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Document Contact: *Michele Sedlak: Lab Quality Coord*
Area: *Laboratory-Quality*
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Proper Handling of Unlabeled / Mislabeled Specimens

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

A. The purpose of this procedure is to define the process which laboratory staff members are to follow to handle unlabeled/mislabeled specimens.

II. DEFINITIONS:

A. **Unlabeled Specimen**: Specimen with no patient identification (handwritten or computer-generated) on the specimen container.

B. **Mislabeled Specimen:** Specimen collected from patient A, but labeled with the patient information from patient B. (handwritten or computer-generated)

III. PROCEDURE:

A. **For unlabeled/mislabeled specimens: Non-invasive**

1. If a new, properly labeled specimen can be obtained at **no great inconvenience** to the patient, this should be done. Examples of such *non-inconvenient* specimens (from **adult** patients) include:
   a. Venous or capillary blood
   b. Urine (random collection)
   c. Stool (random collection)
   d. Arterial lines
2. When unlabeled/mislabeled specimens of this type arrive in the laboratory, lab staff should:
   a. Notify the sender (if known) that a new specimen is needed. For Outreach specimens, enter information as a follow up task in Beaker or call Customer Service.
   b. For unlabeled specimens, complete the Inpatient Unlabeled Specimens Received Record (Attachment C). These records should be stored in the laboratory for a two-year period.
   c. Unlabeled/mislabeled inpatient specimens are placed in a problem bucket and discarded after 7 days. **For Outreach specimens**, specimens are held in a problem rack/bin until the follow up

task is resolved by Customer Service.

d. Cancel the test orders in the computer system. Document specifically "why" the tests are canceled and who was notified of the cancellation.

3. Note: If the collector explains that there are **extenuating circumstances** associated with the patient (e.g., urine culture mislabeled, but patient now on antibiotics), refer the incident to a manager for evaluation and immediate follow-up.

B. **For unlabeled/mislabeled specimen: Serious/inconvenient to recollect:** If the unlabeled/mislabeled specimens **cannot be recollected** or if the patient would be **seriously inconvenienced or jeopardized** with recollection, then it is the responsibility of the **individual who collected the specimen** to:

1. Come to the laboratory, correctly identify and properly label the specimen, and sign the Specimen Relabeling Form (Attachment A), assuming responsibility for the identity of the specimen.
   a. NOTE: This step must be completed prior to sending the specimen to another laboratory location.
   b. NOTE: For inpatient specimens collected at another Corewell location:
      i. Send the Specimen Relabeling Form (Attachment A) to the collector at the originating site. Do not send the specimen back to the originating site.
      ii. The laboratory staff member will label the specimen once the form is returned and document this on the form.
2. For Outreach specimens, enter information in as a follow up task or call Customer Service.
3. Examples of specimens which are considered **inconvenient to recollect** from a patient include:
   a. Cerebral spinal fluid (CSF)
   b. Various body fluids (pleural, ascites, synovial, peritoneal, pericardial)
   c. Sputum collected by an invasive method
   d. Specimens which cannot be recollected because the patient has been started on antibiotics
   e. Blood specimens from infants and pediatric patients
   f. Catheterized-urine specimens from infants and pediatric patients
   g. Fresh or fixed tissues
   h. Bone Marrow
   i. Biopsies
   j. Fine Needle Aspirations
   k. Arterial puncture
4. **NOTE:** For any **UNLABELED** blood gas specimen: Analyze the specimen immediately upon receipt, print a copy of the results, and put the specimen back into the biohazard bag. If the specimen is eventually identified by the collector and a redraw is either inconvenient or not possible (e.g. Cord blood gas), report these results into the laboratory information system (LIS).

C. **For Unlabeled Specimens with the Labels Tucked into the Specimen Bag:** When an unlabeled specimen is received in the Lab, but the collection labels are tucked in the plastic specimen bag with the specimen or rubber-banded around the specimen container(s), follow this process:

1. For non-irretrievable specimens, recollect.

2. **For irretrievable specimens only:**
    a. Using the information on the collection label, phone the nursing unit and inform the person who collected the specimen that the specimen is **unlabeled** and requires labeling before the laboratory can accept it for testing.
    b. Inform the collector that he/she must come to the laboratory, identify and properly label the specimen, and complete the Specimen Relabel Record form (Attachment A).
    c. Once the unlabeled specimen has been properly identified and correctly labeled, and the Specimen Relabel Record form completed, process the specimen for testing.
    d. File the Specimen Relabel Record form in the appropriate logbook. Keep filed for two years. Scan the form and attach to the Event Report Summary (ERS).

D. **Improperly labeled Blood Bank Specimens:** The Blood Bank **cannot** accept incompletely or improperly labeled specimens **under any circumstances**. Incorrectly labeled Blood Bank specimens will NOT be tested and will be discarded.

E. **Occult Blood Tests:** Occult blood tests may be received from the client or patient by mail, inside of a sterile container, on card (s), or in an OBFIT containers. If there is no identification (ID) on the collection device but all patient and physician information is on the card or envelope, order the appropriate test. Place a testing label onto the specimen; this will aid departments researching a specimen issue. This is the only test and exception to the "NO ID" requirement. The reason for this exception is that these collections most often are collected and sent from the patient's residence.

F. **Quality improvement: Variance Reporting**
    1. Complete an Event Report Summary (ERS) in RL Solutions for each unlabeled or mislabeled specimen incident.
    2. For completely unlabeled specimens, use 1111111 as the medical record number (MRN) when documenting into RL.
    3. Attach to the ERS a copy of the completed Specimen Relabel Record (if a relabel was allowed).
    4. Technical personnel should refer these completed Specimen Relabel Record forms to the section manager.
    5. Each ERS will be reviewed and tasked to the appropriate department manager for follow-up.

