POLICY

Specimen/Sample Acceptance and Rejection Criteria
Specimen/Sample Acceptance and Rejection Criteria

Policy
Review Sheet

Approved by:
Robert A. Myers, Ph.D.
Laboratory Director

03/12/12
Date

Revision
Mark E McKinney
Quality Assurance Officer

3/8/2012
Date
Revision History

Specimen/Sample Acceptance and Rejection Criteria Policy

<table>
<thead>
<tr>
<th>REVISION</th>
<th>COMMENTS</th>
<th>DATE</th>
</tr>
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<tr>
<td>Version 2.0.1</td>
<td>Policy re-named. Revised and reformatted.</td>
<td>10/1/2011</td>
</tr>
<tr>
<td>Version 2.0.2</td>
<td>Revision: Section IV(A) – Test Requistion.</td>
<td>3/15/2012</td>
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<tr>
<td></td>
<td>• Removed “clinic” as an authorized person for ordering clinical tests</td>
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<td></td>
<td>Section VI(B)(2) – Laboratory Documentation.</td>
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<tr>
<td></td>
<td>• Added the option for “manual log” in Category 2</td>
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Table of Contents

I. Purpose .........................................................................................................................................5
II. Scope.............................................................................................................................................5
III. Preanalytic Standard Operating Procedures...................................................................................5
IV. Required Acceptability Criteria for Specimen/Samples .................................................................5
A. Test Requisition (or Electronic Test Order) ..........................................................................................5
B. Specimen/Sample Labeling ..................................................................................................................6
C. Specimen/Sample Integrity ....................................................................................................................6
D. Exceptions ........................................................................................................................................................6
V. Procedure for Rejection of Specimens/Samples .............................................................................6
VI. Laboratory Documentation Categories ..............................................................................................7
A. Category 1 .........................................................................................................................................................7
B. Category 2 .........................................................................................................................................................7
C. Category 3 .........................................................................................................................................................8
VII. Accessioning Unit Documentation .....................................................................................................8
VIII. Preanalytic Systems Quality Assessment ..........................................................................................9
IX. Examples of Forms and Logs ...............................................................................................................9
APPENDIX A NOTIFICATION OF REJECTED SPECIMEN/SAMPLE FORM ...............................................10
APPENDIX B SPECIMEN REJECTION LOG ..............................................................................................11
APPENDIX C PREANALYTIC PROBLEM RESOLUTION LOG .........................................................................12
POLICY

Specimen/Sample Acceptance Criteria Policy

I. Purpose
The Laboratories Administration is committed to providing the highest quality test results. Quality specimens/samples are integral to quality results. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems for each specialty and subspecialty of testing performed. This Policy provides guidance for specimen/sample assessment activities that must be in place to ensure positive specimen/sample identification and optimum integrity.

II. Scope
All Laboratories Administration employees shall adhere to this Policy, which applies to all specimens/samples, including specimens on deceased individuals. Each laboratory shall establish and follow written policies and procedures in accordance with this policy.

III. Preanalytic Standard Operating Procedures
Each laboratory shall follow written procedures as outlined in the Guide to Public Health Laboratory Services, the Enviroguide – A Guide to Environmental Laboratory Services and divisional standard operating procedures (SOP) for:
   A. Patient preparation, when applicable,
   B. Specimen/sample collection,
   C. Specimen/sample labeling, including patient name or unique patient/sample identifier and, when appropriate, specimen source, specimen date,
   D. Specimen/sample storage and preservation,
   E. Specimen/sample transport conditions,
   F. Specimen/sample processing,
   G. Specimen/sample acceptability and rejection,
   H. Specimen/sample submission, handling and referral, and
   I. Acceptance criteria specific to each assay.

