

MODULE 7

Specimen Management



My lab collects
and cares for
specimens properly.

SLMTA Participant's Manual

TABLE OF CONTENTS

NOTE: Print this document single-sided and in color if possible.

Activity: Specimen Collection: Phlebotomy Role-Play	1
Activity: Specimen Management	6
Activity: Packaging Specimens for Shipment to Referral Sites	14
Activity: Tracking Referral Specimens	21

ACTIVITY SUMMARY SHEET

ACTIVITY Specimen Collection: Phlebotomy Role-Play Module 7

PURPOSE:

The quality of the specimen obtained in the pre-analytical phase of testing is crucial to the output of accurate and reliable results. A light-hearted phlebotomy role-play reinforces proper phlebotomy techniques and introduces the concepts of competency assessment and customer satisfaction.

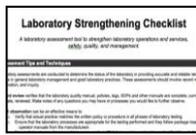
This activity supports the following laboratory management tasks and SLIPTA checklist items

Management Tasks



- 1.4 Assess personnel competency against standards and determine corrective action and training needs
- 7.3 Enforce good specimen handling and processing practices
- 9.4 Conduct customer satisfaction survey to identify areas for improvement

Checklist Items



- 1.5 Laboratory Policies and Standard Operating Procedures Are policies and/or standard operating procedures (SOPs) for laboratory functions, technical and managerial procedures current, available and approved by authorized personnel? (Personnel Training; Competency Assessment; Pre-examination Processes; Laboratory Safety Manual)
- 3.5 Personnel Filing System Are records of personnel maintained and do they include the following?
- 3.6 Laboratory Staff Training Is there a system for training?
- 3.7 Staff Competency Assessment and Retraining Is there a system for competency assessment?
- 4.5 Evaluation Tool and Follow up Is there a tool for regularly evaluating client satisfaction, staff suggestions and is the feedback received effectively utilized to improve services?
- 8.1 Information for Patients and Users Are guidelines for patient identification, specimen collection (including client safety), labelling, and transport readily available to persons responsible for primary sample collection?
- 8.2 Does the laboratory adequately collect information needed for examination performance?
- 9.2 Testing Personnel Are testing personnel identified on the result report or other records (manual or electronic)?
- 12.2 Are the patient care and testing areas of the laboratory distinctly separate from one another?
- 12.12 Handling of Sharps Are 'sharps' handled and disposed of properly in 'sharps' containers that are appropriately utilized?
- 12.16 Personnel Protective Equipment Is personal protective equipment (PPE) easily accessible at the workstation and utilized appropriately and consistently?

**KEY MESSAGES**

- The integrity of the pre-analytic patient sample is a key determinant in the overall quality of the testing process.
- Laboratory supervisors / managers have a responsibility to ensure the quality of services provided in their laboratory. Competency assessment is an important part of that assurance of quality.
- The sole reason for the existence of the laboratory is to provide quality care for the patient. Patient satisfaction is important to the work of the laboratorian.

Can you:

- Provide or supervise the provision of safe & effective venipuncture services?
- Guarantee the pre-analytic integrity of the patient sample for testing?

**SELF-ASSESSMENT**

For this activity, you will need:

- Job Aid 1: Phlebotomy Checklist (701)
- Job Aid 2: Phlebotomy Key Competencies (702)
- Job Aid 3: Phlebotomy Patient Survey (703)

Phlebotomy Checklist⁷⁰¹

GOAL: The phlebotomist will be able to perform a complication-free venipuncture obtaining a quality specimen in a manner consistent with good customer service.

SKILLS CHECKLIST:

1. Checks specimen requirements for ordered tests and stocks tray.	Yes No N/A
2. Greets patient, identifies self, and explains procedure. Exhibits good customer service behaviors.	Yes No N/A
3. Identifies patient using two identifiers. Verbally asks patient name. Verifies name and second identifier. Verifies fasting state.	Yes No N/A
4. Assembles and inspects equipment and has proper supplies at hand.	Yes No N/A
5. Reassures patient and places patient in a safe position.	Yes No N/A
6. Properly applies tourniquet for appropriate amount of time.	Yes No N/A
7. Has patient extend arm and clench fist.	Yes No N/A
8. Selects appropriate needle type depending on assessment of vein.	Yes No N/A
9. Demonstrates good judgment in vein selection (measurable center).	Yes No N/A
10. Uses alcohol or other disinfectant to cleanse site; allows site to dry.	Yes No N/A
11. "Fixes" vein and smoothly enters vein with needle at correct angle.	Yes No N/A
12. A. Smoothly depresses vacutainer tube into holder without changing position of needle.	Yes No N/A
13. B. Draws vacutainer tubes in correct order and fills completely.	Yes No N/A
14. C. Demonstrates proper aspiration techniques when using butterfly.	Yes No N/A
15. Demonstrates good judgment and adjusts technique when blood does not flow immediately.	Yes No N/A
16. Removes tourniquet when good blood flow is established.	Yes No N/A
17. Has patient release fist.	Yes No N/A
18. Removes vacutainer tube from needle holder slowly.	Yes No N/A
19. Smoothly withdraws needle and applies pressure with gauze to arm.	Yes No N/A
20. Mixes anticoagulated samples by inversion thoroughly.	Yes No N/A
21. Labels specimens correctly after the draw is complete.	Yes No N/A
22. Checks puncture site to make sure all bleeding has stopped and bandages site.	Yes No N/A
23. Disposes of contaminated materials properly.	Yes No N/A
24. Completes documentation as required.	Yes No N/A

