LABORATORY MEDICINE SPECIMEN ACCEPTANCE AND REJECTION CRITERIA	Laboratory Services LAB-040

Issuing Authority	**Gena Bugden, Vice President Signed by Gena Bugden Dated: January 19, 2023**
Office of Administrative Responsibility	Laboratory Services
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Level	Two (II)
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Overview

The laboratory will process patients' samples in the safest and most timely manner. Processing samples that do not meet laboratory minimum quality criteria could have serious health and safety consequences for the patient, resident, client, or staff involved. The laboratory adheres to minimum requirements for specimen acceptability according to World Health Organization (WHO) guidelines, Clinical and Laboratory Standards Institute (CLSI) guidelines, Accreditation Standards, Eastern Health testing procedures and similar recognized laboratory literature.

POLICY

Laboratory specimens must be unequivocally traceable, by request and labelling, to an identified patient and where applicable, the site or source of specimen.
Every laboratory specimen must be evaluated for quality upon receipt, prior to testing, to ensure it meets minimum acceptance criteria to prevent result inaccuracies.

Re-collectable specimens that do not meet acceptability criteria, as described in the procedure section of this policy, will not be processed and the submitting physician will be notified indicating the reason(s) for rejection.

Acceptance and rejection of specimens must be documented by laboratory staff according to the laboratory quality procedure for *Specimen Acceptance and Rejection* #7247 and laboratory division-specific procedures applicable.

Scope

Applies to all employees as well as any person, clinic, or private organization that submits specimens to the laboratory for testing.

Purpose

The purpose of this policy is to ensure that specimens submitted to the laboratory for testing meet minimum quality criteria for acceptance and thus avoid rejection of specimens deemed unacceptable.

Procedure

Laboratory Requisitions

Specimens must be accompanied by a completed, approved laboratory requisition or directly entered in the Health Information system. Specimen batches from provincial referring laboratories may be received with shipping batch documents or individual requisitions. The patient and specimen identification information must be on both the specimen and the requisition or shipping batch document as applicable. An incomplete requisition will cause delay in specimen processing and possible rejection of the specimen. Refer to the policy *Laboratory Requisitions* MED-LAB-050 for detailed information on requisition requirements.

Specimen Labeling

All specimens submitted to the Laboratory for processing must be adequately and legibly labeled.

Specimens must be labeled as follows:

- Patient's full first and last names.
- Health care number.
- The name, initials, or computer mnemonics of the person drawing the sample.
- Date of collection
- Time of collection
- Anatomic site and source of specimen as applicable.

If the patient has not been issued a heath care number, use a second unique identifier in accordance with policy PRC-130 Positive Client Identification.

Specimens may be received labeled with a barcode label or will have a barcode label affixed to the specimen by laboratory staff. The label ***must*** include identifiers as stated above. Addressograph identification labels or computer-generated labels should be used wherever they are available.

Specimens received without the required information, or if the information is not legible, are considered mislabeled specimens and will not be processed except in the case of precious specimens.

Specimen **containers must *not* be pre-labelled** as this creates a high risk for specimen mix up. Specimen collection containers must be labeled immediately after collection and in the patient's presence, by the health care professional who collected the specimen, unless the specimen is self-collected. When circumstances (e.g., codes, surgery) result in a specimen being labeled by someone other than the health care professional, the person labeling the specimen must have witnessed the collection and that the patient information was identified properly. (Institute for Quality Management in Healthcare [IQMH], v 8, V.C.2.3 and Clinical and Laboratory Standards Institute [CLSI], QP33 ED2, 4.1)

Specimen Stability – Most laboratory tests have defined stability limits. To ensure accuracy in testing, specimens cannot be processed beyond those stability limits. It is necessary that all specimens are labelled with the collection time so the stability can be determined. Specimens received by the lab outside of the acceptable time/stability limits or not labelled with a collection time will be rejected unless deemed a precious specimen.

Volume of Blood Collected - Specimens may be rejected if the blood in the tube does not meet the fill volume indicated on the tube label. This is to ensure the appropriate blood-to-additive ratio (anticoagulant or clotting factor) and insufficient volume for analysis.

Collection Container Type - Specimens not collected in the specified container may be rejected. The appropriate container type is indicated for each test in Meditech and in the specimen collection manuals available on the Eastern Health intranet Laboratory Services - Laboratory Specimen Collection Manual (easternhealth.ca) and, for externally collected specimens, the laboratory web site Laboratory Services - Laboratory Specimen Collection Manual (easternhealth.ca). The external website does not include specimens that are only collected internally such as surgical tissue specimens.

