Quality and Accuracy - Specimen Acceptability and Transport Guidance

Sample labelling and identification - criteria for acceptance

Pathology and Laboratory Medicine recognizes that the quality and accuracy of laboratory results can only be assured when specimens and test requests meet specific criteria for collection, labelling, and integrity. Laboratories must adhere to strict standards respecting the identity and integrity of specimens. This policy applies to all specimens and test requests submitted to the laboratory.

Each sample is evaluated for sample preservation. In general, no sample is refused for the reason of improper quantity or storage if the accuracy of any test result obtained may not be compromised by deficiencies in this area. However, if the ability to achieve a result may be compromised the referrer will be contacted about the improper sample container.

This document outlines the first level of screening for specimen acceptability.

Specimens collected for laboratory testing must be labelled with a permanently attached label in the form of a computer generated label or written legibly in indelible ink.

All specimens must be legibly labelled at **minimum** with:

- Patients legal name (first name and last name) or unique code in the case of anonymous testing **and**
- A second **unique** identifier that can be traced directly back to the patient such as Provincial Health Card Number, Medical Record number, Clinic #, chart #)
- Date of collection and time of collection (if applicable)

The laboratory recognizes that, in certain cases where the specimen is less common, involves an invasive procedure or could not otherwise be easily recollected, it may be acceptable to apply an exception to specimen rejection. Exceptions are applied using strict and explicit criteria in accordance with established procedures.

Responsibility

The requestor (or designate) is responsible for:

- Ensuring the sample has met all acceptance criteria before submission to the Laboratory, and
- Authorizing correction of information for all samples where a major deficiency or discrepancy has been identified and an approved exception applies.

Medical, Scientific or Professional personnel (or designate) are responsible for approval of sample and test request or requisition exceptions when unusual circumstances not defined in this policy are identified.

Laboratory Personnel are responsible for:

- Accepting samples and tests requests only when defined criteria are met,
- Approval of sample and test requests exceptions when defined criteria are met,
- Contacting requesters and/or patients when samples and test requests are not acceptable and advising of next steps,
- Bringing concerns or unusual circumstances not identified in this policy to the attention of Medical, Scientific or Professional personnel for direction, and
- Documenting any sample acceptance non-conformances according to laboratory procedures.

General Rejection Criteria

Reasons for rejecting a sample may include, but is not limited to the following:

- Improper labelling: mislabelled/unlabelled
- Improper collection container
- Not adhering to special collection requirements when applicable (e.g. draw the sample in a pre-chilled tube)
- Excessive delay between collection and receipt in the laboratory
- Improper timing of collection
- Specimen damaged in transit
- Specimen not properly sealed (leaking)
- Specimen received with needle still attached
- Insufficient sample for analysis
- Specimen not stored properly
- Clotted/hemolyzed blood specimen
- Specimens contaminated and/or containing substances or particles that interfere with testing or extraction

- Expired blood tube
- Any specimen submitted in a manner which could create a health or safety hazard to laboratory personnel is considered unacceptable (e.g. leaking specimens, syringes or blood products with needles attached)
- For Transfusion Services, any hospital registered specimen that is not designated in the Hospital
- Information System as having been "collected" by the nurse is automatically rejected.

Labelling of Sample Containers

A positive link between the patient and sample must be present to avoid medical errors such as switched or mislabelled samples prior to accessioning. Two identifiers on the specimen containers/slides must be matched to a completed requisition to unequivocally identify the patient for whom the test is ordered.

Do not use "pre-named" tubes/containers

A specimen is mislabelled when the requisition bears the name of one patient and the accompanying specimen bears the name of another patient.

Mismatched specimens are defined as specimens that are submitted with a requisition on which the identifying information does not exactly match that which appears on the specimen (e.g., a common name is used on the specimen and the formal name is used on the requisition).

The laboratory reserves the right to refuse improperly labelled specimens.

Label tube at the patient's bed side or clinic/lab chair using information from the arm band (or identification card) and computer generated label(s). Labelled tubes should be initialed by the collector.

Under no circumstances will a specimen be returned to the ward/clinic.