Phlebotomy Key Competencies⁷⁰²

1. Selects the most appropriate, accessible vein; checks antecubital fossa area first. Evaluates patient's veins and clinical situation to select best venipuncture site. Identifies an appropriate draw site whenever possible; listens to patient's preference on vein selection.
2. Identifies the patient both verbally and by checking the name and medical record number on the armband. Does not draw patients without an armband physically on the patient. Matches label name and MR# to armband. Resolves discrepancies before drawing the patient. Places barcode labels appropriately on all tubes after blood is drawn.
3. Communicates effectively with the patient and other internal and external customers. Displays a caring approach to every patient.
4. Inserts needle bevel up at no more than a 30° angle of insertion. Insert needle no deeper or further than necessary to achieve adequate blood flow.
5. Accurately assesses depth of needle insertion required to perform venipuncture without development of hematoma/bruising.
6. Consistently draws samples without QNS, hemolysis, IV contamination, or clotting.
7. Accurately describes and follows "standard precautions" for all blood collection procedures. Utilizes safety needles and plastic tubes for all draws.
8. Performs a successful venipuncture on 85% of patients at end of six weeks of daily rounds. Improves unable rate to less than 5% in the first year.
9. Takes appropriate corrective action when complications occur (Ex: syncope, hematoma, bleeding)
10. Assures stoppage of bleeding prior to leaving the patient. Applies pressure in cases of excessive bleeding. Does not draw if contraindications exist (edema, mastectomy).
11. Applies tourniquet for no more than two minutes. Removes tourniquet 100% of the time prior to needle removal.
12. Aseptically draws blood culture specimens per standard laboratory protocol with no reported incidents of blood culture contaminants.
13. Consistently signs and dates all Blood Bank specimens. No incidents of failure to sign or date reported by Blood Bank.
14. Follows Phlebotomy, Laboratory, and hospital policies and procedures 100% of the time.
15. Assesses equipment carefully for blood contamination, cleanliness, and safety before using on the patient; never uses contaminated supplies or reuses needles; puts gloves on in front of patient and changes gloves between patients.

The employee listed below has been assessed and is competent in all of the above competency areas.

Employee's Name: _____

Supervisor's Name: _____

Supervisor Signature: _____

Date: _____

Phlebotomy Patient Survey⁷⁰³

Patient Name: _____ **Site:** _____

Date: _____ **Time:** _____

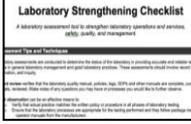
Phlebotomist: _____

1. Did the phlebotomist identify him or her self?	YES	NO
2. Did the phlebotomist explain the procedure?	YES	NO
3. Did the phlebotomist ask your name and identify you?	YES	NO
4. Was the phlebotomist neat and clean?	YES	NO
5. Did the phlebotomist wear gloves?	YES	NO
6. Did the phlebotomist open a new needle package?	YES	NO
7. Did the phlebotomist have the necessary equipment?	YES	NO
8. Was the phlebotomist skilled at drawing your blood?	YES	NO
9. Did you feel any discomfort during the blood draw?	YES	NO
10. Would you like this phlebotomist to draw you again?	YES	NO

Any comments to help us improve?

ACTIVITY SUMMARY SHEET

ACTIVITY	Specimen Management	Module 7
PURPOSE:		
<p>The quality of the inputs to the laboratory directly determines the quality of the outputs. Assuring that specimens are acceptable is an important function of laboratory management and is highlighted by this role-play.</p>		

This activity supports the following laboratory management tasks and SLIPTA checklist items	
<p>Management Tasks</p> 	<p>7.3 Enforce good specimen handling and processing practices</p> <p>9.4 Conduct customer satisfaction survey to identify areas for improvement</p>
<p>Checklist Items</p> 	<p>1.5 <u>Laboratory Policies and Standard Operating Procedures</u> Are policies and/or standard operating procedures (SOPs) for laboratory functions, technical and managerial procedures current, available and approved by authorized personnel? (Advisory Services; Identification and Control of Nonconformities)</p> <p>1.6 <u>Policy and SOPs Accessibility</u> Are policies and SOPs easily accessible/available to all staff and written in a language commonly understood by respective staff?</p> <p>2.1 <u>Routine Review of Quality and Technical Records</u> Does the laboratory routinely perform a documented review of all quality and technical records?</p> <p>2.2 <u>Management Review</u> Does the laboratory management perform a review of the quality system at a management review meeting at least annually?</p> <p>3.6 <u>Laboratory Staff Training</u> Is there a system for training?</p> <p>4.3 <u>Laboratory Handbook for Clients – information to users</u> Is there a laboratory handbook for laboratory users that includes information on location of the lab, services offered, laboratory operating times, instructions on completion of request forms, instruction for preparation of the patient; sample collection including patient collected samples, transport, agreed turnaround times, acceptance and rejection criteria, availability of advice on examination and interpretation of results; lab policy on protection of personal information, laboratory complaints procedure?</p> <p>8.1 <u>Information for patients and users</u> Are guidelines for patient identification, specimen collection (including client safety), labelling, and transport readily available to persons responsible for primary sample collection?</p> <p>8.2 Does the laboratory adequately collect information needed for examination performance?</p> <p>8.3 Are adequate sample receiving procedures in place?</p> <p>8.7 <u>Documentation of Examination Procedures</u> Are examination procedures documented in a language commonly understood by all staff and available in appropriate locations?</p> <p>11.2 <u>Quality Management System Improvement Measures</u> Does the laboratory identify and undertake continual quality improvement projects?</p> <p>11.4 Are quality indicators (TAT, rejected specimens, stock-outs, etc.) selected and tracked?</p> <p>11.5 Is the outcome of the review of quality indicators used to improve lab performance?</p> <p>11.6 Are the actions taken checked and monitored to determine the effectiveness of improved quality of lab performance?</p>

**KEY MESSAGES**

- To preserve the quality of laboratory inputs, one must not accept specimens that are of poor quality, dangerous, improperly labeled, or not accompanied by a complete requisition.
- Courteous, respectful, helpful communication is required in all customer service interactions and communications.
- Specimen rejection is an opportunity for education. Combining verbal and written communication regarding specimen acceptability is important for education of providers. The ultimate goal is to preempt and prevent specimen rejection.

