

Northern Health Medical Health Officer Position Statement on the use of rapid antigen detection (RAD) tests for SARS-CoV-2 (COVID-19) detection in industrial settings

January 2021

Background

Testing modalities: PCR vs RAD

Polymerase chain reaction (PCR) testing on an appropriate respiratory sample, such as a nasopharyngeal swab or saline gargle, remains the gold standard for diagnosis of SARS-CoV-2 infection. It is very sensitive and accurate, and is the best method for diagnosing COVID-19 infection in people with new symptoms. All suspected COVID-19 cases must be confirmed by a PCR test.

However, when used outside the context of investigating COVID-19-like symptoms, PCR testing can over-diagnose recovered cases, who may continue to test positive for weeks or months after their initial infection, even though they are no longer infectious. A person may not be aware that they had a previous infection, especially if their initial symptoms were very mild and they were never tested. Outside the context of a known outbreak and no known community transmission, this the likeliest explanation for a positive result in an asymptomatic person.

RAD testing is somewhat less reliable, being more prone to false negatives and false positives. Any non-negative result and some negative results require confirmation using a subsequent PCR test (see below for when a negative RAD test result can be considered reliable). However, its advantages include that it provides more rapid results than PCR testing in settings that are remote from laboratories that can process PCR tests; and it is much less likely to over-diagnose non-infectious recovered cases in asymptomatic individuals.

Legal requirements for testing by private businesses

Requirements for testing go well beyond acquiring physical equipment approved by Health Canada. Testing is a medical procedure, and therefore must adhere to legal standards for health care. In particular, testing processes must ensure oversight by a medical provider licensed by the College of Physicians and Surgeons of British Columbia (CPSBC), appropriate clinical assessment, consent, accountability, technical quality assurance, documentation, privacy and confidentiality, and communication.

It is the responsibility of the health care provider and the business providing testing to become familiar with, and adhere to, applicable legal requirements. If testing services do not adhere to these requirements, legal liability and consequences may result.

Medical Health Officers are not the legal authority in this matter and are unable to provide detailed guidance. For information on legal requirements relating to COVID-19 testing, please consult the

CPSBC's Diagnostic Accreditation Program (DAP). See <https://www.cpsbc.ca/programs/dap/accreditation/laboratory-medicine> for details.

In addition, COVID-19 is a reportable communicable disease under BC's *Public Health Act*. This means that, by law, all positive results must be promptly reported to the local Medical Health Officer or their delegate. More information relating to this requirement is provided below.

Requirements for communication and coordination with NH and provincial public health systems

If a business chooses to implement a testing program, they must, at their expense, ensure that the process and infrastructure are integrated with provincial public health systems, and avoids any negative impact to these systems.¹ This is consistent with the guiding principle that industrial sites are self-sufficient with respect to their own health service needs to the greatest extent possible, and to minimize impacts to local health systems. As such, the business must assume responsibility for public health management among their workers, and demonstrate that these activities will be carried out to the satisfaction of NH. NH will review and provide ongoing support to the business partner.²

COVID-19 is a reportable communicable disease, meaning that under BC's *Public Health Act*, all positive test results must be reported to public health and must be followed up by regional public health authorities. Reporting to provincial public health ensures that public health authorities are able to maintain awareness of all COVID-19 cases and trends in the province, for public health management and reporting purposes. As RAD testing is an emerging technology, the BC Centre for Disease Control (BCCDC) may have additional reporting requirements that are not yet defined. Please ensure that you confirm reporting requirements with DAP and the BCCDC.

All positive results must be managed by the site's medical service provider per required public health follow-up and to the satisfaction of NH, inclusive of prompt notification of all positive test results to the individual and the local Medical Health Officer or their delegate, isolation of positive patients, confirmatory PCR testing, identification of close contacts, follow up with and isolation of close contacts, and active daily monitoring for the duration of the isolation period (inclusive of those who are isolating on and off employer-provided sites), and health care delivery to cases who are in employer-provided isolation sites, all in alignment with current best practices. Case management and contact tracing is to be done in accordance with provincial public health guidelines and is the legislated responsibility of the local Medical Health Officer to oversee. Business processes must be in

¹ See Dr. Bonnie Henry's June 17, 2020 letter re: PHO advice to businesses seeking to conduct private testing of asymptomatic employees (https://www2.gov.bc.ca/assets/gov/health/about-bc-s-health-care-system/office-of-the-provincial-health-officer/covid-19/pho_letter_testing_in_industry.pdf)

² See the case and contact management resource on the Office of Health and Resource Development's website (<https://www.northernhealth.ca/services/programs/office-health-and-resource-development# covid-19-communications-to-industry-partners>)

full alignment with British Columbia's current provincial public health guidance and any other quality standards established by NH.³

In the event of a cluster or outbreak of COVID-19 cases at the industrial site, the business must promptly provide NH with any other information deemed necessary by the Medical Health Officer in order to manage the situation.⁴

Position statements

Note: For clarity, the below position statements address the acquisition and use of technology to detect SARS-CoV-2 infection in workers by private businesses operating separately from the public health care system. These statements do not address workers in industrial sites being assessed by health care providers working in the public system, and having tests ordered and processed by public laboratories, but having test specimens physically collected at the industrial site. Guidance for the latter situation is discussed in a separate guidance document.⁵

A. Position on testing individuals with new COVID-19-like symptoms

All individuals with new COVID-19-like symptoms should be evaluated by a health care professional and tested by PCR in accordance with current provincial recommendations, available at <http://www.bccdc.ca/health-info/diseases-conditions/covid-19/testing/testing-information>. Such testing is available through the public system.

