

Ministry of Health

COVID-19 Provincial Testing Guidance

V. 15.3 January 25, 2023

This document is an update to the October 6th version (V. 15.2) of the COVID-19 Provincial Testing Guidance, and may be updated as the COVID-19 situation continues to evolve.

It is expected that this guidance will be consistently applied across all regions in Ontario to guide decision making regarding COVID-19 testing, in conjunction with other [setting-specific guidance](#) as appropriate.

In the event of any conflict between this guidance document and any applicable legislation or orders or directives issued by the Minister of Health or the Chief Medical Officer of Health (CMOH), the legislation, order or directive prevails. Please see Ontario's [COVID-19 website](#) for more general information as well as for updates to this document.

Updates to this document include:

- the revision of eligibility for molecular testing based on age, medical conditions, and vaccination status, to reflect current clinical guidance regarding nirmatrelvir/ ritonavir (Paxlovid) treatment
- the addition of asymptomatic close contacts who are staff of highest risk settings to the list of those eligible for molecular testing, for the purposes of facilitating return to work
- the removal of detailed information regarding molecular testing for influenza and other seasonal respiratory viruses, with a link to the Public Health Ontario Laboratory Test Information Sheet to support access to current information

Table of Contents

1	Types of COVID-19 Tests Available in Ontario	3
1.1	Molecular tests (including laboratory-based and rapid molecular tests).....	3
1.2	Rapid antigen tests	5
1.3	Serology tests.....	8
2	Requirements associated with testing	8
3	Variant of concern screening and genomic sequencing	9
4	Diagnosing COVID-19	9
4.1	Case Definition	9
4.2	Guidance for Symptomatic Individuals.....	9
4.3	Influenza and other seasonal respiratory virus testing.....	10

1 Types of COVID-19 Tests Available in Ontario

1.1 Molecular tests (including laboratory-based and rapid molecular tests)

Description: Molecular tests (also known as “nucleic acid amplification tests” or NAAT), detect nucleic acid (also known as “gene,” “genetic,” or “RNA”) fragments of the SARS-CoV-2 virus, the cause of COVID-19. Most molecular tests are based on a detection technology called polymerase chain reaction (PCR), but other technologies are also used (see CDC’s [Nucleic Acid Amplification Test](#) web page for a list of common molecular test technologies).

Laboratory-based molecular tests are usually tests of high complexity (including most PCR tests) requiring extensive validation for laboratory professional use only. Refer to the Public Health Ontario (PHO) [Coronavirus Disease 2019 \(COVID-19\) PCR Test Information Sheet](#).

Rapid molecular tests are tests of moderate to low complexity requiring less extensive validation and are authorized by Health Canada for point of care use in which analysis can be done by non-laboratory professionals at or near the point of specimen collection.

Specimen collection: A nasopharyngeal swab (NPS) or lower respiratory tract specimen (e.g. tracheal aspirate or bronchoalveolar lavage) are the preferred collection methods for SARS-CoV-2 in hospitalized patients. Other specimen collection methods, including combined oral and nasal swabbing or saliva collection, may be used for non-hospitalized patients to support access to testing and maximize test uptake. Samples may be self-collected (if using a self-collection kit) or collected by a trained individual.

Purpose: Molecular testing is primarily used for diagnostic purposes. Priority groups eligible for molecular testing are listed below.

Symptomatic people who fall into one of the following groups:

- People aged 60 years of age and older
- People aged 18 years of age and older who have one or more [comorbidity that puts them at higher risk of severe COVID-19 disease](#)
- People aged 18 years of age and older who are unvaccinated or have not completed their primary vaccine series
- People aged 18 years of age and older who completed their primary vaccine

series AND received their last COVID-19 vaccine dose more than 6 months ago AND have not had a SARS-CoV-2 infection in the past 6 months

