TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	4/26/2018
Department:	All staff	**Due Date:**	5/17/2018
		Implementation:	**5/17/2018**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Specimen Acceptability Requirements SGAH.L44 v4

This has been converted to a system SOP

Description of change(s):

Header: Added other sites

Section 5: Added criteria to reorder inadequate samples and responsibilities (*changed to match Cancelling SOP*)

Section 6: Removed retired SOP, added form

Section 9: Added appendices

Note – content of the Hemolysis, Icteria and Lipemia Interference (HIL) policy has been added as 2 appendices ; that SOP will be retired

This revised SOP will be implemented on May 17, 2018

Document your compliance with this training update by taking the quiz in the MTS system.

Non-Technical SOP

Title	**Specimen Acceptability Requirements**	
Prepared by	Leslie Barrett	Date: 10.2.2009
Owner	Robert SanLuis	Date: 3.5.2013

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:	

Review:		
Print Name	**Signature**	**Date**

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1. PURPOSE

To define specimen acceptability requirements and provide guidance for handling specimens that do not meet established acceptability criteria.

2. SCOPE

This procedure applies to all specimens received in the laboratory. The procedure outlines specimen acceptability standards and provides guidance for:

A. Handling specimens that do not meet established criteria.
B. Processing unusual test requests or unclear collection instructions.
C. Salvaging irreplaceable specimens that do not meet established criteria.

3. RESPONSIBILITY

All laboratory staff members must understand and adhere to this policy for accepting and rejecting specimens for laboratory testing.

4. DEFINITIONS

A. **Adequacy** – An adequate specimen is one that is sufficient for testing. Characteristics that should be considered when evaluating the adequacy of a specimen include, but are not limited to, the following.
    a. Accurate specimen labeling
        i. Patient name and medical record number are required.
        ii. Patient billing number (FIN) may be used in place of the medical record number during periods of computer downtime.
        iii. Specimen must contain date and time of collection.
        iv. Specimen must contain initials or identification of the person who collected or labeled the specimen.
    b. Accurate paper requisition, when present. If a paper requisition is sent with a specimen, information on the requisition must match information on the specimen label.
    c. Correct specimen container

d. Adequate specimen volume
e. Timely specimen delivery (as outlined by the stability standards for the requested test(s).
f. Accurate blood-to-anticoagulant ratio as indicated by the collection tube and test requirements
g. Adequate visual inspection of the tube/container.
    i. Specimen does not appear to be contaminated.
    ii. Specimen is not leaking.
    iii. Visual clots are not seen.
    iv. Gross hemolysis is not seen.
h. Accurate correlation of specimen collection time when timed specimens are collected.

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

C. **Replaceable specimen** – A specimen that can be replaced through repeated venipuncture or non-invasive specimen collection, i.e. blood, random urine, sputum, or stool.

D. **Unacceptable** – A specimen that will not be accepted for testing in the laboratory.

E. **Unusual order or instruction** – Any situation in which an unrecognized test order is received or an order is not handled using the normal process.

F. **LIS** – Laboratory information system

G. **HIS** – Hospital information system

5. PROCEDURE

A. Specimen labeling

a. All specimens will be labeled at the bedside, in the presence of the patient, at the time of specimen collection.
b. Specimen labels will contain two unique patient identifiers.
    i. Patient name and medical record number are routinely used by the laboratory.
    ii. Patient billing account (FIN) number may be used in place of the medical record number during periods of computer downtime.
c. Specimen labels will contain date and time of specimen collection.
d. Specimen labels will contain initials or identification of the person who collected and/or labeled the specimen.
e. **Type and screen specimens have additional labeling requirements.** Refer to procedure, "Blood Bank Specimen Collection and Labeling" in the Phlebotomy procedure manual.

