

Guidance on Rapid Point-of-Care Diagnostic Testing for Rural, Remote, First Nations and Indigenous Communities

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This guidance is intended for those administering rapid point-of-care tests for diagnostic purposes in rural, remote, First Nations and Indigenous communities. It is based on known evidence as of March 01, 2022.

Contents

Introduction	2
Background	3
Use of Point-of-Care Tests	3
Overview of Available Point-of-Care Tests	5
Table 1: Point-of-Care Test Characteristics and Resources	5
Reporting Requirements.....	6
Informed Consent	6
Table 2: Pre-Test Likelihood, Result Interpretation and Follow-Up	7
Investigation of Clusters in Rural, Remote, First Nations or Indigenous Communities	9
Appendices.....	10
Appendix A: Information to be Provided to MHO to Facilitate Interpretation and Action	10
Appendix B: High-risk groups considered for COVID-19 therapies.....	11
Appendix C: References	13



Introduction

Guidelines for COVID-19 testing in British Columbia (BC) are periodically updated based on COVID-19 epidemiology, new clinical information, implemented public health measures, testing and contact tracing capacity, and evolving understanding of test performance in various settings. As a result, B.C. guidelines may differ from other national or provincial guidelines.

This guidance is for the use of point-of-care (POC) COVID-19 (SARS-CoV-2) to **assist with the diagnosis of symptomatic individuals within rural, remote, First Nations and Indigenous communities in B.C. where laboratory-based diagnostic testing is not readily available** (e.g., any situation where barriers or delays exist between testing and receipt of results by clients, or key decision-makers where applicable), and where a diagnosis informs the appropriate support and care of the individual and/or community.

This guidance is intended for trained individuals to use POC diagnostic testing with technology that has already been approved by Health Canada and that has undergone field and laboratory validation in B.C. or Health Canada.

These guidelines were developed in recognition of the challenges and barriers to accessing laboratory-based testing and care in remote, rural, First Nations and Indigenous communities. These guidelines also recognize the strength and resilience of First Nations and Indigenous communities, and the inextricable role of culture, ceremony, tradition, community and family togetherness as part of health and resilience. Led by Indigenous communities' identified needs, these guidelines intend to offer alternative pathways for Indigenous health leadership to bring COVID-19 testing closer to home. This document also recognizes that Indigenous peoples experience widespread, systemic racism and discrimination within the B.C. health care system and that this remains an ongoing barrier in Indigenous peoples' access to care.



Background

Timely testing and receipt of results for the diagnosis of acute COVID-19 infection continues to be an important part of B.C.'s COVID-19 pandemic response and transition into an endemic state. Delays between the time of sample collection to the receipt of results can occur in rural, remote, First Nations and Indigenous communities due to transport related issues, digital inequity, intermittent laboratory staffing and delays inherent to reporting pathways.

The focus of these guidelines is on the use of POC tests for diagnostic testing in **symptomatic** clients and detecting the presence and extent of clusters in remote, rural, First Nations and Indigenous communities.

Key benefits and risks to testing:

- Benefits: Rapidity, ease of use, accessibility, frequency.
- Risks: Compliance with public health measures can decrease due to a false sense of security based on results from a test with a lower sensitivity. Test performance may be lower if performed by untrained individuals.

NOTE: Clinical decisions for clients who present with shortness of breath or other features requiring possible transport to a medical centre should be based on clinical judgment and not COVID-19 testing. If medical transport is required, please call Patient Transfer Services at 1 866-233-2337.

Use of Point-of-Care Tests

The use of POC diagnostic testing for COVID-19 can improve the turnaround time of tests for **symptomatic** individuals, including those who present sporadically for care, thereby allowing for improved public health and medical management, including treatment, of the client.

COVID-19 POC tests generally have a reduced sensitivity compared to the standard PCR test. Therefore, the clinical signs and symptoms, local epidemiology, vaccination status, risk factors and reason for ordering the test may be factored into the interpretation of both positive or a negative test results and decisions for follow up.

