

# **FACT SHEET**

# **COLLECTING SPECIMENS AND REQUISITIONING LABORATORY TESTS**

#### Introduction

This Fact Sheet provides Registrants of the College of Naturopaths of Ontario with important information about collecting specimens and requisitioning laboratory testing. It supersedes and replaces any previous information provided by the College.

## **Authority**

The authorities used in creating this Fact Sheet include the *Naturopathy Act, 2007*, the General Regulation made under that Act, the Regulations made under the *Laboratory and Specimen Collection Centre Licensing Act (LSCCLA)*, and the Standards of Practice for Naturopaths as set out by the College. The principles of patient centred care and ethical obligations of Naturopathic Doctors (NDs) under the Code of Ethics are also considered.

#### Overview

Before getting into the various relevant pieces of legislation that interconnect to create the framework for NDs to access laboratory testing, there are several principles to bear in mind.

A specimen collection centre has the infrastructure, protocols and processes in place to ensure the integrity and sterility of samples are maintained from the moment they're collected to the time they're tested.

When an ND orders lab tests for their patients, the patient is paying the costs for the testing as it is not funded through the public system. A model which places the patient at the centre of care would

suggest that only those tests that are clinically required should be ordered.

By extension, because lab tests ordered by NDs are paid for by the patient and not by the Ontario Government, labs earn added income from these tests. As a result, the laboratories want your business and that of your patients. Care should be taken when reviewing lab promotional materials about tests to ensure that the test is one that will best meet the needs of your patients and your ability to diagnose illness or monitor conditions.

Drawing blood from a patient is a controlled act that has been authorized to the profession, however, the authorization is limited to seven Point of Care (PoC) tests as described below. Drawing blood for any purpose other than these tests would represent a breach of the controlled act provisions of the Regulation.

### **Collecting Blood and Non-blood Specimens**

Although blood and non-blood specimens are best collected in a specimen collection centre, there are three situations where an ND is authorized to undertake the collection in office.

Blood for PoC Testing – An ND can collect blood from a patient in office for the purposes of performing one or more of <a href="seven">seven</a> PoC tests listed in the General Regulation under the Act and the regulations made under the LSCCLA and in accordance with the Standard of Practice on Point of Care Testing. These tests must be performed in the ND's office or clinic. It is important to note that outside of performing these seven tests, an ND is prohibited from collecting a blood sample in office.

Non-blood Specimens for PoC Testing – An ND can collect urine, a vaginal swab or a throat swab from a patient in office for the purposes of performing one or more of ten PoC tests listed in the Regulations under the LSCCLA in office, and in accordance with the Standard of Practice on Point of Care Testing. These tests must be performed in the NDs office or clinic.

Non-blood Specimens for Lab Testing – An ND can collect stool, urine, saliva, hair, tissue / discharge / sputum, and breath from a patient in office for the purposes of one or more of 61 tests — provided that the specimens are sent to an Ontario licensed laboratory.

# Requisitioning Blood and Non-blood Specimens

Even though these blood and non-blood specimens are being collected in a specimen collection centre, NDs are limited in terms of which tests they can order.

Requisitioning a Blood Sample – An ND can requisition the taking of a blood sample for the purposes of one or more of 133 tests, provided that the specimen is collected in an Ontario Licensed Specimen Collection Centre that sends those specimens to an Ontario licensed laboratory. It is important to note that an ND may not requisition a blood draw for a test that is not included among these 133 tests.

Requisitioning a Non-blood Sample – An ND can requisition the taking of a stool, urine, saliva, hair, breath and tissue / discharge / sputum sample for the purposes of one or more of the same 61 tests (of the total 133) noted in the prior bullet point, provided that the specimen is collected in an Ontario Licensed Specimen Collection Centre that sends those specimens to an Ontario licensed laboratory. It is important to note that an ND may not requisition the collection of a non-blood specimen for a test that is not included among these 133 tests.

# Summary - What an ND may do

This means that an ND may:

- **Collect** in office samples for testing in office for one or more of 17 tests (7 on blood, 10 on other specimens) performed in office.
- Collect specimens in office for one or more of 61 tests and send those specimens to an Ontario licensed laboratory.
- Requisition one or more of 194 tests (133 on blood, 61 on other specimens) from an Ontario Licensed Specimen Collection Centre who will send the specimens to an Ontario licensed laboratory.

# Summary – What an ND may not do

This also means that an ND may not:

- Collect a specimen or blood sample that they are not authorized to collect.
- **Requisition** collection or taking of a specimen that they are not authorized to requisition.
- Collect a specimen or blood sample from a patient and send that specimen directly to a laboratory that is not licensed under the LSCCLA, including laboratories outside of Ontario.
- Requisition the collection of a specimen or testing on a specimen directly from a laboratory that is not licensed under the LSCCLA, including collection centres and laboratories outside of Ontario.

### Implications of the Regulations

As NDs are authorized to collect certain blood and non-blood specimens and requisition others through two unrelated but equally important regulatory frameworks, there are certain implications that may not be specifically set out but can be concluded based on the totality of the regulations.

**US-based Testing** – When requisitioning tests or taking specimens, the purpose has to be for a test authorized to NDs in the regulations, and when a laboratory is involved (non-PoC tests) the laboratory has to be licensed in Ontario; **an ND** may not order a lab test **directly** from a lab outside of Ontario. Put simply, an ND cannot requisition a lab test directly from a US laboratory or collect a

specimen or blood sample and send it directly to a US laboratory. This does not affect the ability of an Ontario licensed laboratory from sending a specimen or blood sample out of province for testing.

