2015 Version

CROSS-CUTTING

SLMTA Trainer's Guide

Overview

CROSS-CUTTING

Several activities cover broad topics that cut across all work areas or modules. Several tools are presented to support the improvement focus of the curriculum. “Process Mapping” is a diagnostic/analytic tool and “Balanced Scorecard” is a performance-monitoring tool. Tools for organizing time and the physical work environment facilitate the coordination of tasks and transform mediocrity into excellence. The planning, implementing, and reporting of improvement projects is carefully outlined. Scenarios provide real-life experience in managing and improving a laboratory.

Checklist Items Supported by These Activities

These cross-cutting activities support the requirements for the following items from the SLIPTA Checklist:

1.1, 1.2, 1.4, 1.5, 1.6, 1.7, 1.8, 1.10, 1.11, 2.1, 2.2, 3.1, 3.2, 3.5, 3.6, 3.7, 4.1, 4.5, 5.1, 5.6, 5.10, 5.11, 5.15, 5.16, 6.1, 6.2, 7.1, 7.4, 7.5, 7.7, 7.9, 7.10, 7.12, 8.1, 8.2, 8.7, 8.9, 8.10, 8.12, 8.13, 8.14, 9.1, 9.2, 9.3, 9.5, 9.6, 10.1, 10.2, 10.3, 10.4, 10.5, 11.1, 11.2, 11.3, 11.4, 11.5, 11.6, 12.2, 12.3, 12.4, 12.5, 12.6, 12.7, 12.10, 12.11, 12.12, 12.16, 12.18, 12.19, 12.21

ACTIVITY TITLE	PURPOSE	DURATION
Process Mapping	Mapping a process (all the steps from the beginning to the end of an activity) is a tool that allows analysis and optimization of workflow and service delivery. In this activity, participants will map and create a table analyzing the process of specimen flow through the laboratory.	1 hr 30 min
Using the Improvement Method	The activity provides a new method of approaching issues that arise in the day-to-day work of managers. Participants are introduced to the improvement model and are given an opportunity to address a typical management issue using this model.	1 hr 52 min
Managing Performance – The Balanced Scorecard	The balanced scorecard, a performance management tool, provides a snapshot of laboratory functions by presenting key quality indicators in an easy-to-read format. Scenarios provide practical opportunities to analyze and investigate laboratory quality data, and implement the improvement cycle.	2 hours

Overview

ACTIVITY TITLE	PURPOSE	DURATION
Workstation Set-up	A workstation's design influences the productivity and efficiency of the workflow. An organized workstation places all essential items within easy reach in an orderly manner. This allows timely completion of all duties assigned to the workstation. In this activity, participants progressively construct an efficient workstation based on learning throughout the ten modules. Elements of the workstation are added at the conclusion of each module with a facilitation time of 25-35 minutes per module.	4 hrs 20 min
What Would You Do?	In this activity, participants integrate laboratory management concepts learned from the ten training modules and apply them to case study scenarios. One or two case studies are presented at the conclusion of each module with a facilitation time of 20 – 30 min per module.	4 hrs 10 min
Planning Improvement Projects – Master Class	Actual measurable laboratory improvement is the desired outcome of this program. In this small-group learning activity, each participant receives one-on-one coaching in turn to develop an individualized implementable plan for his/her improvement project.	3 hrs 5 min
Reporting Improvement Projects	Reporting improvement projects promotes reflection on accomplishments made, lessons learned, and challenges faced. This activity encourages participants to synthesize, summarize, and share this information, thereby building a learning network among in-country peers.	20 min Plus IP Reports
Using the Checklist to Improve the Laboratory	The Laboratory Accreditation Preparedness Checklist serves several purposes, including: 1)an objective tool to measurably assess laboratories; 2)an educational guidance document to show the way toward laboratory improvement; and 3)a training monitoring tool. This activity allows participants to become familiar with the Checklist, to gain experience using it in an actual laboratory assessment, and to focus on using it to improve the laboratory.	1 hour 5 min Plus Site Visits & Debrief
TOTAL ACTIVITY TIME: **(Spanning across all 10 modules)**		**18.5 hrs** Plus IP Reports, Site Visits & Debrief

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ACTIVITY Process Mapping — Cross-Cutting

PURPOSE:

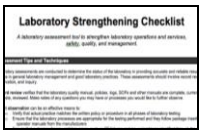
Mapping a process (all the steps from the beginning to the end of an activity) is a tool that allows analysis and optimization of workflow and service delivery. In this activity, participants will map and create a table analyzing the process of specimen flow through the laboratory.

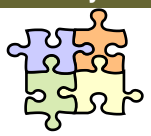
RESOURCES FOR FACILITATOR:

- ❑ PowerPoint slides XC.2 to XC.9, and XC.10 or 7.4 – 7.6
- ❑ Tool 1: Process Mapping Cards (XC 0.5)
- ❑ Paper (8.5 X11 or 8.5 X 5.5) or index cards in multiple different colors
- ❑ Painter's tape or Masking tape (multiple rolls)
- ❑ Flipchart & Markers

RESOURCES FOR PARTICIPANT:

- ❑ Handout: Specimen Flow Process Table (XC 01)
- ❑ Job Aid: Tips for Using Process Mapping (XC 02)

This activity supports the following laboratory management tasks and SLIPTA checklist items	
Management Tasks 	Cross-cutting
Checklist Items 	Cross-cutting

This activity is related to the following activities:	
	Crosscutting: Managing Performance – The Balanced Scorecard, Planning Improvement Projects – Master Class Module 1: Process + Structure = Outcome, Improving A Problem Floor Plan, Mapping Out the Floor Plan of Your Lab, Redesigning the Floor Plan of Your Lab, What are the Benefits of a Standardized Process Module 6: Using Standard Operating Procedures

ACTIVITY AT-A-GLANCE				
Step		**Time**	**Resources**	**Key Points**
1	Introduce process mapping	10 min	Slides XC.2 to XC.7	
2	Introduce the Mapping Activity	5 min	Slide XC.8 Sets of Testing Phase Cards Sets of Process Step Cards	
3	Mapping Activity	15 min	Tape	
4	Debrief the Mapping Activity	15 min	Slide XC.9 Job Aid	
5	Introduce the Process Table Activity	10 min	Slide XC.10 (or 7.4 – 7.6) Process Table Cards	
6	Process Table Activity	15 min	Tape	
7	Debrief the Process Table Activity	15 min	Handout	
8	Conclude the Activity	5 min		
	TOTAL TIME:	**90 min**		

PROCESS

Preparation

Mapping Activity (Steps 2-4: Arranging steps in the process)

- Determine how many groups you will have for this activity. (Suggested Group Size: No more than 6 persons per group.)
- Use Tool 1: Process Mapping Cards to produce one set of cards for the inputs, output, and outcome listed below. Use paper, index cards or sticky notes.

Inputs	Specimen Reagents Supplies	Personnel Equipment Infrastructure	Document & Record System Policies & Procedures
Output	Information		
Outcome	Improved Health for All		

- Use Tool 1 to produce one set of Testing Phase Cards and one set of Process Step Cards for each group.
  - For Testing Phase Cards - Write or print the three phases noted below on paper or index cards – one phase per paper/card
  - For Process Step Cards - Write or print each of the steps noted below on paper or index cards – one step per page/card, preferably on paper/card of a different color than phase cards
  - Write/print with large fonts to ensure legibility for all participants.
  - Shuffle each set so the items are out of sequence

PRE-ANALYTICAL PHASE
Order placed
Patient presents to laboratory
Requisition completed & reviewed by laboratory staff
Specimen type determined for collection
Specimen collected
Specimen logged
Specimen accepted or rejected
Specimen assigned according to test request/s
ANALYTICAL PHASE
Routine quality checks completed
Specimen analyzed
Test results analyzed
POST-ANALYTICAL PHASE
Test results recorded
Test results communicated / reported
Documents and records maintained, filed & stored

Process Table Activity (for Steps 5-7: Complete the process table)

- Use Tool 1 to produce one complete set of the Process Table Cards (4 categories – noted below - for each of the 14 steps – 56 cards total), for the entire group.
  - For Process Table Cards - Print/write on paper (8.5 X 11 or 8.5 X 5.5) or index cards each item from the four categories of the process table – one item per card/paper. Use a different color paper or marker for each category noted below.
    - What happens?
    - Who's responsible?
    - Procedures needed?
    - Pitfalls
  - Write/print with large fonts to ensure legibility for all participants.
  - Keep items from the same category in the same set but shuffled.

Step 1. Introduce process mapping 10 min

- Project Slides XC.2 to XC.3. Introduce the 5 guidelines for providing assurance of the quality of services offered in the laboratory.
- Project Slides XC.4 to XC.7. Define process and process mapping. A process is "a series of actions or steps taken in order to achieve a particular end". In other words, a process encompasses "all the steps taken from the beginning to the end of an activity". A process map "visually depicts the sequence of events or steps required to produce an outcome". Draw a line with multiple steps (boxes) on the flip chart to depict the process & map.
- Discuss the value of process mapping. Mapping a process is an important management tool that can be utilized to improve flow, promote efficiency, and streamline work. By mapping and analyzing the individual steps of a process, one can pinpoint problems, analyze the problem step/s, and then begin the improvement cycle to remedy the problem. This tool can be used with any process, not just the specimen flow process. Process mapping is an important tool for managers.
- Share examples of processes that can be mapped and how this information can be used by various organizations.
- State that we are going to map the process of specimen flow through the laboratory. We will order all the steps beginning with the placement of the clinician's order through the return of the result to the clinician.
- All processes have inputs, outputs, and outcomes. Ask participants to list the inputs, output, and outcome to/from the laboratory specimen flow process. Attach the input cards/sticky notes (previously created) to the flipchart at the left of the previously drawn process line. Attach the output and outcome cards/sticky notes (previously created) to the flipchart at the right end of the line.

Step 2. Introduce the mapping activity 5 min

- Project Slides XC.8. Divide participants into groups of preferably no more than 6 people.
- Give each group one set of Testing Phase Cards, one set of Process Step Cards,

and a roll of tape. Explain that the tape is for sticking cards to the wall.