- These diagnostic testing guidelines **are a support, and not a replacement**, for clinical judgement.
- Results from POC testing only identifies the presence of COVID-19 infection at the time the test is taken. Some clients may not have high enough viral load for detection within first 24 hours of symptom onset. Repeat testing is recommended, particularly if individuals are eligible for treatment or if they develop new or worsening symptoms.
- Any use of POC tests for diagnostic testing that is outside of this guideline should be discussed with an MHO or clinician responsible for COVID-19 testing prior to use.

Due to potential barriers to accessing care and laboratory-based testing, individuals who live or work in rural, remote, First Nations and Indigenous communities are recommended to receive testing if they have symptoms of COVID-19 infection, regardless of vaccination status or previous COVID-19 infection. For simplicity,



vaccination status has not been included in the pre-test likelihood, interpretation and actions of test results in Table 2 of these guidelines.

In rural, remote, First Nations or Indigenous communities with difficulty accessing NAAT-based testing¹ and secondary or tertiary care:

- Point-of-care programs may be set up in the following order of preference depending on the resources available:
 - Option 1 (Preferred): Trained testers to receive self-collected nasal swabs and perform POC testing within the community.
 - Option 2: Video observed self-collection and self-testing.
 - Option 3: Self-testing with telephone-guidance by a health-care professional or trained tester.
 - Option 4: Unobserved self-collection and self-testing.

- Test **symptomatic** individuals within the first five days of symptom onset in, but not limited to, the following scenarios:
 - Individuals who present sporadically for care.
 - Shelters or long-term care facilities.
 - COVID-19 exposure cases.
 - Returning international travelers.
 - A community with a cluster of individuals with symptoms. Identification of one or more of these being positive for COVID-19 allows detection of an outbreak.

¹ In the case of Abbott PanBio and BD Veritor, where NAT or Abbott ID Now testing is not readily available.



Overview of Available Point-of-Care Tests

The federal government has allocated and distributed a number of POC tests to B.C., including nucleic acid amplification (NAAT)-based tests:

- Abbott ID NOW™
- Lucira Checkit

And antigen-based tests:

- Abbott Panbio™
- Artron
- BD Veritor™
- SD Biosensor
- BTNX
- Roche

Additional tests may become available in the future. Validation studies have been performed on these commercial kits by the BCCDC PHL and/or the National Microbiology Laboratory and implementation guidance documents for all of these tests are developed by the BCCDC. POC tests are available for deployment to all health authorities, including the Provincial Health Services Authority (PHSA) and First Nations Health Authority (FNHA), and distribution is under the direction of medical officers or medical health officers (MHOs). Lucira has been specifically provided by the federal government for use in First Nations and Indigenous communities.

The sensitivity of NAAT-based tests are higher than those that can be obtained by the antigen-based tests and equivalent to PCR tests for viral load ranges that are associated with transmission.

Table 1: Point-of-Care Test Characteristics and Resources

Nucleic acid amplification test (NAAT)-based assays			
	Sensitivity*	Specificity*	Notes, instructions and training
Abbot ID Now	79.8%–96.2%	94.3%–100%	Requires an analyzer and trained operator
Lucira	91.7% (95% CI: 85.6%-95.8%)	98.2% (95% CI: 95.8%-99.4%)	Single sample vial and a test unit (analyzer). A nasal sample is collected and extracted in the sample vial
Antigen-based assays			
	Sensitivity	Specificity	Notes, instructions and training
Abbot Panbio	51.6%–100%	100%	Instructions and procedures for the Abbott Panbio™ Training videos for the Abbott Panbio™
BD Veritor	61.5%–92%	99.5%	Package of 30 tests and 30 buffer ampoules Instructions and procedures for the BD Veritor™ Training videos for the BD Veritor™ (Password BDVeritor123)
*Sensitivity and specificity values taken from various clinical validation studies.			