Diagnostic, prevention or treatment - The collection of specimens (blood and non-blood) or the requisitioning and testing of specimens is authorized for diagnostic, prophylaxis (prevention) or treatment purposes. The implication of this wording is that any test that is not for one of these purposes, such as a test for research or information purposes, may not be requisitioned by an ND.

Interpreting Test Results – It is an important underpinning of the laboratory and specimen collection centre system that a person requisitioning a test on a specimen from a patient be able to interpret the test results. Simply put, in requisitioning a test, and ND must first understand the associated level of complexity of resulting laboratory values for that test and be able to interpret the results.

Critical Value Referrals – Registrants are reminded that it is a standard of practice of the profession that the member must immediately refer the patient to a member of the College of Physicians and Surgeons of Ontario, or a member of the College of Nurses of Ontario who holds a certificate of registration as a Registered Nurse in the extended class, if the patient's laboratory test result from a laboratory licensed under the LSCCLA is a critical value test result. This is specified in section 13(6) of the General Regulation made under the *Naturopathy Act*, 2007 and in the Standard of Practice on Laboratory Testing.

#### **Lab Test Kits**

Test kits that are provided by a laboratory may impact an ND in two different ways.

First, if an ND recommends a patient use a lab test kit or provides the lab test kit to a patient, the ND is "requisitioning" the test. As a result, the lab test kit can only relate to one of the tests described above. An ND cannot send a patient home with a test kit for a test that is not authorized to them in the Regulations and that is not from a laboratory licensed in Ontario.

Second, some patients will search out their own lab test kits, collect the specimen and send the specimen to the lab that provided the kit. The patient will then often bring the test results to their ND for information and to be used as part of their diagnosis and treatment plan. While an ND can use these results, you should be skeptical about these results. You may want to consider:

- Was the laboratory wherever it may be, licensed and accredited to perform this specific test?
- Is there information available about the accuracy and reliability of this test?
- Is the test valid for diagnostic, preventive or treatment purposes (some tests are limited to informational or research purposes)?
- Do you have the knowledge, skill and judgment to interpret these test results?
- Is a similar test available to you in Ontario under the LSCCLA regulations that you might order for confirmatory purposes?
- Is there other information in the patient file and their health history that assists in confirming any diagnosis you would make based on these test results? Essentially, are the results consistent with their health history or an outlier?

You may also want to consider what the patient might tell the College if they were to file a complaint. Was the recommendation to use the lab test kit implied based on their discussions with you?

# **Lyme Disease Testing**

NDs are permitted to order Lyme Disease Antibody testing for their patients. To do so, they must requisition the collection of blood from a Licensed Specimen Collection Centre who will send it to a licensed laboratory.

The College has been and continues to recommend that NDs requisition Lyme Disease Antibody testing using the <u>Public Health Ontario</u> test requisition form available from the Public Health Ontario website.

Using a Public Health Laboratory has two distinct advantages for your patient. First, the test meets Ontario's standards for Lyme Testing and the results can be relied upon for your patient and for public health reporting.

Second, when you requisition a Lyme Disease Antibody test for your patient using a Public Health Laboratory, your patient will not be required to pay a fee for the testing to be completed. This is in keeping with a patient centred care model.

When completing this requisition form, you should leave the "Clinician Initial/Surname and OHIP/CPSO No." field blank and complete in full the "cc Doctor/Qualified Health Care Provider Information" section in full.

### What's the big deal?

A lot of time has been spent by many people in several organizations worrying about laboratory testing being conducted by NDs lately. As an ND, you have to ask yourself why that is the case? As noted above, many laboratories have tests ordered outside of the public system as a line of business. Of course, if we ask that question about others, we need to be prepared to answer it ourselves as the regulatory authority. The simple truth is that we cannot regulate, including holding NDs accountable for the lab tests they requisition, if it's unclear to NDs what tests are available to them.

The College's mandate is clear – we regulate the profession in the public interest to ensure Ontarian's have access to safe, competent, ethical care. The public interest mandate includes ensuring patients are safe from any harm, much like the Naturopathic Oath. However, the "harm" means more than many might initially contemplate. It includes:

- Physical, psychological, financial harm.
- Dishonesty and disrespect.
- Poor quality care.
- Sexual abuse.
- Breach of laws.
- Ineffective or unnecessary care.

# **Summary Reference Table**

Procedure/Function	Authorisation	Limitation
Take blood sample in office	Only for 7 PoC tests.	No other blood samples may be drawn by an ND in accordance with the Standard of Practice on Point of Care testing.
Requisition collection of blood sample.	Only for 133 tests.	Blood collected in Ontario licensed Specimen Collection Centre; specimen sent to an Ontario licensed laboratory.
Collect non-blood specimens in office.	Only for 10 PoC tests.	Limited to in office testing on urine, vaginal swabs or throat swabs in accordance with the Standard of Practice on Point of Care testing.

	Only for 61 tests.	Specimen collected in office and sent to an Ontario licensed laboratory.
Requisition collection of	Only for 61 tests.	Specimen collected in Ontario licensed Specimen Collection
non-blood specimens.		Centre; specimen sent to an Ontario licensed laboratory.