**TRAINING UPDATE**

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| **Lab Location:** | GEC, SGAH & WAH | **Date Distributed:** | 5/14/2012 |
| **Department:** | All Staff | **Due Date:** | 6/14/2012 |

**DESCRIPTION OF PROCEDURE REVISION**

| **Name of procedure:** |
|---|
| **Specimens Acceptability Requirements      GEC.L39, SGAH.L44, WAH.L42  v002** |
| **Description of change(s):** |
| Section 5: add re-confirm labeling in step 2.c,<br>revise specimen disposition in step 3.a,<br>update PI form to Quality Variance form |

**EMPLOYEE SIGNATURES**

I have read and understand the procedure described above:

| Name | Signature | Date |
|---|---|---|

Employee signatures are not necessary. Document your compliance with this training update by taking the quiz in the MTS system.

**Approved draft for training all sites (version 002)**

Non-Technical SOP

| | | |
|---|---|---|
| **Title** | **Specimens Acceptability Requirements** | |
| **Prepared by** | Leslie Barrett | Date: 10/2/2009 |
| **Owner** | Lori Loffredo | Date: 12/15/2010 |

| **Laboratory Approval** | | |
|---|---|---|
| **Print Name and Title** | **Signature** | **Date** |
| *Refer to the electronic signature page for approval and approval dates.* | | |
| | | |
| | | |
| Local Issue Date: | Local Effective Date: | |

| **12 month (or new) management review and approval:<br>Signature acknowledges SOP version remains in effect with NO revisions.** | | |
|---|---|---|
| **Print Name** | **Signature** | **Date** |
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## 1. PURPOSE

To define specimen requirements and provide guidance for handling of any specimen that does not meet the requirement or specimens with unusual test requests or instructions.
To salvage certain “irreplaceable” specimens obtained by invasive techniques that are received in the laboratory unlabeled or incorrectly labeled, or where test orders are not clear or contain specific testing instructions.
The policy delineates which specimens are to be recollected and which cannot be recollected.

## 2. SCOPE

This procedure applies to all Laboratory staff.

## 3. RESPONSIBILITY

Phlebotomy, Specimen Processing and Technical staff must demonstrate competency for proper labeling and handling of applicable specimens.

Specimen Processing and Technical staff must demonstrate competency for determining specimen adequacy and the process for unacceptable specimens.

## 4. DEFINITIONS

**Adequacy –** an adequate specimen is one that is sufficient for testing if

- the specimen collection container is correct
- the specimen volume is adequate
- the specimen delivery is timely (within 2 hours of collection)
- anticoagulated blood must be free of clots
- the blood anticoagulant ratio is accurate as indicated by the blood volume in the tube
- the specimen does not appear to be contaminated, i.e. specimen container leaking
- the specimen has no visible indications that may jeopardize testing, i.e. hemolysis, clots, etc

- the collection time for tests requiring a timed draw correlates with the draw time
- the specimen is labeled with two unique patient identifiers patient name and medical record number. The patient billing (account) number is acceptable during computer downtime.
- when accompanied by a paper requisition, the patient identification on requisition and specimen label match. If applicable, the specimen source on both must also match.

**Irreplaceable specimen –** a specimen obtained by invasive means that is not easily obtained or replaced, i.e. CSF, body cavity fluids, fine needle aspirations, surgical biopsies, etc.

**Replaceable specimen –** a specimen that can be replaced through a repeated venipuncture or specimen collection - such as random urine, sputum, and stool.

**Unacceptable –** a specimen that will not be accepted for testing

**Unusual order or instruction –** anytime an unrecognized test is ordered or an order is not handled in the usual process

**LIS –** Laboratory Information System
**HIS –** Hospital Information System

## 5. PROCEDURE

1. **Specimen Labeling**
   a. All specimens must be labeled at the bedside at the time of collection.
   b. Labeling must contain two unique patient identifiers. The identifiers routinely utilized are patient name and medical record number. The patient billing (account) number is acceptable during computer downtime.
   c. **BLOOD BANK SPECIMENS have additional labeling requirements. See Blood Bank Specimen Collection and Labeling procedure in Phlebotomy procedure manual.**
   d. Date and time of collection and initials/code of collector is requested on all specimens.

2. **Receiving Specimens (Specimen Processing)**
   a. Upon receipt in the laboratory, the specimen(s) is accessioned into the LIS matching the Medical Record Number, Patient Name, and test from the HIS requisition.
   b. Upon verification of this information, the collection date and time, as well as the applicable phlebotomy code is entered into the LIS.
   If the time is not on the requisition or tube, enter a collect time in the LIS of 5 minutes earlier than the current time.
   Utilize one of the following codes for non-phlebotomy collected specimens.
      1) 850 – RNC – Nurse draw
      2) 860 – EDC – ER draw
      3) 870 – MDC – Dr. draw
      4) 880 – PTNC –Patient to collect (usually urine, sputum stool).
      5) 888 – Unknown

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c. When the LIS receiving process is complete, an LIS accession number is generated, and a laboratory bar code label prints. The laboratory bar code label is placed on the specimen without covering original patient identification. The labeler must re-confirm patient identification on bar code label matches specimen label.

d. In addition to patient demographic information, the laboratory bar code label carries the LIS accession number and tests to be performed. The specimen is then ready for testing.