Specimen Integrity - Specimens that are assessed as having quality issues such as hemolysis, icterus, clotting, lipemia, inadequate centrifugation, leaking or other factors that may compromise the integrity of the specimen may be rejected

depending on the severity and type of issue. If the specimen is not rejected, but quality of the specimen may be compromised, the report will provide an interpretive comment for the health care provider.

Processing Precious Specimens – Laboratory staff will endeavor to process in the safest and most timely manner any mislabeled or compromised specimen considered to be a non-recollectable (precious) specimen. The laboratory will provide a *Verification Form for Precious Specimens* ch-1480 that must be completed and signed by the requestor. Specimen labeling will be completed by the requestor except in instances where they are off-site; in these cases, the laboratory staff will label the specimen using the information provided on the *Verification Form for Precious Specimens.* In such cases, where the compromised precious specimen has been accepted for testing, the final report must indicate caution and state the nature of the issue.

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

- Accreditation Canada (2018). *Standard requirements for biomedical laboratory services*, v.14.
- Accreditation Canada (2018). *Standard requirements for transfusion services,* v.14.
- Canadian Society of Cytopathology (2019) *Guidelines for practice and quality assurance in cytopathology*, fifth revision.
- Clinical and Laboratory Standards Institute (2011). AUTO12-A *Specimen labels: content and location, fonts, and label orientation,* 1st ed.
- Clinical and Laboratory Standards Institute (2019). GP33 ED2 *Accuracy in patient and sample identification,* 1st ed.
- Clinical and Laboratory Standards Institute QMS01-A4 (2011). *Quality management system: A model for laboratory services; approved guideline*, 4th ed. (6.1.4).
- Clinical and Laboratory Standards Institute GP44-A4 (2010). *Procedures for the handling and processing of blood specimens for common laboratory tests,* 4th ed.
- CSA Z316.7-12 (2012). *Primary sample collection facilities and medical laboratories — Patient safety and quality of care — Requirements for collecting, transporting, and storing samples*.
- CSA Z902-20 (2020) *Blood and blood components*
- IQMH - Institute for Quality Management in Health Care. Standard version 8 (V.C.2.3, V.C.2.8).
- International Standards Organization ISO 15189:2020 *Medical laboratories — Requirements for quality and competence*.
- World Health Organization (2002). *Use of anticoagulants in diagnostic laboratory investigations.*

- World Health Organization (2011). *Laboratory quality management system handbook.*

Linkages

- Laboratory Collection Manual available on the Intranet
  Laboratory Services - Laboratory Specimen Collection Manual (easternhealth.ca)
- Laboratory Requisitions MED-LAB-050
- Occurrence Reporting and Management Policy QRM-080
- Positive Client Identification Policy PRC-130
- Requirements for the Creation of a Patient, Resident, Client Record Policy RM-CR(III)-120
- Specimen Acceptance and Rejection (lab quality procedure) #7247
- Verification Form for Precious Specimens form # ch-1480

Key Words

Recollectable Specimen, Precious Specimen, Adequate Label, Labeling, Acceptable, Limits, Stability, Specimen, Sample, Laboratory

Definitions & Acronyms

Agent	A person, other than an employee, authorized by Eastern Health to act on its behalf. This term includes physicians, volunteers, and pastoral care workers as well as staff of contractors and other persons working within Eastern Health Facilities or affiliated with Eastern Health.
Laboratory Specimen	Laboratory specimens are the raw materials on which laboratory personnel perform examinations that generate the results used for patient diagnosis and treatment.

Precious Specimen	A specimen that is obtained by an invasive technique or otherwise deemed to be of critical importance. Specimens that fall into this category may include, but are **not limited to:** ▪ Cerebrospinal fluid (CSF) ▪ Surgically acquired specimen ▪ Suprapubic tap urine ▪ Bronchoalveolar lavage fluid and protected brush ▪ Deep wound aspirate ▪ Stone ▪ Bone Marrow ▪ Amniotic fluid ▪ Aphaeresis sample ▪ Autopsy samples ▪ Timed tests requiring stimulation or injection. ▪ Neonatal Blood Gas ▪ Cord blood Gas Each laboratory department will determine when specimens for their department will be processed as precious specimens.
Specimen Stability	The capability of a sample material to retain the initial property of a measured constituent for a period of time within specified limits when the sample is stored under defined conditions (ISO Guide 30, 1992).