SPECIMEN COLLECTION - PRIVATE CLINICS AND COLLECTORS	Laboratory LAB-230

Issuing Authority	**Gena Bugden, Vice President Medical Services Signed by Gena Bugden Dated: October 5, 2022**
Office of Administrative Responsibility	Laboratory Medicine
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Overview

This policy is written to ensure quality standards are met and patient safety is protected in regard to specimens submitted by external collectors in accordance with appropriate standards and guidelines and the following laboratory quality policy statement:

Laboratory Medicine is committed to providing the community with appropriate, timely, and comprehensive services by:

- Developing and maintaining a quality management system.
- Implementing continual quality improvement processes.
- Providing therapeutic, diagnostic, and consultative services of the highest quality.
- Utilizing evidence-based best practices.
- Ensuring that all personnel are aware of and adhere to the quality management system at all times. (Quality Policy Manual v4, p. 15)

POLICY

Requirements for the collection, handling, and submitting of laboratory specimens to the laboratories of Eastern Health must adhere to internationally recognized

standards and guidelines to ensure specimen is of sufficient quality for provision of accurate test results.

Internationally recognized standards and guidelines include but are not limited to:

- International Organization Standards Organization (ISO) 20658 *Medical laboratories - Requirements for collection & transport of samples*
- Canadian Standards Association (CSA) Z316.7-12 Primary sample collection facilities and medical laboratories
- Clinical and Laboratory Standards Institute (CLSI) guideline GP41 *Collection of Diagnostic Venous Blood Specimens*

Specimens collected external to Eastern Heath will be accepted only by agencies (individuals, private clinics, or private companies) that have entered into a signed Agreement (for external specimen collectors) with Eastern Health. The Agreement outlines the responsibilities of both Eastern Health and the Specimen Collector.

In order to enter into the Agreement, a formal application process must be undertaken, and the application must be approved by the laboratory program prior to signing the agreement.

Scope

This policy applies to any person, clinic, or organization that collects laboratory specimens to submit for testing in Eastern Health laboratories.

This applies *only* to specimens collected *outside* of Eastern Health facilities by agencies or independent phlebotomists offering specimen collection services. Examples of agencies are private physician clinics and private specimen collection companies. Independent phlebotomists include any individual conducting phlebotomy services including employees of Eastern Health who collect specimens in the community *outside* of work hours and job responsibilities.

This policy also applies to all employees of Eastern Health laboratories to ensure the parameters of this policy are abided by and enforced.

Purpose

This policy is developed to provide guidance to specimen collection professionals for specimens collected external to the Eastern Regional Health Authority in order to promote a common quality standard across all modes of service delivery and to assure a culture of quality throughout all phases of laboratory diagnostic activity.

The phlebotomy industry in Newfoundland and Labrador is unregulated. Therefore, Eastern Health has developed a program to ensure external specimen collectors have a level of training and competency suitable to collect and submit

specimens that meet the standard of quality required for true and accurate test results. Entering into an Agreement facilitates the provision of resources and guidelines to external collectors and improves access to primary health care.

Procedure

1. External Specimen Collectors must access the external collections information and guidelines, including the *Application Instructions* from the Eastern Health website

   For external collectors – Laboratory Medicine (easternhealth.ca)

2. Complete the application and submit along with all required documentation (as noted on the application) and email to the given laboratory email address.

   If the application is incomplete or any required information is not submitted, the applicant will be contacted and directed to resubmit.

3. Review and consideration will be given to the application by an application review committee to determine approval or rejection.

   - If the application is approved, the applicant will be provided with the Agreement for signing.
   - If the application is rejected, a committee member will provide an explanation to the applicant.

4. Once the Agreement has been signed, the applicant will be provided with an educational opportunity on the Eastern Health requirements for specimen collection, handling, and transport.
5. Compliance with the terms of the Agreement is necessary for it to remain in-effect until the expiry at which time it may be renewed in accordance with the Term & Termination clause in the Agreement. Aspects of the agreement are audited, and nonconformities documented.
6. Non-compliance with the terms of the Agreement may result in suspension or termination of the external collector's privileges.

Guideline

The Agreement *for Specimen Collection by External Agencies* outlines the responsibilities of both the collection agency and Eastern Health and includes, but is not limited to, the following provisions:

- Adherence to the Laboratory Requisitions policy MED-LAB-050.
- Adherence to the Laboratory Specimen Acceptance and Rejection Criteria policy LAB-040.
- Adherence to various procedures for specimen collection, handling, processing, transport, and delivery of specimens.

- Collector training and competency requirements.
- Adverse event reporting.
- Insurance requirements and liability.
- Provision of a formal communication pathway between collection agencies and Eastern Health including a pathway for urgent patient safety issues.
- Required and recommended standards and guidelines for the collection of clinical laboratory specimens.
- Requirements to protect the privacy of health and business information.

Test Menu

An external collector laboratory test menu is developed by the laboratory which limits the tests external agencies are permitted to collect. The test menu is based on review of specimen stability limits and collection requirements in order to identify tests that can be safely collected outside of an Eastern Health facility.

A process is in place to consider requests for extra tests to be added to the menu. This must be brought to the laboratory management and Division Chief for consideration and approval.

Should a situation arise where extra tests outside of the test menu need to be collected in the interest of patient safety and is of an urgent matter, the collector must first reach out to the lab to verify that the lab will be able to process the specimen (i.e., all collection, handling, and stability requirements will be met to ensure acceptance of the specimen and accurate test results).

Requisitions

Requisitions submitted with specimens must meet the requirements set out in the Laboratory Requisitions Policy MED-LAB-050

The specimen collector must not materially change the original requisition. Material changes to the requisition include, but are not limited to:

- adding or deleting tests requested by the authorized prescriber
- changing the priority level of a test
- adding or removing patient demographic information
- adding or removing physician information
- editing any of the information entered on the requisition by the requesting health care provider.

Notes are permitted on the requisition to allow for information on specimens collected to alert the laboratory (e.g., not all specimens collected). Notes by collector must be dated and initialed.

Supporting Documents *(References, Industry Best Practice, Legislation, etc.)*

- Canadian Standards Association (2012). CAN/CSA-Z316.7-12. *Primary sample collection facilities and medical laboratories – Patient safety and quality of care – Requirements for collecting, transporting, and storing samples.*
- Clinical and Laboratory Standards Institute (2017). GP41-ED7 *Collection of diagnostic venous blood specimens*, 7th ed.
- Institute for Quality Management in Healthcare (2019). *Medical Laboratory Accreditation Requirements,* v 8
- International Organization for Standardization (2012). ISO15189 *Medical laboratories – Requirements for quality and competence*, 3rd ed.
- Medical Care Insurance Act O.C. 96-132
- Medical Care Insurance Beneficiaries and Inquiries Regulations CNR 20/96

Linkages

- Agreement for External Specimen Collectors document #20692
- Application for Collectors Agreement form ch-2318
- External Collector Change to Information form ch-2319
- External Collector Privileges Revoked form ch-2320
- Laboratory Medicine Specimen Acceptance and Rejection Criteria policy LAB-040
- Laboratory Requisitions policy MED-LAB-050
- Laboratory Quality Policy Manual v4 #5836Privacy and Confidentiality policy ADM-030

Key Words

Laboratory, Specimen, External Collector, Private Collector, Collection, Collector, Blood Test, Urine Test, Phlebotomy, Phlebotomist.

Definitions & Acronyms

Phlebotomy	The surgical opening or puncture of a vein in order to withdraw blood.