- Instruct the participants to arrange the cards in the correct order to depict the process of specimen flow through the laboratory. Note that one set of the cards represent the three phases of laboratory testing, and the other set represents the 14 steps of the specimen flow process. Have participants arrange the cards horizontally from left to right, beginning with step 1 and proceeding to step 14, with the phases placed above the steps. This detail is important in order to allow for the later completion of the process table.
- Designate wall space in the training room for each group for the exercise.
- State that 15 minutes will be given to complete the activity.
- Note: Remind participants that this represents a generalized specimen flow process. The specifics of their laboratories or specific testing may vary and dictate different steps or a different order. This is presented to stimulate thought and to provide hands-on practice in using a valuable tool.

Step 3. Conduct the mapping activity — 15 min

- Monitor the activity. Make sure participants are on task and can complete the assignment within 15 minutes. Provide clarification if necessary.
- Select one group's work to debrief.

Step 4. Debrief the mapping activity — 15 min

- Ask participants to gather around the steps on the wall of the selected group.
- Walk through the process created by the group and invite comments from the participants
- Correct any mistakes if necessary to achieve the correct sequence
- Conclude by emphasizing that 'process mapping' is a management tool that can be used with any process – from making a meal in one's home to complex issues in one's laboratory. For the laboratory manager, this tool is a very useful way to analyze problems in the lab.
- Project Slides XC.9. Share Job Aid: Tips for Using Process Mapping with the participants. These tips illustrate how to use the mapping process as an improvement tool in an individual laboratory. Remind participants that the actual mapping exercise in his or her laboratory may take several hours and may be conducted over the course of several days. (Note: The timing of the mapping exercise has been significantly shortened for classroom purposes by predetermining and assigning the steps.)
- Presentation Alternatives for the Process Table portion of this activity:
  - Present at the beginning of Module 7, Specimen Collection and Processing, when the discussion of the specimen flow process begins.
  - Present immediately following the mapping of the steps.

Step 5. Introduce the process table portion of the activity — 10 min

- Transition to the next phase of the activity – Completing the Process Table. State that after mapping the individual steps, we should look at each step more carefully. By dissecting each step in the process, we are able to determine "Who does what and when". We can then determine where potential or actual problems/pitfalls lie and what procedures will be needed to clarify and

standardize the process.

- Select one group's process for this activity. Make sure the process is accurate.
- Direct participants' attention to the wall space where the chosen process is mapped.
- Project Slides XC.10 or 7.4 – 7.6. Announce that the class is going to complete the process table by identifying, for each step in the procedure: What happens, Who's responsible, Procedures needed, and Pitfalls.
- Divide the participants into 4 groups. Each group gets one category of the Process Table Cards representing either: What happens, Who's responsible, Procedures needed, or Pitfalls.
- Each group will arrange the cards from their assigned category. Then each group will place their cards on the wall, in turn, using the tape. Start with the group with the 'What happens' cards, followed by 'Who's responsible', 'Procedures needed' and 'Pitfalls'.

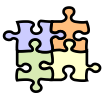
Step 6. Complete the Process Table 15 min

- Monitor the activity. Make sure participants are on task and can complete the assignment within assigned time. Provide clarification if necessary. Keep the pace moving.

Step 7. Debrief the Process Table Activity 15 min

- Ask participants to gather around the completed process table.
- Walk through each element for each step in the process. Invite comments from the participants
- Correct any mistakes if necessary to achieve the correct match.
- Emphasize the fact that variance does not lead to consistently reliable results. Highlight that standardization is the antidote to variance. Note that putting standardized procedures into place and assuring that they are followed can largely control the pitfalls that are seen at these steps.
- Throughout modules 6-10, refer back to the pitfall section of the process table. Note how these pitfalls can be addressed by implementing standard laboratory procedures (SOPs). Use a visible 'X" to strike through pitfalls that can be avoided. Assure that all pitfalls have been addressed by the completion of the training.
- After completing the table portion of this activity, refer participants to the completed table, Handout: Specimen Flow Process Table.

Step 8. Conclude the activity 5 min



- Link to *Process + Structure = Outcome, Improving A Problem Floor Plan, Mapping Out the Floor Plan of Your Lab, Redesigning the Floor Plan of Your Lab, What are the Benefits of a Standardized Process, Using Standard Operating Procedures, Managing Performance - the Balanced Scorecard, and Planning Improvement Projects - Master Class* activities. Mapping a process can be used in multiple circumstances to accomplish improvement.
- Highlight or reiterate the key messages below.
- Make sure participants achieved the objectives of the activity.

KEY MESSAGES

- Mapping and analyzing processes are useful management tools. They provide an organized method of improving flow and evaluating issues that arise in the laboratory.
- Any process may be mapped, not just specimen flow.
- Reiterate that the Job Aid: Tips for Using Process Mapping, presents valuable guidance for using the process mapping tool to jumpstart improvement upon returning to individual laboratories.
- The use of standardized procedures prevents variation in the system; thereby avoiding many pitfalls.

Can they:

- Map a process?
- Complete a process table?
- Use the process-mapping tool to improve flow and resolve problems in the laboratory?

ACTIVITY OBJECTIVES MET?

Arranging the steps in the process

Arranging the steps in the process

Completing the process table

Completed process table

➢➢ Connections and Applications

- **Improvement Projects** – Mapping a process will invariably show areas where flow is compromised and changes need to be made. Thus an improvement project is needed. Change is best directed and monitored using change theory and the PDCA cycle. The need for improvement is established in this activity. How to implement the improvement cycle is further developed in the *Balanced Scorecard Activity*.
- **"Systems thinking"** – Analyzing a process promotes "systems thinking", allowing the whole process to be examined, highlighting the interconnectedness of the steps.
- **6-S** – The 6-S is a tool used to organize the workplace. **Safety, Sort, Straighten, Shine** – The first four deal with cleanliness, safety and organization. **Standardize and Sustain** - The last two form the foundation of the 'Lean' Management System.
- In this activity we begin to note the importance of standardization – doing something the same way every time to assure consistently reliable results. This concept of standardization will be stressed throughout the curriculum. Note the following two applications:
  - Reducing **Variation** – In the laboratory, promoting flow is vital to efficient work. Variation slows flow. Anytime that standardization can be implemented, then variation will be reduced. Therefore, mapping, analyzing, and improving processes to improve flow is very important to laboratories.
  - **SOPs** – Standardization of procedures is a basic tenet of laboratory service. The job of the manager is to put these procedures into place, assuring that all personnel have read and are familiar with the procedures, and have signed off on the procedures. Then the manager must assure that these procedures are followed routinely.

Handout: Specimen Flow Process Table

	Step	What happens?	Who's responsible?	Procedures needed?	Pitfalls
PRE-ANALYTICAL PHASE	**1. Order placed**	Clinician determines need	Clinician	Ordering protocols	▪ Unauthorized person ordering Inappropriate order
	2. Patient presents to laboratory	Laboratorian interacts with patient	Patient / Laboratorian	Customer Service	▪ Lack of timely service ▪ Interaction not client-friendly
	3. Requisition completed & reviewed by laboratory staff	Requisition reviewed for proper information	Clinician, Clerk, or Laboratorian	Criteria for specimen acceptability	▪ Incomplete patient data ▪ Incomplete clinical history ▪ Clerical errors
	4. Specimen type determined for collection	Note specific test requested and determine what type of sample is needed	Laboratorian	Specimen requirements for (venous) blood collection SOP for each analyte	▪ Not checking or following specimen requirements ▪ Inadequate communication to patients regarding specimen self-collection
	5. Specimen collected	Blood drawn from patient; Sputum, urine, stool, or other specimen is collected	Blood - Clinician or Laboratorian, Non-blood specimens – Clinician or Patient	Phlebotomy key competencies Phlebotomy training checklist	▪ Blood - Wrong tube, incorrect amount of blood, ▪ Injury ▪ Non-blood specimens – incorrect specimen or incorrect collection procedure; improper labeling
	6. Specimen logged	Appropriate information recorded in specimen log	Laboratorian	Specimen management	▪ Clerical errors ▪ Inadequate information ▪ Clerical error
	7. Specimen accepted or rejected	Specimen accepted or rejected based on meeting acceptance criteria	Laboratorian	Specimen management Criteria for specimen acceptability	▪ Unsatisfactory specimen ▪ Specimens with hazardous handling conditions ▪ Inadequately labeled specimen
	8. Specimen assigned according to test request/s	Requests reviewed for ▪ Testing priority – STAT versus routine ▪ If multiple tests to be done, sequential workstations versus aliquoting ▪ Centrifugation required ▪ Send out versus in-house testing	Laboratorian	Guidelines for STAT testing Guidelines for multiple test from one sample Specific SOPs for each analyte SOP for send outs (specimens referred to other facilities for testing)	▪ Processing not performed in a timely fashion as ordered ▪ Missing some tests on a requisition with multiple tests requested ▪ Centrifuge not performed in a timely manner ▪ Send out tests not referred in a timely matter or transported inappropriately

Handout: Specimen Flow Process Table

	Step	What happens?	Who's responsible?	Procedures needed?	Pitfalls
NALYTICAL PHASE	**9. Routine quality checks completed**	Prior to testing, determine if proper routine QC, reagent validation, equipment maintenance and calibration completed	Laboratorian	SOP for each analyte, Guidelines for quality checks of all Log / Charts for each analyzer or test	QC not done or out of control, Inadequate troubleshooting or follow up of QC Improper calibration Inadequate equipment maintenance
	10. Specimen analyzed	Run analysis on specimen	Laboratorian	Specific SOP for each analyte	Not following SOP Taking shortcuts
	11. Test results analyzed	Review test results for accuracy, legibility, & validity; Cross-checking Assure proper quality monitoring	Laboratorian, Supervisor	Specific SOP for each analyte,	Release of test results without validation or interpretation Inadequate cross-checking
POST-ANALYTICAL PHASE	**12. Test results recorded**	Transfer test results into logbook, Record results accurately	Laboratorian, Clerk	Test Reporting SOP; Specimen Management	Clerical errors, Analyte printout results listed in different order than logbook reporting columns
	13. Test results communicated / reported	Notify Clinician of results via written report Verbal reporting if necessary Critical Values reporting Assure that referral specimens are properly tracked	Laboratorian, Nurse	Specimen management Client satisfaction guidelines	Results not communicated in a timely fashion Results lost Critical values not reported Confidentiality breached Failure to track referral specimens or failure to follow-up on overdue specimens
	14. Documents and records maintained, filed & stored	File & store results in a retrievable fashion Transfer files to long term storage Dispose of files at an appropriate time	Laboratorian	SOP for document & record management (Including Document & Record Retention)	Unable to retrieve information when needed Lack of adherence to document retention schedule Water or moisture damage