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B. Specimen Receipt (Specimen Processing)

a. Upon arrival in the laboratory, specimens are reviewed for adequacy. Any specimen that does not meet established criteria will be rejected or further investigated for acceptability.
   i. The accessioner will visually inspect the tube for adequacy.
   ii. The accessioner will ensure specimen labeling meets established standards (patient name, medical record number, time/date of collection, collector's initials/identification).
   iii. The accessioner will compare the information listed on the paper requisition (if present) to the information on the specimen tube label for accuracy. If present, information on the paper requisition must match information on the specimen.

b. The specimen will be accessioned into the LIS by matching the following information.
   i. Patient medical record number
   ii. Patient name
   iii. Test ordered

c. The date and time of collection will be entered into the LIS from the specimen label.

d. The applicable phlebotomy code will be entered into the LIS. **It is unacceptable to leave this field blank.**
   i. The laboratory tech code will be entered when the specimen is collected and/or labeled by laboratory personnel.
   ii. One of the following codes will be utilized when the specimen was collected and/or labeled by non-laboratory personnel.
      1. 850 – RNC – Collected by nursing staff
      2. 860 – EDC – Collected by emergency department staff
      3. 870 – MDC – Collected by physician staff
      4. 880 – PTNC – Collected by the patient (generally stool collections for outpatients).
      5. 888 – Unknown

e. When the LIS receipt process is complete, the LIS will assign an accession number to the specimen(s) and the corresponding laboratory barcode label(s) will print.
   i. The laboratory barcode label will be placed on the corresponding specimen without covering the original patient identification data.
   ii. The labeler will verify that the patient identifiers on the barcode label match the patient identifiers on the original specimen label.

f. Specimens are then prepared for testing.

C. 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 will be rejected.

a. If a specimen is correctly labeled with the patient's name and medical record number but is missing the date of collection, time of collection, or collector's

initials/identification, the person who originally collected and/or labeled the specimen may add the missing information in the confines of the laboratory.

b. If the specimen contains an erroneous date or time of collection, the person who originally collected and/or labeled the specimen may correct the information within the confines of the laboratory.
c. If a paper requisition is submitted with the specimen **and** the specimen label and requisition do not match the specimen is rejected and must be recollected.
d. If the laboratory is notified that a specimen was collected or labeled with the wrong patient information **or** if the order was placed and specimen collected on an incorrect patient and
    i. The test has **not yet been performed**, the sample will be rejected and a new sample will be requested. Refer to procedure, "Cancelling Tests or Orders."
    ii. The test **has been performed**, a notation must be added to the results indicating the result does not belong to the patient. **Do not delete results once they have been entered.** Laboratory personnel will document the date, time, and identification of the person who notified the lab of the issue.
e. Any mislabeled blood bank specimen will be rejected and recollected.
f. Samples with labeling problems will be documented on a laboratory PI/Variance form. These include samples that are mislabeled and samples that are unlabeled.
g. All communication will be documented in the LIS, using approved Sunquest Cancellation / Reschedule Reasons. Refer to procedure, "Cancelling Tests or Orders."
h. Rejected samples will be stored in the following manner.
    i. Rejected samples will be discarded.
    ii. Irreplaceable samples will be held for one week.
    iii. Any sample that has been rejected but must be saved for further investigation or follow-up must be CLEARLY identified with the word "REJECTED."
i. No specimen will be corrected or altered by laboratory staff.

D. Irreplaceable Specimens

Notify the laboratory supervisor or medical director any time a sample that is deemed "irreplaceable" does not meet acceptability standards.

a. The laboratory supervisor or medical director will notify the charge nurse.
b. Formal documentation will be initiated via the Laboratory PI/Variance form.
c. The physician will be notified.
d. The specimen may be relabeled if there is reasonable certainty that the specimen belongs to the patient in question.

E. Questionable or Unclear Orders/Instructions

a. Unclear orders must be resolved prior to testing. Contact the charge nurse caring for the patient at the site of collection for clarification of the requested tests.
b. When unusual or questionable testing instructions or orders are received, a copy of the original request will be sent to the testing bench for technical staff to resolve and clarify. The testing tech will contact the supervisor on duty if further clarification is necessary.

