

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

Version 4.0 March 23, 2021

Key Updates

- Updated guidance on use of certain Health Canada-approved molecular COVID-19 POCT tests in the laboratory setting (page 2)
- Updated Table 1 to clarify that when GeneXpert® is used as a validated assay in a licensed laboratory, confirmatory testing is not required (page 5)

Point-of-care testing (POCT) refers to testing that employs a COVID-19 medical device authorized by the Minister of Health (Canada) for point-of-care use and is also referred to as 'rapid testing'. Some POCT assays, both molecular and antigen tests, are now approved for use by Health Canada and available in Ontario. 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 POCT assays.

Notification to the Public Health Unit

- A positive result issued from an **antigen** POCT assay is considered a **preliminary positive result** and must be reported to the local public health unit (PHU), in accordance with the [Health Protection and Promotion Act](#).
- Where a Health Canada approved **molecular POCT** assay has been reviewed and approved for final reporting by the Ministry of Health, results can be issued and reported to the local public health unit as **final**.
 - See Table 1 below for the specific clinical scenarios where a POCT final report can be issued. Molecular POCT assays currently being deployed by the Ministry of Health include: GeneXpert® Xpress SARS-CoV-2 and ID NOW™ COVID-19.

- Certain Health Canada-approved molecular COVID-19 POCT tests are also Health Canada approved for use in the laboratory setting. When such assays are used as laboratory-based NAATs, confirmatory testing is not required, provided performance characteristics are deemed acceptable by the testing laboratory during validation to ensure accurate results and patient safety.
- All positive molecular COVID-19 POCT results must be reported to the local PHU in which the person from whom the specimen was taken resides, in accordance with the [Health Protection and Promotion Act](#).
- Physicians and practitioners performing antigen or molecular COVID-19 POCT are required under section 25 of the [Health Protection and Promotion Act](#) to report positive COVID-19 test results, including a preliminary positive result from antigen POCT, 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 determined.
- Where possible, results from molecular COVID-19 POCT should be entered into the Ontario Laboratories Information System (OLIS) for reporting to the PHU through Case and Contact Management. If OLIS entry is not possible, individuals performing COVID-19 molecular POCT must report all positive results directly to the local PHU through an alternate secure manner (e.g., electronic fax).

Confirmatory Testing for POCT Assays

- Any positive **antigen** COVID-19 POCT result is considered preliminary, regardless of the setting it is obtained in, and requires additional testing such as parallel (i.e. dual swab collection at the same time as POC specimen collection) or repeat (i.e. subsequent swab collection following POC testing) testing using a laboratory-based nucleic acid amplification test (NAAT).
- Health Canada-approved molecular COVID-19 POCT for which positive results have been approved as final by the Ministry of Health do not necessarily require confirmatory testing, and are sufficient for classifying the case as 'confirmed'. However, additional testing may be recommended for further clinical/public health management of the case (see Table 1 below).

- **Additional testing using a laboratory-based NAAT is recommended in the following scenarios:**
 - **Negative** molecular POCT result in **high** pre-test probability settings. These include :
 - persons (symptomatic or asymptomatic) who are contacts of confirmed cases;
 - symptomatic persons tested when community prevalence is high (e.g. >10% of NAAT tests are SARS-CoV-2 positive);
 - symptomatic persons beyond the early phase of illness (e.g., beyond 7 days of symptom onset).
 - **Positive** molecular COVID-19 POCT result in symptomatic or asymptomatic persons in an **isolated or remote** community for which the positive molecular COVID-19 POCT result is the first recent positive case identified in the community.
 - All POCT done in the setting of an **outbreak**, including symptomatic or asymptomatic patients. Parallel collection should be performed in this scenario.
- For more guidance on interpretation of POCT results and when parallel or subsequent repeat testing is recommended, see the MOH's [COVID-19 Quick Reference Public Health Guidance on Testing and Clearance](#) and the [COVID-19 Provincial Testing Guidance Update](#).