Job Aid: Tips for Using Process Mapping

Using Process Mapping to Improve Your Laboratory

Step 1. Assemble your team for a quick walk through

Step 2. Return to meeting room and draw your map (use butcher block paper with post-it notes)

Step 3. Once the initial map is drawn, take your team back for a thorough walkthrough while considering the following:

- Cycle times associated with each step
- Places where there is potential for specimen bottlenecks or excessive queuing by patients
- Transport distances and time
- Potential sources of variation

Step 4. Return to meeting room and make any changes to the map

Step 5. Discuss problems encountered such as bottle necks, excessive queuing, and significant variation

Step 6. Brainstorm solutions to problems

Step 7. Write Solutions on your Process Map & Implement changes

Step 8. Begin the Plan-Do-Check-Act (PDCA) Cycle to assess effect of changes

ACTIVITY Using the Improvement Method — Cross-Cutting

PURPOSE:

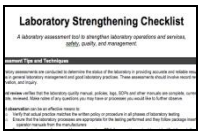
This activity provides a new method of approaching issues that arise in the day-to-day work of managers. Participants are introduced to the PDCA Improvement Model and are given an opportunity to address a typical management issue using this model.

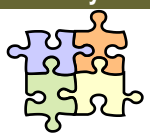
RESOURCES FOR FACILITATOR:

- ❑ PowerPoint slides: XC.11 to XC.17.
- ❑ Tool: PDCA Cycle (XC02.2)

RESOURCES FOR PARTICIPANT:

- ❑ Handout: Management Scenarios (XC 02.1)
- ❑ Worksheet: Quality Improvement Project Plan (XC 30)
- ❑ Job Aid: PDCA Example [Sample Rejections] (XC 02.3)
- ❑ Flipchart and markers

This activity supports the following laboratory management tasks and SLIPTA checklist items	
Management Tasks 	1.11 Implement measures to motivate staff to improve quality of work and productivity (e.g., training, job rotation, employee of the month, thank-you letter, etc.) 1.12 Develop and implement lab improvement plans based on best practices and feedback from staff, patients, customers, quality indicators, and external assessment
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? (Resolution of Complaints and Feedback; Identification and Control of Nonconformities; Corrective Action; Preventive Action; Continual Improvement; Internal Audits) 2.2 Management Review Does the laboratory management perform a review of the quality system at a management review meeting at least annually? 6.2 Audit Recommendations and Action Plan & Follow up 10.1 Are all identified nonconforming activities/ work identified and documented adequately? 10.2 Root Cause Analysis Is documented root cause analysis performed for non-conforming work before corrective actions are implemented? 10.3 Is corrective action performed and documented for non-conforming work? 10.4 Are implemented corrective actions monitored and reviewed for their effectiveness before closure/clearance? 10.5 Preventive Actions Are documented preventive actions implemented and monitored for their effectiveness? 11.2 Quality Management System Improvement Measures Does the laboratory identify and undertake continual quality improvement projects? 11.5 Is the outcome of the review of quality indicators used to improve lab performance? 11.6 Are the actions taken checked and monitored to determine the effectiveness of improved quality of lab performance?

This activity is related to the following activities:	
	Cross cutting: Process Mapping Cross cutting: Managing Performance – The Balanced Scorecard Cross cutting: Planning Improvement Projects – Master Class Cross cutting: Reporting Improvement Projects

ACTIVITY AT-A-GLANCE				
Step		**Time**	**Resources**	**Key Points**
1	Share a "typical" management story	5 min	Slide XC.11	
2	Discuss the management story	10 min	Flipchart & markers	
3	Present the Improvement Model	30 min	Slide XC.12 to XC.13 Tool Worksheet	
4	Debrief the management story	10 min	Slide XC.14 Worksheet	
5	Introduce the activity	2 min	Slide XC.15 Handout Worksheet	
6	Conduct the activity	20 min		
7	Debrief the activity	30 min	Job Aid	
8	Conclude the activity	5 min	Slides XC.16 to XC.17	
	TOTAL TIME:	**1 hour 52 min**		

PROCESS

Preparation

- Using several flipchart sheets, create a large wall chart by replicating Tool: PDCA Cycle.
- Post the wall chart where all participants can easily see.
- Select a management story to share with the class which demonstrates the manager's failure to successfully solve a problem when you conduct the debrief (Step 4). In the story, important aspects and principles of the PDCA cycle must be skipped. Therefore, when you debrief the story in Step 4, you will be able to demonstrate a manager's failure to seek to understand the real problem, use data and teams to solve the problem and implement measurable solutions. See below for an example of a management story that you can use.

A Management Story

The laboratory manager of ____Hospital Laboratory leaves the lab for the bi-monthly meeting with the laboratory supervisor for the province. On his way out, he meets the director of the hospital, who is also the resident pediatrician at the hospital. She does not look happy at all. After he greets her, she bursts out saying that she was actually on her way to see him and that she is not happy at all with the service the laboratory has been providing to the pediatric unit. She complains that, at the last hospital meeting, it was agreed upon that all the requests from the pediatric department should be treated as urgent and the results should be received within two hours. She goes on to explain that all the results are received very late and that this is compromising patient care. She would like this situation resolved immediately. The laboratory manager explains that not all tests have a less than two-hour turnaround time (TAT) and promises to send the doctor a copy of their TATs for all tests. He also promises to talk to his staff about treating all pediatric samples as urgent. He promises the hospital director that he will ensure all their results will be received within the stated TAT's. The laboratory manager returns to the laboratory and quickly calls all his staff together then shouts at them for failing to release results for the pediatric unit within the labs TAT's. He gives the staff an ultimatum -all the results must be released within the TAT's without fail and those who do not comply will receive disciplinary action. Without giving room for the staff to respond, the manager quickly departs for his meeting.

Optional Overnight Homework: After this activity, ask participants to prepare for Cycle II using Job Aid: PDCA Example [Sample Rejections]. Indicate that they are to refine this improvement project by completing the PLAN phase using the information learned from the DO, CHECK, and ACT phases of the job aid. Ensure sufficient time to review the homework is scheduled the following day.

Step 1. Share a "typical" management story — 5 min

- Project Slide XC.11.
- Share a specific management story and the problem that arises. Tell participants that the manager makes a decision about how to handle the problem, implements the solution, and communicates the new solution to the staff.

Step 2. Discuss the management story 10min

- Use a flipchart & markers. Create two columns – "What did you like?" and "What would you change?" on the flipchart. Have participants provide their assessments. Listen and record, but do not offer additional comments at this time.

Step 3. Present the Improvement Model (PDCA Cycle) 30 min

- Project Slide XC.12 to XC.13.
- Introduce the PDCA cycle as a model to approach problems through trial and learning. It is a management tool that is used to coordinate continuous improvement efforts. Due to its cyclic nature, the PDCA method allows for multiple attempts to get to the root cause of a problem, thereby solving the problem.
- Explain the PDCA Cycle has four stages to get from "problem faced" to "problem solved".
- Highlight the importance of teamwork and the use of data when applying this model.
- Move to the PDCA Cycle wall poster. Make sure that all participants can clearly see. Explain the 4 stages of the Cycle.

PLAN	In the planning phase you would like to address three key questions: ○ What is really the problem? ○ What changes can we make that will result in an improvement? ○ How will we know that improvement has taken place? 1. Before we attempt to resolve a problem, it must first be clearly identified. ○ Ask yourself the question, "What is really the problem?, What is it that is going wrong?" ○ Use all the available resources at your disposal to try and understand the problem. ✓ Process Mapping ✓ Baseline Data ✓ Meeting with relevant individuals 2. Data is needed to clearly define the problem. In some cases this is your baseline data. By understanding the problem, you are able to define: ○ WHAT is wrong ○ WHERE is it happening ○ WHO is involved ○ WHEN is it happening 3. Once the problem is clearly understood, the next step is to determine possible causes. ○ Link each possible cause with a possible solution by asking, "What changes can we make that will result in improvement?" ○ Evaluate and brainstorm potential solutions with your

	team. ○ Avoid the temptation to propose *Quick Fixes*. 4. Once potentially effective solutions have been determined, develop an action plan, clearly defining your aim by asking, "What is it that we want to achieve?" Your aims and objectives must be Specific, Measurable, Achievable, and Realistic and to be done over a defined period of time. 5. Since data is needed to assess and understand the impact of the changes to be implemented, additional tasks or actions may be required to bring about the proposed change. Once you know what you would like to achieve, consider how you will monitor and measure progress by asking, "How will we know that improvement has taken place?" Identify a measurable element and plan how data for this measure will be collected and analyzed.
DO	1. Put your plan into action for a pre-established amount of time. 2. Monitor progress of implementation at specific time periods (e.g., weekly, monthly or whatever applies to your improvement project). 3. Monitor and document how the plan is being executed, record results and collect data.
CHECK	At the end of a pre-determined time: 1. Check if changes are achieving desired results/outcomes as expected during the PLAN phase. Describe the measured results and how they compare to the expectations. 2. Look for differences between expectations and results achieved with respect to resources used and how easy or difficult it has been to achieve results or failure. 3. Check for unseen consequences. This information is very useful for the next phase where you will act on the findings.
ACT	**If successful** (i.e., the desired or expected goals were achieved), 1. Standardize the process or the changes across the laboratory. For example: a lab experiences increased sample rejection rates and the problem appears to be poor sample collection techniques. As part of its action plan, the lab provides the wards and outpatients department with proper collection tools (e.g. vacutainer tubes) and trains the staff on proper collection techniques. If this intervention results in a reduction in number of samples rejected, then providing all sites with vacutainer tubes and training the staff regularly on proper sample collection should be standardized. 2. These changes then need to be communicated to all involved/affected by the changes to ensure implementation. 3. If needed, provide training in new methods/new process to staff involved.