- People who are immunocompromised
- Pregnant people
- Patients seeking emergency medical care or other outpatients for whom a diagnostic test may guide clinical management, at the discretion of the treating clinician
- Patient-facing healthcare workers
- Staff, volunteers, residents/inpatients, essential care providers, and visitors in highest risk settings
 - Highest risk settings include: hospitals (including complex continuing care facilities and paramedic services), and congregate living settings¹ with medically and socially vulnerable individuals, including, but not limited to long-term care homes, retirement homes, First Nation elder care lodges, group homes, shelters, hospices, correctional institutions, and hospital schools.
- Household members of staff in highest risk settings and patient-facing health care workers
- Home and community care workers
- International Agriculture Workers in congregate living settings
- People who are underhoused or experiencing homelessness
- First responders, including fire, police and paramedics

Symptomatic/asymptomatic people:

- Individuals who are from a First Nation, Inuit, Métis community, and/or who self-identify as First Nation, Inuit, and Métis, and their household members
- Individuals travelling into First Nation, Inuit, Métis communities for work

¹ See the COVID-19 Guidance: Long-Term Care Homes, Retirement Homes, and Other Congregate Living Settings for Public Health Units . *People in each of these groups may be eligible for COVID-19 treatment if they test positive, based on clinical criteria including risk factors and vaccination status.

- On admission/transfer to or from hospital or congregate living setting²
- People in the context of confirmed or suspected outbreaks in highest risk settings as directed by the local public health unit
- Individuals, and one accompanying caregiver, with written prior approval for out-of-country medical services from the General Manager, Ontario Health Insurance Plan (OHIP)
- Any patient with a scheduled surgical procedure requiring a general anaesthetic 24-48 hours prior to procedure date
- Newborns born to people with confirmed COVID-19 at the time of birth within 24 hours of delivery, with a repeat test at 48 hours after birth if baseline test is negative, or if the parental test results are pending at the time of discharge
- People 24-48 hours prior to treatment for cancer or prior to hemodialysis, at the discretion of the treating clinician
- Staff of highest risk settings who, within the last 10 days, have had close contact with an individual with symptoms compatible with COVID-19 or an individual who has tested positive for COVID-19, for the purposes of facilitating return to work, as directed by sector-specific guidance or Infection Prevention and Control (IPAC) or Occupational Health staff.

Confirmatory testing: At this time, positive results from molecular tests (either lab-based or rapid) can be considered [confirmed cases](#) and do not require further confirmatory testing.

Testing of previously cleared cases: Confirmed COVID-19 cases may continue to test positive by molecular testing even after clearance from isolation. Re-testing within 90 days after clearance of a confirmed case should be based on clinical indications for testing (e.g. in the context of new COVID-19 symptoms) or as directed in the context of a new exposure or outbreak investigation.

1.2 Rapid antigen tests

Description: Rapid antigen tests (RAT) (also known as “rapid antigen detection tests” or RADT) detect protein fragments of the SARS-CoV-2 virus. Most rapid antigen tests are based on a detection technology called lateral flow immunoassay testing (LFIA or LFT), but other technologies are also used. Most rapid antigen tests are of low

² While people on admission/transfer are eligible for molecular testing, the decision of whether to test should be based on clinical, epidemiological, and/or organizational factors.

complexity requiring minimal validation and are authorized by Health Canada for point of care use in which analysis can be done by non-laboratory professionals at or near the point of specimen collection.

Purpose and eligibility: There are several potential uses for rapid antigen tests:

- A) **For people with [COVID-19 symptoms](#) who are not included in [molecular testing priority groups](#)³:** A single negative rapid antigen test in an individual with COVID-19 symptoms does not rule out a COVID-19 infection. If two consecutive rapid antigen tests, separated by at least 24-48 hours, are both negative, the symptomatic individual may be less likely to have a COVID-19 infection. See the [Management of Cases and Contacts in Ontario](#) for isolation recommendations based on rapid antigen test results.