Case Classification

- Additional testing for confirmation through standard laboratory-based NAAT testing should be obtained for preliminary positive results from antigen COVID-19 POCT assays until further evaluation of their test performance.
- Final case status (Probable, Confirmed or Does Not Meet Case Definition) should be based on the confirmatory laboratory-based NAAT result, and the timing of that specimen relative to the initial specimen collection (see Table 1 below).

Table 1: Interpretation and Classification of Results from Molecular Point-of-Care Testing (POCT) Assays Approved for Final Reporting

Clinical/Exposure History	Final Molecular POCT Result*	Initial Case Classification	Confirmatory laboratory NAAT result****	Final Case Classification
Symptomatic individual without known contact with a positive case (includes school-aged children with 1 or more symptoms)	Positive	Confirmed	Not required, but if collected and indeterminate	Confirmed case
			Not required, but if collected within 24 hours of POC test and is negative***	Does not meet case definition
	Negative	Does not meet case definition**	Not required, but if collected and is positive	Confirmed case
			Not required, but if collected and indeterminate	Probable case
			Not required, but if negative or invalid	Does not meet case definition
	Any individual (symptomatic or asymptomatic) with known contact with a positive case	Positive	Confirmed	Not required, but if collected and is positive, indeterminate, or invalid
Not required, but if collected within 24 hours of POC test and is negative***				Does not meet case definition
Negative		N/A	Confirmatory testing is required, and if positive	Confirmed case
			Confirmatory testing is required, and if not performed or indeterminate repeat confirmatory testing	N/A - Individual would remain as a contact until repeat test result is available

Clinical/Exposure History	Final Molecular POCT Result*	Initial Case Classification	Confirmatory laboratory NAAT result****	Final Case Classification
Asymptomatic individual without known contact with a positive case	Positive	Probable	Confirmatory testing is required, and if positive	Confirmed case
			Confirmatory testing is required, if collected within 24 hours of POC test and is negative***	Does not meet case definition
			Confirmatory testing is required and is indeterminate or invalid	Probable case
	Negative	N/A	N/A	Does not meet case definition

* If POCT result is 'invalid', repeat testing as per manufacturer's direction

**Consideration should be given to clinical and/or exposure history, disease prevalence in the community, and the risk/vulnerability of the population to determine if confirmatory testing is warranted in these scenarios.

*** Confirmatory testing that is negative, and obtained >24 hours after a positive POCT specimen, may represent a true change in case status (positive to negative), or that the POCT positive result was a false positive. Interpretation and subsequent case management should be based on the context of the case, and their clinical and epidemiological situation.

**** When GeneXpert® is used as a validated assay in a licensed laboratory, confirmatory testing is not required.

Table 2: Interpretation and Classification of Results from Antigen Point-of-Care Testing (POCT)

Description	Antigen POCT Result*	Initial Case Classification	Confirmatory Laboratory NAAT Result**	Confirmatory specimen obtained ≤24 hours after specimen for preliminary result	Final Case Classification
Asymptomatic individual without known contact with a positive case (screening test)	Positive	Probable	Positive	Yes or No	Confirmed case
			Negative	Yes	Does not meet case definition
			Negative	No	Probable***
			Not performed or invalid	N/A	Probable
	Negative	Does not meet case definition	Not required or recommended, but if collected and test is negative	Yes or No	Does not meet case definition
			Not required or recommended, but if collected and test is positive	Yes or No	Confirmed case

* If POCT result is 'invalid', repeat testing as per manufacturer's direction

** 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 **final positive** result from a Health Canada approved molecular COVID-19 POCT assay should be classified as a **confirmed case** of COVID-19 and PHUs should conduct case and contact management.
- A **positive result** on a serology POCT does not need to be reported to or actioned by the PHU.
- A **preliminary positive** result from a Health Canada approved antigen COVID-19 POCT 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](#).
 - 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.