Interim Guidance on Point-of-Care Diagnostic Testing for Remote, Rural and Indigenous Communities

This guidance is intended for health-care providers. It is based on known evidence as of March 16, 2021.

Contents

Background ........................................................................................................................................ 2
Reporting Requirements ................................................................................................................... 3
Informed Consent ............................................................................................................................ 3
Use of Point-of-Care Tests ............................................................................................................... 4
Table 1: Pre-Test Likelihood, Result Interpretation and Follow-Up .................................................. 6
Investigation of Clusters in Rural, Remote or Indigenous Communities ........................................ 8
Appendices ....................................................................................................................................... 9
  Appendix A: Information to be Provided to MHO to Facilitate Interpretation and Action .......... 9
  Appendix B: References .................................................................................................................. 10
Guidelines for COVID-19 testing in British Columbia are periodically updated based on COVID-19 epidemiology, new clinical information, public health measures in place, 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 interim guidance is for health-care workers for the use of point-of-care (POC) COVID-19 (SARS-CoV-2) diagnostic testing to assist with the diagnosis of symptomatic individuals within rural, remote and Indigenous communities in B.C. where laboratory-based diagnostic testing is not readily available (e.g., any situation where unavoidable barriers or delays exist between testing and receipt of results by clients, or key decision-makers where applicable).

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

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. Delays between the time of sample collection to the receipt of results can occur in rural, remote and Indigenous communities due to transport related issues, poor connectivity, intermittent laboratory staffing and delays inherent to reporting pathways.

The federal government has allocated and distributed three types of POC tests to B.C.: Abbott IDNow nucleic acid amplification tests (NAT), Abbott PanBio antigen tests and BD Veritor antigen tests. The BCCDC public health laboratory (PHL) has performed validation and developed implementation guidance documents for these tests. All three POC tests are available for deployment to health authorities, including the Provincial Health Services Authority and First Nations Health Authority, and distribution is under the direction of medical officers or medical health officers (MHO).

The focus of these interim guidelines is on diagnostic testing in symptomatic clients and detecting the presence and extent of clusters in rural, remote 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.

**Abbott ID Now:** The ID Now test requires an analyzer and trained operator. Its overall sensitivity is 82.5% compared to NAT sensitivity of 98.4%. This assay was able to identify positive cases with NAT quantitative values of Ct values <30. No false positive cases were identified.

**Abbott PanBio™:** A clinical validation demonstrated the sensitivity of the NP Panbio™ ranged from 100%, when the Ct cut-off for COVID-19 positive NAT samples was ≤21, to 51.6%, when the Ct cut-off was <40.
Another study found the sensitivity of the nasal PanBio™ was 79.3%, when the Ct cut-off for COVID-19 positive NAT samples was ≤21, 83.8% when the Ct cut-off was <29 and 65.3% when the Ct cut-off was <40. The specificity was 100% for both.

**BD Veritor™**: The Veritor™ has reduced sensitivity compared to nucleic acid amplification tests. The sensitivity, as determined by the clinical validation, ranged from 92% when the Ct cut-off was ≤21 for all standard of care NAT positive samples, to 61.5%, when the Ct cut-off was <40. The specificity was found to be 99.5%.

**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.

**Reporting Requirements**

The following needs to be reported to the to the health authority communicable disease unit (CDU) or the MHO:

- All positive results as per usual processes for the geographic region.
- Negative results if moderate or high pre-test likelihood of COVID-19 (refer to table 1 below).

Negative results with low or lower pre-test likelihood are not required to be called to the MHO or CDU team (refer to table 1 below).

All positive POC tests must be registered via an eform for entry into the provincial lab information system.

- If the eform is not available, a hard copy of the results should be sent to the MHO or CDU team following a call.
- Reporting to the health authority MHO or CDU team is in addition to documentation in the client’s chart as per standard client documentation practice.

**Informed Consent**

Clients must be advised that:

- Regardless of test result, the requirement to self-isolate must be followed. The requirement to self-isolate is based on established recommendations, such as when an individual has symptoms, is a contact of a confirmed COVID-19 case or has returned from an overseas location.
- Collection of additional test samples may be necessary as determined by the MHO and as outlined in this document. **If the client does not agree to two (or more) samples, collecting one sample for standard NAT testing must be followed.**
- Clients must:
  - Wait or agree to return for the result. **If the client does not agree to wait or return, standard processes for NAT testing must be followed.**
  - Continue to self-isolate until they receive further guidance.
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 medical management of the client.
- More prompt contact tracing.
- Earlier determination of the existence and extent of an outbreak to facilitate early outbreak management.

It is important to note that, in general, most screening tests have a high sensitivity and reduced specificity. The COVID-19 POC tests have a reduced sensitivity and higher specificity compared to the standard PCR test. Therefore, the clinical signs and symptoms, risk factors and reason for ordering the test must 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 are a snapshot of the client at the time the test is taken.
- The client may not have high enough viral load for detection within first 24 hours of symptom onset. Repeat testing is recommended.
- Any use of POC tests for diagnostic testing that is outside of this interim guideline should be discussed with an MHO prior to use.

In rural, remote and Indigenous communities where NAT testing\(^1\) is not readily available or results are delayed:

- Test symptomatic individuals within first five to seven\(^2\) days of symptom onset in, but not limited to, the following scenarios in:
  - 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 public health to detect an outbreak.