### 3. Labeling Issues

The laboratory must ensure confidence in specimen identification. The integrity of patient care and quality results are jeopardized whenever a specimen is mislabeled. Any specimen received in the Laboratory that is unlabeled or incorrectly labeled and is deemed **"irreplaceable"** must be brought to the immediate attention of the Laboratory Supervisor and/or Medical Director. **An "irreplaceable" specimen is defined as a specimen obtained by invasive means that is not easily obtained or replaced.**

a. If the specimen label and the requisition **DO NOT MATCH**:
   1) If the specimen is "irreplaceable", e.g., CSF, the nurse manager will be contacted by the Laboratory Supervisor or Medical Director. Formal documentation will be initiated on a Quality Variance form. The physician(s) will be notified. The specimen will be allowed to be relabeled if it can be determined with reasonable certainty that the specimen belongs to the patient in question.
   2) If the specimen is such that it can be re-collected, e.g., blood, the nursing unit is notified that the specimen is not acceptable due to mislabeling and a recollect is requested.
   3) If the Laboratory is notified that an order was placed on the wrong patent and the test **has not yet been performed,** follow the procedure for 2) above.
      If the test has been resulted, a notation will be made indicating the result does not belong to patient. Laboratory personnel will document date, time, and identification of caller notification of wrong order.
   4) **Any incorrectly labeled Blood Bank specimens must be re-collected.**
   5) All labeling problems are documented with a Quality Variance form.
   6) All communication is to be documented in the LIS.
   7) Disposition of specimens:
      - "irreplaceable" specimens are held for one week
      - if a specimen must be retained for further investigation or follow-up, it must be clearly labeled as "REJECTED"
      - all other improperly labeled specimens are discarded

b. If the specimen is **NOT LABELED**, contact the charge nurse on the unit or the nurse caring for the patient.
   1) Request another specimen if the specimen is a replaceable specimen. Generate a Quality Variance form and document specimen rejection and request for resubmission. Discard the specimen.
   2) If the specimen is an irreplaceable specimen contact the Laboratory Supervisor and/or the Medical Director and proceed as in 3.a.1) above.
   3) Laboratory staff may **not** correct or alter a specimen collection label.

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4. **Questionable or Unclear orders or instructions**
   a. Unclear orders must be resolved prior to testing. Contact charge nurse or nurse caring for the patient at the site of collection for clarification of tests requested.
   b. With unusual or questionable testing instructions or orders, send the original request form with the specimen to the testing bench for the technologist to resolve and clarify orders or instructions. If the technologist needs further clarification, contact the supervisor or manager on duty.

5. **Unacceptable specimens**
   a. Any specimen not meeting the definition of adequacy or
      1) a "short draw" in an anticoagulated tube
      2) quantity of specimen is not sufficient to perform the test
      3) visual specimen contamination, gross hemolysis, and gross lipemia
         **Note**: Acceptance of such a sample must be approved in accordance with the policy 'Hemolysis, Icteria and Lipemia; Interference from'.
      4) If moderate hemolysis
         - All coagulation specimens must be recollected
         - Chemistry specimens should be given to the department for testing and handled per the policy 'Hemolysis, Icteria and Lipemia Interference'.
   b. When a specimen is deemed unacceptable
      1) Contact charge nurse or nurse caring for the patient.
      2) Cancel orders in LIS and document reason for the cancellation as well as nurse contacted. This documentation will appear on the patient record.
      3) Credit the patient for the test if previously resulted.
      4) Complete a Quality Variance form to provide a mechanism to identify and resolve specimen adequacy issues.
      5) Retain the specimen per routine procedure

6. **Misdirected Specimens**
   Any specimen that is delivered to the laboratory from an outside source will be directed to the Laboratory Supervisor for disposition.

7. **Sub-optimal results**
   Specimens that are slightly hemolyzed can be analyzed, but must have the comment code 'HMS' appended to the result. Appropriate comments are made regarding any issues warranting a sub-optimal test result on the report.

## 6. RELATED DOCUMENTS

Hemolysis, Icteria and Lipemia Interference, Laboratory policy
Retention of Records and Materials, Laboratory policy
Specimen Processing Duties and Receipt, Specimen Processing procedure
Blood Bank Specimen Collection and Labeling, Phlebotomy procedure
Quality Variance Forms, QA procedure

## 7. REFERENCES

Code of federal Regulations, 21 CFR 606.151, current edition

## 8. REVISION HISTORY

| Version | Date | Reason for Revision | Revised By | Approved By |
|---|---|---|---|---|
| | | Supersedes SOP L011.002 | | |
| 000 | 12/15/10 | Update owner<br>Section 4: add time frame for delivery | L. Barrett | L. Loffredo |
| 001 | 5/3/12 | Section 5: add re-confirm labeling in step 2.c, revise specimen disposition in step 3.a, update PI form to Quality Variance form<br>Section 6: update SOP titles | L. Barrett | L. Loffredo |
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## 9. ADDENDA AND APPENDICES

None

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