Framework for the Evaluation of Laboratory Test Submissions

1. Introduction

The Council of the College of Naturopaths of Ontario is required to review requests from individual practitioners, system partners and patient advocates for changes or additions to the list of laboratory tests that can be performed and ordered by Naturopathic Doctors.

The regulation governing these tests is one that is made under the *Laboratory and Specimen Collection Centre Licensing Act* (LSCCLA), which is not under the rubric of the *Regulated Health Professions Act, 1991* or the *Naturopathy Act, 2007*. As such, the College Council does not have direct control over these regulations; however, historically, the Ministry of Health, which does have control over the LSCCLA regulation, has sought the support of the College for any requests for changes to the laboratory test list. This was true in the lead up to proclamation of the *Naturopathy Act, 2007* when commensurate changes to the LSCCLA regulation authority laboratory testing and requisitioning by NDs officially allowed NDs access to Ontario's laboratory system. It is also true in late 2024 when the Ministry received a request from a system partner for changes and asked that the organization first seek the support of the College Council.

2. Development of the Framework

This framework is being developed based on the initial discussions with the Ministry of Health in the lead up to proclamation of the *Naturopathy Act, 2007* in 2015 and on current discussions with the Ministry of Health, both the Health Workforce Regulatory Oversight Branch and Ontario Laboratory Medicine program.

3. Purpose of the Framework

The purpose of creating a framework for the evaluation of laboratory test submissions is to ensure transparency in the evaluation process, as well as to support the mandate of the Council and the College, which is to serve and protect the public interest. In the absence of such a framework, the public, the profession and system partners would have no clear understanding of what the Council might support and why. By establishing the framework, it is clear to all involved which tests might be approved by the Council.

Although the Ministry of Health has been consulted in the development of the framework, the framework does not bind the Ministry to accede to a request for laboratory testing that is supported by the Council of the College. The decisions on inclusion of laboratory testing belong exclusively to the Ministry based on parameters that are set by the Ministry.

DRAFT

4. The Framework

This framework addresses both Point of Care testing and Laboratory Testing that an ND can requisition.

4.1 Point of Care (PoC) Testing

For the purposes of this section, a point of care test is a test that is performed by an ND on their own patient in their office on a specimen that they have collected from their patient using a device that was designed for the purposes of testing on that specimen. The regulation under the LSCCLA allows NDs to collect blood, urine, and swabs (throat, vaginal) for testing in office.

4.1.1 No Additional PoC Testing will be Added

Currently, the profession is authorized to perform seven Point of Care tests in office on blood specimens collected from their patients and 10 Point of Care in office tests on non-blood specimens. No additional Point of Care testing will be considered by the Council for PoC testing. Rationale: Testing on blood is considered high risk due to infectious and communicable diseases. Such testing requires detailed safety protocols and careful handling and disposal of the specimen. Similarly, testing on non-blood specimen should be undertaken in the controlled environment of a Specimen Collection Centre where safety protocols are in place for both the public and individual patients.

4.1.2 Replacement for existing testing

Existing PoC tests authorized to the profession will be updated with a new test provided that the new test is developed and intended for the same purpose, is supported by clinical evidence to be a more appropriate test and it meets all the criterial set out in 4.3 below. Rationale: Given decisions already in place for this testing, there is a public interest in maintaining the degree of PoC testing that is available through the profession.

4.2 Collecting Samples for Test Requisition

This section governs situations where NDs are authorized to collect a specimen from their own patient in their own office for the purposes of sending the specimen to a licensed Ontario laboratory. Currently, NDs are authorized under the LSCCLA to collect specimens from their patients and send those specimens to a licensed Ontario laboratory for the purposes of 61 tests set out in the Regulation under that Act.

4.2.1 Specimen cannot be collected in a Collection Centre

Adding a new test to the list of tests where the ND collects the sample in office and delivers the specimen and requisition to a laboratory for testing requires that all of the criteria in 4.3 have been met and that the specimen required for the test requires the performance of a procedure that is authorized to NDs in Ontario and cannot be collected in a Specimen Collection Centre due to its invasive nature. Rationale: Specimen Collection Centres are uniquely positioned to collect specimens of all natures safely and effectively. The centres are associated with a licensed and accredited laboratory and their

DRAFT

employees are, through accreditation, properly trained and the centres have the processes in place to ensure the integrity of the samples and public health protection with respect to specimen handling.

4.2.2 Replacement Test

Existing tests where NDs are authorized to collect the specimen and send the specimen and a requisition to a laboratory will be updated with a new test provided that the new test is developed and intended for the same purpose, is supported by clinical evidence to be a more appropriate test and it meets all the criterial set out in 4.3 below. Rationale: Given decisions already in place for this testing, there is a public interest in maintaining the degree of specimen collection that is available through the profession.

4.3 Test and Sample Requisition

This section of the framework governs tests where the specimen is collected in a Specimen Collection Centre which is then sent to the associated laboratory for testing. The Council of the College will only consider tests that meet the following criteria.

4.3.1 Individual Named Test

The test to be considered must be a single identified test. Groups or categories of tests will not be considered. Rationale: The LSCCLA requires that a specific test be authorized. A category of tests or an open reference to tests on a particular sample cannot be added. Furthermore, without a named test, the remainder of the criteria of this framework cannot be applied and the College does not have the resources to undertake the necessary research to identify specific tests.