Label Notes

- Label is placed lengthwise on the tube without obscuring the level of blood in the tube or any other patient demographic label
- Label must not obscure the level of blood in the tube.
- Label should match the requisition exactly.
- Do not pre-label the collection tube prior to collecting the specimen
- Label immediately *following* collection and in the presence of the client ensuring positive patient identification using two unique identifiers

Glass Slides

All glass slides (stained and unstained sections) must be labelled using lead pencil, etching or indelible ink labels. Note: The actual slide must be labelled not the slide container.

Unlabelled Sample Containers

Unlabelled samples received without a requisition or electronic order will be rejected.

Unlabelled samples received with a requisition will be rejected if they can be recollected and are not irretrievable (e.g., venous blood samples, urine, sputum, stool, etc) and can be easily recollected. The physician/nurse/floor will be notified so that a new specimen may be drawn.

Incorrectly Labelled (Mislabelled) Sample Containers

Samples that are labelled with the wrong patient's name compared to that of the accompanying requisition or with a different patient's ID number, the same criteria as for Unlabelled Specimens apply.

Incorrect Container or Preservative

Specimens received in an incorrect container, or without appropriate preservative, which would invalidate the results, will required recollection. The requestor will be informed.

Insufficient Specimen

If insufficient specimen is received for all procedures requested and the specimen is easily able to be recollected, a repeat collection will be requested. If the specimen is not easily able to be recollected (CSF fluids, etc.) the requestor will be contacted to establish a priority order of tests to be performed.

Unsuitable Specimen for Procedures

Specimens which are received and are unsuitable for the procedure requested (urine for a blood test, etc.) or if the specimen has been in transit too long for a valid result, the specimen will be rejected. The requestor will be informed so a proper specimen can be collected.

Exceptions: difficult-to-collect and irretrievable specimens

Definition:

Irretrievable - impossible to recover; describes something that cannot be retrieved, restored, fixed or put right; unrecoverable

Procedures for difficult-to-collect are necessarily different from those for samples which may readily be collected. The following list is not inclusive but indicates those samples to which special attention should be paid by both the physician and the laboratory.

Examples:

- Histopathology specimens including biopsies
- Cytology specimens (Other than PAP's, 'voided' urines and sputums)
- Body fluids: Synovial fluid, CSF, Pleural, Pericardial
- Blood cultures in height of fever
- Abscess fluids
- Kidney stones
- Intrauterine devices (IUD) for culture
- Specimens from neonates (Transfusion medicine samples excluded)
- Arterial blood gases and other arterial specimens
- Any prenatal, perinatal or fetal specimen
- Some DNA samples

Process:

1. The Physician's office/nursing unit will be contacted. **The laboratory will make no effort to verify the identity of the patient or alter the requisition in any way.**
2. The person responsible for collecting the specimen may be permitted to come to the laboratory to identify (re-label) the specimen only if it is an irretrievable sample.

Authorization to proceed with testing in any of the above situations may be given by the Medical or Lab Director or designate. In this case, the sample is accessioned and test results will be accompanied by a disclaimer.

Note: Irretrievable specimens should never be transported via the pneumatic tube

Requisitions

Each test request should be made on the laboratory's requisition form or by Laboratory Information System request; if an incorrect form is used, the laboratory may request additional information that has not been provided. In this case a request will be put forth for the submitting party to fill out the requisition form of the host Laboratory.

When requesting specialized/uncommon tests, please refrain from using abbreviations/acronyms/short forms/antiquated names. Instead, write out the full name of the commonly accepted test name to ensure unambiguous interpretation.

Labelling of Requisitions:

Requisitions received with specimens **must** include:

1. Patient's first and last name
2. Date of birth
3. Gender
4. One of the following:
    1. Provincial Health Card Number (PHN) and Province
    2. Hospital Patient Identification Number (MRN)
5. Full name of the referring physician and the CPSO number
6. Complete address for the referring physician including email and fax number
7. Collection/procedure time, collection date and the name of the person who collected the specimen
8. Relevant clinical / family history, treatment, medication, special instructions, disease status
9. Specimen type and origin – source/site, surgical number

For Hereditary Genetic testing:

10. Full name of the genetic counsellor (if applicable) and contact information
11. Collection method
12. Reason for referral
13. Race and Ethnicity (preferred)

For Alloimmunized Fetal Blood Group Genotyping:

14. Estimated Due Date
15. Number of Fetuses
16. Antibody results

Tests referred out from MSH laboratories

An up-to-date and completed requisition for the **referral lab** must be received with the sample.