Information on the use of other rapid tests are available from BCCDC: [Rapid Antigen Testing for COVID-19](#).

Reporting Requirements

Negative results are not required to be reported (refer to Table 2 below).

Positive POC tests may be reported by those performing the tests via an [eform](#) for entry into the provincial lab information system. A [training video on use of the eform](#) is available from PHSA. Reporting positive POC tests performed by regulated health professionals via the [eform](#) fulfills their reporting requirements under the *Public Health Act* (Section 10).

Informed Consent

Clients must be advised that:

- They may need to either self-monitor or self-isolate based on [established recommendations](#) and those provided to them by public health. Relevant considerations may include but are not limited to their vaccination status, pre-test likelihood of having COVID-19 infection, if they are a contact of a confirmed COVID-19 case, recent travel and local COVID-19 epidemiology.
- Collection of additional test samples may be necessary as determined by the MHO and as outlined in this document.
- Clients must:
 - Wait or agree to return for the result.
 - Continue to self-isolate until they receive further guidance.

General Guidelines for Interpretation

- For more specific guidance, see Table 2 below.
- A positive test result is indicative of the presence of SARS-CoV-2 RNA infection. Clinical correlation with client history and other diagnostic information is required to determine the client's COVID-19 status.
- Confirmatory PCR testing following a positive rapid point-of-care test is not recommended unless under direction by the MHO.
- Considerations for a negative test:
 - A negative test result is a presumptive negative, but may be falsely negative.
 - Depending on the pre-test likelihood and the client's eligibility for [available COVID-19 treatments](#) (see Appendix B), consider NAT-based testing (if presenting within three days of symptom onset), repeat POC testing within 24 hours, or repeat POC testing with a different type of POC test.
 - A single negative POC test should not be used alone to rule out COVID-19 for the purpose of directing client care.



Table 2: Pre-Test Likelihood, Result Interpretation and Follow-Up

Step 1 of 2: Determine Pre-Test Likelihood of COVID-19 in Symptomatic* Client†

Low	Moderate	High
<p>One or more of:</p> <ul style="list-style-type: none"> • Fever or chills • Cough • Loss of sense of smell or taste • Difficulty breathing • Sore throat • Loss of appetite • Extreme fatigue or tiredness • Runny nose • Sneezing • Headache • Body aches • Nausea, vomiting or diarrhea <p>AND all of:</p> <ul style="list-style-type: none"> • No confirmed or suspected cases in community. • No cluster known in community. • Not a known close contact of a confirmed or suspected COVID-19 case. • No recent travel to areas or communities with widespread COVID-19 transmission 	<p>One or more of:</p> <ul style="list-style-type: none"> • Fever or chills • Cough • Loss of sense of smell or taste • Difficulty breathing • Sore throat • Loss of appetite • Extreme fatigue or tiredness • Runny nose • Sneezing • Headache • Body aches • Nausea, vomiting or diarrhea <p>AND Symptomatic cluster in community without confirmed cases.</p> <p>AND all of:</p> <ul style="list-style-type: none"> • Not a known close contact. • No known connections with a social circle of a cluster. <p>Note: May have travelled out of community <i>without</i> exposure to congregate setting or visiting others.</p>	<p>One or more of:</p> <ul style="list-style-type: none"> • Fever or chills • Cough • Loss of sense of smell or taste • Difficulty breathing • Sore throat • Loss of appetite • Extreme fatigue or tiredness • Runny nose • Sneezing • Headache • Body aches • Nausea, vomiting or diarrhea <p>AND one of:</p> <ul style="list-style-type: none"> • Known case contact (including household members). • Travel out of community with exposure to congregate setting or visiting others. • Connection within social circle of a cluster.

*The symptom lists presented are not exhaustive and should not be relied upon in lieu of clinical judgment, particularly in situations where clinical suspicion is high.