If unsuccessful, go back to the Plan phase

- Use the information collected during the DO and CHECK phases as your data for analysis and identification of the problem.

For example, the training of staff from the wards and outpatients department on proper sample collection does not result in reduction of the number of samples rejected.

- Does this mean the problem was not with collection techniques (WHAT)?
- Is the problem after the samples have been collected (WHERE)? Re-examine the rejected samples by reason of rejection.
- If the main reason for rejection of samples is hemolysis and these hemolysed samples come from referring sites that are further away, is it due to improper storage after sample collection (WHAT) or transportation to the laboratory (WHERE)?

- Once the root cause of the problem is identified, possible solutions can be listed and the improvement plan updated.
- The cycle continues to PDCA cycle 2

- Distribute or refer participants to Worksheet: Quality Improvement Project Plan. Relate the 4 phases of the PDCA cycle to Worksheet.

Step 4. Debrief the management story 10 min

- Project Slide XC.14.
- Contrast the typical manager's desire to fix the problem with his/her own solutions versus the use of the improvement model. Note the following three factors that may be missed with the typical management approach:
  - Consider the **appropriateness** of the manager's solution. The manager may not actually know anything about the front-line process, so she/he may miss the best solution entirely.
  - Is the manager's solution **measurable**? Even if the manager's solution may indeed be the best solution, without measurement, it will not be known whether it leads to improvement. Consider the possibility that the intervention could have made the situation worse.
  - In addition, when unilaterally making decisions, the manager misses an opportunity to create a teaching moment. If the improvement team includes the front-line staff, they will start to have an understanding of the improvement process and begin to implement the improvement cycle and test solutions for themselves. This is where the culture transformation occurs – when staff members are empowered to affect their own continuous improvement. The improvement model provides the tool for this empowerment.

- Refer participants to Worksheet. Use the management story to demonstrate the use of the worksheet in planning IP's. Together with the participants walk through the 4 phases of the PDCA cycle discussing how the worksheet would be completed.

Step 5. Introduce the activity — 2 min

- Project Slide XC.15.
- Divide the participants into 4 groups. Assign one management scenario to each group (Handout: Management Scenarios).
- Instruct each group to complete the PLAN section of the Worksheet.

Step 6. Conduct the activity — 20 min

- Monitor the activity.

Step 7. Debrief the activity — 30 min

- Ask each group to briefly summarize their plan (3 minutes each).
- Refer to Job Aid: PDCA Example [Sample Rejections] to illustrate the cyclical nature of the PDCA improvement method.
- Explain that using the improvement model is a new way of thinking and doing. This model, when consistently applied, can change culture because it empowers laboratorians with the ability to change their immediate environment.
- Encourage participants to involve their fellow laboratorians in their improvement teams when returning to their own laboratories.
- Follow this activity with the *Planning Improvement Projects - Master Class* Activity (Cross-cutting) and Worksheet to assure success of improvement projects.

Step 8. Conclude the activity — 5 min

- Project Slides XC.16 to XC.17.
- Highlight or reiterate the key messages below.
- Make sure participants achieved objectives of the activity.

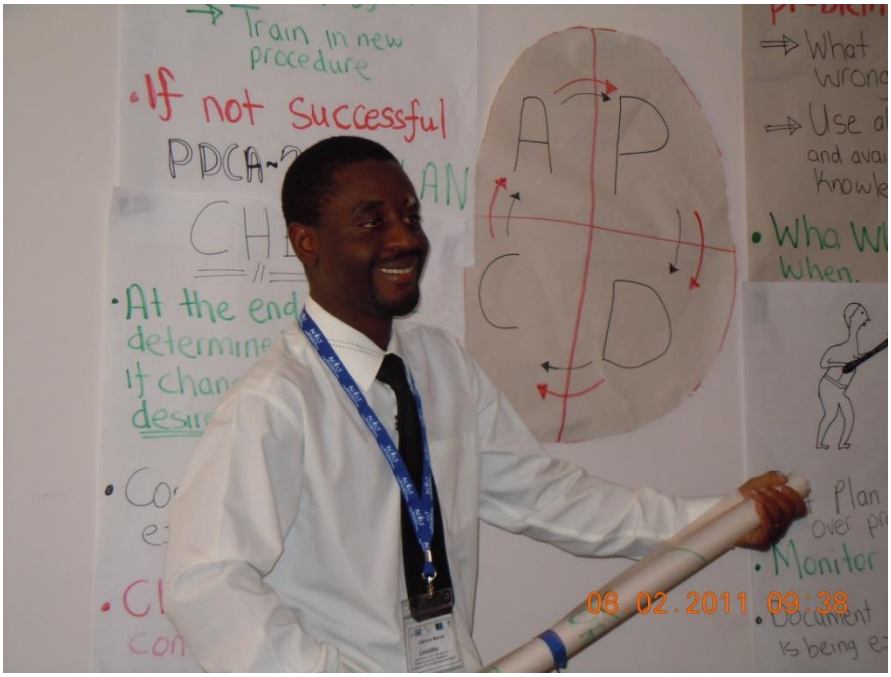
KEY MESSAGES

- The improvement model / PDCA cycle is a very powerful trial-and-learn tool.
- Appropriate measures must be used to assess the impact of improvement efforts.
- Creation of a learning organization instates improvement as a way of life.
- Improvement is continuous and cyclic.

ACTIVITY OBJECTIVES MET?

Can they:

- Describe the PDCA cycle, noting how to implement each step?
- Expound on each of the four phases of the cycle:
  - Plan
  - Do
  - Check
  - Act
- Apply the improvement model to routine laboratory issues?



➢➢ Connections and Applications

- **Guidelines for Quality Assurance – Use data to improve services:** Data is needed to assess and understand the impact of changes designed to meet an AIM.
- **The PDCA Cycle:** This is a learning method to discover what is an effective and efficient way to change a process. These cycles need not necessarily be long-term in nature. These can be "rapid-cycle" with the time frame based on the characteristics of the project. They can be carried out in days to weeks.
- This improvement model requires pre-planning, support, time & energy. Managers need to allow for these factors as the teams form and work.
- Process mapping is an important tool to assess the current situation and analyze root causes of problem areas. Process mapping can highlight where workflow is compromised and changes need to be made.
- It is important to identify potential sources of any system's weaknesses or errors. Some possible sources to use are:
    - Findings from occurrence reporting.
    - Feedback from customers, including laboratory staff.
    - Findings from internal and external assessments or audits.
    - Changes noted from a quality indicator.
- When defining your ELEMENT TO BE MEASURED ensure it supports what you are trying to accomplish, your AIM. Define the specific components of the ELEMENT TO BE MEASURED. Specify the numerator and denominator if it is a percentage. If it is a score, such as a satisfaction score, indicate how the score is derived. Define what data domains will be used in your ELEMENT TO BE MEASURED (e.g. all patients vs. only outpatients, all testing interruptions vs. only interruptions due to stockouts and not equipment failure, all specimens vs. only after-hours specimens, etc.).

Tool: PDCA Cycle

ACT

If successful…

- Standardize the process
- Make changes across the lab
- Communicate the changes to all affected staff
- If necessary, train

If unsuccessful…

- Use information collected during DO and CHECK for problem analysis => post-improvement data from Cycle 1 become baseline data for Cycle 2

Start 2nd PDCA cycle → PLAN

PLAN

1. Clearly identify a problem
   - What's the real problem?
   - Use all available resources to understand the problem

DATA (base)

Clearly define the problem → collect baseline data

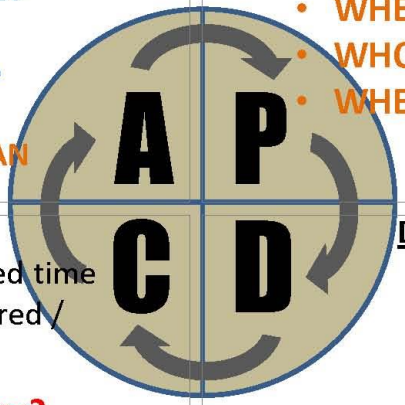
2. Define:
   - **WHAT** is wrong?
   - **WHERE** is it happening?
   - **WHO** is involved?
   - **WHEN** is it happening?

3. Determine possible causes and brainstorm solutions

~~Quick Fixes~~

4. Clearly define **AIM** (What do you want to achieve?)
   → **SMART** objectives
   - **S**pecific
   - **M**easurable
   - **A**chievable
   - **R**ealistic
   - **T**ime

5. Create an action plan



CHECK

At the end of pre-determined time

1. Did changes result in desired / expected outcomes?

Results = Expectations?

2. How easy or difficult was it to achieve results or failure?
3. Check for unforseen consequences to help in next phase

DO

1. Put plan into action
2. Monitor progress during implementation
   - Over pre-determined time
   - **DOCUMENT** how the plan is being executed
3. Record results

DATA (post)

Handout: Management Scenarios

Directions:

I. Discuss the assigned **scenario** (below).

II. Focus on how your group would **apply the improvement model** in this situation using the 4 phases of Plan, Do Act and Check.

III. Consider the following questions in your discussions: 1). How will we know if a change is an improvement? 2) What changes can we make that will result in an improvement?

IV. Complete the PLAN section of the **Improvement Project Plan** (Worksheet).

Scenario A: ART Clinic at Hospital Laboratory X

In a recent hospital management meeting, the Hospital Director reports that the staff from the ART clinic is complaining that patients are leaving before the laboratory can provide their chemistry, FBC and CD4 results. Since most of the patients come from far away, they end up leaving before a decision can be made on whether to initiate them on ART. The clinic has given a reason that it is because the laboratory delays in giving patients their results.

Scenario B: Sample rejections from Mt Tabor Clinic

The Nursing Officer in charge at Mt Tabor Clinic, located 85 Km up the highlands of Mount Tabor called last week to complain about high rejections of their samples. She indicated that most of the samples they sent are returned with no results. In most of the cases, it is indicated on the sample request form "Sample rejected, please re-draw". This is adversely affecting the initiation of their patients on ART since by the time they get the lab report, patients would have long gone to do a redraw.