Can you:

- Determine specimen acceptability?
- Communicate specimen acceptability policies clearly to laboratory users?
- Plan & implement an improvement project with the goal of preempting and preventing specimen rejection?

**SELF-ASSESSMENT**

For this activity, you will need:

- [Job Aid 1: Criteria for Specimen Acceptability \(704\)](#)
- [Job Aid 2: Specimen Rejection Documents \(705\)](#)
- [Job Aid 3: Quality Improvement Project Plan \(706\)](#)

Criteria for Specimen Acceptability⁷⁰⁴

Statement of Policy

Proper specimen procurement and handling are an essential part of obtaining accurate, timely pathology and laboratory results. All specimens delivered to the laboratory must meet defined acceptance criteria for identification/labeling, collection, volume, preservation, and container type in order to be processed. If any criteria are not met, the attending physician, phlebotomy staff, or nursing unit personnel will be notified immediately so that corrective action can be taken.

Scope

Specimen acceptability requirements apply to all specimens submitted to the laboratory.

Procedures

To be acceptable, specimens must meet the following four (4) general criteria:

1) Satisfactory Specimen Quality

If a specimen is collected, handled, or transported in such a way as to alter the substances or constituents to be analyzed, then the specimen will be deemed unsatisfactory.

Criteria for Specimen rejection include:

- a) Specimen collected in the wrong tube, container, preservative, or media.
- b) Specimen inappropriately handled with respect to temperature, timing, or storage requirements.
- c) Quantity not sufficient - QNS.
- d) Lipemic or grossly hemolyzed specimens may be rejected depending on test requested.
- e) Specimens with IV fluid or other peripheral line contamination.
- f) Specimen collection device past expiry dates.

2) Properly Labeled Specimen

If any specimen is unlabeled, mislabeled, or improperly or incompletely labeled, it may be rejected.

Corrective Action for Labeling Errors:

If a specimen is determined to be unacceptable, the nursing unit, phlebotomist, or physician will be contacted and informed of the reasons for the unacceptable specimen and that a new specimen must be submitted. The reason for the rejection must be documented on the laboratory report or other log. If the specimen is irreplaceable such as CSF, certain Microbiology, and tissue specimens, the physician or other approved personnel must come to the laboratory to positively identify the specimen, affix the proper label, and complete an unlabeled / mislabeled specimen documentation form.

3) Specimens should be submitted without hazardous handling conditions

Any specimen submitted in a manner which could create a health or safety hazard to laboratory personnel is considered unacceptable. The following situations are grounds for specimen rejection:

- a) Specimens submitted in syringes with needles are considered unacceptable.
- b) Specimens submitted in cracked or leaking containers with external contamination of blood/body fluids.

Note: Specimens that cannot be re-obtained (CSF, fluid aspirates, surgical tissue) will have acceptability assessed and the ordering location notified to come to the laboratory and transfer the specimen to an acceptable leak proof container.

4) Laboratory Requisition must accompany specimen

All laboratory specimens must be accompanied by an adequate requisition/order slip for the test. Paper or electronic requisitions must include the following: 1) adequate patient identification information, 2) patient sex, 3) date of birth or age, 4) name of physician or legally authorized person ordering the test, 5) tests requested, 6) time and date of specimen collection when appropriate, 7) initials of person collecting the specimen if applicable, 8) source of specimen when appropriate, and 9) clinical information when appropriate.

Responsibilities

Laboratory staff will determine the acceptability of all specimens for testing and will follow this procedure for rejection of specimens and notification of persons obtaining specimens. Laboratory supervisors will assure that all laboratory staff are educated on the policy and are in compliance with the policy.

Specimen Rejection Documents⁷⁰⁵

Document of Laboratory Specimen Rejection due to Compromised Sample Integrity & Communication of Problems with Sample Integrity with Non-laboratory Personnel.		Time, Date of Communication Signature of lab personnel
Reported to: (non lab)		
	Not met special requirements before specimen collection, e.g. fasting	
	Incorrect patient identification	
	Incorrect tube or container or not mixed well	
	Inadequate volume	
	Specimen with haemolysis	
	Specimen compromised with IV fluid	
	Collected at improper time	
	Incorrect temperature when received	
	Not protected from light, as needed	
	Received past recommended time; not separated prior to transport after prolonged storage	
	Uncovered; exposed to air	

Reasons for Sample Recollection due to Specimen Problems Arising During Venipuncture

1. Improper identification of patient.
2. Failure to check patient adherence to dietary restriction.
3. Use of improper equipment or tubes.
4. Prolonged tourniquet application.
5. Failure to allow site to dry after cleansing.
6. Inserting needle bevel down.
7. Wrong insertion depth of needle.
8. Venipuncture above an intravenous line.
9. Venipuncture in an unacceptable area.
10. Wrong order of tube draw.
11. Incomplete tube fill.
12. Vigorous shaking.
13. Neglecting to release tourniquet before needle withdrawn.
14. Mislabelling of tubes.
15. Failure to put initials, date, and time on requisition.
16. Neglecting to chill specimens requiring refrigeration.
17. Slow transport of specimens to laboratory.

