

Laboratory Quality Program
Process Control-General

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Purpose: To provide guidelines for specimen labeling and specimen rejection.

Policy:

- 1. Specimens submitted for laboratory testing must be accurately labeled to assure positive patient identification throughout the collection, testing, and reporting process.
- 2. For patient safety and in accordance with lab regulatory and DNV standards, all specimens must be labeled at the time of collection, in the presence of the patient.
- 3. Specimens may be rejected that do not meet the patient preparation, collection, labeling, processing, and storage requirements needed for testing.
- 4. The reason for specimen rejection will be documented in the patient's medical record, and an event report will be filled out.

Procedure:

I. Processing Problem Specimens:

Problem specimens are those that do not meet the acceptability/labeling requirements described in this policy.

- A. Specimen acceptability issues-Central Processing, Central Collection or Technical staff should be consulted to determine if testing should be performed.
- B. Specimen labeling issues-Consult on call Manager, Supervisor, Lead or in-charge tech when unsure if specimen should be accepted.

II. Electronic Test Orders

- A. Lab personnel draw specimens after receiving an electronic test order or written test order signed by the provider or designee.
- B. Nurse collected specimens are matched to the electronic orders.
- C. Orders must include:
 - 1. Patient Name
 - Medical Record Number
 - 3. Patient Location
 - 4. Test Priority
 - 5. Patient Sex
 - 6. Date of Birth
 - 7. Test requested
- D. Specimens will not be collected without an electronic or written order unless it is a medical emergency, in which case a verbal order from a nurse or provider is acceptable. An electronic order must be placed as soon as possible for testing to be run.

III. Specimen Label/Test Requisition Requirements (Outside Clients: Nursing homes, clinics, Provider offices)

A. Specimens and requisitions should include the following information:

| | <u> </u> | |
|---|---|--|
| Specimen Label Requires: | Laboratory Requisition | |
| Patient first and last name | Patient first and last name | |
| Patient Birthdate (DOB) | Patient Birthdate and Sex | |
| Specimen source for body fluid, | Specimen source for body | |
| wound, and micro/histo/cyto | fluid, wound, and | |
| specimens | micro/histo/cyto specimens | |
| Collection time and date | Collection time and date | |
| Collectors' initials or tech code | Collectors' initials or tech code | |



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| Specimen type(if not in the original tube) | |
|---|---|
| Plasma (EDTA, sodium citrate) Serum Urine (clean catch, foley, straight cath, bagged) Sputum | |
| | Ordering provider's full name Ordering provider's signature Tests ordered Billing Information Diagnosis |

B. If any of the above information is missing, the Patient access or Central Processing team will contact the ordering location and request the missing/correct information. The returned information will be added to the requisition, scanned into the electronic medical record, and an event report will be filled out. A new requisition may be requested if necessary.

IV. Patient Identification

- A. It is the responsibility of the staff collecting the specimen to identify and draw the patient correctly and label the specimen at the point of collection. The patient's identity must be verified prior to specimen collection, by using at least two identifiers and in accordance with **St. Luke's Hospital Patient Identification Policy.**
 - 1. Inpatient and ED specimens: An initialed identifying wristband must be on the patient. Verify the patient's name and MRN by checking the patient wristband, scanning with the handheld collection device (lab team) and verbal confirmation of patient's spelling of last name and DOB.
 - a) If the patient is unconscious or not competent, and the armband is not initialed, verify the patient ID with a nurse or a family member.
 - 2. Outpatient specimens: Compare labels to the verbal confirmation of the patient's spelling of last name and DOB.

NEVER state the patient's name and ask them if it is correct. Always make them verbalize their name and birthdate.

