



## Guideline for the appropriate use of SARS-CoV-2 (COVID-19) Antibody (Serology) Testing

Aug 14, 2020

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Guidelines for COVID-19 testing in B.C. are periodically reviewed and updated based on COVID-19 epidemiology, seasonality, public health measures in place, testing capacity, and our evolving understanding of test performance in clinical settings. As a result, B.C. guidelines may differ from other national or provincial guidelines.

### Message from the BCCDC Public Health Laboratory

The provincial microbiologists and the Provincial Medical Laboratory Services have developed this guidance document for the appropriate use of SARS-CoV-2 (COVID-19) serology testing. This document is consistent with the recent Canadian Medical Association Journal review [article](#) entitled: SARS-CoV-2 (COVID-19) serology: implications for clinical practice, laboratory medicine and public health.

Together with BC Children's, BC Women's and St. Paul's hospitals, we have collaborated on the validation of commercial laboratory-based SARS-CoV-2 serology.

Based on the published literature, commercial laboratory-based assays are about 95% sensitive at ~30 days post symptom onset and the specificity is approximately 99.5%.

At present clinical applications for serology are limited, and appropriate indications for ordering serological testing are outlined in this guidance document.

As of August 10, 2020, the BCCDC Public Health Laboratory (BCCDC PHL) is providing *limited* SARS-CoV-2 serological testing for the following clinical and public health indications:

#### Hospitalized patients:

- Patients who present with atypical clinical manifestations such as inflammatory syndromes; ie. multisystem inflammatory syndrome in children (MIS-C).
- To help diagnose patients who are SARS-CoV-2 RNA negative, but present with a compatible syndrome, or who present later during their disease course. It is important to note that serological testing becomes reliable after 14 or more days post-symptom onset. Testing at earlier time points may result in false negative results.
- Case-by-case testing after consultation with a clinical/medical microbiologist.



Testing will also be available to address public health needs based on guidance from provincial and regional medical health officers.

To request testing, indicate COVID-19 serology on a serology or hospital requisition and submit a 5 mL gold top serum separator tube (SST). For detailed ordering information please visit the [elab handbook](#).

The BCCDC PHL will be performing orthogonal testing i.e., specimens will be screened by one manufacturer's assay and all positives will undergo supplemental testing to improve specificity. Positive or inconclusive serological tests performed in other laboratories, should also undergo supplemental testing with a second manufacturer's test to improve specificity.

This testing guideline will be adapted as our knowledge of SARS-CoV-2 continues to evolve.

## Key Points

At this time, COVID-19 antibody testing is **NOT** available in BC for routine clinical use **NOR** is it recommended for clinical diagnostic purposes in outpatient populations.

Use of antibody testing is currently only recommended for

- a limited number of clinical scenarios, *or*
- at the direction of medical health officers as part of public health investigations, *or*
- epidemiologic and research studies

Requests for serological testing for clinical purposes require prior approval by a clinical or medical microbiologist.

## Introduction

SARS-CoV-2 (COVID-19) antibody testing detects the presence of antibodies made in response to a COVID-19 infection. Unlike direct viral detection methods such as nucleic acid testing (NAT) that identify acutely infected persons, antibody tests help determine if a person has been infected with COVID-19 in the past, as it can take 14 days or longer for antibodies to be reliably detected.

In low prevalence settings such as B.C., positive antibody results will be rare, and when they occur, many positive antibody results may in fact be false-positives. In general, tests that are conducted in low prevalence settings have lower accuracy. Antibody testing will, therefore, be of **most use in people who have a higher pre-test probability of infection**, including individuals with a history of symptoms suggestive of COVID-19, or a higher chance of having been exposed to someone with COVID-19 infection (e.g., contacts of a confirmed COVID-19 case).

As a novel virus, there are many outstanding questions regarding the immune response to COVID-19 infection, including whether antibodies provide protection from re-infection. B.C. is currently part of national research and public health initiatives to collect the evidence needed to answer many of these questions.

Provincial and regional health authority laboratories are continuing to assess the accuracy and performance of antibody testing, including high volume Enzyme Immuno-Assays (EIA) and point-of-care test kits.



## Indications for testing

### 1. Clinical care

There are a limited number of clinical scenarios for which antibody testing **may provide clinical utility**, in particular in individuals with a higher pre-test probability of infection. These scenarios include:

- **The diagnosis of patients who present with atypical clinical manifestations that may be due to COVID-19 infection for whom COVID-19 NAT results are negative and antibody test results will affect clinical management, such as Multisystem Inflammatory Syndrome in Children (MIS-C).** To increase clinical sensitivity of serology, testing is best performed 14 days or more after symptom onset.
- **To aid in the diagnosis of acutely ill, hospitalized patients for whom COVID-19 NAT results are negative, yet clinical signs and symptoms are highly suggestive of COVID-19 infection.** For these cases, serological testing is not useful in the early stages of infection, and a negative result could be falsely reassuring. Testing should only be considered when the results will be used to guide patient management or an outbreak response.

Antibody testing is **NOT** recommended for:

- **The routine diagnosis of acute or recent COVID-19 infections.** As antibodies can take 14 days or more to be reliably detected, and by 14 days after symptom onset most patients with COVID-19 infection are no longer considered infectious, serology provides limited information to guide immediate clinical or public health action. NAT remains the test of choice for diagnosis of acute COVID-19 infection. Furthermore, as time passes and the SARS-CoV-2 virus continues to circulate, a positive antibody result may be due to a prior infection and not necessarily reflect the cause of an individual's current symptoms.
- **Determining an individual's immune status or past exposure.** Antibody testing to document immunity to SARS-CoV-2 is NOT recommended as it has not yet been established whether the presence of antibodies provides protection from re-infection. It is also apparent that not everyone with past COVID-19 infection mounts a measurable antibody response that can be detected by laboratory testing, or for how long the antibodies persist. Therefore, antibody results cannot be used as proof of immunity for subsequent decision-making (e.g., decisions related to the use of personal protective equipment, adherence to physical distancing or other public health or workplace recommendations). Antibody testing is also not recommended to verify past exposure as a condition to employment or travel, in schools, prior to surgery or other medical procedures.

### 2. Public health indications

Medical health officers may recommend antibody testing for individuals who are part of a public health investigation of a case, cluster or outbreak, regardless of symptom profile.

### 3. Other uses

Serological testing is also being performed in B.C. as part of public health and clinical research studies, including sero-prevalence surveys, sero-immunity studies, therapeutic trials of donor blood plasma, and assessment of the immunogenicity of candidate vaccines to the SARS-CoV-2 virus.



## Ordering, collection, and interpreting results

Ordering COVID-19 serology does NOT follow routine serology testing procedures. To request serology for COVID-19 for clinical purposes on a case-by-case basis, please consult your local or BCCDC clinical or medical microbiologist. They will be able to advise on test utility, timelines for availability, and provide assistance with test interpretation.

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