F. Unacceptable Specimens

a. Any specimen that does not meet adequacy or testing specifications will be rejected.
   i. Hemolyzed, icteric, and lipemic samples may be accepted or rejected in accordance with ~~procedure~~ Appendix A, "Hemolysis, Icteria, and Lipemia Interference."
   ii. Processing staff are responsible for follow up process for unacceptable samples identified at the front end (accessioning) and technical staff perform follow up for samples identified at the bench.
   ~~iii. If moderate amounts of hemolysis are noted,~~
      ~~1. Coagulation specimens will be recollected.~~
      ~~2. Chemistry specimens will be given to technical staff and handled per procedure, "Hemolysis, Icteria, and Lipemia Interference."~~

b. When a specimen is rejected,
   i. Notify the charge nurse or nurse caring for the patient.
   ii. Cancel the order in the LIS system and document the reason for cancellation as well as the nurse contacted. This documentation will appear in the patient's medical record.
   iii. Credit the patient for any test that was resulted prior to rejection.
   iv. Refer to procedure "Cancelling Tests or Orders" for details.
   v. Complete a laboratory PI/Variance form for any sample that is rejected because it is mislabeled or unlabeled **and** samples that would otherwise be rejected but have been accepted because they have been deemed irreplaceable.
   vi. Retain or discard specimens per routine procedures.

G. Misdirected Specimens

Any specimen that is delivered to the laboratory from an outside source will be directed to the supervisor for disposition.

H. Sub-Optimal Results

a. Specimens that are slightly hemolyzed may be analyzed. However, the comment "HMS" will be appended to the result(s).
b. Appropriate comments are made on the report regarding any issues warranting a sub-optimal test result.

6. RELATED DOCUMENTS

~~A. Policy: Hemolysis, Icteria, and Lipemia Interference~~
B. Policy: Retention of Records and Materials
C. Policy: Cancelling Tests or Orders
D. Processing Procedure: Specimen Processing Duties and Receipt
E. Phlebotomy Procedure: Blood Bank Specimen Collection and Labeling
F. QA Procedure: Quality Variance Forms
G. Form: HIL Index Alert Values (AG.F247)

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7. REFERENCES

None

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SOP L011.002		
000	12/15/10	Update owner 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 Section 6: update SOP titles	L. Barrett	L. Loffredo
002	3/5/13	Updated owner Updated wording and formatting throughout the procedure for clarity Section 4: add time/date of collection and collector's ID to definition of adequacy Section 5: Add time/date of collection and collector's initials to acceptability requirements. Added instructions to allow collecting personnel to add time, date, and ID to an otherwise acceptable specimen in the lab. In "Labeling Issues" section, changed errors in specimen orders to errors in specimen labeling.	S. Codina	R. SanLuis
003	4/18/18	Header: Added other sites Section 5: Added criteria to reorder inadequate samples and responsibilities Section 6: Removed retired SOP, added form Section 9: Added appendices Footer: Version # leading zero's dropped due to new EDCS in use as of 10/7/13.	L. Barrett S. Codina	R. SanLuis

9. ADDENDA AND APPENDICES

A. Hemolysis, Icteria and Lipemia Interference
B. HIL Interference Chart

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Appendix A

Hemolysis, Icteria and Lipemia Interference

1. DEFINITIONS

Hemolysis – alteration or destruction of red blood cells in such a manner that hemoglobin is liberated into the medium in which the cells are suspended

Hemolysis Grading System (see Appendix A)

Slight: ≈ 100 mg/dL hemoglobin
Moderate**:** ≈ 200 mg/dL hemoglobin
Gross: ≈ or > 500 mg/dL hemoglobin

Icteria – The yellow greenish color of the serum or plasma cause by bilirubin, a byproduct of old red cells.

Lipemia – Is manifested by a milky appearance of the serum or plasma caused by an excess of lipids in the blood.

2. PROCEDURE

Handling visible hemolysis:

1. Remove the specimen from the centrifuge. Make a visual assessment of the specimen's integrity, before testing.

2. If the plasma or serum portion of the specimen has an obvious pink to reddish appearance, compare it to the Hemolysis chart (Appendix B) to estimate the degree of hemolysis. Borderline readings should be reported to the next higher category.

3. If the hemolysis is slight (~100-200 mg/dL) the specimen should be given to the technical staff for testing in all the departments.