4.3.2 Testing is required for the Purpose of Diagnoses

To be considered, a test must be available for use in diagnosis of diseases, disorders or dysfunctions. As such a test that is designed for use only in research cannot be authorized. The test must be necessary for the purposes of diagnosis as opposed to a test that would be a good test to have available. Rationale: Section 26 of the Regulation made under the LSCCLA exempts NDs from prohibitions on specimen testing and requisition lab tests only for the exclusive purpose of diagnosing or treating their patient in their practice. A test that is not intended for the purposes of diagnosis would likely violate this requirement in the regulation. Given that patients are paying for the testing being conducted through the profession, the need for the test to be conducted is important to avoid unnecessary costs.

4.3.3 Test Available in Ontario Laboratories

Through the LSCCLA, Ontario NDs are allowed to access laboratory testing in the Province; however, by inclusion under this regime, NDs cannot use laboratories that are not licensed in Ontario. Rationale: The legislation authorizes NDs to collect certain specimens for specific authorized purposes, including some in office, PoC testing or testing by an Ontario licensed laboratory. Collecting a specimen for the purposes of sending the specimen to a laboratory outside of Ontario would breach the LSCCLA.

DRAFT

Important note: certain laboratories in other Canadian provinces have agreements for testing specimens that are collected in Ontario through a Specimen Collection Centre for an Ontario laboratory which then outsources the testing to a lab outside of Ontario. This is not a concern of the College because the specimen is collected by a Collection Centre owned by a licensed laboratory who can then undertake the necessary testing by whatever means necessary,

4.3.4 Clinical Interpretation Guidelines are Widely Available

Clinical Interpretation Guidelines for laboratory tests are structured recommendations that help regulated health professionals accurately understand and apply lab test results in clinical practice. These guidelines ensure that laboratory data is interpreted consistently, safely, and in a way that supports effective patient care. Rationale: the absence of clinical guidelines places the patient at risk of ineffective care as NDs would have no clear means of ensuring their understanding of the results and supporting patient care.

4.3.5 Test is used in General Practice

Many laboratory tests are used in general practice, meaning that a regulated health practitioner who treats a wide range of diseases, disorders or dysfunctions can interpret the results of a laboratory test. However, there are also laboratory tests that require additional knowledge, skill and judgement beyond general practice. These tests require specialized knowledge to know when the test might be used and what the test results are indicating about the patient's condition and/or treatment progress. Test that are intended for specialist use will not be considered for use by NDs. Rationale: The profession will not have the knowledge, skill and judgement to order the test, interpret the results and apply the results in a treatment regime.

4.3.6 Test is NOT a Public Health Test

For the purposes of this framework, there are two relevant types of laboratories in Ontario. Private laboratories that are paid for testing through Ontario's publicly funded system, and Public Health Laboratories that are owned and operated by the Province of Ontario. Public Health tests are the exclusive domain of Ontario's Public Health Laboratories. Tests conducted in these laboratories are not paid for by the Province as a test would be for a privately owned laboratory. Rationale: Since Public Health Laboratories do not receive money for specific tests but are essentially employees of the Crown, there is no mechanism for a patient to pay for a public health test when it is performed such as there is for testing in privately owned laboratories. Even if there were such a mechanism, the Public Health Laboratory is funded through the tax dollars of Ontarians and as such, a patient should not be paying for testing twice.

4.3.7 Test is not a DNA Test

Deoxyribonucleic acid (DNA) is a molecule that carries genetic instructions for life and is found in nearly every cell of the body. It is often used for the purposes of ancestry and ethnicity, paternity and family relationships, medical and health insights, forensics and genetic research. Rationale: DNA testing will not determine whether a patient has a disease, disorder or dysfunction but rather, whether a patient may be

DRAFT

predisposed to certain illness based on their genetics. As such, it is not a reliable measure for health status and is not used for the purposes of diagnosing or treating a patient.

4.3.7 Test is with the Scope of Practice of the Profession

The test must be used for diagnosis or treatment for conditions that are within the scope of practice of the profession. The scope of practice of the profession is identified through a combination of the Scope Statement and the controlled acts authorized to the profession as set out in the *Naturopathy Act, 2007*, as well as through the designated drugs set out in the regulation that may be prescribed, dispensed, compounded or sold, and the prescribed substances that may be administered by injection or inhalation. Clear examples of how the test will be used practically in naturopathic practice will be essential to making the scope determination. Rationale: enabling access to testing that will result in diagnosing conditions that cannot be treated or managed by NDs is not placing the patient at the centre of care because the patient will be required to visit another health care provider to obtain a confirmed diagnosis and treatment plan.

4.3.8 Best test for the patient

The test must be the best test for the patient in naturopathic practice. Rationale: Given that the patient is paying for the test to be conducted, the test should be the best available test for diagnostic purposes. A pre-screening test that requires a second confirmatory test to diagnose might not be the best test in the patient pays scenario.

5. Application of the Framework

In keeping with the purpose of this framework, any submission for inclusion of a laboratory test that does not meet the established criterial will be returned by the Chief Executive Officer of the College to the submitting party for further work and information. Any laboratory test that likely meets the criteria will be referred to the Council for a final determination that the test meets the criteria and as to whether the Council supports access to the test by the profession. The decision is solely at the discretion of the Council and its determination of whether the use of any testing by NDs is in the public interest, is within the scope of the profession, and can be used safely, ethically and effectively.

Tests that are deemed appropriate for use by Naturopathic Doctors in Ontario will be forwarded to the Ministry of Health, along with the information provided to the College and any additional information obtained by the College through expert reviews. Final decisions on inclusion of a test on the regulation made under the Laboratory and Collection Centre Licensing Act will be made by the Minister of Health.

DRAFT