Quality Improvement Project Plan⁷⁰⁶

Use all the resources available to you to try and understand the problem, propose solutions and develop an action plan.

SECTION A- Identifying the problem

I. State the apparent problem:

II. Collect Baseline Data:

What data will be collected? _____

Method - How will the data be collected? _____

Who is responsible for collecting data? _____

What are the tools/forms/checklists to be used? _____

Over what period of time will the data be collected? _____

When will the data be reviewed? _____

III. Analyze the baseline data:

What is wrong? _____

Where is it happening? _____

When is it happening? _____

Who is involved? _____

IV. Identify possible causes:

V. Propose possible solutions:

SECTION B: Action Plan

I. Identified problem: _____

II. AIM Statement (overall goal of this project) _____

III. Actions to be implemented (following brainstorming of possible solutions).

Action item	Responsible Person	Timeline	Signature

IV. Select and Define ELEMENT TO BE MEASURED (to monitor effectiveness of implemented actions) _____

V. Results of element measured at baseline _____

VI. Acceptable results (target for this measure) _____

VII. Data Collection

How will the data be collected? _____

Who is responsible for collecting data? _____

What are the tools/forms/checklists to be used? _____

How often will the data be collected? _____

How often will the data be reviewed? _____

How often will the data be analyzed to monitor effectiveness of implemented actions?

DO

IMPLEMENT Action Plan

Collect data on element to be measured (to be done throughout the implementation period; document problems and unexpected observations)

Summary of data collected on element to be measured									
Date of Review									
Results									

Depending on the element measured, results may be presented in a different format than table above e.g. before and after pictures.

Monitor how the plan is being executed.

Action item	Responsible Person	Timeline	Signature	Action Plan review		
				R 1	R 2	R 3

CHECK

Was change effective? _____

If **yes**, how easy or difficult was it to achieve results? _____

Unexpected Observations:

ACT

If successful develop and implement plans to standardize the process, communicate changes and train as necessary.

If unsuccessful, use information collected during DO and CHECK for problem analysis (Repeat PDCA)

PLAN-DO-CHECK-ACT (Next Cycle)

Plan & Implement Cycle II of Improvement Project:

Proposed date to begin Cycle II of improvement project _____

Signature of Reviewer _____ Date _____

Laboratory Director _____ Date _____

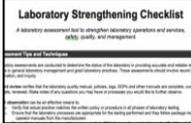
ACTIVITY SUMMARY SHEET

ACTIVITY	Packaging Specimens for Shipment to Referral Sites	Module 7
-----------------	---	-----------------

PURPOSE:

Referral testing requires proper packaging and shipping of patient specimens to preserve their integrity and suitability and to protect all persons involved in their transportation. In this activity, participants learn the importance of safe and effective specimen packing and practice appropriately packing samples with available materials of varying levels of sophistication.

This activity supports the following laboratory management tasks and SLIPTA checklist items

<p>Management Tasks</p> 	<p>7.3 Enforce good specimen handling and processing practices</p> <p>7.4 Ensure adherence to specimen referral requirements</p>
<p>Checklist Items</p> 	<p>1.5 <u>Laboratory Policies and Standard Operating Procedures</u> Are policies and/or standard operating procedures (SOPs) for laboratory functions, technical and managerial procedures current, available and approved by authorized personnel? (Examination by Referral Laboratories and Consultants; Pre-examination Processes)</p> <p>8.4 <u>Pre-examination Handling, Preparation and Storage</u> Where testing does not occur immediately upon arrival in the laboratory, are specimens stored appropriately prior to testing?</p> <p>8.5 <u>Sample Transportation</u> Are specimens either received or referred packaged appropriately according to local and or international regulations and transported within acceptable timeframes and temperature intervals?</p> <p>12.16 <u>Personnel Protective Equipment</u> Is personal protective equipment (PPE) easily accessible at the workstation and utilized appropriately and consistently?</p> <p>12.18 <u>Post Exposure Prophylaxis</u> Are post-exposure prophylaxis policies and procedures posted and implemented after possible and known exposures?</p> <p>12.20 <u>Biosafety Training</u> Are drivers/couriers and cleaners working with the laboratory trained in Biosafety practices relevant to their job tasks?</p>

**KEY MESSAGES**

- Proper specimen packaging and shipping is important to ensure quality results and the safety of laboratory and courier personnel.
- The three factors necessary for specimen packaging and shipping are:
 - The right packaging
 - The right temperature
 - The right timeframe
- Regardless of the sophistication of the packaging materials, it is possible to properly package and ship specimens for referral testing.

Can you:

- Identify the components of the triple packaging system and their purpose?
- Package specimens appropriately with the provided packaging materials?