4. If moderate or gross hemolysis is observed, the specimen should be handled in the following manner
   Moderate - All coagulation specimens must be recollected
   - Chemistry specimens should be given to the department for testing.
   Gross - All specimens should be recollected

   Note: The Dimension chemistry system will calculate the HIL and Auto-verification rules in Data Innovation (Instrument Manager will flag appropriate action).

5. The staff member handling the sample will query the computer system to determine if other blood specimens have been drawn on the patient at the same time. Each specimen drawn will be located and examined for hemolysis. If moderate (for

coagulation only) or gross hemolysis exists in any of the primary tubes, these must also be recollected.
Note: *Staff should exercise due diligence in determining if an alternate, acceptable specimen, might be available for testing before requesting recollection. For example: a green top tube might have been drawn in addition to a red top tube and could be an acceptable alternative for various chemistry assays.*

For nurse-collected specimens:
a) Notify the nurse that the specimen is being canceled due to hemolysis.
b) The Lab will place the order for a re-draw

For Lab-collected specimens:
a) Notify the nurse that a specimen is being canceled due to hemolysis.
b) The Lab will order for a re-draw and a phlebotomist will be notified to re-collect the specimen.

6. Specific specimens
   a) For coagulation specimens, analyze the slightly hemolyzed specimen and report with the comment @HMS (Slight Hemolysis). Lipemia and icteria do not affect coagulation testing.

   b) For chemistry specimens, analyze the specimen and report according to section 8 below.

7. Grossly hemolyzed specimens (500 mg/dL or greater) should not be analyzed without the express permission of the Medical Director, or pathologist on call (example: post-mortem analysis) except when hemolysis does not effect a specific analyte. *For chemistry values refer to related document HIL Index Alert Values.*

8. The Siemens Dimension clinical chemistry analyzer is set to measures HIL with every analyte tested, which is based on the spectral characteristics of a serum or plasma sample. The HIL provides an index to alert the user to potential interference from hemolysis, icterus, and lipemia in the sample, where:

   H = hemoglobin resulting from lysis of red blood cells
   I = icterus resulting from endogenous bilirubin
   L = lipemia or turbidity caused by insoluble lipids

   a) When instrument reports are printed the technologists must check the instrument printouts for "HIL interference" codes. Under normal operation the Data Innovation (Instrument Manager) will flag HIL interference and guide the technical staff with appropriate result commenting or remedial action instruction.

   b) Append the canned comment HIR (Results may be inaccurate due to specimen hemolysis) to all analytes that have the "HIL interference" code for hemolysis.

   c) Append the canned comment IIR (Results may be inaccurate due to specimen icteria) to all analytes that have the "HIL interference" code for icteria.

d) If the "HIL interference" code for lipemia is displayed, repeat the test(s) after ultra-centrifuging the specimen for all tests except AMON (NH_3).

Note: At GEC, if the "HIL interference" code for lipemia is displayed, the specimen is referred to SGMC Laboratory for testing.

e) For LDH and K results with the "HIL interference" code for hemolysis, remove the numeric results and result with the canned comment HLK (unable to analyze due to hemolysis).

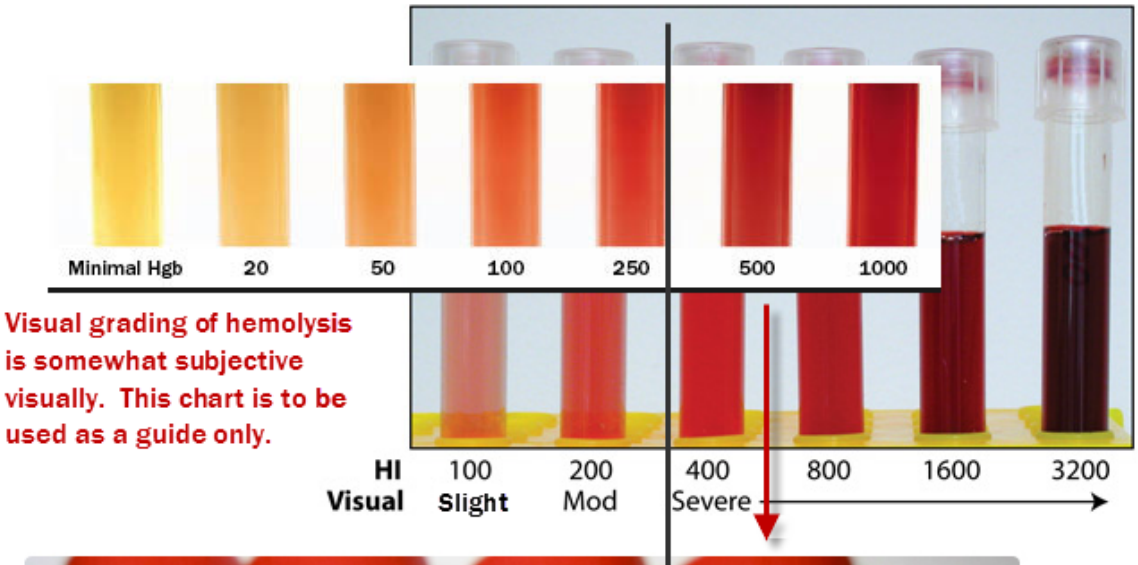
f) For NH_3 results with the "HIL interference" code for lipemia, remove the numeric results and result with the canned comment LLK (unable to analyze due to lipemia), then send out the specimen for testing.