RAD testing may also be offered in industrial sites and camps (or similar congregate settings that are at risk of large outbreaks and are distant from laboratories that can process PCR tests) for the purpose of providing more rapid results than PCR testing.

However, **RAD testing must not replace PCR testing:** in many cases, confirmatory PCR testing is also required. The need for confirmatory PCR testing depends on the RAD test result, the individual's symptom and exposure history as determined by a health care professional, and the local epidemiological context:

- **All positive or indeterminate RAD test results must be confirmed with a PCR test.**
 - While the PCR test result is pending, symptomatic individuals with positive RAD test results should be managed as true infectious COVID-19 cases.
- **Negative RAD test results can be considered reliable (and PCR testing is unnecessary) only when all of the following conditions are met.** If these conditions are not met, a person with new COVID-19-like symptoms and a negative RADT result must still be tested by PCR testing before COVID-19 can be considered ruled out and isolation can be discontinued.

³ Northern Health has developed resources to support you. Please visit the Office of Health and Resource Development at <https://www.northernhealth.ca/services/programs/office-health-and-resource-development#covid-19-communications-to-industry-partners>

⁴ See BCCDC guidance on Protecting Industrial Camp Workers, Contractors, and Employers Working in the Agricultural, Forestry, Natural Resource Sectors During the COVID-19 Pandemic (http://www.bccdc.ca/Health-Info-Site/Documents/COVID_public_guidance/All-sector-work-camps-guidance.pdf)

⁵ See Northern Health's COVID-19 Testing in Industrial Camps: Guidance for camp operators (https://www.northernhealth.ca/sites/northern_health/files/services/office-health-resource-development/documents/COVID-19-industrial%20camps-testing-guidance.pdf)

1. The person has no specific history of recent COVID-19 exposure;
2. The person's symptoms are mild and non-specific, as determined by a health care professional; and,
3. The site is not in the midst of an outbreak or a large cluster.

Please note that as RAD testing for COVID-19 is a new technology, evidence and best practice recommendations will continue to evolve. If further guidance is published by BCCDC in the future on the subject of testing individuals with COVID-19-like symptoms, that guidance may complement or replace the guidance provided here.

B. Position on testing individuals with no symptoms (mass asymptomatic testing)

In the course of a cluster or outbreak investigation, a Medical Health Officer may order testing of various groups of people, including some who may be asymptomatic or presymptomatic, using either RAD or PCR testing.

Outside of that context, **mass asymptomatic testing has the following important risks:**

1. **Over-diagnosis of non-infectious, recovered cases:** This risk arises primarily with PCR-based tests. All positive results must be managed as if they are infectious. This will cause unnecessary operational impacts for the project, as the apparent case and all of their close contacts must be isolated. It also causes a considerable impact for Northern Health's public health team, who must carry out an investigation and meet additional communication demands. We are hopeful that the RAD test will be less problematic in this regard, given it is a less sensitive test than PCR.
2. **False sense of security from a negative test:** A person who tests negative can still develop active COVID-19 infection at any time. No test can detect COVID-19 during a person's "incubation period": the period between the time they were first exposed, and the time they become infectious and symptoms develop. This period can be up to 14 days long. However, many people mistakenly assume that a negative test means they are risk-free, and consequently they neglect to adhere to routine safety measures. This risk arises regardless of the type of test. Many outbreaks have occurred among groups of people who had all tested negative prior to arrival in a congregate setting because both the tested individuals and those responsible for overseeing the setting mistakenly assumed that the negative results meant there was little or no risk.

A comprehensive infection prevention and control plan that is well implemented, including effective mechanisms to detect individuals with symptoms and ensure they are isolated and tested, is the best defense against COVID-19. The additional benefit of routine mass testing is relatively small, but may provide a modest layer of additional protection in settings that are especially vulnerable to outbreaks, including industrial sites. However, because of the above risks, mass asymptomatic testing may do more harm than good. Therefore:

- **We recommend against asymptomatic PCR testing** except where specifically requested by a Medical Health Officer as part of a cluster or outbreak investigation.