**SELF-ASSESSMENT**

For this activity, you will need:

- [Job Aid 1: Triple Packaging System](#) (707)
- [Job Aid 2: Specimen Packaging and Shipping](#) (708)

Triple Packaging System⁷⁰⁷

Primary Receptacles

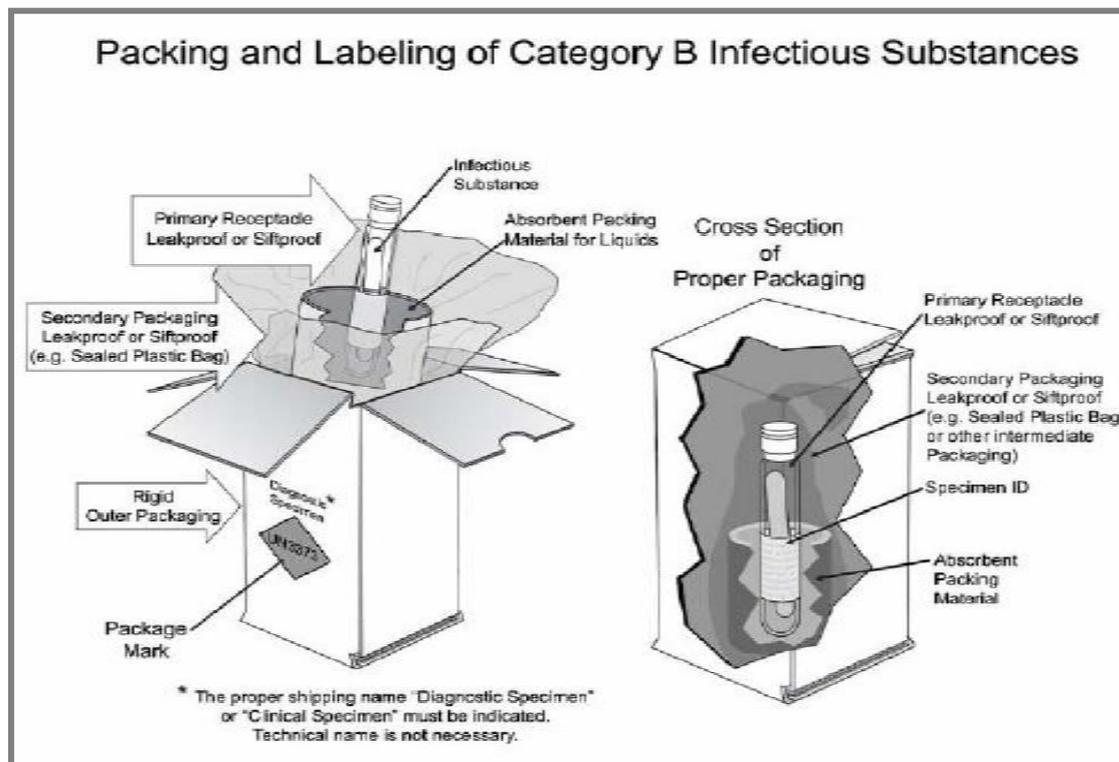
- Contains the specimen
- Must be watertight and leak proof
- Must be appropriately labeled as to content.
- Wrapped in enough absorbent material to absorb all fluid in case of breakage or leakage.

Secondary Packaging

- Encloses and protects the primary receptacle
- Must be watertight and leak proof
- Several wrapped primary receptacles may be placed in a single secondary packaging.

Outer Packaging

- Protects secondary packaging from physical damage while in transit
- Contains specimen data forms, letters, and other types of information that identify or describe the specimen and identify the shipper and receiver, and any other documentation required.
- Must be a sturdy container with a latch or able to be taped shut



Specimen Packaging and Shipping⁷⁰⁸

- Utilize PPE when packaging specimens.
- Ensure specimens are in the appropriate transport media (primary containers) for the specimen collected and the test requested (primary containers). Ensure that primary containers will not leak
- Determine the requirements temperature (ambient temperature vs refrigerated) and the referral timeframe (i.e., 6 hours) for the specimen collect and the test requested.
- Consult the driver/courier schedule to ensure that the sample will reach the referral center within the necessary referral timeframe.
- Place cool packs on the bottom of a secure leak-proof secondary container to properly preserve the specimens during shipping (specimens shipped at ambient temperature may not require cool packs, although it is often still advisable in warm climates.)
- Place the primary container(s) in the secondary container with sufficient absorbent material—paper towels, cotton balls, commercial products—to absorb the entire contents of the primary containers.
 - *Ambient temperature specimens can be transported in the same secondary packaging as refrigerated specimens, but should be packed as far away from the cool pack as possible and be insulated by at least one layer of absorbent material.*
- Ensure secondary container(s) is labeled properly with a biohazard sticker or stamp.
- Place secondary container(s) in an outer shipping container that can be secured with a screwtop, latch mechanism or sealed with tape.
- Place test requisition forms in a plastic sheath (if possible) inside the outer shipping container with specimen tracking form.
- Confirm that the contact information for the laboratory is clearly marked on the outer shipping packaging and/or in paperwork inside the outer packaging
- Note the date and time of pick-up on the specimen tracking form and/or the driver/courier logbook.
- Ensure that the drivers/couriers have received basic safety training in the transportation of specimens.
- Disinfect the bench where the specimens were packaged.

