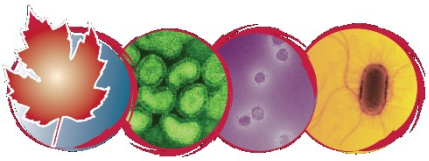

# The Canadian Public Health Laboratory Network (CPHLN) Statement on Point-of-Care Serology Testing in COVID-19

## RESPIRATORY VIRUS INFECTIONS (ReVI) WORKING GROUP

May 1, 2020

Point-of-care (POC) serology tests for SARS-CoV-2, the virus that causes COVID-19, detect the human antibody response to infection rather than the virus itself. Most are qualitative immunochromatographic (lateral-flow) based assays that detect IgM and/or IgG from a finger prick and can provide results in under 30 minutes. While there is widespread interest in adopting POC serology tests for SARS-CoV-2, there are currently significant limitations to this testing modality including the lack of understanding of the immunological response in COVID-19, limited clinical validation data, and variability in performance among different POC tests.

### Current position for acute diagnostics

Serology POC tests for SARS-CoV-2have not currently been validated for use as a diagnostic tool for acute infection and none are approved by Health Canada to date. In general, these antibody tests often do not become positive until a week or more after symptoms have started, and therefore are not suitable for diagnosis of acute SARS-CoV-2 infection at this time. We recommend that nucleic acid detection (*e.g.* real-time PCR) remain the first line test for the diagnosis of acute SARS-CoV-2 infection, as advised by the World Health Organization.

### Key points

- It can take up to 7-12 days after symptom onset for antibodies to SARS-CoV-2 to develop, therefore the use of serology POC tests in the early phase of infection can result in false negative results at a time when patients are most infectious (*i.e.* a negative result does not rule out infection).
- Since serology POC tests do not detect virus, a positive or negative result does not determine whether a person is infectious.
- Positive results may be due to past or present infection with SARS-CoV-2.
- False positives may occur if these kits cross react with antibodies from recent or past exposure to other coronaviruses, including human seasonal coronaviruses (HKU1, NL63, OC43, 229E), SARS-CoV-1, or MERS-CoV. Other infections, as well as non-infectious conditions (*e.g.* rheumatoid factor positive diseases) may also cause false-positive results. Any kits used need to be thoroughly evaluated for such cross reactivity before being used clinically.
- False negative results may occur in elderly and immunocompromised patients.

## Where it could be used

The role of serology in the diagnosis of acute SARS-CoV-2 infection and patient management is likely to be of limited utility. However, once the dynamics of the serological response in COVID-19 are better understood, serology will play an important role in the public health response. A key aspect is understanding whether antibody production correlates with protective immunity and what the duration of protection is. The ease of use and quick turnaround time with POC assays make it an ideal testing modality in remote areas with limited access to centralized laboratory-based testing and/or limited local laboratory infrastructure, and in situations that would benefit from immediate triaging. Examples include:

- Seroepidemiology, used to better understand the proportion undiagnosed in the population over time and to provide more accurate attack rates and mortality rates.
- Informing targeted diagnostic testing strategies (by PCR), where priority would be given to populations/areas with no evidence of immunity.
- Detecting seroconversion and assessing immunity in healthcare workers and other essential/frontline workers.
- An adjunct to PCR for diagnostic testing in patients who are PCR-negative and in the late course of their illness to implement control measures and to effectively manage patients.
- Testing high-risk populations exposed to SARS-CoV-2 to assess their risk of developing infection.
- Detecting seroconversion as a surrogate for effectiveness of control measures.
- Once a vaccine is available, it may be used to determine who should be prioritized for earlier vaccination.
- Support of clinical trials that are assessing novel therapies, such as the use of neutralizing antibodies.

## Important considerations for implementing POC testing

- Having a well validated test that has been evaluated against a gold standard (viral neutralization assays or another laboratory-based serological assay). Performance characteristics (sensitivity, specificity, positive and negative predictive values, cross-reaction to other coronaviruses) should be established using sera from patients infected with SARS-CoV-2, other respiratory viruses, including seasonal coronaviruses, and healthy controls.
- Adequate training of healthcare workers to administer the test and interpret the result.
- Assessing risk of infection with SARS-CoV-2 and bloodborne infections for the operator.
- Provisions to ensure the capture of testing data for individual patient records and surveillance purposes and requirement for participation in external quality assessment (EQA) to maintain high-quality testing.

Based on currently available information, CPHLN recommends that SARS-CoV-2POC serological assays not be used for clinical testing in any capacity at this time. As more information becomes available on test performance, and assays are validated against gold standard serological methods, clinical application of POC assays will be re-evaluated. Molecular testing, such as real-time PCR, remains the primary test method for laboratory confirmation of acute SARS-CoV-2 infection and diagnosis of COVID-19.