g) The ordering doctor should be notified every time a NH_3 result is removed.

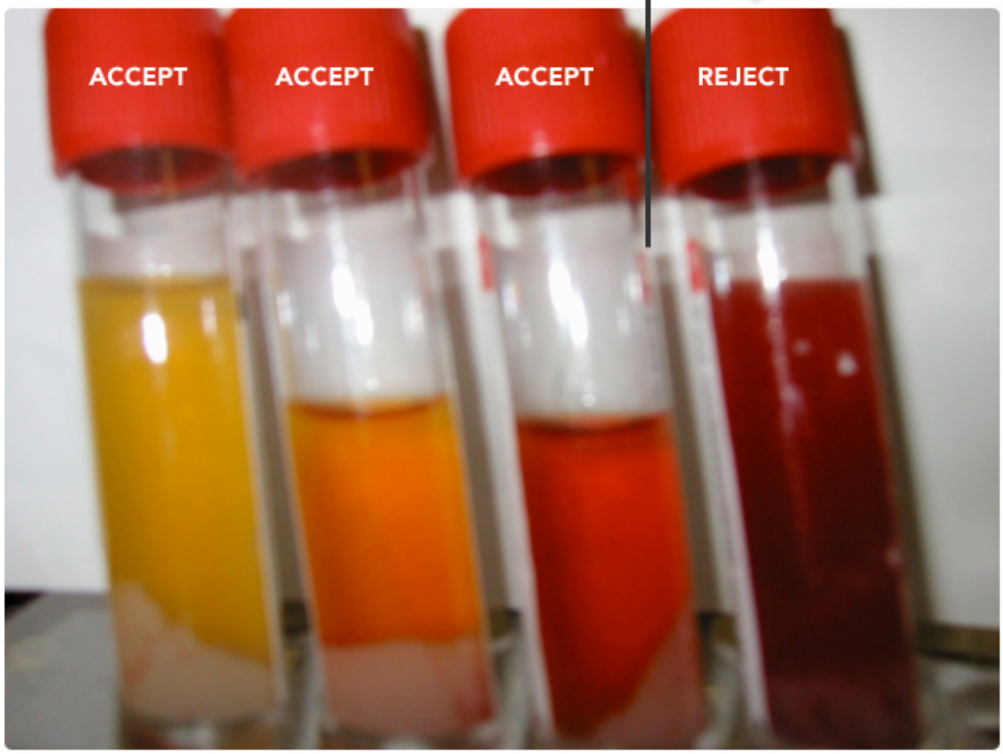
9. For the processing of lipemic and icteric hematology specimens see the procedure Sysmex XN Series Operation for CBC and Reticulocytes.

Appendix B

Hemolysis, Icteria, and Lipemia Interference



Visual grading of hemolysis is somewhat subjective visually. This chart is to be used as a guide only.



Note: It can be difficult to establish hemolysis when in combination with icteria and/or lipemia. In addition, special consideration/care should be taken when evaluating bullet tubes.

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