Step-by-Step Specimen Packaging Example



1. Collect specimens in primary containers and packaging materials



2. Place absorbent into bottom of secondary container.



3. Wrap each tube in paper towel.



4. Place tubes and biohazard marker in secondary container



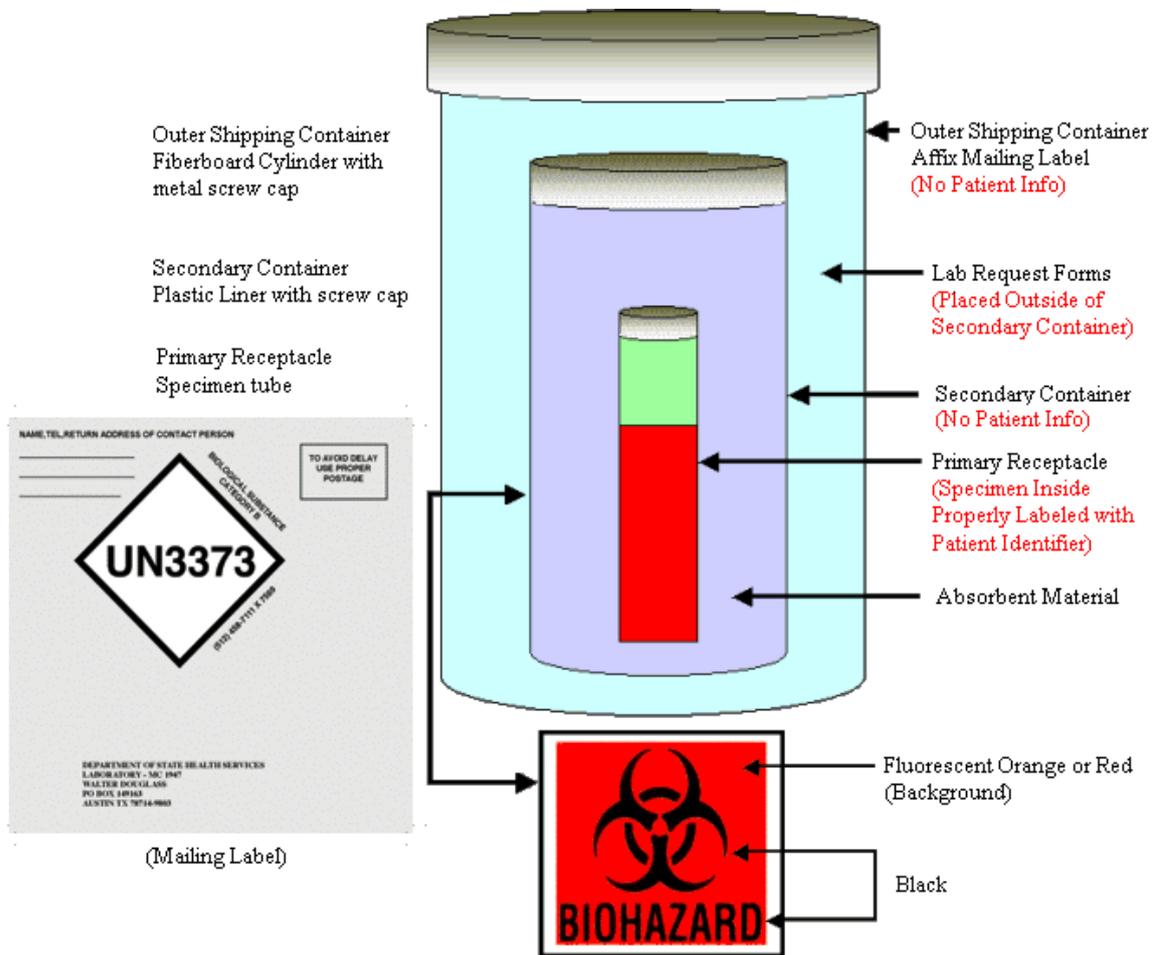
5. Put absorbent on top of tubes and screw on cap.



