Ontario

Case Definition – Coronavirus Disease (COVID-19)

These case definitions* are for surveillance purposes and they are current as of February 18, 2021. They are not intended to replace clinical or public health practitioner judgment in individual patient assessment and management.

A. Probable Case

A person **who**:

1- Has symptoms compatible with COVID-19 (see footnote 9)

AND:

a. Traveled to or from an affected area (including inside of Canada, see footnote 10) in the 14 days prior to symptom onset; **OR**
b. high-risk exposure (i.e. close contact) with a confirmed case of COVID-19 (see footnote 2); **OR**
c. Was exposed to a known cluster or outbreak

AND:

a. In whom a laboratory-based nucleic acid amplification test (NAAT)-based assay (e.g. real-time PCR or nucleic acid sequencing) for SARS-CoV-2 either has not been completed **OR** is inconclusive (see footnotes 4, 5, 12); **OR**
b. SARS-CoV-2 antibody is detected in a single serum, plasma, or whole blood sample using a validated laboratory-based serological assay for SARS-CoV-2 collected within 4 weeks of symptom onset (see footnote 11).

OR

2- Is tested with a validated Health Canada-approved point-of-care (POC) NAAT or POC antigen test for SARS-CoV-2 and the result is preliminary positive detected (see footnote 6)

B. Confirmed Case

A person with laboratory confirmation of SARS-CoV-2 infection documented by:

1- Detection of at least one specific gene target by a validated laboratory-based NAAT assay (e.g. real-time PCR or nucleic acid sequencing) performed at a community, hospital or reference laboratory (e.g. Public Health Ontario Laboratory or the National Microbiology Laboratory) (see footnote 7, 8, 9).

OR

2- A validated POC NAAT that has been deemed acceptable by the Ontario Ministry of Health to provide a final result (i.e. does not require confirmatory testing) (see footnote 6).

OR

3- Demonstrated seroconversion within a four-week interval in viral specific antibody in serum or plasma using a validated laboratory-based serological assay for SARS-CoV-2. (see footnote 11).

C. Confirmed Case of Reinfection

1. A person with a primary and secondary laboratory-confirmed infection with SARS-CoV-2, with time-based or test-based clearance in between the two infections, where genome sequencing indicates that the two SARS-CoV-2 infections either i) belong to different genetic clades or lineages OR ii) sufficient single nucleotide variations to correlate with the probability that the two episodes are caused by different viral lineages.

OR

2. A person with a primary and secondary laboratory-confirmed infection with SARS-CoV-2, with time-based or test-based clearance in between the two infections, where:
    a. The secondary infection episode is confirmed to be a variant of concern (VOC) OR is epidemiologically linked to a confirmed case with a VOC (i.e., known close contact or part of an outbreak); AND
    b. The primary infection occurred before November 1, 2020, when VOC were rare in Ontario; AND
    c. Sequencing of the specimen from the primary infection is not possible to compare to the secondary infection.

*Case Definition Footnotes

1. The median incubation period of COVID-19 is 5 days. Allowing for variability and recall error and to establish consistency with the World Health Organization's COVID-19 case definition, exposure history based on the prior 14 days is recommended at this time.
2. A **close contact** is defined as a person who had a high-risk exposure to a confirmed or probable case during their period of communicability. This includes household, community and healthcare exposures as outlined in Ministry guidance on cases and contacts of COVID-19.
3. There is evidence documenting SARS-CoV-2 presenting as a co-infection with other pathogens. At this time, the identification of one causative agent should not exclude COVID-19.
4. Inconclusive is defined as an indeterminate result on a single or multiple real-time PCR target(s) and is not detected or remains indeterminate by an alternative real-time PCR assay or without sequencing confirmation, or a positive test with an assay that has limited performance data available.
5. An indeterminate result on a real-time PCR assay is defined as a late amplification signal in a real-time PCR reaction at a predetermined high cycle threshold (Ct) value range (note: Ct values of an indeterminate range vary by assay and not all assays have an indeterminate range). This may be due to low viral target quantity in the clinical specimen approaching the limit of detection of the assay, or alternatively in rare cases may represent nonspecific reactivity (false signal) in the specimen. When clinically relevant, repeat testing is recommended.
6. All positive results (preliminary and final) issued from point-of-care assays are reportable to public health. Parallel/repeat specimens for confirmation through standard laboratory-based testing should be obtained for all preliminary point-of-care testing until further evaluation of their test performance. Final case status (Confirmed or Does Not Meet Case Definition) should be based on the confirmatory laboratory-based test result. If no parallel/repeat specimen is collected, the case status should remain as probable. Under specific scenarios (see Provincial Testing Guidance), final results can be issued from certain Ministry of Health approved point-of-care assays that have been evaluated, and do not require further testing for confirmation Additional testing may be recommended to guide case and public health management.

7. Laboratory tests are evolving for this emerging pathogen, and laboratory testing recommendations will change accordingly as new assays are developed and validated.
8. Some hospital and community laboratories have implemented COVID-19 testing in-house and report final positive results, which is sufficient for case confirmation. Other hospital and community laboratories will report positives as preliminary positive during the early phases of implementation and will require confirmatory testing at another licenced laboratory with a validated SARS-CoV-2 NAAT assay, which can be a community, hospital or reference laboratory (e.g. Public Health Ontario Laboratory or the National Microbiology Laboratory).
9. Information on symptoms compatible with COVID-19 illness and provincial testing guidance are available on the Ministry of Health's website.
10. Affected areas are updated regularly in the World Health Organization's Situation Reports. Current epidemiology in Canada is available through the Public Health Agency of Canada. For affected areas in Ontario, please refer to COVID-19 Response Framework: Keeping Ontario Safe and Open
11. Only results from a laboratory in Ontario that is licensed to conduct serology testing AND where testing is done for clinical purposes will be reported to the Medical Officer of Health and used for case classification.
12. COVID-19 antibody testing should not be used as an acute screening or diagnostic tool or used to determine a patient's immune status, vaccination status, or infectivity. Results should be interpreted in the context of the clinical and exposure history. Serology testing should not be used for patients who have been previously diagnosed with COVID-19 or who have received a SARS-CoV-2 vaccination.
13. Any case classified as probable based on a high risk exposure (i.e. close contact) or exposure to a known cluster or outbreak , which subsequently tests negative/not detected for the SARS-CoV-2 virus should no longer be classified as a probable case. Exceptions may be made for negatives on a compromised sample or if NAAT testing is delayed (e.g. >10 days following symptom onset), whereby such persons remain as probable cases.