COVID-19 Key Messages on Serology Topics

Key Messages to address Serological testing, Immunity Task Force, & WHO Solidarity II

Issue Statement: The many aspects of serology testing are addressed in these key messages. These include: how serological tests work to detect antibodies; the role of the Immunity Taskforce; the role of the National Microbiology Laboratory (NML) in serology testing and determining how long immunity lasts; Canada's participation in the WHO Solidarity II Serological Study; and Health Canada's role in approving serological tests.

Note: These are previously approved key messages except for the NML key messages.

General Key Messages for Serological Testing

- Serological tests are authorized to detect antibodies specific to the virus. Serological tests provide evidence of a previous exposure to the virus that causes COVID-19 by testing for the presence of antibodies.
- Serological tests will play an important role in tracking how widely the virus has spread.
- Serology testing will contribute to a better understanding of the immune status of those who have been infected.
- Using validated and effective serological tests for COVID-19 will be an important step in Canada's public health response.
- Information made available through the results of serological testing could also prove valuable in estimating potential immunity and vulnerabilities in our population.
- Serological surveys can also help guide important public health decisions once a vaccine becomes available.

****

Key Messages for Health Canada's Serological Test Approval:

- Following scientific review, Health Canada has now authorized the sale of five serological tests:
  - DiaSorin LIAISON® test (authorized May 12)
  - Abbott ARCHITECT SARS-CoV-2 IgG Assay (authorized May 14)
  - Roche Elecsys Anti-SARS-CoV-2 (authorized June 5)
  - Ortho Clinical Diagnostics VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack (authorized June 8)
  - Abbott Laboratories Diagnostics Division SARS-CoV-2 IgG (authorized June 11)
- Serological tests are authorized to detect antibodies specific to the virus. Serological tests provide evidence of a previous exposure to the virus that causes COVID-19 by testing for the presence of antibodies.

[APG]

- Health Canada authorized the tests after completing scientific reviews that were supported by evidence to ensure that the tests will provide accurate and reliable results.
- A complete list of testing devices for COVID-19 is available on Health Canada's website.
- Health Canada will continue to focus on the health and safety of Canadians while expediting the supply of safe and effective health products related to COVID-19.
- The Government of Canada has finalized a contract with Abbott Laboratories for 140,000 serological test kits.
- These kits can detect the presence of previous exposure to COVID-19 and will be used for research studies that are being coordinated by the Immunity Task Force.

Supplemental messages:

- These tests must be carried out in a laboratory setting.
- Serology-based tests are essential to understanding the immune response to virus infection and will play a key role in determining the extent of exposure to the virus though sero-surveillance studies.
- Further research is required to fully comprehend the relationship between positive antibody tests and protection against re-infection.
- In accordance with Health Canada's Guidance on serological tests, a condition is applied to the authorization issued to serology-based tests in order to monitor the ability of the test to perform as intended once in use by the Canadian health care system.
- Serology-based tests should be used in conjunction with the testing strategy outlined by municipal, provincial or territorial public health authorities.
- Nucleic acid-based tests are the only authorized testing devices in Canada to diagnose an active infection with COVID-19.

If pressed on Canada's approach to authorizing COVID-19 testing devices

- As an emergency public health measure, the Minister of Health signed an Interim Order to allow expedited access to COVID-19-related medical devices, including testing devices.
- Only testing devices authorized by Health Canada can be imported or sold in Canada. Unauthorized tests may not produce accurate results.
- Health Canada has confirmed that authorized COVID-19 tests are well supported by evidence that they will provide accurate and reliable results. More than 20 COVID-19 testing devices are now accessible in Canada. The list of authorized testing devices is posted on Health Canada's website.

[APG]

- Canada has maintained a science-informed approach to managing the pandemic, including maintaining requirements for pre-market authorization of testing technologies.

- Providing the Canadian population and individuals with accurate information about infection status is a pillar of the country's response to the pandemic.

- Health Canada's position on the use of serological assays is in line with the World Health Organization's view that serological assays will play an important role in research and surveillance.

- The Public Health Agency of Canada's National Microbiology Laboratory (NML) and its partners are working on assessing a variety of commercial serological tests for the SARS-CoV-2 virus. This pan-Canadian collaboration includes members of the Canadian Public Health Laboratory Network, clinical researchers from front-line health care settings, and Canadian Blood Services, all of whom are working to establish the materials needed for both the evaluation and implementation of serologic testing across Canada.

- Health Canada continues to review other serological technologies in accordance with its Guidance on serological tests. Health Canada will authorize other serological tests that show high sensitivity and specificity. For additional information, please consult the serological testing devices for use against COVID-19.

Questions and Answers

Q1. What is serological testing used for?
Serology-based tests are essential to understanding the immune response to virus infection. They will play a key role in determining the extent of exposure to the virus though sero-surveillance studies.