6. Roll lab form around the outside of the secondary container. Place in outer container. Screw on cap.

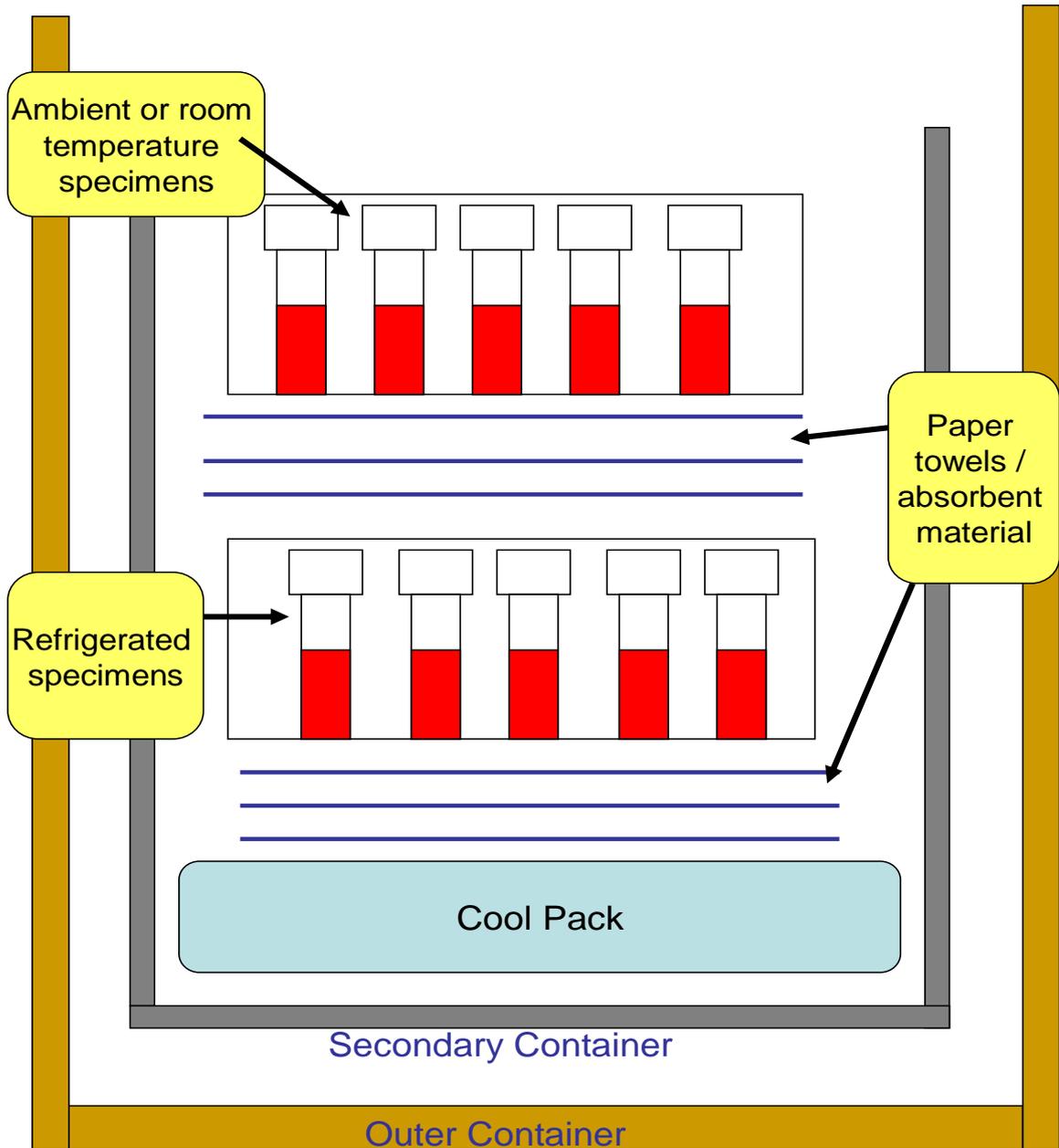
Specimen Packaging Diagram

DO NOT put any patient information on outer container or secondary containers or lids.



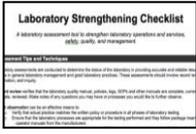
Biohazard Label should be on Secondary Container.
DO NOT put Biohazard Label on Outer Container.

Cross Section of Refrigerated Specimen Packaging



ACTIVITY SUMMARY SHEET

ACTIVITY	Tracking Referral Specimens	Module 7
PURPOSE:		
<p>Referral specimen status is essential for specimen management to ensure the timely return of test results. In this case study, participants learn to use a log to track referral specimens, follow up on an issue, and document the occurrence.</p>		

This activity supports the following laboratory management tasks and SLIPTA checklist items	
Management Tasks 	<p>6.8 Review occurrence log for patterns/trends and take corrective action</p> <p>7.5 Track specimen referral status and review referral reports to ensure timely return of test results</p> <p>9.2 Ensure test results reach referral sites or test requestors</p>
Checklist Items 	<p>1.5 <u>Laboratory Policies and Standard Operating Procedures</u> Are policies and/or standard operating procedures (SOPs) for laboratory functions, technical and managerial procedures current, available and approved by authorized personnel? (Examination by Referral Laboratories and Consultants; Identification and Control of Nonconformities; Corrective Action)</p> <p>2.1 <u>Routine Review of Quality and Technical Records</u> Does the laboratory routinely perform a documented review of all quality and technical records?</p> <p>2.2 <u>Management Review</u> Does the laboratory management perform a review of the quality system at a management review meeting at least annually?</p> <p>8.6 Does the laboratory select and evaluate referral Labs and Consultants?</p> <p>10.1 Are all identified nonconforming activities/ work identified and documented adequately?</p> <p>10.2 <u>Root Cause Analysis</u> Is documented root cause analysis performed for non-conforming work before corrective actions are implemented?</p> <p>10.3 Is corrective action performed and documented for non-conforming work?</p> <p>11.2 <u>Quality Management System Improvement Measures</u> Does the laboratory identify and undertake continual quality improvement projects?</p> <p>11.3 <u>Communication System on Laboratory Operations</u> Does the laboratory communicate with upper management regularly regarding needs for continual improvement?</p>

KEY MESSAGES

- Weekly review of the specimen referral log ensures referred specimens are properly tracked.
- It is the laboratory's responsibility to ensure test reports for specimens referred to another laboratory are returned in a timely manner to the provider.
- Occurrence reports assist the laboratory to identify and to address problems that affect laboratory operations.

Can you:

- Review a specimen referral log and track a specimen's referral status?
- Follow-up on referral reports that are outstanding and document the investigation?

SELF-ASSESSMENT

For this activity, you will need:

- [Handout 1: Specimen Referral Log](#) (709)
- [Handout 2: Occurrence Report Example](#) (710)
- [Worksheet 1: Referral Log Questions](#) (711)
- [Worksheet 2: Occurrence Report Form](#) (712)

