

Interim guidance for self-collected specimens for acute COVID-19 diagnosis in settings without accessible health services

Updated: December 8, 2020

***Guidelines for COVID-19 testing in B.C. are updated based on changing epidemiology, testing capacity, validation of new test technologies or procedures, sample stability during transport and evolving understanding of test performance in clinical settings within the province. As a result, B.C. guidelines may differ from other national or provincial guidelines.***

***This guideline describes an overall provincial approach for supporting self-collection in settings without accessible health services. Where self-collection is available, and how these guidelines are implemented will be determined in collaboration with participating health authorities.***

## 1. Introduction

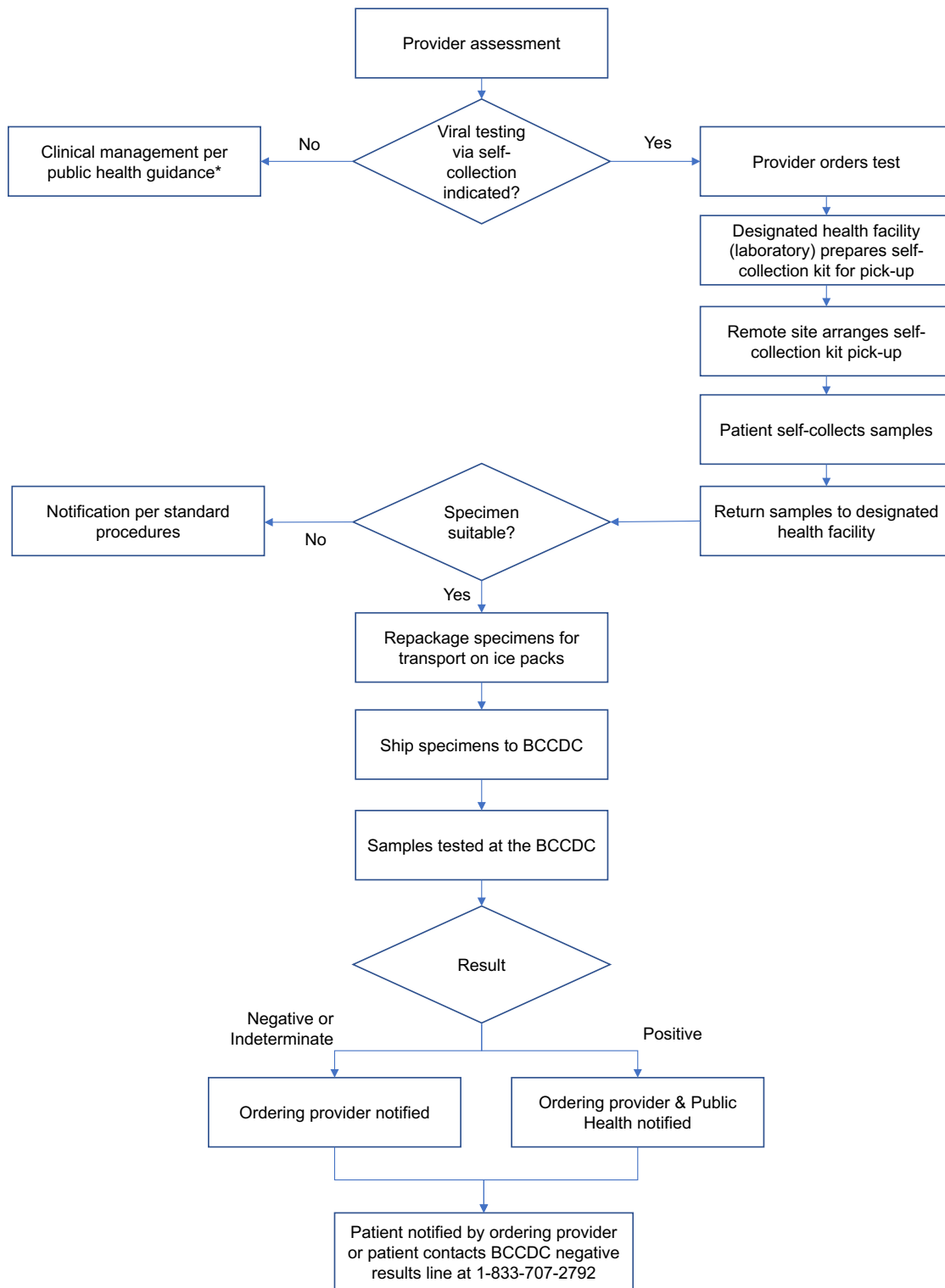
- Nucleic acid amplification testing (NAT) for the SARS-CoV-2 virus is the method currently available in B.C. for the diagnosis of COVID-19, which is most commonly performed on nasopharyngeal (NP) samples collected by health-care providers.
- The objective of this document is to provide guidance for specimen collection and diagnosis of acute COVID-19 infection in settings where health-care provider assisted or observed collections are not possible, such as remote work sites.
- Saline gargle is an approved alternative to NP swab collection when performed correctly with the assistance of a health-care worker. The quality assurance of unassisted self-collected saline gargle samples has not yet been fully evaluated. Therefore, the current recommendation for unassisted self-collection is to include additional samples from the throat and nostrils, in addition to saline gargle. This will improve overall virus detection, and support the validation of unassisted sample collection.
- For further information regarding the rationale for self-collection, please see Appendix A.

