REQUIREMENTS FOR ESTABLISHMENT OF COVID-19 TESTING IN THE PRIVATE SECTOR

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1 CURRENT CONTEXT

All residents of Newfoundland and Labrador (NL) requiring COVID-19 testing and meeting public health criteria are offered COVID-19 testing without charge through the four regional health authorities (RHAs) in this province.

COVID-19 testing in Newfoundland and Labrador is available through private clinical laboratories accredited for diagnostic testing for COVID-19 for asymptomatic individuals wishing to be tested prior to travel to and from the province; asymptomatic individuals who do not qualify for public health testing; and, asymptomatic individuals who are participating in an occupational screening program.

Private clinical laboratories operating in the province may perform serology (i.e., antibody) testing of specimens for research purposes; however, antibody tests as part of a clinical service is not permitted. COVID-19 serology testing is available by Medical Officer of Health (MOH) authorization in specific circumstances, only. Performing antibody tests as part of a clinical service is not permitted without MOH approval.

2 DEFINITION OF TERMS

The distinction between a screening and diagnostic test is established by the purpose for which a test is used. In some cases, the same test can be used for either disease screening or diagnosis depending on the context in which it is used. In some situations the term “diagnostic tests” or “diagnostic testing” are applied as general terms covering all potential applications of testing (i.e., screening, diagnosis, monitoring, prognosis) by a clinical diagnostic laboratory facility. The specific application of the terms “diagnostic tests” and “screening tests” with respect to COVID-19 are described below.

Laboratory nucleic acid amplification tests (Lab-based NAAT): Tests that detect the virus’ genetic material (RNA) usually by a technique called reverse transcriptase - polymerase chain reaction (RT-PCR) testing. Lab-based NAATs are available at the Public Health and Microbiology Laboratory (PHML) in St. John’s, and at private clinical laboratories authorized to perform COVID-19 testing. These lab-based molecular tests

are considered the gold standard for diagnosing COVID-19 infection in patients with symptoms.

Rapid NAAT: Rapid tests that target virus' genetic material (RNA) and provide results much faster than the lab-based NAATs. Many, but not all, rapid NAATs have Health Canada approval for testing symptomatic individuals only. Many rapid NAATs are approved for point of care testing (POCT)/rapid testing by individuals trained in use of the device, but without formal clinical laboratory training. Rapid NAATs are less accurate than lab-based NAAT tests, and are more prone to test positive in individuals without COVID-19 infection (i.e., false-positives) and test negative in individuals who would test positive for COVID-19 by lab-based NAATs (i.e., false-negatives).

Antigen tests: Rapid tests that target specific proteins on the surface of the virus. Antigen tests are less accurate than lab-based NAATs and produce higher rates of false-positive and false-negative results. Health Canada has licensed these tests for use in symptomatic people within seven days of initial symptom onset, and serial testing for asymptomatic individuals.

Serology tests: Tests that detect the antibodies produced by an individual after they have been exposed to a virus for a week or more, and are mounting an immune response to an infection. Serology tests are not appropriate for screening for or diagnosing COVID-19. These tests are not recognized to accurately confirm immunity to COVID-19.

Diagnostic tests for COVID-19: Lab-based NAATs that can establish diagnosis of COVID-19 infection in both symptomatic and asymptomatic individuals without the need for another test. These diagnostic tests for COVID-19 identify a current infection in individuals with symptoms of infection and in asymptomatic persons that have had recent suspected exposure. Most rapid NAAT and all antigen tests approved so far by Health Canada are not sufficiently reliable for diagnosing COVID-19 in areas where there is low prevalence of COVID-19. Rapid NAAT and antigen tests are not currently used to diagnose COVID-19 in the private sector in Newfoundland and Labrador.

Screening tests for COVID-19: Rapid tests that determine increased likelihood that an individual has COVID-19, whether that person is asymptomatic or symptomatic. Screening tests are applied to individuals for whom there may or may not be suspicion for exposure to COVID-19. Screening tests cannot definitively establish that an individual has COVID-19. Screening tests may produce higher rates of false-positive and false-negative results. Most rapid tests (i.e., rapid NAAT and antigen tests) that are used as screening tests for COVID-19 do not identify asymptomatic carriers of COVID-19 as accurately in comparison to lab-based NAAT tests.

3 SCOPE

The terms and conditions outlined in this document are applicable to all testing for COVID-19 where testing is requested outside of public health criteria and RHAs, including both laboratory-based testing and point of care testing (POCT) (also called rapid tests).

3.1 ISO STANDARDS

ISO 15189:2012 is an international standard that specifies requirements for quality and competence in medical laboratories. This standard covers testing performed for screening, diagnosis, monitoring, and prognostic purposes. Private clinical laboratories offering diagnostic testing in NL are required to conform to ISO 15189:2012 and other relevant ISO and national standards directly applicable to operation of specific clinical diagnostic laboratory services.