V. Specimen Labeling Process

- A. All received specimens must be correctly labeled with the patient's name and collection information on the portion of the container that contains the specimen.
- B. All samples must be labeled at the patient's bed side immediately after collection and within sight of the patient.
- C. Specimens should be labeled with computer generated bar-code labels. Chart labels/hand labeling should only be used if the care area does not have a blaster printer or during computer downtime.
- D. Confirm the patient's identification while labeling the sample by comparing the labeled tube or container to the patient's wristband information.
- E. Blood Bank Specimens that may be used for <u>pre-transfusion</u> (TYSC or BBHOLD orders) must be labeled with:
 - 1. Patient's first and last name



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- 2. Medical Record Number/CSN or Red B Band number (if MRN is not available)
- 3. Collectors' tech code for lab personnel or initials for nursing personnel
- 4. Time and date of collection

A B Band must be placed on the patient if the patient is not wearing a hospital ID band, or is an OP infusion center patient, or an OP. See Labeling Specimens for instructions

F. Point of Care testing-The primary specimen container labeling requirement (CAP COM.06100) does not apply to the labeling of specimens collected for immediate bedside patient testing performed in the presence of the patient. If, however, the specimens are (or may be) utilized for testing away from the patient, the specimen must be labeled with two patient identifiers. Room number is NOT an acceptable identifier.

VI. Criteria for Specimen Rejection

- A. **Recollectable** specimens submitted for testing are rejected based on the following criteria:
 - 1. Inadequate specimen identification:
 - a) There is no label on the specimen.
 - b) The patient's first and/or last name is missing from either the specimen container or requisition.
 - c) The patient's first and/or last name and a second unique identifier (as defined by the Hospital SOP) on the specimen container and the requisition do not match.
 - d) The specimen is labeled with more than one patient label that do not match each other.
 - e) Specimen label is <u>only on the lid</u> of the container and not present on the primary specimen container (if Urine straight cath or Urine IP Peds/NICU, ask the nurse who collected to come relabel and fill out the specimen label verification form).
 - 2. Inappropriate volume of blood (not enough volume, or tube too full).
 - 3. Use of incorrect container for collection of the specimen.
 - 4. Specimen handling instructions for collection or transport of specimen have not been followed.
 - 5. Wrong specimen type submitted for the ordered test.
 - Specimen quality is inadequate for testing (i.e. hemolyzed, IV contaminated, or clotted specimen). See Definitions Table at the end of this policy.
 - 7. Specimen container is broken, grossly contaminated or leaking.
- B. **Irretrievable** specimens are those which, due to either the site they are obtained from or timing of the collection, are not recollectable. In these cases, labeling errors will be handled differently. The following specimen types are considered irretrievable:
 - 1. Specimens collected in surgery
 - 2. Tissue specimens for histology/pathology
 - Suprapubic urines



- 4. Body fluids
- 5. CSF
- 6. Cervical/vaginal specimens for Fetal Fibronectin Testing
- Kidney Stones
- 8. Cord Gases
- 9. Tissue cultures or bone fragments

VII. Processing and Documentation of Rejected Specimens

| | Recollectable | Irretrievable |
|---------------|------------------------------------|------------------------------|
| In-Patient/ED | Refer to Specimen Rejection | Initiate corrective sample |
| | Standard Work | identification by contacting |
| Out-Patient | Complete Gen106_EPIC | unit or clinic and then |
| | notification of Outpatient | Complete Specimen Label |
| | Sample Rejection | Verification Form. |
| | | Proceed with testing only |
| | If ordered in SQ refer to | after sample has been |
| | Cancel/Credit SW | properly identified |
| | | Ensure report contains |
| | | clinician responsible for |
| | | accepting sample ID |