## 2. Overall approach

- The recommended approach is to provide a symptomatic patient with a specimen collection kit with appropriate instructions for how to self-collect.
- Self-collection requires a clinical assessment and COVID-19 testing to be ordered by a health-care provider.
- Self-collection kits will be stored at locations determined by participating health authorities.
- The following specimens are recommended to be self-collected:
  - Saline gargle/mouth rinse specimen
  - Throat swab and nasal swabs (from both nostrils) into one collection tube
- User-testing of the process has suggested that some patients may feel more comfortable with assistance during the self-collection process from a designated attendant (e.g., work site supervisor or first aid attendant), or through remote observation by a health-care provider.



### 3. Description of steps



\* <http://www.bccdc.ca/health-info/diseases-conditions/covid-19/self-isolation>



**Specific procedures for 3.1 Assessment & ordering test, and 3.3 Returning samples to be determined by implementing Health Authorities in coordination with remote sites and/or camps**

## 3.1 Assessment & ordering test

### Assessment

- The need for testing must be determined by a medical provider, based on their clinical judgement and the [COVID-19: Adult Viral Testing Guidelines for British Columbia](#).
- Ordering provider should provide an overview of the self-collection process and advise patient to not eat, drink, brush teeth, smoke, or chew gum for one hour before sample collection.
- Self-collection kits will be available and distributed through designated health facilities, work sites, or other locations determined by public health.
- Ordering provider or remote work site to initiate process for kit preparation and pick-up.

### Lab form

- A blank lab form (Appendix B) is included in the self-collection kit to be completed by patient, unless the ordering provider completes and sends the lab form to the patient/work site prior to collection

All sections on the lab form must be completed before packaging and transportation of the collected specimens, including:

- Company name, work site location, and work site supervisor phone number (yellow box) if testing is conducted in a camp setting. It is important to provide the work site identification/location for follow up traceback.
- Section 1 – Patient information
- Section 2 – Health-care provider information
- Section 3 – Sample collection information

## 3.2 Collecting samples

### Kit components (supplies for testing)

- Specimen collection instructions
- Printed lab form and labels
- Swabs for throat and nostril collection with transport tube containing media
- Sterile container and saline package for saline gargle/mouth rinse collection
- Biohazard specimen bags with absorbent material
- Safe packaging and shipping materials (Transportation of Dangerous Goods Category B)

### Self-collection instructions

See Appendix C for details



## Specimen labeling

All specimens (cylindrical tube) must have an attached label with:

- Patient name
- Personal Health Number or Date of Birth
- Date & time of collection

## 3.3 Returning samples & transportation

- The kit contains the materials necessary for packaging per [Transportation of Dangerous Goods Category B](#), with instructions for the patient during collection
- Return kit to the designated health facility (laboratory) as soon as possible following sample collection
- Verify packaging for unsuitable specimens (e.g., leakage) at the designated health facility (laboratory)
  - Ordering provider or remote site notified if samples were unsuitable for transportation
- Repackage verified specimens for transportation to the BCCDC Public Health Laboratory for testing.
  - **Temperature:** Ideally, the specimen should be transported at refrigerator temperature (2-8°C), e.g. in a cooler with a cool gel pack or ice pack. If this is not feasible, swabs may be transported at room temperature.
  - **Labelling:** Transportation of Dangerous Goods Category B.

## 3.4 Delivery and interpretation of results

### Communication of test results

- Results can be obtained by patients using one of the methods on the [Test Results webpage](#).
- Results will be returned to the ordering provider. All positive results are reported by the BCCDC public health leadership to the local medical health officer for follow-up through the existing reportable communicable diseases process.
- All results and other personal health information will be treated as strictly confidential. Positive results will be reported to public health, who will contact the patient to discuss contact tracing and self-isolation. If the patient is at a work site, those responsible may need to be notified by public health in order to enable isolation, but they will also be required to keep the patient's identity confidential.