- **Asymptomatic RAD testing is not routinely recommended, but may be considered if all of the following conditions are met:**
 1. The testing strategy is only one part of a comprehensive and effective COVID-19 infection prevention and control plan that is well implemented;
 2. The testing strategy includes effective measures to specifically mitigate the risks listed above;
 3. Confirmatory PCR testing for asymptomatic individuals who test positive as a result of a RAD mass asymptomatic testing program are processed through a private accredited laboratory, at no expense to NH or the public system in general;
 4. Testing is carried out in a manner that also meets the following best practice guidelines for COVID-19 testing at industrial sites.

Best practice guidelines for COVID-19 testing at industrial sites

Any business planning to implement independent COVID-19 testing at an industrial site must submit for approval a written plan to Northern Health's Office of Health and Resource Development, which meets the following requirements:

1. Adheres to all legal and regulatory requirements for diagnostic testing, as determined by the College of Physicians and Surgeons of BC (for the testing process) and Health Canada (for the technology).
2. Articulates clear goals, and specifies how testing and other infection control measures operate together to achieve those goals.
3. Articulates the roles and qualifications of the medical providers responsible for overseeing the use of the testing technology and the testing process overall, and of the medical providers ordering and collecting the tests on individuals.
4. Ensures NH is provided with up-to-date contact information and an organizational chart of who to contact at the site and/or the business for information about COVID-19 cases and contacts, including the most responsible clinician and operational directors.
5. Specifies how clinical assessment by health professionals will be used in conjunction with testing.
6. Identifies potential unintended consequences of inaccurate, misleading, or misunderstood test results, and articulates how those consequences will be mitigated.
7. Demonstrates a commitment to taking on primary responsibility, and articulates business strategies, to meet the requirements and coordination with NH and provincial public health systems (noted above).
8. Articulates clear processes for communicating with provincial public health and NH public health.
9. Provides a detailed communication plan of how positive test results and case assessment results are communicated to NH and BCCDC. Negative results should not be routinely communicated to NH unless specifically requested.
 - a. To report to NH, email your encrypted line list to CentralCDHub@northernhealth.ca, and copy resource.development@northernhealth.ca
 - b. Contact DAP or BCCDC to learn of the provincial reporting requirements.
10. Demonstrates how the privacy and confidentiality of COVID-19 cases and contacts will be protected.

11. Describes how, at all times, an up-to-date line list will be maintained (as per the template provided by Northern Health⁶) of all confirmed cases, close contacts, and symptomatic individuals awaiting testing or test results, and ensures this information is shared with NH in real time (within 24 hours of any significant update) and on a regular basis.
 - a. The individual(s) overseeing the line list must have a clinical background.
 - b. The line list must include all information on cases in accordance with current NH requirements, in a format specified by NH. Find the latest information at <https://www.northernhealth.ca/services/programs/office-health-and-resource-development>.
12. Demonstrates a commitment to provide NH with any other information deemed necessary by the Medical Health Officer in the event of a cluster or outbreak, to enable effective public health management of the situation.
13. If testing is conducted in a jurisdiction outside of BC and prior to workers' travel to BC, all of the same principles (best practices) apply,⁷ and:
 - a. The testing strategy must specify how impact on that local health jurisdiction will be minimized;
 - b. If a worker arrives in BC with a pending test result from another jurisdiction, any positive result that is subsequently received must also be reported to NH and the provincial public health systems by the business or their contracted medical service provider, just as if the test had been carried out in BC.

Additional resources

For further information, key guidance documents on COVID-19 testing include:

- National polymerase chain reaction (PCR) testing indication guidance for COVID-19 (Public Health Agency of Canada): <https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/guidance-documents/national-laboratory-testing-indication.html>
- Interim guidance on the use of rapid antigen detection tests for the identification of SARS-CoV-2 infection (Public Health Agency of Canada): <https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/guidance-documents/use-rapid-antigen-detection-tests.html>
- COVID-19 testing information for the public (BC Centre for Disease Control): <http://www.bccdc.ca/health-info/diseases-conditions/covid-19/testing/testing-information>
- COVID-19 testing information for health professionals (BC Centre for Disease Control): <http://www.bccdc.ca/health-professionals/clinical-resources/covid-19-care/covid-19-testing>
- COVID-19 testing in industrial camps: Guidance for camp operators (Northern Health): <https://www.northernhealth.ca/services/programs/office-health-and-resource-development>
- PHO advice to businesses seeking to conduct private testing of asymptomatic employees (Dr. Bonnie Henry, BC Provincial Health Officer, June 17 2020): https://www2.gov.bc.ca/assets/gov/health/about-bc-s-health-care-system/office-of-the-provincial-health-officer/covid-19/pho_letter_testing_in_industry.pdf

If you have further questions, or would like to discuss any of the above, please contact:

⁶ Access from <https://www.northernhealth.ca/services/programs/office-health-and-resource-development#covid-19-communications-to-industry-partners>

⁷ DAP accreditation is not required to test outside of BC, but we will seek to understand how the best practice principles are applied to testing strategies irrespective of where testing is completed.



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