General guidelines for interpretation:

- For more specific guidance, see table 1 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.
- A negative test result is a presumptive negative, but may be falsely negative.
- Considerations for a negative test:
  - A follow-up NAT test will be required in most clinical scenarios to confirm a negative result, OR repeating POC testing every one to two days, up to five days after symptom onset, if NAT follow up is not available.

---

1 In the case of Abbott PanBio and BD Veritor, where NAT or Abbott ID Now testing is not readily available.
2 Five days for Abbott PanBio and BD Veritor, 7 days for Abbott ID Now.
A single negative POC test should not be used alone to rule out COVID-19 for the purpose of directing client care.
## Table 1: Pre-Test Likelihood, Result Interpretation and Follow-Up

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

<table>
<thead>
<tr>
<th>Very low</th>
<th>Lower</th>
<th>Moderate</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td>All of:</td>
<td>One or more of:</td>
<td>One or more of:</td>
<td>One or more of:</td>
</tr>
<tr>
<td>- No confirmed or suspected cases in community.</td>
<td>- Fever or chills.</td>
<td>- Fever or chills.</td>
<td>- Fever or chills.</td>
</tr>
<tr>
<td>- No fever, cough, chills, loss of smell or taste, difficulty breathing.</td>
<td>- Cough.</td>
<td>- Cough.</td>
<td>- Cough.</td>
</tr>
<tr>
<td>- Symptom(s) &lt; 24 hours:</td>
<td>- Loss of sense of smell or taste.</td>
<td>- Loss of sense of smell or taste.</td>
<td>- Loss of sense of smell or taste.</td>
</tr>
<tr>
<td>- Sore throat</td>
<td>- Difficulty breathing.</td>
<td>- Difficulty breathing.</td>
<td>- Difficulty breathing.</td>
</tr>
<tr>
<td>OR</td>
<td>Two or more of the following symptoms for &gt; 24 hours:</td>
<td>Two or more of the following symptoms for &gt; 24 hours:</td>
<td>Two or more of the following symptoms for &gt; 24 hours:</td>
</tr>
<tr>
<td></td>
<td>- Sore throat.</td>
<td>- Sore throat.</td>
<td>- Sore throat.</td>
</tr>
<tr>
<td></td>
<td>- Extreme fatigue or tiredness.</td>
<td>- Extreme fatigue or tiredness.</td>
<td>- Extreme fatigue or tiredness.</td>
</tr>
<tr>
<td></td>
<td>- Body aches.</td>
<td>- Body aches.</td>
<td>- Body aches.</td>
</tr>
<tr>
<td></td>
<td>- Nausea, vomiting or diarrhea.</td>
<td>- Nausea, vomiting or diarrhea.</td>
<td>- Nausea, vomiting or diarrhea.</td>
</tr>
<tr>
<td>AND/OR Symptomatic cluster in community without confirmed cases.</td>
<td>AND:</td>
<td>AND:</td>
<td>AND:</td>
</tr>
<tr>
<td>AND All of:</td>
<td>Travel out of community with exposure to congregate setting or visiting others.</td>
<td>Travel out of community with exposure to congregate setting or visiting others.</td>
<td>Travel out of community with exposure to congregate setting or visiting others.</td>
</tr>
<tr>
<td>- Not a known close contact.</td>
<td>OR</td>
<td>OR</td>
<td>OR</td>
</tr>
<tr>
<td>- No known connections with a social circle of a cluster.</td>
<td>- Connection within social circle of a cluster.</td>
<td>- Connection within social circle of a cluster.</td>
<td>- Known case contact (including household members).</td>
</tr>
</tbody>
</table>

*The symptom lists presented are not exhaustive and should never be relied upon in lieu of clinical judgment, particularly in situations where clinical suspicion is high.*
## Step 2 of 2: Interpretation and Action of Results

<table>
<thead>
<tr>
<th>Test result</th>
<th>Pre-test likelihood</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Very low</td>
</tr>
<tr>
<td><strong>Positive</strong></td>
<td></td>
</tr>
<tr>
<td>Interpretation</td>
<td>Consider whether could be false positive.</td>
</tr>
<tr>
<td>Actions</td>
<td>- Report to MHO.</td>
</tr>
<tr>
<td></td>
<td>- Consider confirmatory NAT testing.</td>
</tr>
<tr>
<td><strong>Negative</strong></td>
<td></td>
</tr>
<tr>
<td>Actions</td>
<td>- Re-test once in one to two days.</td>
</tr>
<tr>
<td></td>
<td>- Consider confirmatory NAT testing if repeat testing not possible.</td>
</tr>
<tr>
<td></td>
<td>- Call to MHO/CD team not required.</td>
</tr>
</tbody>
</table>

**Reminder:**
- 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-test 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 testing is required for POC positive cases.
Investigation of Clusters in Rural, Remote 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 cluster\(^3\) 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.
- Consider parallel NAT tests (nasopharyngeal or gargle) every three days in parallel to daily POC tests in an outbreak investigation/ring screening.

\(^3\) 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.
Appendices

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

- Client symptoms and when they started.
- Geography of community (remote/isolated, rural or urban).
- Note any congregate settings (work, school, travel, other).
- Vulnerability of community (medical, social).
- Which 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: References