† For the purposes of simplicity and in recognizing the settings in which these guidelines are intended for use, vaccination status is not included in Table 2.



Step 2 of 2: Interpretation and Action of Results

Test result	Pre-test likelihood		
	Low	Moderate	High
Positive			
Interpretation	Consider whether could be false positive.	Positive.	Positive.
Actions	<ul style="list-style-type: none"> - Inform case to self-isolate and refer to http://www.bccdc.ca/health-info/diseases-conditions/covid-19/if-you-have-covid-19 for information on self-management and notifying contacts - Health-care provider to report via e-forms or fax to CD Hub - Call to MHO/CD team if cluster of positive cases 		
Negative			
Interpretation	Likely negative	Unknown whether COVID-19 case.	Unknown whether COVID-19 case.
Actions	<ul style="list-style-type: none"> - Repeat testing usually not required - Advise individual to follow strict mask adherence, practice good hand and respiratory hygiene, and to avoid high-risk settings and vulnerable individuals - Advise individual to re-test if new or worsening symptoms 	<ul style="list-style-type: none"> - Consider re-test within 48 hours if emergence of symptomatic cluster in community or individual's status as a contact changes - Advise individual to follow strict mask adherence, practice good hand and respiratory hygiene, and to avoid high-risk settings and vulnerable individuals - Advise individual to re-test if new or worsening symptoms - Consider call to MHO/CD team if symptomatic cluster. 	<ul style="list-style-type: none"> - Re-test within 48 hours - Advise individual to follow strict mask adherence, practice good hand and respiratory hygiene, and to avoid high-risk settings and vulnerable individuals - Consider call to MHO/CD team if symptomatic cluster.
	<ul style="list-style-type: none"> - For any negative rapid test result in an individual who is eligible for available COVID-19 treatments (see Appendix B) and who presents within the first 5 days of symptom onset, consider NAT-based testing, repeat rapid testing in 24 hours, or repeat rapid testing with a different type of rapid test 		
<p>Reminder:</p> <ul style="list-style-type: none"> - In all cases, maintain isolation based on symptoms and/or established self-isolation recommendations if individual is a contact or return traveler, NOT test results. - POC testing is a snapshot of the viral infection at that point in time. Re-evaluate and re-testing may be necessary based on symptoms/screening criteria/clinical judgment. - Assess client based on current pre-test likelihood if clinical situation changes (e.g., cases arise in community or symptoms worsen). - If whole genome sequencing is required, then a sample for NAT-based testing is required for POC positive cases. 			



Investigation of Clusters in Rural, Remote, First Nations or Indigenous Communities

POC testing can be used to assist in:

- Identifying the presence of SARS-COV-2 within a cluster of symptomatic cases (SARS-COV-2 is not known to be circulating in community).
- Providing a preliminary assessment of extent of outbreak (SARS-COV-2 is known to be circulating in community).

When using POC testing:

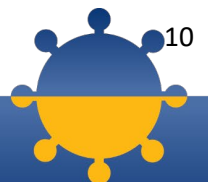
- Test everyone (or as many people as possible) in the cluster² with symptoms consistent with COVID-19.
 - A cluster may include those within a known social connection OR if in a relatively closed community (e.g., a remote community), amongst those where there is no apparent connection.
 - If a positive result arises within a symptomatic cluster, consider all symptomatic individuals to be epi-linked and commence second round of contact tracing (unless confirmatory testing available within 24 hours). Rapid implementation of second round contact tracing is particularly important in settings with over-crowding, difficulty with isolation or high vulnerabilities.

² Consider the potential for symptomatic individuals in community to be a part of a cluster for testing purposes, even where connections may not be immediately apparent.