Instructions for sample requirements, forms, labelling, and requisition requirements are available on the referral laboratory website(s). **All** pages of requisition are required.

Discipline-specific criteria and instruction

Hematology:

The following specimens for CBC testing will be rejected:

- Clotted specimens
- 4.0 mL EDTA tubes filled with less than 1.0 mL of blood or 3.0 mL EDTA tubes filled with less than 0.5 mL of blood
- Any sample that the lab has been informed was drawn from the wrong patient
- CBC samples received > 48 hours after the blood has been drawn
    - **Note:** CBC samples processed >24 hours and <48 hours after the Blood has been drawn should have a CBC comment "CBC specimen is greater than 24 hours old, interpret CBC results with caution" attached to the report.
- Any sample that appears to have been exposed to extremes of temperature

Blood Transfusion Services:

- Any specimen that is not designated in the Hospital Information System as having been "collected" by the nurse is automatically rejected

Flow Cytometry:

- Specimens that have been refrigerated, severely hemolyzed, clotted, under-filled, wrong anti-coagulant, not maintained at room temperature, and >30 hours old may be rejected.
- Body fluids, bone marrow, fine needle aspirations, other tissue specimens will not be rejected.

Surgical Pathology:

- All tissue specimens that are submitted are considered irretrievable. It is the department's policy that no specimens submitted to the Surgical Pathology lab are rejected. All efforts are to be made to identify a patient to the specimen and/or requisition.
- All specimens must have an accompanying requisition.

Genetics

- DNA for testing is to be submitted in TRIS-HCL or H2O only (no EDTA). However, blood is the preferred specimen type and DNA received that does not meet laboratory standard will be rejected or will be issued as inconclusive reports.
- Clotted samples will be rejected as are samples sent in tubes containing anticoagulants that will inhibit extraction and testing (i.e. green top tubes containing sodium or lithium heparin submitted for molecular testing).
- Due to issues related to the validation of our test methods, the availability of reagents for DNA extraction and the amount and/or quality of DNA obtained from other tissues, MSH cannot generally accept other tissue types (e.g., buccal swabs, fresh tissue or blood spot cards) for DNA extraction and testing. Contact the Laboratory Manager or Director for cases where collection of blood or Formalin fixed tissue samples for DNA extraction is not feasible.
- Hereditary genetics test requests are accepted only from a Medical Geneticist, Pathologist, or Clinician with experience in Genetics, Genetic Counselor (with an accompanying clinician of record) or Laboratory Director.

Tissue Requirements:

- Preferred: Tumour tissue block.
- Alternate: Unstained slides for Immunohistochemistry or FISH submit on positively charged slides. Unstained slides for Molecular tests must be on Uncharged slides. For RNA/DNA based molecular tests, follow appropriate molecular microtomy cleaning protocols between each tissue block (see Paraffin Block Cutting Instructions). All biomarkers are validated with tissue fixed in 10% neutral buffered formalin for 6 to 72 hours (as per CAP/ASCO guidelines). Microwave processed and decalcified samples are not suitable for testing. Mercurochrome use as a dye marker is not recommended.

Fetal Genotyping

- All fields on the requisition must be completed.
- Samples must reach the laboratory in time to be processed during laboratory working hours within set time limits after venepuncture. Sample reception is open around the clock, but it is preferred that samples arrive during working hours Monday to Friday if possible.
- Transport time limits exist for these tests :
    - Referrals for Kell: must be received within 48 hours days of venepuncture
    - Referrals for RhD, Rhc, RhE and RhC: must be received within 72 hours of venepuncture

Timing is a guide to suitability of samples for testing, but other factors may affect sample condition (e.g. exposure to fluctuation in temperature, heat, incompletely filled EDTA tubes). Samples which have lysed due to prolonged time or adverse conditions in transit or which are not in the requested anticoagulant will be rejected and reported as such.

