible** persons is incorporated into the fee paid for other pharmacy services related to publicly funded COVID-19 tests (i.e. specimen handling, specimen collection, and point-of-care testing). For more information, please see the most recent version of the EO Notice: Publicly Funded COVID-19 Testing Services in Ontario Pharmacies on the ministry's website.

62. Can my pharmacy bill a Patient Ineligibility Screening Fee for handling test kits that are distributed by other organizations with the ordering clinician section in test requisition already completed?

No, a Patient Ineligibility Screening Fee cannot be billed for handling these specimens. Instead, a pharmacy would bill the Self-Collected COVID-19 Specimen Handling Fee (Other) PIN.

63. At our pharmacy we screen for COVID-19 symptoms prior to administering the flu vaccine. Am I able to bill for a Patient Ineligibility Screening Fee?

No. Only participating pharmacies that provide in-store COVID-19 specimen collection or **point-of-care PCR testing** services may submit claims for a Patient Ineligibility Screening Fee.

Additional Questions

64. Is there any additional follow-up or care required for providing the publicly funded COVID-19 testing services? How will patients be notified of their test results?

<u>Information for Patients Waiting for Test Results</u>

Please refer to the current testing guidance: <u>COVID-19 Provincial Testing Guidance</u> for the most up-to-date information, including information on what to do if patients have symptoms and are concerned they may have COVID-19 or patients that have been identified as a close contact.

Pharmacies must NOT provide patients the contact information of the laboratory processing their tests. The laboratory will not provide patients with any information about the test. Instead, pharmacies are responsible for communicating test results to patients as outlined below.

Results Communication for Lab-Based PCR Testing (of Specimens Collected In-store and Self-Collected) when Pharmacist is the Ordering Clinician¹

Once the test has been processed by the licensed laboratory, the ordering pharmacist will be notified of the patient's test result (via fax²). Alternatively, pharmacists obtain results from the clinical viewers, point of care systems, or OLIS Portal (ConnectingOntario/ClinicalConnect) using their ONE ID credential. Pharmacies utilizing the OLIS-MORE system must note that the use of OLIS-MORE does not change any reporting requirements that are outlined below.

Positive Results

In the event of a positive result, the pharmacist must contact the patient to inform them of their test result and provide information on potential next steps, which includes directing the patient to self-isolate immediately. The recommended duration of self-isolation depends on relevant clinical factors such as age, vaccination status, severity of infection, and immune status, refer to Management of Cases and Contacts of COVID-19 in Ontario (gov.on.ca) for more details.

¹ It is the responsibility of the ordering clinician indicated on the test requisition form to report results to the patient and Public Health Unit

² All results (positive and negative) will be sent to the pharmacies via fax

Pharmacists are also required to report all positive results to the Public Health Unit in which the patient resides.

Negative Results

In the event of a negative result, pharmacists are not required to inform the patient unless the patient is unable to obtain their results online.

Patients who present their green health card at the time of their test will be able to obtain their test results online, through the <u>Ministry of Health's access portal</u>. Patients who present without a health card or with a red and white health card will not be able to access their results online; for these patients, **pharmacists must communicate all results including negative test results**.

If pharmacies are utilizing the OLIS-MORE application, then patients with a Red and White Health Card and those without a health card number will be able to look up their results on the COVID-19 Patient Results Viewer website. OLIS-MORE generates a Medical Record Number (MRN) and verification code to allow patients to look up their results.

Indeterminate Results

In the unlikely event of an indeterminate result, a pharmacist will contact the patient to communicate that their test result was indeterminate, advise that a second swab is required, and direct the client to be re-tested at a pharmacy or assessment centre. Pharmacies may provide patients with a copy of the indeterminate fax results received from the processing laboratory. **Please remove/black out the laboratory information** on the fax before providing it to the patient.

Cancelled or Rejected Results

For in-store specimen collection and self-collection for lab-based PCR testing, a pharmacist will need to review the requisition form to confirm all required information is filled-in and legible. If information is missing, the pharmacist will need to reach out to the patient for any missing information.

In the event of cancelled or rejected samples, a pharmacist is responsible for contacting the patient to communicate that their test was cancelled and advise that a second swab is required and direct the client to be re-tested at a pharmacy or assessment centre. Pharmacies may provide patients with a copy of the cancelled fax report received from the processing laboratory. Please remove/black out the laboratory information on the fax before providing it to the patient.

Failed OLIS-MORE Submissions

In the event of an unsuccessful submission, and the patient did not have a green and white health card, the MRN is not generated and the Pharmacist is responsible for contacting the patient to communicate their results.

Results Communication for In-Store Point-Of-Care PCR testing (ID NOWTM)

Pharmacists are required to report all ID NOWTM test results into the Ontario Laboratory Information System (OLIS) on the same day that the test was conducted using Ontario Health's Mobile Order Results Entry (OLIS-MORE).

Positive Results

Patients with a positive ID NOWTM COVID-19 test result should be informed of their positive results as soon as possible and be advised to stay home and self isolate. **All positive test results must also be reported to the Public Health Unit in which the patient resides**, in accordance with the *Health Protection and Promotion Act*.

Negative Results

In the event of a negative result, pharmacists are not required to inform the patient unless the patient is unable to obtain their results online.

All patients will be able to obtain their test results online, through the COVID-19 Patient Results Viewer. Patients who present without a health card or with a red and white health card will use the OLIS-MORE generated Medical Record Number (MRN) to look up their results on the Viewer.

Indeterminate Results

In the unlikely event of an indeterminate result, a pharmacist will contact the patient to communicate that their test result was indeterminate, advise that a second swab is required and direct the client to be re-tested at a pharmacy or assessment centre.

65. A patient is requesting proof of their negative test result. What should I provide them?

If proof of a negative test result is required, the pharmacy can provide a printout or copy of the test result (that was faxed to the pharmacy from the laboratory or received from the ID NOWTM instrument) to the patient OR if the patient can access their own test results online, they can show their results to those requesting it on their mobile device. **Please remove/black out the laboratory information** on the fax before providing it to the patient.