IV. Required Acceptability Criteria for Specimen/Samples
A. Test Requisition (or Electronic Test Order)
   1. The approved test requisition must have the following information:
      a. The name and address or other suitable identifiers of the authorized person(s), or laboratory requesting the test and, if appropriate, the name and address of the individual responsible for using the test results,
      b. The patient’s name or unique patient/sample identifier matching what is labeled on the specimen/sample,
      c. The test(s) to be performed, and
      d. The date of specimen/sample collection
2. When appropriate to the testing system, the following may be required:
   a. The source of the specimen/sample,
   b. The sex and age or date of birth of the patient,
   c. The time of specimen/sample collection, and
   d. Any additional information relevant and necessary for a specific test.

B. Specimen/Sample Labeling
   The specimen/sample must be properly labeled and include (Note: Each specimen/sample within a kit must be labeled):
   1. The patient’s name or unique patient/sample identifier matching the test requisition or electronic test order,
   2. If appropriate, the date and time of specimen/sample collection, and
   3. Any additional information relevant and necessary for a specific test.

C. Specimen/Sample Integrity
   The specimen/sample must be:
   1. Collected in the correct, non-expired, intact, container, device or transport media,
   2. Transported under the correct conditions,
   3. Processed/handled according to approved laboratory procedure,
   4. Sufficient quantity to perform testing (includes no specimen/sample received),
   5. Received within acceptable time limitation; specific criteria to be determined by each lab.

D. Exceptions
   1. All requests for exceptions shall be referred up the chain of command to the Supervisor, Division Chief, Deputy Director, and/or Director.
   2. Potential exceptions may include but are not limited to:
      a. Outbreak investigations,
      b. Specimens from deceased patients, or
      c. Other extenuating circumstances

V. Procedure for Rejection of Specimens/Samples
   A. Evaluate specimens/samples for acceptability,
   B. Document the reason(s) for rejecting a specimen/sample,
   C. Notify the submitter/authorized person promptly by telephone or electronically (e.g. – StarLIMS, Fax…) when a specimen/sample does not meet acceptability criteria (refer to Section IX),
   D. Maintain records of efforts to resolve problems and all associated documents,
   E. Maintain a written or electronic specimen/sample rejection log (refer to Section IX),
   F. Store rejected specimens/samples properly prior to problem resolution/rejection/disposal,
   G. Hold specimens/samples for a minimum of seven (7) working days following the rejection report.
VI. Laboratory Documentation Categories

A. Category 1
1. The Required Acceptability Criteria for Specimen/Samples are not met but require only a verbal resolution (refer to Section IV of this policy).
2. Document call on the lab report, or StarLIMS communication log, or manual log, with full name of contact, date and time of call. No written documentation is required from the submitter.
   Examples may include but are not limited to the following:
   o Incomplete or illegible name on either the test requisition or specimen
   o Missing specimen source
   o Missing date of collection
   o Submitter request for entire test cancellation
3. If the information cannot be verified, the specimen may be rejected and is noted on the rejection log.

**No test ordered** requires verbal resolution and request for written documentation, per CLIA 493.1241 (D5303 CLIA Interpretive Guide). The laboratory may proceed with testing and reporting based on verbal orders. Document verbal orders and the request for written documentation on the test requisition and/or communication log in StarLIMS.

B. Category 2
1. The Required Acceptability Criteria for Specimen/Samples are not met and require written resolution (refer to Section IV of this policy).
2. In addition to the phone call required in category 1, the lab must receive from the submitter, a corrected test requisition or other signed traceable documentation (e.g. - cover letter, letter head), a description of the discrepancy and a resolution. Document call on the lab report, or StarLIMS communication log, or manual log, with full name of contact, date and time of call.
   Examples may include but are not limited to the following:
   o Mismatched name or unique patient/sample identifier on test requisition and specimen
   o No name or unique patient/sample identifier on test requisition with name or unique patient/sample identifier on specimen/sample
   o Incorrect container, device or transport media for test ordered
   o No test requisition provided (if traceable)
   o No submitter information on test requisition (if traceable)
3. If the written documentation is not received, the specimen will be rejected and is noted on the rejection log.
C. **Category 3**

When a problem affects at least two laboratory divisions or one or more laboratory division(s) and an outside agency/submitter, in addition to the steps taken for categories 1 and 2, a Problem/Corrective Action Report will be completed and forwarded through the chain to the Administration QA Officer. Examples may include but are not limited to the following:

- An internal mix-up occurred; specimens were mis-routed in the lab; etc.
- An entire shipment of specimens/samples was delayed in the courier system; or
- A repetitive problem exists

**VII. Accessioning Unit Documentation**

A. The Accessioning Unit must document specimens/samples that do not meet the acceptance criteria.

1. All comments or statements written on the test requisition will be in **red ink**; initialed and dated.

2. Preprinted color labels will be used for documenting comments.

   a. Pink label used for:
      - NSR-No specimen received
      - BIT-Broken in transit
      - LIT-Leaked in Transit
      - NRR- No Test Request Received
      - Test requisition written in accessioning when no lab request form is received (information taken from specimen/sample).
      - No ID on specimen-no identifier is on specimen (name or number)
      - Name taken from specimen-No name on test requisition

      | □ NSR   | □ BIT   | □ LIT   | □ NRR |
      |---------|---------|---------|-------|
      | 🗑 Test requisition written in Accessioning |
      | 🗑 No ID on specimen |
      | 🗑 Name taken from specimen |

   b. Yellow label used for:

   Name on the specimen and name on test requisition **do not** match. The name of the patient as it appears on the specimen will be written on the line provided.

      □ Name on specimen and name on test requisition do not match.
      Patient Name on specimen: ____________________________

B. The Accessioning Unit will maintain a rejection log for specimens/samples received in error. (Appendix C)
VIII. Preanalytic Systems Quality Assessment
   A. Each division/unit must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems.
   B. The preanalytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of preanalytic systems quality assessment reviews with appropriate staff.
   C. Each division/unit must document all preanalytic systems quality assessment activities.

IX. Examples of Forms and Logs
   A. Refer to Appendices A-C for manual documentation, and/or
   B. Refer to StarLIMS for electronic documentation.
      1. Communication Log/ Rejection Notification – found in Edit Clinical or Edit Released Clinical (equivalent to Appendix A)
      2. Rejection Log – generated after reports have been released in the Reports and Queries (equivalent to Appendix B)
**APPENDIX A  NOTIFICATION OF REJECTED SPECIMEN/SAMPLE FORM**

TO BE SENT/FAXED TO SUBMITTER

<table>
<thead>
<tr>
<th>SUBMITTER</th>
<th>PHONE #</th>
<th>FAX #</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SUBMITTER ADDRESS

This is to acknowledge receipt of a __________________ specimen collected on ________________

and received by our laboratory on ________________ for the following patient:

<table>
<thead>
<tr>
<th>NAME</th>
<th>SS#</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DHMH LAB#</th>
<th>TEST(S) REQUESTED</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Please submit another specimen/sample.  
The laboratory is unable to process this specimen for the following reason:

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>No specimen/sample</td>
<td>9</td>
<td>Damaged – improper</td>
</tr>
<tr>
<td></td>
<td>received</td>
<td></td>
<td>transport media</td>
</tr>
<tr>
<td>2</td>
<td>Quantity not</td>
<td>10</td>
<td>Damaged – improper</td>
</tr>
<tr>
<td></td>
<td>sufficient</td>
<td></td>
<td>temperature</td>
</tr>
<tr>
<td>3</td>
<td>Hemolyzed</td>
<td>11</td>
<td>Damaged – lab accident, unsalvageable</td>
</tr>
<tr>
<td>4</td>
<td>Lipemic</td>
<td>12</td>
<td>Damaged – too old</td>
</tr>
<tr>
<td>5</td>
<td>Damaged - broken or</td>
<td>13</td>
<td>No specimen/sample ID</td>
</tr>
<tr>
<td></td>
<td>leaked in transit</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Damaged - contaminated</td>
<td>14</td>
<td>Specimen/sample ID cannot be established</td>
</tr>
<tr>
<td>7</td>
<td>Damaged – expired</td>
<td>15</td>
<td>Specimen/sample ID illegible</td>
</tr>
<tr>
<td></td>
<td>transport media</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Damaged – improper</td>
<td>16</td>
<td>Collection site inappropriate for test</td>
</tr>
<tr>
<td></td>
<td>preservation</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Specimen/sample type unacceptable for test

No test requisition received.