Transport and delivery to MSH laboratories

The transport of laboratory specimens is regulated by the Canadian Transportation of Dangerous Goods Act & Regulations (TDG). This legislation requires packaging that will protect specimens during transport and prevent contact with the public and the environment.

Persons packaging and/or transporting such specimens must possess current TDG certification or comply with Transport Canada Temporary Certificate TU 0764.

All specimens must be packaged carefully to avoid breakage or leakage of the specimen.

The use of a three part packaging system is required:

Transport and Integrity:

- Blood samples must arrive in sealed tubes.
- Blood tubes should be opened only at the laboratory. The sample tube must not be opened following blood collection or used for any testing prior to being sent to Mount Sinai Hospital.
- Send samples as soon as possible after collection

All patient specimens (with the exception of paraffin blocks, histology slides, and DNA extractions), are to be packaged and shipped as Category B Biological Substances, even if such specimens meet the classification requirements for exempt patient specimens.

Specimen packaging and transport

Packaging Instructions

Samples should be packaged in a way as to maintain patient confidentiality and prevent leakage and/or contamination with adherence to the Transportation of Dangerous Goods legislation.

The quality of some tests will be affected if samples are collected in the wrong containers, stored at extreme temperatures or delayed in transit. This may result in the failure of the test.

Shipping instruc**tions:** Collect and ship samples on the same day.

Specimens should be packaged in compliance with IATA P.I. 650 shipping standards and the Transportation of Dangerous Goods Act summarized below:

- A water tight primary receptacle (e.g., blood specimen tube)
- A water tight secondary leak proof container with sufficient absorbent material to absorb the fluid should a leak occur
- An outer package of adequate strength for its intended use e.g. cardboard box, Styrofoam container or purchased specific purpose “transport bag”.
- Note: cold or ice packs should not touch the samples – separate with cardboard or absorbent material

Note: See also specific separate procedures for shipping samples in freezing conditions, refrigerated conditions or ambient temperatures.

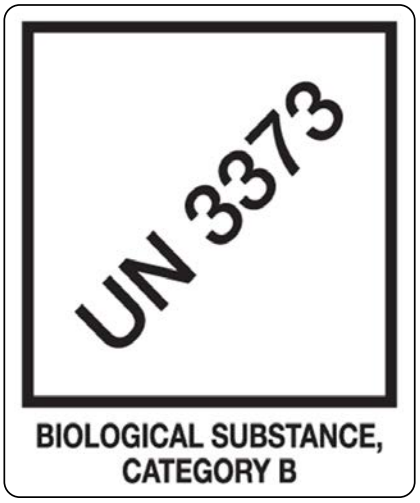
Labelling Instructions

Ensure that the specimen transport container is labelled in accordance with the Transportation of Dangerous Goods Regulations or Transport Canada Temporary Certificate TU 0764

Label the rigid outer container (capable of passing a 1.2 meter drop test):

- Add the appropriate UN label (must be 100mm in size) and add in any required notations next to it, e.g.: "BIOLOGICAL SUBSTANCE, CATEGORY B" and "IN CASE OF DAMAGE OR LEAKAGE IMMEDIATELY NOTIFY LOCAL AUTHORITIES AND 1-888-CAN-UTEC (226-8832)"
- All patient specimens (with the exception of paraffin blocks, histology slides, and DNA extractions), are to be packaged and shipped as Category B Biological Substances, even if such specimens meet the classification requirements for exempt patient specimens.
- Packages with Dry Ice will need the additional UN1845 Class 9 designation and label. Provide the weight of dry ice on the UN1845 label.
- Include the name, address and phone number of the shipper and receiver

Example Label



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Labelling and Packaging Checklist:

- ☐ Delivery and sender address is clearly indicated on the package
- ☐ No excessive wrapping, tape or string
- ☐ Package is not uneven or lopsided
- ☐ Specimens are properly sealed with absorbent e.g. paper towel with secondary containment such as resealable plastic storage bags
- ☐ Package is not leaking
- ☐ There is no crossed out information on the package

Note: It is the responsibility of the shipper of the sample to determine whether packages for transport meet the TDG and IATA DG Regulations.

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