State of Maryland DHMH
LABORATORIES ADMINISTRATION

POLICY

Specimen/Sample Acceptance and Rejection Criteria

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Policy
Review Sheet

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Approved by:
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Laboratory Director

Date

Mark E McKinney 3/8/2012

Revision
Mark E McKinney
Quality Assurance Officer

Date

Revision History

Specimen/Sample Acceptance and Rejection Criteria Policy

REVISION	COMMENTS	DATE
Original	Original Format – Preanalytic Systems Quality Assessment Policy	2/1/2006
Version 2.0.1	Policy re-named. Revised and reformatted.	10/1/2011
Version 2.0.2	Revision: Section IV(A) – Test Requistion. • Removed "clinic" as an authorized person for ordering clinical tests Section VI(B)(2) – Laboratory Documentation. • Added the option for "manual log" in Category 2	3/15/2012

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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:

   - Incomplete or illegible name on either the test requisition or specimen
   - Missing specimen source
   - Missing date of collection
   - 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:

   - Mismatched name or unique patient/sample identifier on test requisition and specimen
   - No name or unique patient/sample identifier on test requisition with name or unique patient/sample identifier on specimen/sample
   - Incorrect container, device or transport media for test ordered
   - No test requisition provided (if traceable)
   - 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)

Maryland Department of Health and Mental Hygiene
Laboratories Administration
201 W. Preston Street
Baltimore, MD 21201

APPENDIX A NOTIFICATION OF REJECTED SPECIMEN/SAMPLE FORM

TO BE SENT/FAXED TO SUBMITTER

SUBMITTER	PHONE #	FAX #
SUBMITTER ADDRESS		

This is to acknowledge receipt of a _____ specimen collected on _____

and received by our laboratory on _____for the following patient:

NAME	SS#
DHMH LAB#	TEST(S) REQUESTED

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

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

This form completed by (Laboratories Administration employee):

Lab Employee:	Unit:	Date & Time:
Phoned to:		
Faxed to :	Comments:	

Maryland Department of Health and Mental Hygiene
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201 W. Preston Street
Baltimore, MD 21201 MONTH_____YEAR_____

APPENDIX B SPECIMEN REJECTION LOG

Lab ID #	Date Rec'd	Date Collected	Name of Patient (Patient ID)	Submitter	Rej Code	Date of phone call	Contact	Tech Initials	Comment

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

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APPENDIX C PREANALYTIC PROBLEM RESOLUTION LOG

Date/Time Rec'd	Accession #	Patient name	Submitter	Code	Comment	Date/ Time of Call	Submitter Contact - Full Name	Date Fax Rec'd	Initials

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

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