LOGAN HEALTH

Laboratory Services

Specimen Collection & Rejection Procedure

As required by both the Clinical Laboratory Improvement Amendment (CLIA) regulations and the College of American Pathologist's (CAP) Accreditation Standards for Laboratory and Pathology Services, the laboratory must establish, and follow, written policies and procedures for specimen labeling and specimen acceptability and rejection. Included in these policies and procedures will be criteria for the disposition of rejected specimens.

The primary focus for a specimen rejection policy is to insure patient specimen identification and specimen integrity in order to maintain patient safety and accurate test results.
Mislabeled specimens can lead to morbidity and even death.

- **It is the responsibility of all departments involved with the collection of specimens to ensure that the system affords no opportunity for specimen misidentification or inadequate preservation.**

- **It is the responsibility of the laboratory to reject patient specimens which are compromised by incorrect or incomplete identification, inadequate sampling, improper storage, delayed transportation, or any other factor which impinges upon specimen integrity.**

The Logan Health Medical Center Laboratory (LHMCL) accessioning staff will follow these guidelines when mislabeled specimens are received and/or questions with specimens arise.

1. LHMCL Staff will contact the Medical Practice on **ONE** occasion to inform the medical practice that they have received a specimen with a discrepancy. Laboratory staff will fax the discrepancy document to the medical practice/department to correct/acknowledge the discrepancy.
2. If they do not speak directly to an individual, they will leave a message to contact the Logan Health Laboratory this will include the following;

   My name is "", I have a mislabeled specimen that needs your immediate attention. I have sent the discrepancy document to your fax number, ####, please complete the document and return to the LHMC Laboratory via FAX (number on the Form) as soon as possible so that your patient's specimen can be processed for testing.

If we do not receive the correct information within the 24 hour time period the specimen will be rejected.

This is reviewed and approved annually by the Logan Health Medical Center Laboratory Medical Director and Administrative Director

Specimen Collection and Labeling Requirements

- Collected in the appropriate container or test tube with preservative or anticoagulant as designated. Verify using the Logan Health Test Catalog, https://logan.testcatalog.org
- Properly labeled using legible handwriting in the **presence of the patient** (NO GEL PENS).
- **Outpatient specimen(s)** accompanied by the appropriate **requisition**, which include:
    - **Patient's legal First and Last name**
    - **Sex**
        - Photo Id's issued by local, state or federal agency (LH Policy – A318)
        - Use the name and sex as listed on the current photo ID only. Name change individuals must have an ID that verifies the name change
    - **Address –** current address only
    - **Birth date**
    - **Date & time of collection**
    - **Cultures and Body Fluids Only - (Specimen type & Specimen Source required)**
    - **Test(s) requested**
    - **The patient name must match exactly with the name on the specimen container.**
    - **Collector information ,**
        - **Logan Health Staff** (Mnemonic)
            - ***Do not interfere with the tube bar code label***
        - **Private Practice** (Initials)
    - **Label should always be applied to the specimen container. It should never be added to the Biohazard bag or lid.**

For inpatient requests, a separate requisition is not needed since the orders are transmitted through the computer system.

Required specimen labeling includes the following:

Two (2) forms of patient identification, including:

1. The **patient's LEGAL first and last name** (except for special "confidential cases")

AND

2. A **unique identification number** (**preferably the** patient's birth date or health record number).

AND

3. **Date and time of collection**. These are critical to insure specimen integrity.
   In addition, the initials (private practice) or Logan Health Meditech Mnemonic of the collector are also required in case a problem arises with the specimen, and the laboratory needs to contact the collector.

Specimen Integrity Rejection

- Lavender-top tubes:
  - — Clotted specimens will be rejected
  - — Less than 1 mL of blood will be rejected
- Blue-top tubes:
  - — Less than 80% full tube will be rejected
  - — Less than 90% but >80% full tube will be accepted, but result will be reported with comment "Blue-top tube not full; results may be affected".

- Hemolysis of specimens can compromise results of many tests. If the level of hemolysis is within defined tolerance limits, the test will be reported with an interpretive comment.

