

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

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Key Updates

- Positive molecular POCT results can be used as confirmatory testing for asymptomatic individuals who tested positive on a rapid antigen screening test.

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

- 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 molecular tests, 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 molecular COVID-19 POCT 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 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. Where OLIS is not available, results should be reported as per Ontario Health guidelines and in accordance with the Health Protection and Promotion Act. Individuals performing COVID-19 molecular POCT (except for molecular self-tests) 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 confirmatory 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 POCT) testing using laboratory-based molecular testing or rapid molecular COVID-19 POCT.
- 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 molecular test 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).
- Persons with **positive antigen** COVID-19 POCT result followed by a **negative molecular** COVID-19 POCT result.
- **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 molecular testing or a rapid molecular COVID-19 POCT should be obtained for all positive results from **antigen** COVID-19 POCT assays.
- Case status (Probable, Confirmed or Does Not Meet Case Definition) is mostly based on the confirmatory laboratory-based molecular test 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 ¹	Initial Case Classification	Confirmatory laboratory Molecular Test Result ²	Final Case Classification
<u>Symptomatic individual</u> without known contact with a positive case (includes school-aged children with 1 or more symptoms)	Positive	Confirmed	Not required ³	Confirmed case
	Negative	Does not meet case definition ⁴	Not required ³	Does not meet case definition
Any individual (symptomatic or asymptomatic) with known contact with a positive case	Positive	Confirmed	Not required ³	Confirmed case
	Negative	N/A as confirmatory testing is required	Positive	Confirmed case
			Negative	Does not meet case definition
Indeterminate	Probable case			

¹ If POCT result is 'invalid', repeat testing as per manufacturer's direction

² When GeneXpert® is used as a validated assay in a licensed laboratory, confirmatory testing is not required.

³ If laboratory-based molecular testing was performed on a specimen obtained within 48 hours of the POCT specimen, then the result of the former laboratory-based test should be used to determine final case classification instead of the POCT result. The laboratory-based molecular test overrules that of the POCT (even if considered final, and regardless of whether the POCT result was positive or negative)

⁴ Consideration should be given to clinical and/or exposure history, vaccination status, disease prevalence in the community, and the risk/vulnerability of the population to determine if confirmatory testing is warranted in these scenarios.

Clinical/Exposure History	Final Molecular POCT Result ¹	Initial Case Classification	Confirmatory laboratory Molecular Test Result ²	Final Case Classification
Asymptomatic individual without known contact with a positive case (screening test)	Positive	Probable Confirmatory testing is required	Positive	Confirmed case
			If collected within 48 hours of POC test and is negative ⁵	Does not meet case definition
			Indeterminate	Probable case
	Negative	Does not meet case definition	Not required	Does not meet case definition
Asymptomatic individual obtaining confirmatory testing due to a positive rapid antigen screening test	Positive	Confirmed	Not required ³	Confirmed case
	Negative	N/A Confirmatory testing is required	Positive	Confirmed case
			If collected within 48 hours of POC test and is negative ⁵	Does not meet case definition
			Indeterminate	Probable Case

⁵ Confirmatory testing results that are negative, and obtained >48 hours after a positive POCT specimen, may represent a true change in case status (positive to negative), or may indicate that the POCT positive result was a false positive. The interpretation and subsequent case management should be based on the context of the case, and their clinical and epidemiological situation.

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

Description	Antigen POCT Result*	Confirmatory Result**	Final Case Classification
Asymptomatic individual without known contact with a positive case (screening test)	Positive	Positive molecular test	Confirmed case
		Negative laboratory-based molecular test	Does not meet case definition (individual never reported to health unit)
		Negative molecular POCT	Confirmatory laboratory-based molecular test required
		Not performed	N/A
	Negative	Not required or recommended, but if collected and test is negative	Does not meet case definition
		Not required or recommended, but if collected and test is positive	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 [guidance on the management of indeterminate results](#).

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.
- Positive results from antigen POCT assays are not reported to public health and not considered probable cases for surveillance purposes. Individuals with positive antigen results are required to self-isolate immediately and obtain confirmatory laboratory-based PCR testing or molecular COVID-19 POCT (as outlined in Tables 1 and 2). They should remain in isolation until they receive a negative confirmatory result by laboratory-based molecular testing OR have completed 10 days of isolation from the positive antigen result as per the [Quick Reference Guidance on Testing and Clearance](#).
- If confirmatory laboratory-based molecular testing is negative, from a specimen obtained ≤48 hours after the specimen was obtained for the preliminary positive molecular POCT, PHUs should update the case classification from probable to '**Does not meet**' case definition and case and contact management can be discontinued.
- Confirmatory laboratory-based molecular testing that is negative, and **obtained >48 hours** after a preliminary positive molecular POCT or an antigen POCT specimen, may represent a true change in case status (positive to negative), or may still indicate that the preliminary positive or antigen 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. As confirmatory testing is required for all positive antigen tests and for positive molecular tests from asymptomatic individuals with no known exposures, a negative laboratory-based molecular confirmatory result obtained >48 hours after POCT is generally sufficient to consider as not a case.
- Individuals who were tested as an asymptomatic contact with high risk exposure to a case AND remain asymptomatic AND had an indeterminate result on confirmatory testing: Case and contact management as a probable case should be continued including continuation of case isolation and contact self-isolation.