ISO 22870:2016 is a standard that is applicable to POCT/rapid testing, and is supplemental to ISO 15189:2012. As such, private companies offering POCT/rapid testing for COVID-19 in NL are required to conform to ISO 22870:2016. All private companies offering POCT/rapid testing in the public and private sector must have oversight of their quality management activities provided by an accredited clinical laboratory (accredited to ISO 15189:2012 standards) and is, therefore, subject to the same standards of quality assurance, staff competence and patient safety, as the clinical laboratory.

Compliance to these ISO standards and under the auspices of an accreditation framework reduces the risk for harm to persons being tested, and inappropriate disclosure of personal health information related to COVID-19 testing, such as the results of diagnostic and screening tests. Further information on ISO standards is available here: https://www.iso.org/home.html

3.2 REGULATIONS

Regulations under the **Health and Community Services Act** require ministerial approval for the establishment or operation of clinical diagnostic testing laboratories including POCT/rapid testing and for disease screening, diagnosis, monitoring, or prognostic purposes in the province. The **Diagnostic and Public Health Laboratories Regulations** state:

Prohibition

2. *A person shall not establish or operate within the province a facility or laboratory for the purpose of providing diagnostic or public health services unless that person has the written permission of the minister appointed under the* ***Executive Council Act*** *to administer the* ***Public Health Act.***

Exemption

3. *These regulations shall not apply to a hospital or other health facility providing the services referred to in section 2 on the commencement of these regulations if the hospital or health facility is operated by government or by a hospital board.*

The legislative regime above does not apply to self-administered COVID-19 tests (i.e., rapid tests performed on oneself at home). All private companies that promote self-testing at home should consider the information contained herein to guide their testing programs and to protect the privacy and safety of their employees and/or clients.

4 MINISTERIAL APPROVAL

The pursuit of private sector diagnostic testing, including with the use of Health Canada approved POCT/rapid tests, must be done in compliance with the **Public Health Protection and Promotion Act**, the **Health and Community Services Act**, and applicable regulations to assure the safe operation of services, and with written approval from the Minister of the Department of Health and Community Services (HCS) or delegate.

HCS approval requires demonstrating the need for the service and providing evidence that the interests and safety of the public are protected throughout all stages of the testing process including specimen collection, analysis, and reporting of test results to qualified medical professionals. Appendix 1 provides a summary flow diagram for the application and approval process for set up of laboratory-based and POCT/rapid testing sites.

All COVID-19 testing is performed in accordance with applicable standards for quality management, staff competence, and quality assurance, which assures the safety of both the individuals who are performing tests and the individuals who are being tested. ISO 15189:2012 accredited clinical laboratories have the required laboratory medical oversight to establish and monitor quality management frameworks for POCT/rapid test programs for COVID-19. An unaccredited POCT/rapid test program requires oversight of an ISO15189:2012 accredited laboratory. A private company may pursue independent accreditation to ISO15189:2012 standards to offer POCT/rapid testing, which includes oversight from a duly qualified medical director.

5 REQUIREMENTS FOR ALL PRIVATE CLINICAL LABORATORIES AND POCT/RAPID TESTING PROGRAMS OFFERING COVID-19 TESTING:

All COVID-19 testing in clinical laboratory settings or using POCT/rapid testing must comply with the following:

- All private organizations, businesses, or employers wishing to perform screening or diagnostic testing for COVID-19 must receive written authorization to do so by the HCS prior to testing.

- All organizations, businesses, employers operating in the province of NL and carrying out COVID-19 testing for diagnostic purposes must be accredited as a clinical diagnostic laboratory and to ISO 15189:2012 standards. All public and private clinical diagnostic laboratories operating in the province must be accredited to ISO 15189:2012.

- All non-laboratory based testing performed by public and private organizations, businesses, or employers, including that performed using POCT/rapid tests requires quality management systems be in place with oversight provided by an ISO 15189:2012 accredited laboratory prior to any testing.

- Testing devices used in all settings must be approved by Health Canada.

- Testing devices used in all settings must be used according to manufacturer's instructions for the device.

- All tests are ordered by licensed medical practitioners or nurse practitioners with test ordering authorization in this province and is affiliated with the organization, business, and/or employer.

- All tests are performed by qualified health professionals on asymptomatic individuals only.

- All testing and test result reporting must be in compliance with applicable provincial privacy legislation, including the **Personal Health Information Act**, and applicable federal legislation, including the **Personal Information Protection and Electronic Documents Act**.

- All test results generated within their facilities (e.g., POCT/rapid tests) are entered into a secure electronic health record system or paper records are held in secure locations, under the custody and control of a custodian as defined in the **Personal Health Information Act**.

- All positive test results by a screening or diagnostic test for COVID-19 are communicated to the client.