Specimen Referral Log⁷⁰⁹

Date of Review: 12/1/2008

Specimen #	Patient Name	Specimen Type	Referred to	Transported by	Date Transported	Date Returned	Results	Notes
32	Jones, Eileen	AFB -sputum	Mbabane	A.H.	3/1/2008	5/1/2008	negative	#A
32						5/1/2008	negative	#B
18	Smith, David	Malaria- 2 smears	Manzini	A.H.	3/1/2008	8/1/2008	lab accident- recollect	8/1/08 at 1445 called Manzini spoke with Laura, slides broke in lab, need to recollect. Dr Smith updated & patient notified at 1500 LJB (<i>initials of staff member</i>)
87	McCarthy, Tom	AFB-sputum	Mbabane	A.H.	4/1/2008	6/1/2008	negative	#A
87						6/1/2008	negative	#B
93	Roam, Shawn	CD4 - EDTA WB tube	Mbabane	L.S.	4/1/2008	5/1/2008	233 cells/mm3	
19	Clinton, Steve	AFB-sputum	Mbabane	L.S.	4/1/2008			#A
19								#B
25	Jones, Ann	CD4 - EDTA WB tube	Mbabane	A.H.	5/1/2008	6/1/2008	483 cells/mm3	
33	McCain, Elaine	Malaria- 2 smears	Manzini	L.S.	6/1/2008	7/1/2008	negative	
46	McCaine, Elaine	AFB-sputum	Mbabane	A.H.	6/1/2008	8/1/2008	3+	#A report called to Dr Smith 8/1/08 1452 LJB (<i>initials of staff member</i>)
46						8/1/2008	1+	#B
57	Pacheco, Miguel	AFB-sputum	Mbabane	A.H.	7/1/2008	9/1/2008	negative	#A
57						9/1/2008	negative	#B
6	Pacheco, Miguel	CD4 - EDTA WB tube	Mbabane	A.H.	7/1/2008			
15	Smith, David	AFB-sputum	Mbabane	A.H.	8/1/2008	10/1/2008	negative	#A
15							negative	#B
28	Pacheco, Miguel	Malaria- 2 smears	Manzini	C.C.	9/1/2008	10/1/2008	negative	
31	Smith, Susan	AFB-sputum	Mbabane	A.H.	10/1/2008	12/1/2008	8 AFB/field	#A report called to Dr Smith 12/1/08 1500 LJB (<i>initials of staff member</i>)
31							negative	#B
47	Jones, Tom	AFB-sputum	Mbabane	A.H.	10/1/2008			#A
47								#B
59	Rite, Carol	Malaria- 2 smears	Manzini	A.H.	11/1/2008			

Occurrence Report Example⁷¹⁰

DATE OF OCCURRENCE 4/1/08 DATE OF REPORT 12/1/08

TIME OF OCCURRENCE 1500 Requires immediate attention by manager Yes
 No

PERSONNEL REPORTING OCCURRENCE A. Murphy

PATIENT'S NAME Clinton, Steve PATIENT ID 19
(IF APPLICABLE) (IF APPLICABLE)

PATIENT'S CLINICIAN Dr Angelina Smith

LOCATION OF OCCURRENCE in car as specimen was being transported to Mbabane Laboratory

BRIEF DESCRIPTION OF OCCURRENCE Upon reviewing the Specimen Referral Log, the patient's AFB result was overdue (normal TAT – 2 days). The Mbabane Laboratory was contacted (12/1 at 1125- Sue Haverly) inquiring about the test result availability. Sue explained that there is no record of her laboratory receiving this specimen. I spoke with Lisa Sims ,the day driver, at 1155. Lisa looked in the transport car and found the specimen under the driver's seat. The specimen is no longer acceptable for testing

IMMEDIATE ACTION TAKEN (If any) I contacted Steve Clinton on 12/1/08 at 1300 to explain that the specimens must be recollected due to a laboratory accident. Dr Smith, the ordering provider, was contacted at 1330 to update him regarding the test request and that the patient is planning to arrive tomorrow to obtain the specimen cups required for recollection. I completed the test report for the specimen indicating, "No result available due to a laboratory accident. Please accept our apology" and included the documentation regarding patient /doctor notification. I created a new requisition and gave it to the phlebotomy area to complete when Mr. Clinton returns with his specimens. All laboratory logs have been updated with "no result available" and the supporting documentation.

CORRECTIVE ACTION PLAN The specimen, when given to the driver, was not placed in a secure location allowing the specimen to fall off the seat. The laboratory will begin transporting all specimens in a transfer box. It is recommended that the cooler boxes received from previous hematology control shipments be used since they are the appropriate size and will better preserve all specimens during transport. Each driver will receive a transport box. The Specimen Referral SOP will be updated to reflect this change.

FOLLOW-UP ACTION Since this is a unique occurrence, no further changes will be implemented at this time. If this problem continues, then a transmittal slip will be created that must be signed by the receiving laboratory and returned by the driver on the same day.

SIGNATURE OF REVIEWER H. Hines DATE 13/1/08
 CLINIC DIRECTOR _____ DATE _____

Referral Log Questions⁷¹¹

Review Handout 1: Specimen Referral Log and answer the following questions.

1. What is the approximate turn-around time for the following tests:

- AFB sputum _____
- Malaria smears _____
- CD4 _____

2. Provide 2 reasons why Dr. Smith was notified under the “Notes” column.

3. Why is this documentation important?

4. List the patients with outstanding tests that require followed-up by your laboratory?

Occurrence Report Form⁷¹²

DATE OF OCCURRENCE _____ DATE OF REPORT _____

TIME OF OCCURRENCE _____ Requires immediate attention by manager ___ Yes ___ No

PERSONNEL REPORTING OCCURRENCE _____

PATIENT'S NAME _____ PATIENT ID _____
(IF APPLICABLE) (IF APPLICABLE)P

PATIENT'S CLINICIAN _____

LOCATION OF OCCURRENCE _____

BRIEF DESCRIPTION OF OCCURRENCE _____

IMMEDIATE ACTION TAKEN (If any) _____

CORRECTIVE ACTION PLAN _____

FOLLOW-UP ACTION _____

SIGNATURE OF REVIEWER _____ DATE _____

CLINIC DIRECTOR _____ DATE _____