Scenario C: Missing CD4 Results

The laboratory manager, who arrived from the Monday morning hospital rounds, had reported a complaint from Dr Zamosa. Dr Zamosa complained that for most of her CD4 requests, she never received the results back. She cited a few examples by showing patient files with no CD4 results on them. After the hospital round, the lab manager checked with the section supervisor in CD4, who found out that most of these missing results were recorded in the sample registers and had been released to the ward.

Scenario D: Inventory Management

During the weekly lab team meetings, James who is in charge of the store room reports that staff were not correctly using the stock control cards they had implemented 3 months ago. Records were not being captured when staff take stock from the store room or when they receive it from suppliers in his absence. During his monthly stock counts, most of the stock cards have a mismatch on balance indicated and the physical count. The staff indicates that sometimes it is difficult to locate the stock cards for the items.

Worksheet: Quality Improvement Project Plan

Quality Improvement Project Plan

PLAN

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:

_____

_____

Worksheet: Quality Improvement Project Plan

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?

_____

Worksheet: Quality Improvement Project Plan

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 _____

Job Aid: PDCA Example [Sample Rejections]

Sample Rejections

PLAN

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:

Observed high sample rejection rate. There have been an increased number of complaints from clinicians regarding no results available due to lab rejecting unsatisfactory samples for testing.

II. Collect Baseline Data:

What data will be collected? *Sample rejection rate*

Method - How will the data be collected? *Number of samples rejected between February and March 2011 will be counted and rejection rate calculated. Results will be analyzed by reason for rejection and ward/clinic*

What are the tools/forms/checklists to be used? *The revised Sample Rejection log Document # GEN-FRM-001*

III. Analyze the baseline data:

What is wrong? *Sample rejection rate 9%. The main reasons for rejection of samples are mislabeled and hemolysed samples*

IV. Identify possible causes:

Poor sample collection techniques

High staff turnover due to reassignment at collection sites

V. Propose possible solutions:

Resend instructions on proper sample collection techniques to all sites
Train staff at problem sites
Create a job aid on specimen labeling criteria for sites to post

SECTION B: Action Plan

I. Identified problem: *Sample rejection rate 9% at baseline (March 2011)*

II. AIM Statement (overall goal of this project) *To reduce sample rejection rate to below 2% by July 2011*

Job Aid: PDCA Example [Sample Rejections]

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

Action item	Responsible Person	Timeline	Signature
Resend instructions on proper sample collection techniques to all sites	*Tech 1*	*March 30, 2011*	*Tech 1*
Create labeling criteria job aid	*Tech 2*	*March 30, 2011*	*Tech 2*
Analyze sample rejection rates by sending site	*Quality Officer*	*March 31, 2011*	*Quality Officer*

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

Sample rejection rate analyzed by reason for rejection and sending site

V. Results of element measured at baseline *Rejection rate 9%*

VI. Acceptable results (target for this measure) *rejection Rate < 2%*

VII. Data Collection

How will the data be collected? *Samples rejected will be recorded as they are rejected at samples reception and at any stage of testing*

Who is responsible for collecting data? *All lab staff*

What are the tools/forms/checklists to be used? *The revised Sample Rejection log Document # GEN-FRM-001*

How often will the data be collected? *Samples rejected will be recorded daily. The rejection log will be reviewed weekly by the Quality Officer.*

How often will the data be analyzed to monitor effectiveness of implemented actions? *Results will be monitored every week. At the end of each month, a review of the results will be conducted.*

DO

IMPLEMENT Action Plan

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

Dates	WK 1	Wk 2	Wk 3	Wk 4	Wk 5	Wk 6	Wk 7	Wk 8	Wk 9	Wk 10	Wk 11	Wk 12
Rejection Rate	8	8	7.8	8	7	7.6	7.0	7.0	6.9	6	6	5

Job Aid: PDCA Example [Sample Rejections]

CHECK

Was change effective?
Monthly evaluations of the rejection rate

30 April: *Rate 8%. The main reason of rejection is still hemolysed samples as was at baseline. Rejections due to mislabeling have decreased significantly.*

31 May: *Rejection rate is 7%, not significantly lower than the baseline. The problem is still with hemolysed samples. It's been observed that all are from Mt Tabor Clinic.*

30 June *Rejection rate down to 5%, still higher that the target of <2%.*

Corrective Actions proposed at every monthly review

April review: *The Quality Officer visited Mt Tabor for inspection. The sample collector at the clinic was using syringes for blood collection. The correct blood collection equipment was supplied.*

May review: *The rejection rate did not decrease as expected, and hemolysed samples still persist as the main reason for rejection. The Quality officer organized training on proper sample collection techniques for all clinics.*

June Review: *Mt Tabor still persisted with high rejections due to hemolysed samples*

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)

Data was further analyzed for Mt Tabor to check which test was affected most. Chemistry and viral load samples were affected most. The Quality Officer returned to Mt Tabor in July and observed the whole sample collection and transport process. He observed that most samples are collected by 9 am and the sample transporter only picks them up at 1pm and gets to the lab at 3pm. Meanwhile, the clinic keeps the samples on the bench top. The transporter was not using cushions in his back pack and placed samples directly on top of ice packs.

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 Managing Performance - The Balanced Scorecard Cross-Cutting

PURPOSE:

The balanced scorecard, a performance management tool, provides a snapshot of laboratory functions by presenting key quality indicators in an easy-to-read format. Scenarios provide practical opportunities to analyze and investigate laboratory quality data, and implement the improvement cycle.

STOP DO NOT conduct this activity until both the Process Mapping and Using the Improvement Method activities have been completed!

RESOURCES FOR FACILITATOR:

- ❑ PowerPoint slides: XC.18 to XC.40
- ❑ Tool 1: Quality Indicator Quiz Answers
- ❑ Tool 2: Quality Indicator Arrows (XC 02.5)
- ❑ Tool 3: Investigating Quality Indicators (XC 03)
- ❑ Tool 4: Investigating Quality Indicators Guide (XC 04)
- ❑ Manila Envelopes – 9 quantity (10 X 13 inch size)
- ❑ Flipchart and markers
- ❑ Glue

RESOURCES FOR PARTICIPANT:

- ❑ Handout 1: Process Map with Quality Indicators (XC 05)
- ❑ Handout 2: Balanced Scorecard (XC 06)
- ❑ Handout 3: Quality Indicator Monthly Summary – A Case Study (XC 07)
- ❑ Worksheet 1: Quality Indicator Quiz (XC 08)
- ❑ Worksheet 2: Quality Indicator Investigation (XC 09)
- ❑ Job Aid 1: Monthly Laboratory Report Example (XC 10)
- ❑ Job Aid 2: Quality Indicator Monthly Summary Template (XC 11)
- ❑ Job Aid 3: Quality Improvement Project Plan (XC 30)

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

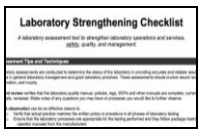
Management Tasks

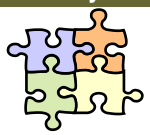
1.10 Create/review/forward reports on lab operations to upper management

1.12 Develop and implement lab improvement plans based on best practices and feedback from staff, patients, customers, quality indicators, and external assessment

6.11 Ensure that SOP are read and understood by staff

9.4 Conduct customer satisfaction survey to identify areas for improvement

Checklist Items	
	1.10 Data Files Are test results, technical and quality records, invalid or discontinued policies and procedures archived for a specified time period in accordance with national/international guidelines? 1.11 Archived Results Accessibility Is there an archiving system that allows for easy and timely retrieval of archived records and results? 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? 5.16 Laboratory Testing Services Has the laboratory provided uninterrupted testing services, with no disruptions due to equipment failure in the last year (or since the last audit)? 7.12 Laboratory Testing Services Has the laboratory provided uninterrupted testing services, with no disruptions due to stock outs in the last year or since last audit? 8.14. Does the laboratory participate in interlaboratory comparison program or alternative assessment systems for all tests? 11.1 Are graphical tools (charts, graphs, tables) used to communicate quality findings and identify trends? 11.2 Quality Management System Improvement Measures Does the laboratory identify and undertake continual quality improvement projects? 11.4 Are quality indicators (TAT, rejected specimens, stock-outs, etc.) selected and tracked? 11.5 Is the outcome of the review of quality indicators used to improve lab performance? 11.6 Are the actions taken checked and monitored to determine the effectiveness of improved quality of lab performance?

This activity is related to the following activities:	
	Crosscutting: Planning Improvement Projects – Master Class, Process Mapping Module 1: Personnel Files, How do you assign personnel to tasks? Module 4: Forecasting & Calculating Order Amount Module 5: Making a Service Call Module 6: Is there more to QC than just plotting the data? Module 7: Specimen Management Module 9: Customer Satisfaction

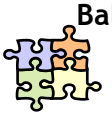
ACTIVITY AT-A-GLANCE				
Step		**Time**	**Resources**	**Key Points**
1	Explain why using data is important for laboratory improvement	10 min	Slides XC.18 to XC.20	
2	Introduce and define key quality indicators – Quiz (Phase I)	15 min	Slides XC.21 to XC.24 Worksheet 1 Tool 1	
3	Relate Key Quality Indicators to the Process Map (Phase II)	20 min	Slides XC.25 to XC.27 Tool 2 Handout 1	
4	Present the Balanced Scorecard	10 min	Slides XC.28 to XC.34 Handout 2 Job Aid 1 & 2	
5	Present Investigating Quality Indicators – A Case Study Activity (Phase III)	35 min	Slides XC.35 to XC.37 Handout 3 Worksheet 2 Tool 3 & 4	
6	Debrief the activity	15 min	Tool 4	
7	Review the PDCA Cycle of Laboratory Improvement	10 min	Slide XC. 38 Job Aid 3	
8	Conclude the activity	5 min	Slides XC.39 to XC.40	
	TOTAL TIME:	**2 hours**		

