

# Case Definition - Coronavirus Disease (COVID-19)

These case definitions are for surveillance purposes and they are current as of January 17, 2022. 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

#### AND:

- a. Had high-risk exposure (i.e. close contact) with a confirmed case of COVID-19 (see footnote 1); OR
- b. 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 has not been completed (see footnote 9); **OR**
- 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 7, 8).

#### OR

2- Has symptoms compatible with COVID-19

#### AND

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 was inconclusive (see footnotes 2, 3);

#### OR

3- Is asymptomatic

#### **AND**

- a. Had high-risk exposure (i.e. close contact) with a confirmed case of COVID-19 (see footnote 1); OR
- b. Was exposed to a known cluster or outbreak

#### AND:

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 is inconclusive (see footnotes 2. 3).



## B. Confirmed Case

A person with 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 5, 6).

OR

2- A validated POC NAAT that has been deemed acceptable by the Ontario Ministry of Health to provide a final result (see footnote 4).

OR

3- Demonstrated seroconversion within a 4 week interval in viral specific antibody in serum or plasma using a validated laboratory-based serological assay for SARS-CoV-2 (see footnote 7).

## C. Laboratory-Based Case of Reinfection

A previously cleared confirmed case of SARS-CoV-2 (see footnote 10) that has a subsequent confirmed infection with SARS-CoV-2 where there is laboratory evidence supporting that these were separate infections caused by different viral lineages (see footnote 11). Laboratory evidence includes:

1- Genome sequencing or Variant of Concern (VOC) screening PCR testing indicates two distinct SARS-CoV-2 infections, as described by identification of i. different genetic lineages or ii. the same lineage but contain sufficient single nucleotide/mutation variation to support two different infections (see footnotes, 12, 13, 14).

OR

2- One of the infections was confirmed to be a variant of interest (VOI)/VOC or the isolate contains mutations associated with VOI/VOC based on genome sequencing or VOC PCR testing (see footnote 14) **AND** the other infection occurred when the VOI/VOC was not circulating in Canada (see footnote 15).



## D. Time-Based Case of Reinfection

A previousy cleared confirmed case of SARS-CoV-2 (see footnotes 10, 16) that has a subsequent confirmed infection of SARS-CoV-2 at least 90 days after the previous infection using episode date (see footnote 17, 18)

#### AND

Does not meet the laboratory based case of re-infection definition.

## **Definition Footnotes**

- 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 <u>Ministry guidance on cases and</u> <u>contacts of COVID-19</u>.
- 2. 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, without sequencing confirmation, or a positive test with an assay that has limited performance data available.
- 3. 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.
- 4. All positive results issued from molecular point-of-care assays are reportable to public health. Final results can be issued from certain Ministry of Health approved point-ofcare assays that have been evaluated, and do not require further testing for confirmation (see <u>COVID-19 Integrated Testing & Case, Contact and Outbreak</u> <u>Management Interim guidance: Omicron Surge</u>). Additional testing may be recommended to guide case and public health management.
- 5. Laboratory tests continue to evolve, and laboratory testing recommendations will change accordingly as new assays are developed and validated.
- 6. Some hospital and community laboratories have implemented COVID-19 testing inhouse 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 (PHOL) or the National Microbiology Laboratory).



- 7. 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.
- 8. 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 routinely used for patients who have been previously diagnosed with COVID-19 or who have received a SARS-CoV-2 vaccination.
- 9. 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 SARS-CoV-2 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.
- 10. For clearance definitions refer to the <u>COVID-19 Intergrated Testing & Case, Contact and Outbreak Management Interim Guidance: Omicron Surge</u>
- 11. A viral lineage is a group of viruses defined by a founding variant and its descendants.
- 12. Where there is no suspected contamination in the primary or secondary infection specimen (i.e. did not contain two virus subpopulations by genome sequencing or VOC PCR testing).
- 13. When reinfection confirmation is based on detection of mutation(s) associated with a variant of concern (VOC) using VOC mutation real-time PCR testing in one of the infection episodes and not in the other episode, both specimens MUST have been screened for the same mutation(s) to ensure there has been a change in mutation status from one episode to the next.
- 14. VOC PCR results are consistent with VOC detection based on current epidemiology as indicated in the lab report (e.g., S gene target failure (SGTF) on the TaqPath™ assay for Omicron, N501Y-negative/E484K-negative for Delta, etc.).
- 15. Refer to the national genomic surveillance dataset on the <u>Public Health Agency of Canada Re-infection case definition</u> for dates of first detection of a particular VOC in Canada. This dataset is updated on a monthly basis.
- 16. Public health or clinical judgement should be used to rule out situations where a possible reinfection has been attributed to prolonged viral shedding (i.e., consider if prolonged viral shedding is more likely than re-infection).
- 17. If case is symptomatic, then episode date uses symptom onset date. If symptom onset date is unavailable or the case is asymptomatic, then the earliest of the following dates could be used as proxy for classification: laboratory specimen collection date, laboratory testing date or reported date.
- 18. The judgement of a Medical Officer of Health or relevant public health authority may be used to identify reinfection cases based on new exposures or symptoms if the time-based case of reinfection criteria are not met. For example, if there is high suspicion of reinfection within 90 days of the previous infection using episode date consider requesting genome sequencing or VOC PCR (if not already done) and follow laboratory-based case of reinfection criteria.