If the hemolysis exceeds these limits the test will be cancelled and a recollection requested.

- All specimens that are **delayed too long before receipt** into the laboratory will be rejected if specimen integrity is compromised. See Logan Health Laboratory Test Catalog, https://logan.testcatalog.org for specific requirements.
- Specimens **not collected or stored appropriately**, according to the requirements outlined in the Logan Health Laboratory Test Catalog, https://logan.testcatalog.org, will be rejected (inappropriate temperature, specimen type, transport medium, etc.)
- **Unpreserved Stool Specimens** - Stool should be added to both vials (Cary Blair and Clean) in the collection kit immediately after collection.
  - >2 hours old and not refrigerated will be *rejected*
  - Unpreserved stool that is refrigerated is acceptable up to 24 hours after collection.
  - Stool specimens for Ova & Parasite examination that were not placed into EcoFix preservative within 30 minutes after passing will be *rejected*.
  - Any stool specimen contaminated with urine will be *rejected*.

- **Urine specimens for urinalysis or culture** must be refrigerated immediately and processed within 24 hours. The only exceptions are culture specimens collected in grey-top urine tubes containing lyophilized preservative. They may be held at ambient temperature or refrigerated, but must be processed within 48 hours.
- **Urostomy bag** - only specimens from a fresh bag will be accepted.
- Unless otherwise specified, containers with insufficient sample will be rejected.
- Sputum specimen not meeting Gram stain criteria (≥25 White Blood Cells (WBC) per low power field, 0-9 Epithelial Cells per low power field) will be rejected.

Unlabeled/Mislabeled Specimens

All unlabeled or mislabeled specimens must be re-collected

An *unlabeled/mislabeled specimen* is defined as a patient specimen (blood, urine, other body fluids, or tissues) that **DOES NOT** have **2** legible forms of identification placed directly on the **specimen container** and the following items listed below.

Required Specimen Identifiers' –

1. Patient's legible, legal first and last name (must have both) is an absolute requirement for 1 of the forms of identification.
    - Nick names are not acceptable – Legal Name Only
    - Local, State or Federal Agency ID to verify identity
    - Newly married or name change – Current Valid ID/Name
2. A unique number, preferably the patient's date of birth or health record number.

The reason for this strict policy stems from the fact that the laboratory frequently receives specimens from 2 patients with the same name on the same day. These may even come from the same hospital floor, physician office, or the Emergency Department. Without the additional unique number identification, a specimen mix-up resulting in a serious or fatal outcome is a real possibility.

Examples of unlabeled/mislabeled specimens:

- Identification label on the biohazard bag holding the specimen is not acceptable, since the specimen can get separated from the bag.
- A specimen is received with **only 1 form of identification**, it is considered to be **unlabeled** and will be **rejected** unless deemed irretrievable by the provider.
- Label not attached securely to specimen container.
- Label attached to the specimen container lid rather than the container (lids can be mistakenly placed on the wrong container).
- Label does not have both the correct legal first and last name and unique identifying number. One or more incorrect letter(s) or number(s) is unacceptable.
- Label shows only the patient's last name and unique number.
- Any portion of the name or number that is **NOT** legible.

For outpatients, if the **name** on the specimen label does not exactly match the name on the test requisition, accessioning staff will contact the sender to determine which is correct (1 phone or message). If the specimen label is correct, the specimen will be acceptable after the sender has sent and the laboratory has received a corrected requisition. If the specimen label is incorrect, then it will be rejected as stated above.

On rare occasions the patient's ordering health care provider will deem a specimen as irretrievable. This instance will be documented by the lab staff using the "Irretrievable Unlabeled/Mislabeled Specimen Form". This form will be completed by lab staff and sent via fax to the ordering provider office fax requesting the required verification and signature. The form provides instruction for completion and return to the laboratory.

