



LABORATORY TESTING & NDs

Introduction

This Fact Sheet has been created in follow up to the College's communication of July 21, 2021, on the subject. It is intended to provide support and guidance to the profession in navigating the complex world of laboratory testing.

Lyme Disease Testing

NDs are permitted to order Lyme Disease antibody testing for their patients. Unfortunately, not every licensed laboratory may be fully aware of this.

The College has confirmed the proper process for Registrants to order Lyme Disease antibody testing is as follows.

NDs must use the [Public Health Ontario Laboratory test requisition form](#) available from the Public Health Ontario website when ordering Lyme Disease testing rather than requisition forms from a specific laboratory, i.e. Life Labs or Dynacare.

Patients should take this form to an Ontario licensed specimen collection centre where a blood sample will be collected. The collection centre will forward the sample to one of 11 Ontario Public Health laboratories for testing.

Using any other requisition form will result in the specimen collection centre refusing to take the sample.

ND Responsibility

It has been suggested that it is not the ND's responsibility to ensure that the lab from which they are ordering a test is licensed to perform the test and will perform it themselves. This information is incorrect.

There are many situations where the onus is on the health professional to confirm information before they act. NDs cannot delegate, for example, until

they have assured themselves that the person receiving the delegation has the knowledge, skill and judgment to perform the controlled act and is able to do so under their own regulatory framework.

Lab testing is no different. When a lab contacts you to promote a new test, you should naturally be

suspect. Innovation in lab tests is not unheard of but it also does not happen every day. Here are a few easy questions to ask the lab and what you might look for in terms of their response.

Q1: Will your lab perform the test, or do you farm it out to someone else? If the latter, to whom are you sending the test?

With this question you are working to find out if the lab performs the test itself which is a requirement under Ontario's Laboratory and Specimen Collection Centre Licensing Act (LSCCLA). If the lab is sending it to someone else, many of the following questions will apply to the lab that will be performing the test.

Q2: Is your lab licensed to perform this test by the Ministry of Health? (Alternatively, is the lab to which you will send the sample licensed to perform the test by the Ministry of Health?)

With this question you are assuring yourself that the lab is complying with Ontario requirements, something about which you would want to assure yourself in terms of everyone you partner with in the care of your patients.

Q3: Is the lab test permitted for diagnostic purposes or limited to research purposes?

This is an important question because in order to properly serve your patients' interests, you want to assure yourself that the test is available for diagnostic purposes. Some tests are available only for research purposes. This means that the information gleaned from the test may be reliable enough for research into various illness but not reliable as a diagnostic tool.

Q4: How accurate is the test and how do you know what its accuracy is?

Test accuracy is critical to its usefulness as a diagnostic tool. Most people can't determine for themselves the accuracy for a test which is the reason for the second part of the question about how the lab knows it is accurate. Typically, you will find that the test has been evaluated by a third-party accrediting agency or a regulator elsewhere. For example, if the FDA in the US has approved the test, then you can be fairly confident that it will be accurate in producing results against what it is intended to measure.

Q5: Can I see an anonymized version of a test report so that I can see what I would be getting so I know if I am able to interpret it?

This is very important for you as a health professional. A test has no diagnostic value for your patients if you cannot read and interpret the results for your patients. Some tests measure so many different parameters that the ability to understand what it is saying about your patient is highly limited. There is no shame in not being able to interpret a test. There is in using it regardless of your ability to understand what it is telling you.

FDA approval of tests

A lot has been said about why FDA approval is necessary for a test. Of course, in Ontario it is not necessary, however—as noted above—FDA approval does help in assuring that the test is reliable. A test that has not been approved by the FDA in the US is either too new and has not been evaluated or has failed the evaluation to ensure it is reliable and providing accurate results for what it is intending to measure. Canadian regulators often look to other jurisdictions to see whether regulatory approval has been granted there when contemplating its use here.

Where FDA approval becomes critical is in the situation where a lab is sending a sample to the US for processing/testing (even though health professionals should not be using a lab that is not performing the test).

Patient's Interests Come First

As a regulated health professional, an ND is obligated to put the patient's interests above their

own self-interest or profession interest. We recognize that NDs when seeking out new lab tests are trying to get the best information about the patient's health status and conditions. However, if the test is not reliable, the motivation is moot. Diagnosing illness or conditions with unreliable data can lead to misdiagnosis and poor treatment outcomes. It can also be highly dangerous to the health and well being of your patient.

Placing the patient's interests first means you are confident that any testing you order is necessary and will provide reliable diagnostic information. This is no different from a situation where you delegate the performance of a controlled act. Would you delegate the mixing of an IV bag to clerical support in your office if they have never had any training in compounding?

Conflicts of Interest

Conflicting interests can arise in many different ways. For example, if a lab promotes your use of a lab test on your patients by providing you a gift or cash incentive and you use that test, you have likely placed yourself in a conflict of interest. You may be placing your personal or financial interests above the patient's interests.

Similarly, organizations can also be in a conflict of interest if they are receiving financial support from other organizations in exchange for promoting their products or services. Some time ago, the College contemplated accepting advertising and sponsorship from third-party organizations related to the practise of the profession. The Council determined that doing so would place the College in a conflict of interest as it might become—or be perceived—to be beholden to those third-party organizations.

In this matter, the College has no conflicting interests. Our interest is in serving and protecting the public interest. It is in the public interest that lab tests being ordered for patients are accurate and reliable. The public is also protected by all of us working within the regulatory framework in Ontario.