

Appendix 9: Management of Individuals with Point-of-Care Results

Some point-of-care (POC) assays, both nucleic acid amplification tests (NAAT) and antigen tests, are now approved for use by Health Canada and available in Ontario. POC testing refers to rapid testing on a device approved for use by Health Canada and is also referred to as 'rapid testing'. This Appendix to the [Management of Cases and Contacts of COVID-19 in Ontario](#) provides information on the public health management of SARS-CoV-2 results from POC tests.

Notification to the Public Health Unit

- A positive result issued from a POC assay should be considered a **preliminary positive result**. Certain operators of COVID-19 POC tests must report all positive test results to the local Public Health Unit (PHU) in which the person from whom the specimen was taken resides.
 - Physicians and practitioners are required under section 25 of the [Health Protection and Promotion Act](#) to report positive COVID-19 test results as soon as possible after the positive test result is obtained
 - Laboratory operators are required under section 29 of the [Health Protection and Promotion Act](#) to report positive COVID-19 test results as soon as possible after the positive test result is obtained.
- Where possible, results from POC assays will be entered into the Ontario Laboratory Information System (OLIS) for reporting to the PHU through Case and Contact Management. If OLIS entry is not possible, operators (named under the Act) must report preliminary positive results directly to the local PHU through an alternate means (e.g., electronic fax).

Confirmatory Testing for POC Assays

- In the initial evaluation phase of some POC assays in Ontario, parallel testing with a second swab obtained at the time of POC testing will occur in a laboratory that is part of the provincial COVID-19 testing network.
- All preliminary positive COVID-19 POC test results require confirmatory testing at a licensed laboratory with a specimen ideally collected at the same time as the POC test specimen, or ≤ 24 hours of the POC specimen. Some preliminary

negative results may also require confirmatory testing during the evaluation phase.

- If a confirmatory laboratory-based NAAT is **not performed**, an individual with a positive POC test result should remain a probable case.
- If a confirmatory laboratory-based NAAT is performed and is **positive** (specimen collection at any point after the POC test), the individual should be considered a confirmed case.
- If a confirmatory laboratory-based NAAT is performed and is **negative** (specimen collection ≤ 24 hours from the POC test), the individual should be considered 'does not meet' case definition. A negative confirmatory result from a specimen collected > 24 hours from a positive POC test may reflect an actual change in case status and the individual should remain a probable case.
 - Negative confirmatory laboratory-based NAAT specimens collected > 24 hours from the POC specimen should be interpreted in the context of the time between the initial preliminary positive and specimen collection for the confirmatory test and the pre-test probability of the individual. (See below for public health management)
- After the initial evaluation phase, guidance may be updated to no longer require parallel confirmatory testing for all POC results from specific assays. Due to differing performance among different assays using the same technology, this analysis will be required for each individual POC nucleic acid or antigen detection assay.

Case Classification

- A preliminary positive result issued from a Health Canada approved POC assay should be classified as a **probable case**.
- Parallel specimens for confirmation through standard laboratory-based testing should be obtained for preliminary positive results from POC assays until further evaluation of their test performance.
- Final case status (Probable, Confirmed or Does Not Meet Case Definition) should be based on the parallel confirmatory laboratory-based test result, and the timing of that specimen relative to the initial specimen collection (see Table 1).

Table 1: Classification of Individuals with Preliminary Point-of-Care Results and Private Testing Results based on their Confirmatory laboratory result

Preliminary result	Initial Case Classification	Confirmatory laboratory NAAT result*	Confirmatory specimen obtained ≤ 24 hours after specimen for preliminary result	Final case classification
Positive	Probable	Positive	Yes or No	Confirmed case
Positive	Probable	Negative	Yes	Does not meet case definition
Positive	Probable	Negative	No	Probable case**
Positive	Probable	Not performed or Invalid	N/A	Probable
Negative	Does not meet case definition	Negative	Yes or No	Does not meet case definition
Negative	Does not meet case definition	Positive	Yes or No	Confirmed case
Negative	Does not meet case definition	Not performed or Invalid	N/A	Does not meet case definition

* If Confirmatory test is 'indeterminate', follow public health case and contact management guidance on the management of indeterminate results.

** Negative confirmatory laboratory-based specimens collected >24 hours after preliminary positive specimen should be interpreted in the context of the time between the initial preliminary positive and confirmatory specimen, and the pre-test probability of the individual based on their clinical and epidemiological context.

Public Health Management

- A preliminary positive result from a Health Canada approved POC assay should be considered a **probable case** of COVID-19 and PHUs should initiate case and contact management while awaiting confirmatory test results.
 - Probable cases should be advised that confirmatory testing is pending, and if confirmatory testing is negative, they may discontinue self-isolation as per the [Quick Reference Guidance on Testing and Clearance](#). If the individual was tested as a close contact, they should continue to self-isolate for 14 days from last exposure.
 - Contacts of these probable cases should be advised that confirmatory testing is pending, and if confirmatory testing is negative, they may no longer be considered a contact and can discontinue self-isolation.
 - Preliminary positives should initiate outbreak assessment/management actions as appropriate to the case and context, and in a manner that they may be quickly discontinued if confirmatory testing is negative.
- If confirmatory testing is negative, from a specimen obtained ≤ 24 hours after the specimen was obtained for the preliminary positive result, PHUs should update the case classification from probable to '**Does not meet**' case definition and case and contact management can be discontinued.
- Confirmatory testing that is negative, and **obtained >24 hours** after a preliminary positive specimen, may represent a true change in case status (positive to negative), or that the preliminary positive was a false positive. Interpretation and subsequent case management should be based on the context of the case, and their clinical and epidemiological situation.
 - Individuals who were **symptomatic at/around the time of initial testing**
 - In general, continue management as a probable case as a change in case status (positive to negative) cannot be excluded, including continuation of case isolation and contact self-isolation.
 - Individuals who were tested as an **asymptomatic contact with high risk exposure** to a case AND remain asymptomatic:

- If specimen collection was ≤ 24 hours of the initial preliminary positive, can discontinue public health management as a probable case, including contact self-isolation. However, the individual should continue to self-isolate based on their exposure to a case. Case classification should be updated to 'does not meet' case definition.
- If specimen collection was > 24 hours after initial preliminary positive, in general, case and contact management as a probable case should be continued as a change in case status cannot be ruled out. However, based on the clinical and epidemiological context of the case and their overall pre-test probability, case status could be updated to 'does not meet' case definition based on a negative confirmatory specimen collected > 24 hours after the initial preliminary positive specimen.