Pathology (Histology/Cytology) Specimens:

- Specimens are generally considered irretrievable, and the collector's initials/mnemonic and date and time of collection are **not** required on the specimen container if correct on the Requisition Form.
- All pathology specimens will be taken to the Histology or Cytology Department with information about the labeling problem.
    - Discrepancy follow-up for Pathology/Histology/Cytology will be performed by the Pathology Department staff members.
- Unlabeled or mislabeled inpatient specimens must be corrected utilizing the "Irretrievable Unlabeled/Mislabeled Specimen Form".
- Outpatient specimens may be returned to the Healthcare Provider's office for corrections, and/or, at the discretion of the Pathology Department member. Additionally, corrections may be completed via telephone and fax using the above "Irretrievable Unlabeled/Mislabeled Specimen Form", when appropriate. Any questions regarding this procedure should be referred to a Pathologist or Pathology Coordinator.

- Blood Bank Specimens (See Lab Test Catalog):

  Labeling requirements are identical to "All Other Specimens" as stated below, except that all pre-transfusion Blood Bank specimens (Type & Screen, ABO/Rh, Historical Type) requires the collector's mnemonics and a verifier's mnemonics (unless using Mobilab for patient ID and labeling).

  The verifier is a second person who independently confirms the patient's identification.

- Confidential Cases:

  On very rare occasions, such as sensitive hospital employee testing, the ordering health care provider may request that the patient's name not be provided on the specimen container or requisition. (They will be assigned a temporary name and account number for identification, e.g., Alert, A002; V10265789)

Irretrievable Unlabeled/Mislabeled Specimens

According to Laboratory and College of American Pathologist's (CAP) guidelines on specimen acceptability and rejection, it is the laboratory's responsibility to **promptly notify** the authorized person when a specimen meets its rejection criteria and is unsuitable for testing.

Accordingly, if a specimen is received that is not labeled with the patient's legible legal first and last name and unique identification number, the laboratory will notify the sending location that, unless the patient's ordering health care provider deems the specimen irretrievable, it will be discarded; and a properly labeled, recollected specimen will be required.

If the specimen is deemed irretrievable, before the laboratory can proceed with processing the specimen, the individual who collected the specimen must perform the following 3 procedures:

1. Complete the **"Irretrievable Unlabeled/Mislabeled Specimen Form".** The form will be initiated by the laboratory staff and sent via fax/tube to the ordering provider.
2. **The form must be signed by the individual who collected the specimen AND the health care provider who ordered the test.**
3. Bring the completed form to the laboratory and properly label the specimen as specified above.

The specimen will be maintained under proper conditions for the type of specimen and test requested until the above is completed.

Analysis will be performed on the specimen only if absolutely necessary, but results WILL NOT be released **until the above has been completed, unless the patient's health care provider contacts the laboratory and provides a verbal order that failure to release results would compromise patient safety more than the labeling problem**.
If such notification is provided, it will be notated **with the provider's name** as a result comment on the patient report.

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If the **name** and **number** on the specimen label **does not exactly match** the name and number on the test requisition, the laboratory will immediately contact the sender to determine which is correct. If the specimen label is correct, the specimen will be acceptable after the sender has sent and the laboratory has received a corrected requisition. If the specimen label is incorrect, refer above.

Otherwise Improperly Labeled Specimens:

Specimens that are not labeled with the legible date and time of collection and specimens with other labeling problems not addressed elsewhere in this policy will be placed in this category. Such specimens will be accepted after the collector or their designee properly completes a **"Specimen Discrepancy Form"** (see "Requisitions" in "Special Instructions").

Inpatient Specimens - the form may be tubed to the collector or their designee, completed, and returned to the laboratory immediately (within 6 hours of receipt)

Outpatient Specimens - the form will be faxed to the originating office, completed, and returned to the laboratory immediately (within 6 hours of receipt)

While waiting for the signed specimen discrepancy form:

1. The specimen will be maintained under proper conditions for the type of specimen and test requested until the above is completed.
2. Analysis will be performed on the specimen only if absolutely necessary, but results will NOT be released **until the above has been completed, unless the patient's health care provider contacts the laboratory and provides a verbal order that failure to release results would compromise patient safety more than the labeling problem**.
   If such notification is provided, it will be notated **with the provider's name** as a result comment on the patient report.