No test ordered on requisition

No specimen/sample collection date on requisition

No specimen/sample collection site on requisition

Test not available.

Other (free text)

Comments:

This form completed by (Laboratories Administration employee):

<table>
<thead>
<tr>
<th>Lab Employee:</th>
<th>Unit:</th>
<th>Date &amp; Time:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

Phoned to:

<table>
<thead>
<tr>
<th>Faxed to:</th>
<th>Comments:</th>
</tr>
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<tbody>
<tr>
<td></td>
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</tbody>
</table>
## APPENDIX B  SPECIMEN REJECTION LOG

<table>
<thead>
<tr>
<th>Lab ID #</th>
<th>Date Rec’d</th>
<th>Date Collected</th>
<th>Name of Patient (Patient ID)</th>
<th>Submitter</th>
<th>Rej Code</th>
<th>Date of phone call</th>
<th>Contact</th>
<th>Tech Initials</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>No specimen/sample received</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Quantity not sufficient</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Hemolyzed</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Lipemic</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Damaged - broken or leaked in transit</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>6</td>
<td>Damaged - contaminated</td>
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<tr>
<td>7</td>
<td>Damaged – expired transport media</td>
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<td>8</td>
<td>Damaged – improper preservation</td>
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</tr>
</tbody>
</table>

1. No specimen/sample received
2. Quantity not sufficient
3. Hemolyzed
4. Lipemic
5. Damaged - broken or leaked in transit
6. Damaged - contaminated
7. Damaged – expired transport media
8. Damaged – improper preservation
9. Damaged – improper transport media
10. Damaged – improper temperature
11. Damaged – lab accident, unsalvageable
12. Damaged – too old
13. No specimen/sample ID
14. Specimen/sample ID cannot be established
15. Specimen/sample ID illegible
16. Collection site inappropriate for test
17. Specimen/sample type unacceptable for test
18. No test requisition received.
19. No test ordered on requisition
20. No collection date on requisition
21. No specimen/sample collection site on requisition
22. Test not available
23. Other (free text)

**EFFECTIVE DATE:** 3/15/2012
## APPENDIX C  PREANALYTIC PROBLEM RESOLUTION LOG

<table>
<thead>
<tr>
<th>Date/Time Rec’d</th>
<th>Accession #</th>
<th>Patient name</th>
<th>Submitter</th>
<th>Code</th>
<th>Comment</th>
<th>Date/Time of Call</th>
<th>Submitter Contact - Full Name</th>
<th>Date Fax Rec’d</th>
<th>Initials</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

Below is the explanation of the codes to be used at the top of this form.

<table>
<thead>
<tr>
<th>Code</th>
<th>Problem</th>
<th>Code</th>
<th>Problem</th>
<th>Code</th>
<th>Problem</th>
</tr>
</thead>
<tbody>
<tr>
<td>BIT</td>
<td>Broken In Transit</td>
<td>LLA</td>
<td>Lost in Lab Accident</td>
<td>UDT</td>
<td>Unable to Determine Test Requested</td>
</tr>
<tr>
<td>ILL</td>
<td>Illegible</td>
<td>NID</td>
<td>No Name/ID on Specimen</td>
<td>NSR</td>
<td>No Specimen Received</td>
</tr>
<tr>
<td>ITM</td>
<td>Incorrect Transport Media</td>
<td>NRR</td>
<td>No test requisition Received</td>
<td>TNP</td>
<td>Test Not Performed (See Written Comment)</td>
</tr>
<tr>
<td>ISC</td>
<td>Incorrect Specimen Container</td>
<td>NSL</td>
<td>Not State Lab Specimen (See Written Comment)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LIT</td>
<td>Leaked In Transit</td>
<td>NTR</td>
<td>No Test Requested</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>