- Individuals who test positive on a POCT/rapid test are advised to follow public health guidance for isolation and testing, available here: https://www.gov.nl.ca/covid-19/public-health-guidance/testing/if-you-test-positive/

- All positive test results by a lab-based NAAT diagnostic test for COVID-19 are recorded in the provincial electronic health record (EHR). Where a private business does not have access to the EHR, this requirement may be waived at the discretion of the Minister of Health and Community Services.

- Under the **Public Health Protection and Promotion Act** and its regulations, positive test results confirmed by an accredited laboratory for COVID-19 must be communicated to Communicable Disease Control intake of the appropriate regional health authority and copied to the Regional Medical Officer of Health within 24 hours.

- All testing must be fully compliant with diagnostic testing requirements of other jurisdictions if testing is performed on samples retrieved from outside the province and/or from non-residents of NL.

6 ADDITIONAL REQUIREMENTS FOR ALL ORGANIZATIONS, BUSINESSES, OR EMPLOYERS:

- All organizations, business and/or employers seeking to implement a COVID-19 testing program should seek legal advice on issues applicable to testing including issues related to:
    - Human and employee rights;
    - Labour and employment regulations;
    - Informed consent, privacy and handling of health information;
    - Occupational health and safety; and
    - Liability insurance to cover harm to any employee, contractor, and others by activities related to COVID-19 testing.

- All private organizations, businesses, and employers involved in or requiring COVID-19 testing for their employees are accountable for all costs related to testing.

7 ADDITIONAL REQUIREMENTS RELATED TO TESTING DEVICES, SAMPLE HANDLING, TESTING AND REPORTING:

- Utilization of POCT/rapid tests for COVID-19 beyond the approved indication by Health Canada must be appropriately validated for the new use and after risk assessment, and with oversight provided by an accredited clinical laboratory.

- The province has not approved the testing of symptomatic individuals in private clinical laboratories, or by private organizations, businesses, and employers.

- All testing devices for COVID-19 must have their performance verified locally and completed under the oversight of an accredited clinical laboratory.

- All samples for COVID-19 testing by screening tests and diagnostic tests (see Section 2 Definition of Terms) must be processed, analyzed, and reported in compliance with the provincial **Personal Health Information Act**, and applicable federal legislation, including the **Personal Information Protection and Electronic Documents Act**. All individuals involved in the testing process from sample collection and order entry to analysis and reporting must align their practice to compliance with applicable international standards (i.e., ISO 15189:2012, ISO 22870:2016.

- Health Canada regulates the sale and import of commercial testing devices related to COVID-19. All testing must be performed in compliance with Health Canada requirements.

- Further information is available on the Health Canada website for Medical Devices.

8 TESTING REQUESTS FROM ASYMPTOMATIC AND SYMPTOMATIC INDIVIDUALS:

- Symptomatic individuals who request testing at a private organization, business, or employer must be redirected by the private entity to the public health guidance

for isolation and testing, available here: https://www.gov.nl.ca/covid-19/public-health-guidance/self-isolation/.

- Asymptomatic individuals requiring COVID-19 testing can arrange testing through an accredited private clinical laboratory or private company offering COVID-19 testing (i.e., lab-based test and/or POCT/rapid test) with oversight from an accredited private clinical laboratory.

References:

Government of Alberta (2021) Guidance for Employer-initiated COVID-19 Testing. Last accessed: March 25, 2021. Accessed from: https://www.alberta.ca/assets/documents/covid-19-relaunch-guidance-industry-initiated-covid-19-testing.pdf

Appendix 1: Process for approval and initiation of COVID-19 testing for private businesses

Build a business case for rapid testing and indicate:

- ✓ How testing will improve workflow or workforce security.
- ✓ Target group for testing and frequency of testing.
- ✓ The testing process from ordering of the test, to collection of samples and reporting of test results into the electronic health record.
- ✓ Which accredited laboratory will provide oversight for quality management of tests.
- ✓ Which Health Canada approved test will be used.
- ✓ How health information (including test results and COVID status) will be protected.
- ✓ Which professional group will be involved in specimen collection and testing.
- ✓ Which health care provider or provider group will order tests and follow-up on results.

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Proposal Submission:

- ✓ Submit proposal to Department of Health and Community Services (DHCS). The applicant is expected to have worked through logistical issues with stakeholder partners prior to submitting an application.

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Review and Decision:

- ✓ Decision on new testing programs will be based on information presented in the business proposals. Incomplete or inadequate proposals will be rejected and the applicant notified.

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Notification:

- ✓ The approval status of new applications will usually be reported back to applicants in about two weeks.

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Progress Reporting:

- ✓ Accredited laboratories providing quality management oversight are required to report back to DHCS on progress on new programs including number of tests distributed and quality assurance issues.
- ✓ Accredited laboratories providing quality management oversight must take appropriate actions to reduce risk to clients when there is evidence of failure to comply with standards of practice.

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Public Accountability:

- ✓ DHCS will provide a list of businesses with approved testing programs in good standing.