Quality Indicator Table		
The Balanced Scorecard activity introduces the nine quality indicators. The table below highlights opportunities throughout the training to explore each quality indicator in-depth, including the definition, the collection specifics, the clinical significance, and the route to improvement for each indicator.		
	QUALITY INDICATORS	**RELATED ACTIVITY**
1	Service interruptions due to staff issues	M1: How do you assign personnel to tasks?
2	Turn Around Time (TAT)	Cross-cutting: Planning Improvement Projects – Master Class, Mapping Out the Floor Plan of Your Lab, Redesigning the Floor Plan of Your Lab
3	Testing Statistics	Cross Cutting: Managing Performance – The Balanced Scorecard
4	Stock Outs	M3: Creating a List of Supplies for a Test
5	Equipment Down Time	M5: Creating a Maintenance and QC Log
6	EQA Results	M6: Is There More to QC Than Just Plotting the Data? M1: Creating a Management Calendar
7	Customer Satisfaction	M9: Customer Service, Meet the Clinician
8	Specimens Rejected	M7: Specimen Management
9	Technologist Productivity	M1: How do you assign personnel to tasks?, Planning and Conducting a Staff Meeting, Creating a Management Calendar

PROCESS

Preparation

Balanced Scorecard only



- Refer to or place the Process Map on the wall (See the *Process Mapping* activity, or alternatively, write the inputs, output, outcome, and steps in the testing process on the flip chart.
- Print and cut out quality indicator arrows using Tool 2: Quality Indicator Arrows
- Copy Tool 3: Investigating Quality Indicators (QIs) (1 copy); divide, and place into the 9 manila envelopes (one envelope for each QI). Glue the title page for each QI on the outside of the corresponding envelope.
- Copy Tool 4: Investigating Quality Indicators Guide (1copy), one page for each QI.
- Select 2-4 facilitators to guide the discussions for the Quality Indicator Investigations. Brief the facilitators on the process for the group discussions - See Step 6 below. Assign facilitators to the specific quality indicator/s for guiding / monitoring.
- Provide the appropriate QI guide and the corresponding manila envelope for each assigned QI to the facilitators.

Quality Indicator Related Activities (See Quality Indicator Table) –

- Facilitate any of these related activities to prepare participants to actually collect data and implement improvement projects.
- Follow any instructions required to facilitate the specific activity.

Step 1. Explain why using data is important for laboratory improvement 10 min

- Project Slides XC.18 to XC.20. Review the Guidelines for Quality Assurance.
- Discuss how using data leads to laboratory improvement. Remind participants "What gets measured, gets fixed". Measurement draws attention to deficits. Monitoring keeps issues in the 'spotlight'. Improvement relies on objective measures to provide assessment of efforts.

Step 2. Introduce and define Key Quality Indicators - Phase I 15 min

- Project Slides XC.21 to XC.22. Reiterate that there are numerous quality indicators that one can monitor; however, these nine were chosen for introduction and definition in this activity.
- Project Slide XC.23. Refer participants to Worksheet 1: Quality Indicator Quiz.
- Ask participants to match the definitions with the appropriate indicators on Worksheet 1. Allow 10 minutes.
- Project Slide XC.24. Refer to Tool 1: Quality Indicator Quiz Answers. Ask participants to share answers with the class. Provide correct answers. Clarify any misunderstandings.

Step 3. Relate Key Quality Indicators to the Process Map - Phase II 20 min

- Refer to the Process Map from the *Process Mapping* Activity.
- Project Slide XC.25. Performance is measured by selecting key indicators for monitoring over time. Note that indicators measure/monitor both laboratory ***structural elements*** and ***processes***. Link this to *Process* + *Structure* = *Outcome Activity*. Reiterate that Structure + Process = Outcome. Discuss that the output of the laboratory is information, i.e., accurate and reliable test results. And the ultimate outcome is improved health of the patients, yes, even improved health of an entire nation.
- Quality indicators are chosen because of their ability to assess laboratory structures or processes at various levels. Taken in groups of three, four, or more, indicators combine to give a good snapshot of overall laboratory function.
- Note that to produce results, the laboratory needs the following ***structural elements*** or inputs to the testing process:
  - Physical Plant / Infrastructure
  - Personnel
  - Stock – supplies & reagents
  - Equipment
  - Documents & Record System
  - Policies & Procedures
- Note also that indicators can monitor ***laboratory processes*** such as the testing process.
- Project Slide XC.26. Ask for 9 volunteers to place Tool 2: Quality Indicator Arrows at the appropriate places in the process map. Some indicators may monitor more than one place in the process. Allow 5 minutes to complete.
- Review QI arrow placement. Proceed through the list of key quality indicators as a group discussion, relating each indicator to the process map. (Refer to Handout 1: Process Map with Quality Indicators.) Reiterate that some indicators may monitor one of the structural elements noted above. Other indicators may provide assessment at some step in the testing process. In the latter case, all the steps and inputs preceding that specific step will affect the indicator.
  - Service Interruptions due to staff issues
  - Turnaround Time (TAT)
  - Test Statistics
  - Stock outs
  - Equipment Down Time
  - External Quality Assessment (EQA) Results
  - Customer Satisfaction
  - Specimens Rejected
  - Technologist Productivity
- Project Slide XC.27. Provide participants Handout 1, as a reference, after the discussion is complete.

Step 4. Present the Balanced Scorecard 10 min

- Project Slides XC.28 to XC.32. Transition to explaining the concept of the balanced scorecard – a performance management tool that provides an easy-to-read snapshot of laboratory operations. Relate the Balanced scorecard (or dashboard) to the analogous dashboard of a car.
- Project Slides XC.33 to XC.34. Present Handout 2: Balanced Scorecard. Note that several QIs have red squares.
- Briefly explain that there are various formats for Balanced Scorecards. This is only one example. The specifics of this example are not so important; however, it is important to see the Balanced Scorecard as a tool for performance monitoring. It is designed to visually present the quality indicators in an easy-to-read, quickly understood format. Remember: "What get measured (and monitored), gets fixed."
- Present Job Aid 1: Monthly Laboratory Report Example, and Job Aid 2: Quality Indicator Monthly Summary Template. These forms are tools to facilitate organized collection of monthly testing statistics and QI data.

Step 5. Present Investigating Quality Indicators – A Case Study – Phase III 35 min

- Project Slide XC.35. Refer to Handout 3: Quality Indicator Monthly Summary: A Case Study.
- Merely collecting the data and knowing the value of the indicators in not enough. Note the case study shows various entries under each indicator. Suggest that there could be many reasons for these results. The improvement cycle requires investigation into the underlying causes of these QIs. More data is needed. Reviewing documents/records, or querying persons will be the next steps.
- Project Slides XC.36 to XC.37. Refer to Worksheet 2: Quality Indicator Investigation.
- Use material as prepared from Tool 3: Investigating Quality Indicators and Tool 4: Investigating Quality Indicators Guide.
- This activity provides an opportunity to look at each indicator, decide what might be occurring, investigate the underlying cause/s, and pose a possible solution.
  - The group will be divided into groups of 5-6 persons.
  - Each group will be given two indicators to investigate over a 20-minute timeframe.
  - Worksheet 2 serves as an investigation guide for participants. The group should always assess the QI Monthly Summary data (Handout 3), state the observed problem, pose a hypothesis as to the cause of the problem, investigate based on this hypothesis, reach a conclusion, and suggest a possible solution.
  - Facilitators will provide additional information (Tool 4) as requested from the manila envelope (Tool 3), allowing participants to investigate further.
- Demonstrate the activity. Work through the *Test Statistics QI* as a group, stating the problem, developing a hypothesis of causation, and requesting data for the investigation as needed. Finally as a group, suggest the underlying

cause for the QI result and a possible solution.

- Assign two QIs to each group for investigation. Place facilitators and the appropriate materials (Tool 3 and Tool 4) with the groups.
- Note: It is most important that participants learn the principles of monitoring data, looking for causes, and improving their laboratories. The exact details of each investigation are less important.
- Allow 20 minutes for investigation.

Step 6. Debrief the activity — 15 min

- Allow each group to present their hypothesis of the issues relating to each QI. Strictly monitor the time allowing 2 minutes for a report.
- Refer to Tool 4: Investigating Quality Indicators Guide. Share any information that was not "uncovered" in the investigation. Reveal final underlying causes.
- Once underlying causes are determined, an improvement project or other corrective action can be planned. The PDCA cycle can be implemented.

Step 7. Review the PDCA Cycle of Laboratory Improvement — 10 min

- Project Slide XC.38.
- Improving quality is a continuous cycle, depicted graphically as the PDCA cycle. See *Planning Improvement Projects - Master Class Activity*.
  - PLAN – Quantifying/measure either a known problem or identify a new problem by evaluating the quality indicators. Then an action plan is devised.
  - DO – Implement the 'action plan'.
  - CHECK – Assess whether the plan worked, and if so, did it work fully or partially.
  - ACT – Based on the results of the assessment, continue the plan, modify the plan, or choose another plan. Hence, the cycle begins again with the plan. Quality improvement is a continuous, cyclic process.
- Present Job Aid 3: Quality Improvement Project Plan.

Step 8. Conclude the activity — 5 min

- Project Slides XC.39 to XC.40. Review connections to the framework tasks and the checklist.
- Link to the *Process Mapping* activity to show how the QIs relate to the process map.
- Link to *Planning Improvement Projects - Master Class Activity*.
- Highlight or reiterate the key messages below.
- Make sure participants achieved objectives of the activity.

KEY MESSAGES

- Using data is a cornerstone of laboratory improvement.
- Quality indicators are metrics used to define and measure progress in improving the quality of laboratory services.
- Key quality indicators are chosen because each one gives a unique viewpoint of the structure and processes of the laboratory. Using two, three, or more indicators simultaneously provides a broad integrative view of overall laboratory function.
- Thoughtful data analysis, investigation, and brainstorming are required to jumpstart the improvement cycle.
- The balanced scorecard is a performance management tool. The balanced scorecard provides an 'easy-to-read' snapshot of laboratory functions.

Can they:

- Define the key quality indicators?
- Use the Balanced Scorecard to monitor laboratory quality and guide continuous improvement?
- Analyze a monthly summary of key quality indicators, investigate and identify possible underlying problems?
- Plan an improvement project using a PDCA cycle?

ACTIVITY OBJECTIVES MET?