Attachments

Attachment A - Specimen Relabeling Form - FH, GP, RO, Troy
Attachment B - Unacceptable Specimen Form Dearborn, Taylor, Trenton, Wayne
Attachment C - Inpatient Unlabeled Specimens Received In Lab Form - FH, GP, RO, Troy

Approval Signatures

Step Description	Approver	Date
CLIA Site Licensed Medical Directors	Ann Marie Blenc: System Med Dir, Hematopath	10/25/2024
CLIA Site Licensed Medical Directors	Kurt Bernacki: System Med Dir, Surgical Path	10/24/2024

Step Description	Approver	Date
CLIA Site Licensed Medical Directors	Jeremy Powers: Chief, Pathology	10/23/2024
CLIA Site Licensed Medical Directors	John Pui: Chief, Pathology	10/23/2024
CLIA Site Licensed Medical Directors	Subhashree Mallika Krishnan: Staff Physician	10/22/2024
CLIA Site Licensed Medical Directors	Muhammad Arshad: Chief, Pathology	10/22/2024
CLIA Site Licensed Medical Directors	Ryan Johnson: OUWB Clinical Faculty	10/21/2024
CLIA Site Licensed Medical Directors	Masood Siddiqui: Staff Pathologist	10/21/2024
CLIA Site Licensed Medical Directors	Hassan Kanaan: OUWB Clinical Faculty	10/21/2024
Policy and Forms Steering Committee Approval (if needed)	Michele Sedlak: Lab Quality Coord	10/21/2024
	Sarah Britton: VP, Laboratory Svcs	10/21/2024
Operations Directors	Joan Wehby: Dir, Lab Services	10/18/2024
Operations Directors	Brittnie Berger: Dir Sr, Lab Operations	10/16/2024
Operations Directors	Elzbieta Wystepek: Dir, Lab Services	10/8/2024
Operations Directors	Christopher Ferguson: Dir, Lab Services	10/4/2024
Operations Directors	Amy Knaus: Dir, Pathology Service Line	10/3/2024
	Michele Sedlak: Lab Quality Coord	10/3/2024

Applicability

Dearborn, Farmington Hills, Grosse Pointe, Royal Oak, Taylor, Trenton, Troy, Wayne

Corewell Health
Farmington Hills • Grosse Pointe • Royal Oak • Troy

Attachment A: SPECIMEN RELABELING RECORD

DATE: **TIME:**

REASON FOR RELABEL:

☐ Wrong Patient ☐ Not Labeled ☐ Other (Explain): _____

	WRONG PATIENT	CORRECT PATIENT
Patient Name		
Patient Number		
Patient Date of Birth		
Room Number / Location		
Accession Number		
Test(s) Ordered		

REASON for allowing specimen labeling/relabeling

"This specimen was collected by me and I certify that it is correctly identified."

PRINT NAME: **EMPLOYEE I.D. #:**

JOB TITLE: **SIGNATURE:**

REASON for NOT allowing specimen labeling/relabeling

LABORATORY EMPLOYEE NAME, SIGNATURE and DATE:

For Laboratory Use Only

☐ Check Chart Review for ALL ordered tests for this date/time.
☐ Notify ALL involved laboratory sections of this change.

Corewell Health
Dearborn • Taylor • Trenton • Wayne Laboratories

QUALITY ASSESSMENT / IMPROVEMENT INCIDENT REPORT
UNACCEPTABLE SPECIMEN

PATIENT INFORMATION

Name: _____

Medical Record Number: _____ Date of Birth: ___/___/_____

Location: _____

Print Container Label Attach Here

NOTIFICATION AND RESOLUTION INFORMATION

Lab Employee's Name: _____ Department: _____

Notification Date/Time: ___/___/_____ at ____:____

Person Notified: _____ **(Notify Charge Nurse for DBN Emergency Patients 1-947-522-9523)**

Resolution:

UNACCEPTABLE SPECIMEN INFORMATION Date/Time: ___/___/_____ at ____:____

Specimen Type (i.e. blood, urine, CSF, surgical, fluid, tissue, wound): _____

Description of Occurrence

- ☐ Mislabeled (Name on the Specimen)_____
- ☐ Unlabeled
- ☐ Other - _____

Complete Notification, Resolution, and Labeling fields.

BLOOD CULTURE Exceptions Date/Time: ___/___/_____ at ____:____

- ☐ No Collect Time
- ☐ Same Time on Both Sets
- ☐ No Collector Identification
- ☐ Proper Labeling not performed per protocol
- ☐ No Order in Epic Beaker

Complete Notification, Resolution, and Labeling fields.

SPECIMENS REQUIRING RELABELING (For difficult recollections and Blood Cultures)

- ☐ Labeled
- ☐ Relabeled
- ☐ Recollected
- ☐ BC Exceptions Corrected: _____

Date/Time of Correction: ___/___/_____ at ____:____

"By signing this form, I assume the responsibility that this specimen is correctly identified and collected."

Caregiver Full Name **(please print legibly):** _____

Caregiver Signature: _____

Corewell Health
Farmington Hills • Grosse Pointe • Royal Oak • Troy

Attachment C: Inpatient Unlabeled Specimens Received in Lab

Date	Time	Patient Name/ MRN if Known	Specimen Type	Location if known	Comments