### Interpretation of test results

- **Negative for SARS-CoV-2:** all specimens are negative
- **Positive for SARS-CoV-2:** at least one specimen positive
- **Indeterminate for SARS-CoV-2:** at least one specimen is indeterminate & all other specimens are negative; results do not rule in or rule out COVID-19 infection in the respiratory tract.
- **Sample invalid/rejected:** sample integrity may be compromised and testing is not possible (e.g. sample leakage)
- Any questions about the interpretation of test results can be discussed with the medical microbiologist on call at the BCCDC (604 661-7033).



## Management of test results

- Patients with negative, positive and indeterminate results from self-collected swabs should be treated in the same way as patients with provider-collected NP swabs with the same results.
- If clinically still warranted, samples with invalid/rejected results can be recollected for testing.
- Clinical judgement remains important in determining the implications of NAT (Nucleic acid Amplification Test) test results, whether a repeat test is indicated for negative or indeterminate results (for example, if there is a worsening of symptoms), or whether urgent direct medical support is required.

## Re-Supply

- Designated health authority collection kit pick-up sites should request a re-supply when half of their kits have been distributed
- A designated health authority contact can request re-supply of kits from the BCCDC.

## Appendix A – Rationale for interim guidance for self-collection

### Clinical and public health need for self-collection:

- Provider-collected specimens for SARS-CoV-2 testing are not feasible in settings where there is no ready access to health services (e.g., work camps or remote communities without a health care provider). Self-collection of specimens is one way to address this gap.
- B.C. guidelines prioritize testing for COVID-19 infection in remote, rural and Indigenous communities; however, there is not yet equitable access to testing services in all of these settings. Self-collection may help to address this gap, allowing symptomatic individuals to remain in their setting/community and not require travel to health-care facilities. This would also minimize the risk of transmission to others that may happen as a result of travel for the sole purpose of testing.

### Current Evidence:

- Three studies to date have examined provider-collected NP swabs compared to a variety of self-collected specimens.
- Two studies have compared provider-collected NP swabs to self-collected specimens for NAT detection of SARS-CoV-2 among patients with symptoms suggestive of COVID-19 infection (Australia, N=236<sup>1</sup>; Washington, N=504<sup>2</sup>; detected prevalence 9-10% in both studies). Patients were provided with instructions and self-collection was unsupervised. In both studies there was very high agreement between provider-collected NP swabs and self-collected specimens, for all respiratory viruses detected including COVID-19 (self-collected throat and anterior nasal



swabs combined, kappa statistic ( $k^1 = 0.89$ ),<sup>1</sup> and for COVID-19 specifically (self-collected tongue swabs,  $k=0.919$ ; self-collected anterior nasal swabs,  $k=0.96$ ; self-collected mid-turbinate swabs,  $k=0.98$ ).<sup>2</sup>

- In both studies there were a small number of detections of SARS-CoV-2 in self-collected specimens that were not detected in provider-collected NP swabs, and vice versa. In the Washington study, positive provider-collected NP swabs were also positive in 90%, 94% and 96% of self-collected tongue, anterior nasal, and mid-turbinate swabs respectively. These results are comparable to studies of influenza, where self-collection of nasal specimens among individuals with influenza-like illness is an established practice.<sup>3</sup>
- A third study (N=56) of patients previously diagnosed as COVID-19 infected or uninfected found substantial agreement between provider-collected NP swabs and supervised self-collected oral and nasal specimens (k statistics between 0.60 to 0.72); overall, supervised self-collected oral and nasal specimens detected more SARS-CoV-2 compared to provider-collected NP swabs.<sup>4</sup> Unsupervised self-collected oral specimens showed moderate agreement with provider-collected NP swabs ( $k=0.46$ ), and overall detected less SARS-CoV-2 than provider-collected NP swabs.
- Self-collection of nasal swabs for influenza virus testing has found high acceptability in patient surveys, with a majority reporting it to be more comfortable than or preferable to provider collection, and simple to conduct.<sup>3</sup>
- Throat and nasal swabs may be hard for self-collection. Saline gargle samples are non-invasive and have been shown to be more sensitive than throat swabs for detection of respiratory pathogens<sup>5</sup>, including SARS-coronavirus<sup>6</sup>
- Saline gargle samples are equivalent if not better than throat swabs for COVID-19 PCR testing<sup>7,8</sup>.

#### Rationale for specimens recommended and approach:

- B.C. validation studies of NAT on self- and provider-collected specimens are not yet available to recommend a single self-collection method. As a result, we are recommending at this time self-collection of multiple specimens (saliva, throat, and nasal -both nostrils<sup>2</sup>) to maximize overall detection of SARS-CoV-2.
- Local regional laboratories will assess the adequacy of collection for each submitted specimen, to minimize error prior to shipping to BCCDC. All specimens will be tested by NAT at the BC Public Health Laboratory, which includes detection of markers of the presence of human cells to aid in interpretation of test results.
- Self-collection is recommended for symptomatic patients **only**, given that studies to date have been on symptomatic patients only, and there will be a higher pre-test probability of COVID-infection compared to asymptomatic individuals, which reduces the likelihood of false positive results.
- Testing of multiple sites will increase the negative predictive value of a negative result.
- Furthermore, in a potential outbreak scenario where more than one individual in a setting has symptoms of COVID-19 infection, self-collection in more than one person will overall increase the likelihood of detecting SARS-CoV-2 in the setting.