Serological testing is not authorized to diagnose COVID-19 infections because it detects antibodies produced by the patient's immune response. Those antibodies are not likely to develop until later in the infection, thereby giving false negative results when used during the early disease phase. By contrast, authorized devices aimed at diagnostic testing for active cases, directly test for the actual virus, using molecular tests performed on swabbed specimens.

Q2. How will the results of serological testing be used?
Using validated and effective serological tests for COVID-19 will be an important step in Canada's public health response.

On April 23, the Government of Canada launched the COVID-19 Immunity Task Force to lead a Canada-wide unified effort to test blood samples for signs of COVID-19 infections.

Rapid and representative national surveys will provide a snapshot of where we stand now, and what to expect in a possible second wave of infection. They can also shed light on the potential immune status of vulnerable populations such as Indigenous communities, and residents of nursing homes and long-term care facilities.

Serological surveys can also help guide important public health decisions once a vaccine becomes available.

[APG]

Q3. Is the government considering the possibility of serological or immunity passports or certificates to allow people with immunity to move freely again?
There is an active international effort to assess whether those who have recovered from illness are safe from re-infection and if so, how long that protection might last. More research is needed before making decisions in Canada.

Other respiratory viruses generally do not provide an individual with 100% immunity after recovery.

Right now, we do not know whether individuals who have recovered from COVID-19 will have immunity, how long that immunity may last, or whether it's possible for individuals to experience less severe or potentially more serious illness if they get COVID-19 a second time.

Q4. How will Health Canada ensure that test kits are safe and effective?
The Interim Order creates a tailored approval pathway for the importation and sale of medical devices that support Canada's response to COVID-19. This Interim Order, and the tailored approval pathway it creates, provides the Minister with flexibility to consider the urgent circumstances relating to the need for the medical device, authorizations granted by foreign regulatory authorities, or possible new uses for medical devices that are already approved in Canada.

As with all drugs and medical devices, Health Canada assesses and monitors the safety and effectiveness of all products authorized under this Interim Order, and will take immediate action if required to protect the health and safety of Canadians.

Manufacturers are still required to follow strict post-market safety requirements such as mandatory problem reporting, recall procedures and complaint handling.

Q5. Why did it take so long for Health Canada to authorize a serological test?
Providing the Canadian population and individuals with accurate information about appropriate public health measures and infection status is a pillar of the country's response to the pandemic. Canada has maintained a science-informed approach to managing the pandemic including maintaining requirements for pre-market authorization of COVID-19-specific tests.

Health Canada authorized the test after completing a scientific review that was supported by evidence to ensure that the test will provide accurate and reliable results. More than 20 COVID-19 testing devices are now accessible in Canada. The list of authorized testing devices is posted on Health Canada's website.

If pressed:

- Each public health laboratory across Canada will decide whether it wants to use authorized serological tests, based on its own needs and scientific review and requirements.

Q6. Is the federal government releasing guidelines to provinces on how to conduct antibody testing?
PHAC and Health Canada do not develop guidelines or directives on which kits to use/not use specifically, or by name. PHAC provides evaluation results and could provide some interpretation of those results.

****

[APG]

Key Messages on the Immunity Task Force

- On April 23, the Government of Canada launched the COVID-19 Immunity Task Force to lead a Canada-wide unified effort to test blood samples for signs of COVID-19 infections.

- The task force will catalyse, support, and harmonize the design and rapid implementation of population-based studies that will generate reliable first estimates of SARS-CoV-2 antibody positivity, overall and in priority populations across Canada.

- Rapid and representative national surveys provide a snapshot of where we stand now, and what to expect in a possible second wave of infection. They can also shed light on the potential immunity status of vulnerable populations such as Indigenous communities, and residents of nursing homes and long-term care facilities.

- Conducting large serological (blood test) surveys of the Canadian population will measure the scope and scale of COVID-19 infections across the country.

- This effort needs to be well-coordinated and well-executed to achieve the best results to inform policy decisions on ways to bring the country back to normal or to a “new normal”.

    - We are establishing a task force of organizations that will work together under the direction of a Governing Board charged with setting priorities and recommending projects for funding to the Government of Canada. The leadership team is comprised of three individuals who are well-renowned for their contributions to research, academia, and innovation in both public health and healthcare both in Canada and internationally.
    - The Governing Board will be co-chaired by:
        - Dr. David Naylor, well known for his scientific and academic leadership and successful management of large and complex organizations;
        - Dr. Catherine Hankins, who brings domestic and international experience in leading large and complex research endeavours and in creating partnerships to advance public health priorities.
    - Dr. Tim Evans, Director, School of Population and Global Health, at McGill University, will lead the Secretariat responsible for the efficient execution of this complex endeavour.

- The Immunity Task Force is working with an Indigenous Advisory Circle with representatives from Indigenous communities across the country to promote immunity testing in Indigenous communities.

- Some projects under the Immunity Task Force have started testing blood samples for COVID-19 antibodies and should be able to produce a more detailed early picture of how many Canadians have been infected with the novel coronavirus by mid-July.

- The Immunity Task Force is aiming to publish first, high-level results in mid-July, followed by a more detailed assessment based on age groups and/or geographic breakdown a few weeks later.