At this time, a positive result from a self-administered or provider-administered rapid antigen test is sufficient evidence of COVID-19 infection to initiate outpatient therapies if molecular testing is not available or would delay treatment initiation.

- B) **For the management of staff returning to work in highest risk settings:** Refer to Appendix A in the [Management of Cases and Contacts in Ontario](#).
- C) **Routine screen testing:** Routine screen testing is frequent, systematic testing of people who are asymptomatic and without known exposure to a COVID-19 case. Screen testing with rapid antigen tests involves routine testing multiple times per week. An individual with confirmed COVID-19 based on a molecular or rapid antigen test may resume asymptomatic screen testing after 90 days from their COVID-19 infection (based on the date of their symptom onset or specimen collection, whichever is earlier). If there is uncertainty about the validity of the COVID-19 infection (e.g. asymptomatic infection with high cycle threshold value result), they may resume asymptomatic screen testing immediately.
- D) **One-off, non-routine/infrequent asymptomatic testing:** Infrequent rapid antigen test use should not be relied on as a measure to enable social activities. If an asymptomatic individual without a known exposure to a COVID-19 case decides to perform a rapid antigen test outside of routine screening programs (for example prior to a social event/gathering/visit in a non-highest

³ Any person who is eligible for molecular testing is strongly encouraged to seek molecular testing rather than using rapid antigen testing if molecular testing access and turnaround time is satisfactory, since molecular tests are substantially more sensitive than rapid antigen tests.

risk setting), they should complete the test as close to the event as possible (e.g. on the same day, ideally within a few hours of the event) and should understand important limitations of rapid antigen test use for this purpose including:

- False negatives:
 - Rapid antigen tests have low sensitivity for COVID-19 in people who are asymptomatic. This means that a negative result could be a false negative.
 - People infected with COVID-19 may test negative for several days before testing positive on a rapid antigen test. Therefore, a negative rapid antigen test may represent a false negative and the infection status of the individual may change within hours of taking the test.
- False positives:
 - Rapid antigen tests have a lower positive predictive value when used for individuals without a known exposure to a confirmed case of COVID-19 or where incidence of COVID-19 is low, meaning that a positive result could be a false positive.

Specimen collection and use: Specimen collection and use of rapid antigen tests should follow the labelling instructions provided by the manufacturer as approved by Health Canada. If the manufacturer's labelling instructions (as approved by Health Canada) do not already include self-swabbing and self-testing, the Ministry of Health is of the opinion that voluntary self-swabbing and self-testing may be performed if the user has the appropriate knowledge, skills, and judgment to self-swab and self-test as per [Ontario Health's swabbing/specimen collection and testing resources](#). If the manufacturer's labelling instructions (as approved by Health Canada) do not already include combined oral and nasal swabbing, users may voluntarily perform the combined oral and nasal swabbing method following the rapid antigen test collection instructions found at [Ontario Health's sample collection guidance page](#) as it may increase test sensitivity compared with nasal sampling alone.

Confirmatory testing: At this time, positive rapid antigen test results do not require confirmatory testing in most settings, or reporting to the public health unit, unless otherwise recommended by the public health unit or sector specific guidance.

Disposal of waste: Waste generated from on-site workplace rapid antigen test use is considered a hazardous waste under the Environmental Protection Act. Waste from these tests is exempt from collection, storage and transportation requirements

as long as the waste is disposed in Ontario. This waste must still be disposed of at a waste facility approved to handle biomedical waste. Anyone collecting, storing or transporting used rapid antigen tests from an on-site workplace screening program should follow Ontario's guidance on the [Safe Handling and Management of Rapid Antigen COVID-19 Testing Waste](#). For waste generated from at-home rapid antigen test use, the regulatory requirements for managing the hazardous waste under the Environmental Protection Act do not apply. Instead, persons undertaking at-home use of rapid antigen tests should consult their local municipality's by-laws on the proper disposal of this waste to ensure it can be disposed of with the household trash.