Connections and Applications

- Listed here are several guiding principles for quality assurance.
  - **Focus on the needs of the users** – Customers are the reason why laboratories exist. See *Customer Service Activity*
  - **Focus on processes to increase the productivity of work** – Mapping, understanding, analyzing, and modifying our processes is the key to improving productivity, efficiency, and removing waste. See *Process Mapping Activity*
  - **Use data to improve services** – "What gets measured (and monitored), gets fixed". This principle is highlighted in this activity.
  - **Use teams to improve quality** - It takes the entire health care team to care for patients. See *Meet the Clinician Activity*
  - **Improve communication** – The majority (70%) of problematic incidents in health care, when investigated, demonstrate a root cause of poor communication. See *Meet the Clinician Activity*
- Each quality indicator monitors an important aspect of the laboratory function.
- Choosing quality indicators is a function of the mission, vision, and values of an organization.

Tool 1: Quality Indicator Quiz Answers

Quality Indicator Quiz

Time: 10 minutes

Instructions: Match each "Key Indicator" (in the ***left*** column) with the appropriate "How Do You Measure?" item (in the ***right*** column). Write the letter of the appropriate measurement method in the space next to the indicator.

		Key Quality Indicators		*How Do You Measure?*
_D__	*1.*	Service Interruption due to Staff issues	*A.*	*Quantify number of days per month that any specific piece of equipment is not functioning*
_H_	*2.*	Turn Around Time (TAT)	*B.*	*Quantify or qualify number of complaints, or change in points on a survey (Dependent on tool used for assessment)*
_G_	*3.*	Testing Statistics	*C.*	*Quantify number of a specific test performed per technologist per hour or day*
_E__	*4.*	Stock Outs	*D.*	*Quantify number of days that staff is out for Meetings (M), Leave (L), or Illness (I). Analyze daily/weekly/ monthly test statistics to determine impact on service provision*
_A__	*5.*	Equipment Down Time	*E.*	*Quantify number of days per month that any specific reagent or supply is stocked out*
_I__	*6.*	External Quality Assessment (EQA) Results	*F.*	*Quantify number of specimens rejected per month and qualify reason for rejection*
_B__	*7.*	Customer Satisfaction	*G.*	*Quantify number of each test performed per month, i.e. Number of FBCs per month*
_F__	*8.*	Specimen Rejection	*I.*	*Indicate either Pass or Fail for each EQA program in which the laboratory is engaged*
_C__	*9.*	Technologist productivity	*H.*	*Measure time from specimen receipt/log in to release of results*

Tool 3: Investigating Quality Indicators

To open to the file, right click here and open Hyperlink.

Tool 4: Investigating Quality Indicators Guide

To open to the file, right click here and open Hyperlink.

Worksheet 1: Quality Indicator (QI) Quiz

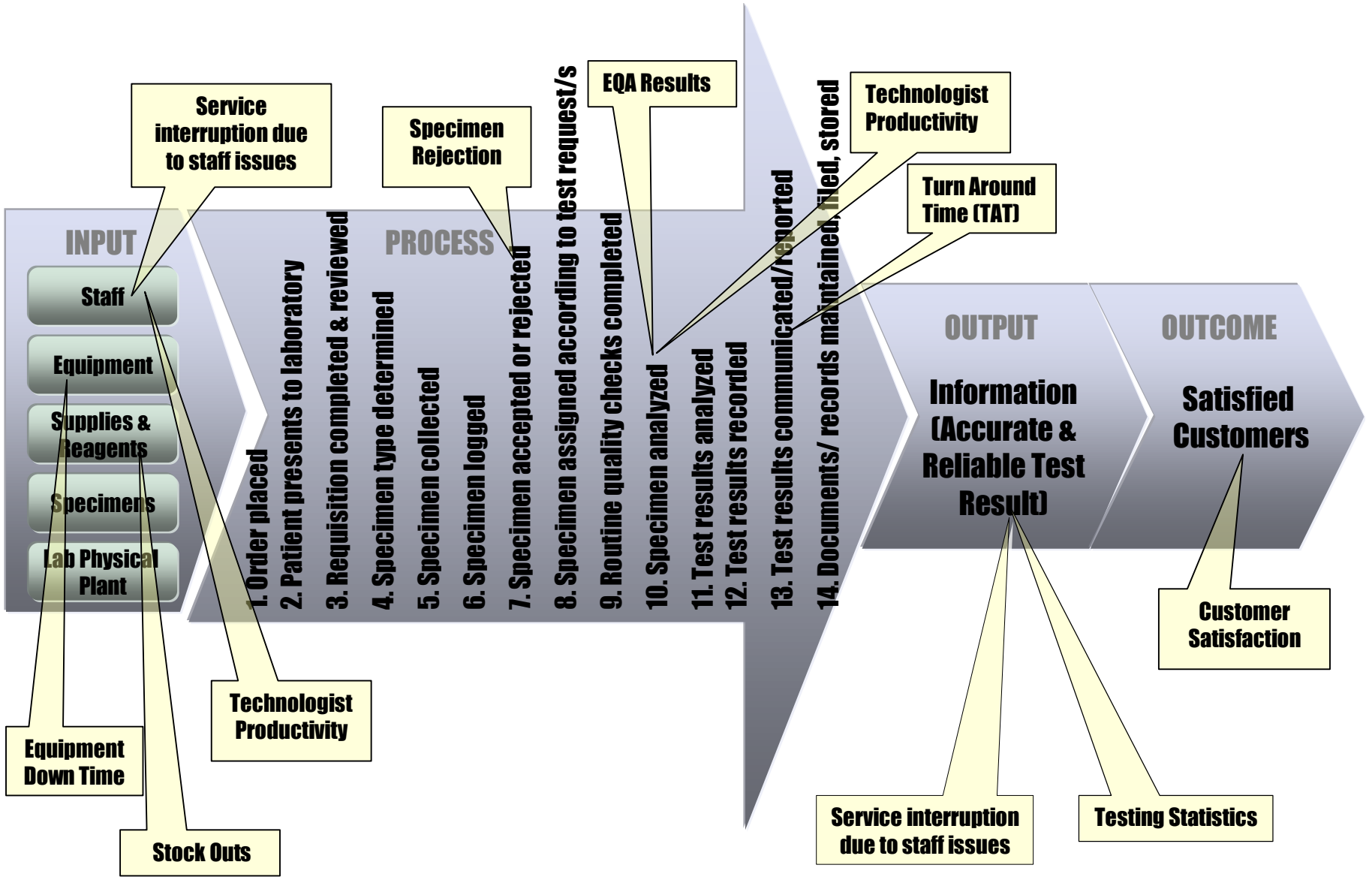
Quality Indicator Quiz

Time: 10 minutes

Instructions: Match each "Key Indicator" (in the ***left*** column) with the appropriate "How Do You Measure?" item (in the ***right*** column). Write the letter of the appropriate measurement method in the space next to the indicator.

		Key Quality Indicators		*How Do You Measure?*
_D__	***1.***	Service Interruption due to Staff issues	***A.***	*Quantify number of days per month that any specific piece of equipment is not functioning*
____	***2.***	Turn Around Time (TAT)	***B.***	*Quantify or qualify number of complaints, or change in points on a survey (Dependent on tool used for assessment)*
____	***3.***	Testing Statistics	***C.***	*Quantify number of a specific test performed per technologist per hour or day*
____	***4.***	Stock Outs	***D.***	*Quantify number of days that staff is out for Meetings (M), Leave (L), or Illness (I). Analyze daily/weekly/ monthly test statistics to determine impact on service provision*
____	***5.***	Equipment Down Time	***E.***	*Quantify number of days per month that any specific reagent or supply is stocked out*
____	***6.***	External Quality Assessment (EQA) Results	***F.***	*Quantify number of specimens rejected per month and qualify reason for rejection*
____	***7.***	Customer Satisfaction	***G.***	*Quantify number of each test performed per month, i.e. Number of FBCs per month*
____	***8.***	Specimen Rejection	***I.***	*Indicate either Pass or Fail for each EQA program in which the laboratory is engaged*
____	***9.***	Technologist productivity	***H.***	*Measure time from specimen receipt/log in to release of results*

Handout 1: Process Map with Quality Indicators



Handout 2: Balanced Scorecard

Balanced Scorecard

Laboratory ___ABC_____

Report for Month Ending __Oct 20xx_____

Indicator	Goal	Prev. Month SEPT 20XX	Cur. Month OCT 20XX	YTD
Service Interruptions	No Interruptions	▼	■	▼
Turn Around Time	90% meet goal	●	■	●
Test Stastics	Report complete	■	■	▼
Stock Outs	None	▼	■	●
Equipment Down Time	< 1 day/month	■	■	■
External Quality Assessment (EQA) Results	90% Pass	●	■	■
Customer Satisfaction (Survey - 40 pt. max)	Score ≥ 32	▼	■	●
Specimens Rejected	< 1% specimens	■	■	▼
Technologist Productivity	75% meet goal	●	■	▼

Key

●	Significant positive change (> 3%)
▼	No significant change (< 3%)
■	Significant negative change (> 3%)
YTD	Overall change Year to Date

Job Aid 1: Monthly Laboratory Report Example

MONTHLY LABORATORY REPORT				
LABORATORY:		LOCATION:		MONTH/YEAR:
Pre-analytical	Results		Acceptable	Comments
	Number	Percentage		
Total Specimens received	426			
Rejected specimens	15	3.5%		10 Mislabeled, 5 clotted samples
Specimens by testing areas				
Biochemistry	288	67.6%		
Hematology	333	78.2%		
CD4	212	49.8%		
HIV Diagnosis	10	2.3%		
Microbiology	60	14.1%		
TB	120	28.2%		
Malaria	180	42.3%		
Syphilis	250	58.7%		
Others	60	14.1%		
Specimens referred to central laboratory	105	24.6%		
Analytical				
Quality control				
Number of time QC has failed	8			6 time Hematolgy Low failed, Creat Low out, 1 Determine failed
Corrective action taken	16			
Proficiency testing (PT)				
PT panel received	3			CD4, HIV RT, Chem
PT panel tested	2			CD4, HIV RT
Satisfactory performance	1			TB Smear
Instrument/Equipment				
No. of equipment failure	4			
Non-schedule maintenance (in-house)	4			
Service Calls	0			
No. Preventive maintenance	1			CD4
Days of Service interruption				
(Stock-out, Equip Failure or Staff)				
Biochemistry	3			Creat and AST stock out
Hematology	2			
CD4				
HIV				
Microbiology				
TB				
Malaria				
Syphilis				
Others				
Laboratory accidents/incidents				
Tests completed within timeframe				
Biochemistry	260	90%		
Hematology	333	100%		
CD4	212	100%		
HIV	10	100%		
Microbiology	45	75%		
TB	108	90%		
Malaria	160	89%		
Syphilis	125	50%		
Others	60	100%		
Post analytical				
Turn around time				
Reports issued	405			
Report completed within timeframe	405			
Reports returned	0			
Request for duplicate	10			
Customer satisfaction				
Complaints	1			CD4 Result Questioned
Employee competency**				
Orientation for new employee	0			
Training	0			
Competency Check	4			HIV RT, Chem x2
Other				
Inventory Checked	yes			
Stock outs	2			Creat, AST

Job Aid 2: Quality Indicator Monthly Summary Template

QUALITY INDICATOR MONTHLY SUMMARY

Tick if condition present or supply data for each day indicator is monitored.