- The Immunity Task Force is working with Canadian Blood Services who cannot trace back the samples to the patients who gave them.

[APG]

- The Immunity Task Force is also partnering with the Canadian Institutes of Health Research to provide new and additional funding related to projects assessed via their recent COVID-19 Rapid Research Funding competition.

- The Immunity Task Force leadership group meets regularly to advance a suite of studies that will provide estimates of the scope of COVID-19 infection and early indication of possible immunity. A separate Executive Committee makes recommendations to the Public Health Agency of Canada on study funding.

****

Key Messages on Canada's contributions to the WHO Solidarity II Serological Study

- Canada's COVID-19 Immunity Task Force is leading the pan-Canadian effort to understand how widespread exposure to the COVID-19 virus has been. Connections with international studies are important and plans for linkages with Solidarity II will be considered as Canada's studies get underway.

- Serological testing identifies antibodies in the blood that indicate if a person has already been infected.

- Solidarity II is a global collaboration of serological studies among different populations around the world.

- Understanding what proportion of the population has been infected with COVID-19, and what proportion may be immune from infection in the future, will inform how local, national and international decision-makers respond collectively to the pandemic.

****

Key Messages on NML's role on serological testing
Please check in with OCPHO before using this content for a media response

- The Public Health Agency of Canada's (PHAC) National Microbiology Laboratory (NML) and its partners are evaluating a variety of commercial serological tests for the SARS-CoV-2 virus.

- This pan-Canadian collaboration includes members of the Canadian Public Health Laboratory Network, clinical researchers from front-line health care settings, and Canadian Blood Services, all of whom are working to establish the materials needed for both the evaluation and implementation of serologic testing across Canada.

- Scientists from the NML have also developed a variety of in-house serological tests including a specialized test to detect "**neutralizing" antibodies.** Neutralizing antibodies are able to directly inactivate virus particles, which means they can usually prevent infection.

- Using these tests, scientists will be able to gain important information on possible immunity and long-lasting protection from re-infection of the virus.

[APG]

  - These types of tests will be instrumental in evaluating possible vaccines to determine their effectiveness before starting clinical trials.
  - Neutralizing antibodies can also be used as treatments for those ill with COVID-19 infections. These treatments are known as “convalescent plasma treatments” and are commonly used for other infectious diseases such as rabies.

- Developing a laboratory test to detect neutralizing antibodies that are sensitive and specific is a challenge. NML scientists are experts on developing and running these types of tests.

- The NML has also created the necessary materials to support quality assurance programmes. These programmes help to ensure that other Canadian public health labs performing serological tests are generating accurate results.

How antibodies work:

- The immune system is the body’s defence against infections. It attacks germs and helps keep us healthy.

- There are two main classes of the immune system—innate and adaptive immune systems.
  - Innate immunity or natural immunity is something everyone is born with, and provides general protection. Skin, the respiratory tract and mucus are examples of innate defences against infection. These are our first line of defence against germs.
  - Adaptive or acquired immunity develops throughout our lives. We develop adaptive immunity when we are exposed to diseases or when we are immunized against them with vaccines. Antibodies are created as part of adaptive immunity and become part of our bodies’ memory system to help fight future infections. Adaptive immune responses are slower to respond as the body needs to “learn” about the new pathogen and create antibodies to fight the invading germs.

How serology tests work:

- Serological tests look for different types of antibodies in blood samples. Different antibodies provide clues about how the immune system responds to the virus. Each antibody provides unique information on the body’s response to infections. Some types of antibodies include:
  - Immunoglobulin M or IgM, which is typically the first antibody to be produced. It is less specific than other antibodies and works to eliminate invading organisms.
  - Immunoglobulin G or IgG is the most common type of antibody for infectious diseases in the body and is often a neutralizing antibody to block infections.
  - Immunoglobulin A or IgA is the most abundant antibody in mucosal secretions and is critical for immune responses in the respiratory tract.

On decreasing levels of antibodies

[APG]

- Early research appears to indicate that neutralizing antibody levels can decrease following recovery from COVID-19. Neutralizing antibodies are one of many immune system responses that hold the clues to long-lasting immunity. More research will be required to determine if decreasing numbers of neutralizing antibodies means that protection from COVID-19 reinfection is possible or not.

On the NML review of tests kits:

- As part of its research efforts, the NML performs scientific reviews of new medical devices.

- In response to the urgent nature of COVID-19, the NML is being asked to perform scientific review and assess the performance of medical supplies, such as COVID-19 test kits. The NML has reviewed approximately 30 commercial COVID-19 serological tests.

- The NML reviews these COVID-19 medical supplies to ensure they meet the gold standard used in public health laboratories and can be used to obtain reliable and accurate results.

- This test verification function is part of scientific research and is independent of Health Canada's regulatory approval process. While this assessment is separate from Health Canada's authorization process, the NML works closely in collaboration with Health Canada to share knowledge gained through the review process.

[APG]