1.3 Serology tests

Description: Serology tests detect antibodies to the SARS-CoV-2 virus. Most serology tests are high complexity tests requiring extensive validation for laboratory professional use only. See [PHO's Coronavirus Disease 2019 \(COVID-19\) - Serology Test Information Sheet](#) for further details.

Purpose and eligibility: Available for the following clinical indications:

- A) Patients presenting with symptoms compatible with Multisystem Inflammatory Syndrome in Children (MIS-C) or Adults (MIS-A) who do not have laboratory confirmation of COVID-19 by molecular testing.
- B) Testing may be considered for patients with severe illness who have tested negative for COVID-19 by molecular testing and where serology testing would help inform clinical management and/or public health action. Serology testing for these patients requires consultation and approval by the testing laboratory.
- C) To inform treatment decisions for [monoclonal antibody treatment](#).
- D) Serology should not be used for screening and diagnosis of acute COVID-19 infection, or for determining immune status or vaccination status beyond the indications defined above.

See the [COVID-19 Case Definition](#) for reporting and surveillance of serology results.

2 Requirements associated with testing

Approved assays: All testing must be performed on assays approved by Health Canada or otherwise validated by the licensed laboratory (i.e., validated laboratory-developed test).

Laboratory licensing: Laboratories used to collect specimens and conduct testing for COVID-19 must be licensed under the *Laboratory and Specimen Collection Centre Licensing*

Act ([LSCCLA](#)) or fall under an exemption under the [LSCCLA](#).

Data entry into OLIS: All molecular test results (except molecular self-tests) and clinical serology test results should be entered with minimum data elements required for laboratory results into the Ontario Laboratories Information System (OLIS). Where OLIS is not available, results should be reported in accordance with the [Health Protection and Promotion Act](#).

Reporting to public health units: Other than rapid antigen tests and self-test kits, positive COVID-19 tests performed using a Health Canada approved test or an assay validated by the laboratory must be reported to the local public health unit as per the [LSCCLA's Reg. 682](#) and/or under the [Health Protection and Promotion Act](#).

3 Variant of concern screening and genomic sequencing

Screening: In Ontario, there is currently no routine targeted variant of concern (VOC) screening. VOC screening may be performed upon request for investigations when required for clinical or public health management. See PHO's [COVID-19 Variants of Concern Test Information Sheet](#) for further details.

Surveillance: Whole genome sequencing is performed for epidemiological surveillance purposes on a representative sample of positive PCR tests across Ontario with cycle threshold (CT) values ≤ 30 as well as specimens from international travellers. In addition, it is possible to request sequencing for patients with suspected reinfection and for certain outbreak investigations. See PHO's [COVID-19 Variants of Concern Test Information Sheet](#) for further details.

4 Diagnosing COVID-19

4.1 Case Definition

Please refer to the current Ontario [Case Definition](#) for information on confirmed, probable and reinfection cases.

4.2 Guidance for Symptomatic Individuals

The following symptoms and signs may indicate infection with COVID-19:

- fever and/or chills; OR
- cough; OR
- shortness of breath; OR

- decrease or loss of taste or smell; OR
- Two or more of any of the following:
 - runny nose/nasal congestion
 - headache
 - extreme fatigue
 - sore throat
 - muscle aches or joint pain
 - gastrointestinal symptoms (i.e. vomiting or diarrhea)

People who are [eligible for molecular testing](#) are encouraged to [get tested](#) using a molecular test, and may be required to access testing based on sector-specific guidance. People who are not eligible for molecular testing may use [rapid antigen testing](#). See the [Management of Cases and Contacts of COVID-19 in Ontario](#) for more information on isolation recommendations for individuals with COVID-19 symptoms.

4.3 Influenza and other seasonal respiratory virus testing

See PHO's [Respiratory Viruses \(Including influenza\) Test Information Sheet](#) for details on molecular testing for influenza and other seasonal respiratory viruses, including clinical indications for testing, eligible specimen types, collection, and requisition information.