- A. Rejected specimens are identified with a special **REJECTED** label including rejection reason, racked or placed in day bucket for storage, and will not be used for any other testing without pathology approval.
- B. Name Discrepancies (outside clients only): Use common sense for name differences. E.g. Robert and Bob are the same name. **Check the EMR for Aliases**. If the name on the requisition and the name on the specimen are different (spelling discrepancy or different patient name), reject the specimen.
- C. Specimens submitted for blood bank testing may be rejected if the patient's first and last name and MRN or Date of Birth on the specimen do not match the requisition and/or the patient's information in the computer. If there are minor handwritten errors (missing/transposed digit, spelling), pretransfusion testing must be approved by a Manager/Lead/Charge and if needed a pathologist, and an RL must be completed.
- D. Microbiology Specimens should be evaluated for their appropriateness before processing. This involves proper identification, acceptable specimen types, appropriate containers, and transport of specimens with minimal delay. See Transport and Receipt of Microbiology Specimens when evaluating questionable specimens.
- E. Anatomic Pathology specimens may be processed at the discretion of the pathologist. See **Receipt of Histology-Cytology Specimens** when evaluating questionable specimens.

VIII. Completed form follow up

A. Specimen Label Verification Form

- 1. Attach completed form to specimen until labeling corrective statement has been added to the test.
- 2. Forward form to QA/Lean Coordinator for scanning into the completed RL or filing.



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Inadequate Specimen Quality Definitions Table

| Clotted specimens | Specimens collected in anticoagulated tubes cannot be clotted, as that will affect test |
|--|--|
| | results (e.g. CBC, Coagulation testing). |
| Contaminated Specimens | |
| Cross contaminated | Never pour a specimen from one tube into another. Many tubes have an anticoagulant in them which affects results when specimens are cross-contaminated. Additionally, the proper order of draw during a multiple blood specimen draw is significant. |
| Heparin contaminated | Blood specimens drawn immediately after infusion of heparin may yield invalid results for some tests. (e.g. APTT) |
| Indwelling line contamination | Never draw above an indwelling line (heparin lock) if it has been flushed with heparin or saline within the previous 5 minutes. |
| Intravenous Fluid contamination (IV) | Never draw blood on the side of an IV site in a patient arm/hand as the fluid will dilute the blood and invalidate test results. If necessary, it is acceptable to have the IV turned off for a minimum of 2 minutes prior to drawing the blood from that arm/hand. |
| Hemoconcentration | Hemoconcentration may result if the tourniquet is left on for longer than 1 minute, thus invalidating some test results. If the tourniquet is left one over 1 minute, blood should not be drawn until 2 minutes after the release of the tourniquet. |
| Hemolysis | Hemolysis can result from difficult blood collection or improper handling of the collected specimen. Gross hemolysis invalidates most laboratory tests. Moderately hemolyzed specimens need to be evaluated for each specific test ordered. |
| Incorrect blood/anticoagulant ratio | The amount of additive placed in a tube is intended for a certain volume of blood. If less blood than required is drawn, the excess amount of additive may adversely affect the accuracy of the test results. (e.g. Coagulation, hematology, chemistry testing). |
| Improper tube/specimen type | An incorrect tube additive can interfere with the analyte being assayed. |
| Quantity not sufficient (QNS) | All efforts will be made to accept a minimal |



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| | volume of specimen for testing; however, there will be some instances where additional specimen must be collected. |
|-----------------------------------|--|
| Mislabeled or Unlabeled specimens | Specimens received in the laboratory without two acceptable identifiers will be considered mislabeled/unlabeled and will require a recollection, unless irretrievable. |

References

- CLSI-GP41 Collection of Diagnostic Venous Blood Specimens pgs.
 7-11
- 2. CLSI-PRE04 Handling, Transport Processing and Storage of Blood Specimens for Routine Laboratory Examinations
- 3. CAP2024: GEN.40490, GEN.40491 GEN.40492 GEN.40493 GEN.40750

Related Documents

- 1. Outpatient Orders
- 2. St. Luke's Hospital Patient Identification Policy
- 3. Transport and Receipt of Microbiology Specimens
- 4. Receipt of Histology-Cytology Specimens
- 5. Specimen Label Verification Form
- 6. Specimen Rejection SW
- 7. Labeling Specimens
- 8. EPIC notification of Outpatient Sample Rejection