

Ministry of Health

# COVID-19 Provincial Testing Guidance

V. 15.0 April 11, 2022

This document is an update to the COVID-19 Provincial Testing Guidance, which incorporates the testing guidance implemented during the Omicron wave. This document replaces the testing content from v3.0 March 28<sup>th</sup> 2022 'COVID-19 Integrated Testing & Case, Contact and Outbreak Management Interim Guidance: Omicron Surge.' This information is current as of April 6, 2022 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:

- Integration of content on testing from the March 28, 2022 COVID-19 Integrated Testing & Case, Contact and Outbreak Management Guidance: Omicron Surge document and from the November 2021 COVID-19 Provincial Testing and Clearance Guidance.
- Elaboration of criteria for molecular testing to support eligibility for COVID-19 treatment.
- Inclusion of all symptomatic people aged 70 and older and all people who are immunocompromised in list of those eligible for molecular testing.

## 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 COVID-19 virus. 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).

**Lab-based molecular tests** are usually tests of high complexity (including most PCR tests) requiring extensive validation for laboratory professional use only.

**Rapid molecular tests** are tests of moderate to low complexity requiring less extensive validation and 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. Refer to the Public Health Ontario (PHO) [Coronavirus Disease 2019 \(COVID-19\) PCR Test Information Sheet](#) for further details.

**Specimen collection:** A nasopharyngeal swab (NPS) or lower respiratory tract specimen (e.g. tracheal aspirate, bronchoalveolar lavage) are the preferred collection methods in hospitalized patients. Other specimen collection methods, including combined oral and nasal swabbing or saliva collection, may be used for non-hospitalized and asymptomatic patients to support access to testing and maximize test uptake. Samples may be self-collected (if using a self-collection laboratory-based PCR 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 70 years and older
- People aged 60 years and older who have less than three doses of COVID-19 vaccine
- People who are [immunocompromised](#)
- Adults aged 18 years and older who have had less than three doses of COVID-19 vaccine and have risk conditions:
  - obesity (BMI  $\geq$  30kg/m<sup>2</sup>)
  - diabetes
  - heart disease, hypertension, congestive heart failure
  - chronic respiratory disease, including cystic fibrosis
  - cerebral palsy
  - intellectual disability
  - sickle cell disease
  - moderate or severe kidney disease (eGFR <60mL/min)
  - moderate or severe liver disease (e.g., Child Pugh Class B or C cirrhosis)
- Other [people at higher risk of severe disease](#) who may be eligible for COVID-19 treatment if they tested positive

- Pregnant people
- 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 settings<sup>1</sup> 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
- Staff and students in Provincial and Demonstration Schools
- Elementary and secondary students and education staff who have received a PCR self-collection kit through their school
- International Agriculture Workers in congregate living settings
- Patients seeking emergency medical care, at the discretion of the treating clinician
- Other outpatients for whom a diagnostic test is required for clinical management, at the discretion of the treating clinician
- 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
- On admission/transfer to or from hospital or congregate living setting
- 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, OHIP
- Any patient with a scheduled surgical procedure requiring a general

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<sup>1</sup> See the [COVID-19: Congregate Living for Vulnerable Populations Guidance](#) for more information.

\*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.

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

**Confirmatory testing:** At this time, positive results from molecular tests (either lab-based or rapid) used for diagnostic purposes 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 COVID-19 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. Rapid antigen tests are of low complexity requiring minimal validation and 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) Routine screen testing:** Screen testing is frequent, systematic testing of people who are asymptomatic and without known exposure to a COVID-19 case with the goal of identifying infectious cases that are pre-symptomatic or asymptomatic. 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 30 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.

**B) For people with [COVID-19 symptoms](#) who are not included in [molecular testing priority groups](#):** 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 is 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 positive 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.

**C) For test-to-work purposes** (see the [Management of Cases and Contacts in Ontario](#))

**D) One-off, non-routine or 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 risk setting), they should complete it 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 results 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

performed if the user has the appropriate knowledge, skills, and judgment to self-swab and self-test as per the training resources available on the [COVID-19 Health System Response Materials](#) page. 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 on the [COVID-19 Health System Response Materials](#) 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 COVID-19 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  $\leq 30$  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 Definitions

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](#), 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

Certain people who are **symptomatic** with an [acute respiratory infection](#) are eligible and recommended to seek molecular testing for influenza and other seasonal respiratory viruses, in addition to COVID-19 testing:

- A) Hospitalized patients
- B) Patients < 18 years old accessing care in emergency departments, at the discretion of the treating clinician
- C) People in institutional settings not in outbreak (e.g. long-term care homes, correctional facilities, congregate living settings)

- D) People in outbreak investigations, on the direction of public health. This includes [symptomatic residents, staff and/or essential visitors](#) in an institutional/congregate living setting (e.g., long-term care homes, retirement homes, correctional facilities, shelters, group homes, etc.) with acute respiratory illness, with testing of up to 4 specimens to identify the causative virus.
- E) People in remote communities

See PHO's [Respiratory Viruses \(Including influenza\) Test Information Sheet](#) for further details including eligible specimen types, collection, and requisition information.