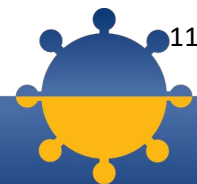
Appendix A: Information to be Provided to MHO to Facilitate Interpretation and Action

- Client symptoms and when they started
- Client COVID-19 vaccination status (self-reported or documented evidence)
- Geography of community (remote/isolated, rural or urban).
- Note any congregate settings (work, school, travel, other).
- Vulnerability of community (medical, social).
- Which rapid POC test was performed (to know performance parameters of test)
- Presence of other cases in community.
- Exposure history of individual.
- Contact with other cases.
- Nurse assessment.
- Intended use of the test result (screening, presumptive diagnosis, repeat).



Appendix B: High-Risk Groups Considered for COVID-19 Therapies

- **Unvaccinated or partially vaccinated individuals ≥ 60 years who are Indigenous**
- **Unvaccinated or partially vaccinated individuals ≥ 60 years with three or more chronic conditions/co-morbidities** (e.g., obesity, diabetes, heart failure, stroke, neurological conditions)
- **Unvaccinated or partially vaccinated individuals aged ≥ 70 years with one or more chronic condition/co-morbidity** (e.g., obesity, diabetes, heart failure, stroke, neurological conditions)
- **Immunocompromised individuals regardless of vaccine status or previous infection.** Generally, these are patients who:
 - Have received a solid organ transplant and are taking immunosuppressive treatment
 - Had a bone marrow or stem cell transplant
 - Are currently being treated for cancer, including haematological malignancies
 - Diagnosed with a moderate to severe primary immunodeficiency
 - Have untreated or advanced HIV ($CD4 \leq 200$ cells/mm³)
 - Are taking immunosuppressive treatment, such as high dose of steroids, biologics (e.g., adalimumab, etanercept, infliximab, interferon products), anti-CD20 agents (e.g., rituximab, ocrelizumab, ofatumumab, obinutuzumab, ibritumomab, tositumomab), B-cell depleting agents (e.g., epratuzumab, belimumab, atacicept, anti-BR3, alemtuzumab), or immunosuppressing agents (e.g., cyclophosphamide, cisplatin, methotrexate)
 - Patients who are on dialysis or have severe kidney disease who are also receiving any immunosuppressants
- **Unvaccinated or partially vaccinated individuals with high-risk conditions.** Generally, these are patients who:
 - Have Cystic fibrosis
 - Have severe COPD or asthma requiring hospitalization in the last year
 - Are on long-term home oxygen; assessment for a lung transplant; severe pulmonary arterial hypertension; severe pulmonary fibrosis/interstitial lung disease
 - Diagnosed with a rare blood disorder: urea cycle defects; methylmalonic aciduria; propionic aciduria; glutaric aciduria; maple syrup urine disease
 - Have had a splenectomy or have functional asplenia
 - Have Insulin-dependent diabetes
 - Have significant developmental disabilities: Down Syndrome, or Cerebral Palsy, or Intellectual Developmental Disability (IDD), or receiving supports from: Community Supports for Independent Living (CSIL) or Community Living British Columbia (CLBC)
 - Have cancer not captured by the CEV 1 and 2 category
 - Are pregnant and have a serious heart disease, congenital or acquired, that requires observation by a cardiologist throughout pregnancy
 - Have neurological or other conditions causing significant muscle weakness around lungs requiring the use of a ventilator or continuous Bi-level positive airway pressure (Bi-PAP)



- Are on dialysis or have stage 5 chronic kidney disease (eGFR \leq 15ml/min) Note: Dialysis and stage 5 CKD is classified as a CEV 2 for vaccine, but regarded as CEV 3 for treatment

Refer to [BCCDC Treatments](#) for further information on COVID-19 therapies and clinical practice guidelines.

Appendix C: References

Alberta Health Services. *COVID-19 Scientific Advisory Group Rapid Evidence Report*. Published November 6, 2020. Accessed Jan 29, 2021. <https://www.albertahealthservices.ca/assets/info/ppih/if-ppih-covid-19-sag-performance-and-feasibility-of-rapid-covid-19-tests-rapid-review.pdf>.

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