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<sup>1</sup> The kappa statistic compares the agreement between provider-collected NP swabs and self-collected specimens. A kappa statistic between 0.41-0.60 indicates moderate agreement, between 0.61 and 0.80 substantial agreement, and between 0.81 and 1.00 as almost perfect agreement.

<sup>2</sup> Anterior nasal swabs are recommended for ease of collection and as can be done with available swabs in BC (versus mid-turbinate swabs which require specific swabs for self-collection).



## Other jurisdictions:

- Based on review of these the three studies above and expert opinion, U.S. authorities now recommend unsupervised self-collected of nasal swabs as an acceptable method for SARS-CoV-2 testing, alongside clear step-by-step instructions (video, pamphlet).<sup>9,10</sup> This recommendation was also in consideration of the reduction in need for PPE that accompanies provider-collected specimens.
- The United Kingdom recommends self-collected swabs of nose and back of throat as an acceptable method.<sup>11</sup>

## Conclusions:

- There is no accepted gold standard for detecting COVID-19 infection, and provider- or self-collected NATs of the upper respiratory tract may not detect COVID-19 infection for a variety of reasons, including inadequate collection technique, stage of infection, or symptom severity. Clinical suspicion remains important in the interpretation of test results, whether provider- or self-collected.<sup>12</sup>
- If provider-collected NP swabs were treated as a gold standard, based on studies above self-collected specimens recommended in these guidelines would have high sensitivity (90-94%) compared to provider-collected NP swabs. The sensitivity of self-collected specimens is considered sufficient to treat results from these specimens the same way as provider-collected specimens.
- This approach will also provide further evidence regarding the correlation between different types of self-collected specimens for detection of SARS-CoV-2, which can inform future changes to self-collection recommendations.

## References:

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12. Interpreting the results of Nucleic Acid Amplification testing (NAT; or PCR tests) for COVID-19 in the Respiratory Tract. 2020; [http://www.bccdc.ca/Health-Professionals-Site/Documents/COVID19 InterpretingTesting Results NAT PCR.pdf](http://www.bccdc.ca/Health-Professionals-Site/Documents/COVID19%20InterpretingTesting%20Results%20NAT%20PCR.pdf).





## Appendix B: Self-collected sample lab form



BC Centre for Disease Control  
 British Columbia Health Services Authority

### COVID-19 Self-Collected Sample Requisition

This form is **CONFIDENTIAL**  
 when completed

If living in a work camp, complete the following:

Company Name      Camp Location      Camp supervisor phone number

#### SECTION 1 – PATIENT INFORMATION

Patient Surname		Patient First and Middle Name	
Personal Health Number (PHN)		Date of Birth (YYYY/MM/DD)	
Gender <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Identify in another way	Priority Group Code (circle one) TREEPL (tree planter)      CGT (communal living/camps)      CMM (Community/non-camp setting)		
Address		City	Province      Postal Code
Phone		Email	

#### SECTION 2 – HEALTHCARE PROVIDER INFORMATION

Ordering Clinician		Clinician billing number (MSP)	
Address		City	Postal Code

Additional Copies to: (address/MSP#)  
 Dr. Linda Hoang (27513)

#### SECTION 3 – SAMPLE COLLECTION INFORMATION

Collection Date (YYYY/MM/DD) and Time	Date of Symptom onset (YYYY/MM/DD): _____
Test Requested  <b>COVID-19 NAT</b>  2 self-collected specimens: - Saline gargle - Throat & Nares (nose) swabs	Symptoms, check those that apply:  Fever <input type="checkbox"/> 37 – 38°C <input type="checkbox"/> >38°C  <input type="checkbox"/> Cough <input type="checkbox"/> Shortness of breath <input type="checkbox"/> Sore throat <input type="checkbox"/> Diarrhea <input type="checkbox"/> Fatigue <input type="checkbox"/> Chills <input type="checkbox"/> Myalgia (muscle aches or pain) <input type="checkbox"/> Phlegm production <input type="checkbox"/> Anosmia (loss of sense of smell) <input type="checkbox"/> Conjunctivitis (redness of the eye) <input type="checkbox"/> Headache <input type="checkbox"/> Other: _____

**NOTE:** Self-collected sampling for COVID-19 virus has not been fully validated.



Ministry of Health



BC Centre for Disease Control

If you have fever, a new cough, or are having difficulty breathing, call 8-1-1.