Month _____ Year _____

Day	**Equipment Down** (Indicate Analyzer affected)	**Stock out** (Indicate Item affected)	**Test Statistics** (See monthly test tally)	**TAT** (Specify test monitored)	**EQA** (Pass or Fail)	**Specimens Rejected**	**Customer Satisfaction** (Note complaint)	**Service Interruption** (Note type)	**Tech Productivity**
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									
11									
12									
13									
14									
15									
16									
17									
18									
19									
20									
21									
22									
23									
24									
25									
26									
27									
28									
29									
30									
31									

Handout 3: Quality Indicator Monthly Summary –A Case Study

QUALITY INDICATOR MONTHLY SUMMARY

Tick if condition present or supply data for each day indicator is monitored.

Month *October* Year *20XX*

Day	**Equipment Down** Indicate Analyzer affected	**Stock out** Indicate Item affected	**Test Statistics** See monthly Lab report	**TAT** Specify test monitored	**EQA** Pass or Fail	**Specimens Rejected**	**Customer Satisfaction** Note complaint	**Service Interruption** Note type	**Tech Productivity** Note test monitored
1	√ Heme Analyzer					4			
2									
3									
4	√ Heme Analyzer			CD4 – 28.9 hrs		0			
5	√ Heme Analyzer					0	Lab tech rude		
6						10			TB Smears 8 / 8 day
7						3			
8						5			
9									
10									
11		√ Chem Reagents		CD4 – 34.7 hrs		2	Specimen lost	Lab Tech #3 at training	
12		√				3	No attention	↓	
13		√				13	Unable to do test	↓	5 / 7 day
14		√				0		↓	
15		√				1	Long wait	↓	
16									
17									
18		√ Chem Reagents		CD4 – 30.1 hrs	F - Heme	3			
19						0			
20						14			9 / 9 day
21						0			
22						2			
23									
24									
25				CD4 – 29.3 hrs		0			
26						2			
27						17			8 / 8 day
28						0	Poor service		
29						1			
30									
31									

Worksheet 2: Quality Indicator Investigation

Quality Indicator Investigation Worksheet

What did you observe about Quality Indicator _____?	
What documents/records or information do you need to further investigate the data? What results did you obtain?	
Data requested	Results
What is your assessment of the underlying cause of this issue?	
What would you do to improve this situation?	

What did you observe about Quality Indicator _____?	
What documents/records or information do you want to further investigate the data? What results did you obtain?	
Data requested	Results
What is your assessment of the underlying cause of this issue?	
What would you do to improve this situation?	

Job Aid 3: Quality Improvement Project Plan

Quality Improvement Project Plan

PLAN

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:

_____

_____

Job Aid 3: Quality Improvement Project Plan

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?

_____

Job Aid 3: Quality Improvement Project Plan

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 Workstation Set-Up Cross-Cutting

PURPOSE:

A workstation's design influences the productivity and efficiency of the workflow. An organized workstation places all essential items within easy reach in an orderly manner. This allows timely completion of all duties assigned to the workstation. In this activity, participants progressively construct an efficient workstation based on learning throughout the ten modules.

RESOURCES FOR FACILITATOR:

- ❑ PowerPoint slides: reference activity write-up for slide numbers
- ❑ See the table below for additional items required

RESOURCES FOR PARTICIPANT:

- ❑ Handout 1: MSDS Sheet (XC 13)
- ❑ Handout 2: Duties for Workstation (XC 14)
- ❑ Handout 3: Environment & Temperature Chart (XC 15)
- ❑ Handout 4: Safety Signs (XC 16)
- ❑ Handout 5: Maintenance Log (XC 17)
- ❑ Handout 6: Reagent Log (XC 18)
- ❑ Handout 7: Corrective Action Log (XC 19)
- ❑ Handout 8: Workstation Critical Value List (XC 20)
- ❑ Handout 9: Signatory Cover Sheet Example (XC 21)
- ❑ Handout 10: Test-specific SOP Example (XC 22)
- ❑ Handout 11: Daily QC Log (XC 23)
- ❑ Handout 12: Levey-Jennings (L-J) Chart (XC 24)
- ❑ Handout 13: Quality Indicator Monthly Tally (XC 25)
- ❑ Handout 14: Restricted Access Sign (XC 26)
- ❑ Handout 15: Report Form (XC 27)
- ❑ Handout 16: Occurrence Report (XC 28)

Additional Items Required for Setting up a Workstation

Module 1

- Large cardboard box
- Markers
- Table
- Scotch tape
- Electrical or masking tape
- Handout 2: Duties for Workstation

Module 2

- Box of gloves
- Other available Personal Protective Equipment (PPE) including mask, lab coat, goggles, etc.
- Gauze
- Bottle labeled 1:10 bleach
- Waste containers (biohazard, sharps, routine)
- Handout 3:Temperature Chart (5 copies)
- Handout 4: Safety Signs
- Folder
- Yellow highlighter marker
- Labels or masking tape
- Jumbled ball of string or yarn to represent electrical cords

Module 3 and 4

- Large bag to represent a case of a consumable
- Small box
- Several consumable items such as sample cups, aliquot tubes, etc placed into the large bag
- Large bottle labeled "70% Isopropyl Alcohol" (include expiration date and lot number)
- Small specimen cup
- Label

Module 5

- Small box labeled 'Tool Kit'
- 3 specimen cups labeled as follows (include lot numbers, expiration dates, etc.):
  - Distilled water
  - Dry and Clean
  - Isopropyl Alcohol
- Binder labeled "Maintenance"
- Binder labeled "Operator's Manual"
- Index card with the analyzer's model and serial number, and customer service number
- Scotch tape
- Handout 5: Maintenance Log (3 copies)
- Handout 6: Reagent Log (3 copies)
- Handout 7: Corrective Action Log (3 copies)
- Paper labeled "Service Report"
- 3-5 blank pieces of paper
- Yellow highlighter marker

Module 6

- Binder labeled "SOP"
- Handout 8: Workstation Critical Value List
- Handout 9: Signatory Cover Sheet Example
- Handout 10: Test-specific SOP Example
- Handout 11: Daily QC Log (3 copies)
- Handout 12: Levey-Jennings (L-J) Chart (3 copies)
- Handout 13: Quality Indicator Monthly Tally (3 copies)
- Pipette, pipette tips, aliquot tubes, plastic transfer pipettes if available
- Specimen cup labeled with "normal saline"
- Scotch tape
- Yellow highlighter marker
- 2 sheets of paper labeled as followed:
  - Reference Range
  - Call List

Module 7	Module 10

▪ Handout 14: Restricted Access Sign
▪ Test tube racks(2)
▪ Blood Tubes
  ○ EDTA (1)
  ○ Red Top (2)
Module 8
▪ Handout 15: Report Form
▪ Two pens, one of them red
▪ Binder labeled "Logbook"
Module 9
▪ Handout 15: Report Form
▪ Handout 16: Occurrence Report
	▪ Large box labeled "Archive" filled with a large amount of unrelated paperwork and three items (listed below) randomly scattered throughout the box:
	  ○ QC log folder
	  ○ "Patient X's" test results
	  ○ Equipment maintenance log folder
	▪ Additional file folders labeled
	  ○ Reagent Log
	  ○ L-J Chart
	  ○ Daily Tally Log
	  ○ Temperature Chart
	▪ Marker
	▪ Stapler or paper clip

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

Management Tasks

Module 1:

1.1 Design workflow for optimal productivity

1.3 Prioritize and assign work according to personnel skill level, workloads, and completion timeframe

Module 2:

2.4 Ensure appropriate physical work environment for testing

2.5 Ensure that safety equipment is accessible and readily available (e.g., place safety equipment such as sharp box and PPE close to work station to encourage use)

2.8 Ensure that waste is properly disposed

Module 3 and 4:

2.7 Ensure reagents & chemicals are stored properly

3.4 Enforce good stock management practices (proper storage, stock cycling, inspection of incoming orders, etc.)

4.2 Place orders as necessary in accordance with needs and budgetary constraints

Module 5:

5.1 Consolidate and post equipment service information (contact, service frequency & dates, etc.) at site

5.3 Perform and record troubleshooting on malfunctioning equipment

5.4 Review and sign maintenance logs to ensure regular preventive maintenance and timely repairs

6.9 Monitor reagent performance

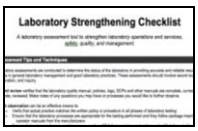
Module 6:

6.6 Review discordant rates and determine appropriate action

6.7 Review records of environmental checks & QC trends to assess impact on testing and take corrective action

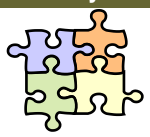
6.10 Customize site-specific SOPs as needed

Module 7:

	7.1 Determine appropriate tests based on test request and assign test responsibility 7.3 Enforce good specimen handling and processing practices Module 8: 8.3 Review test records and findings promptly to ensure accuracy and timely release of test results Module 9: 9.3 Consult with clients regarding specimen quality, test results and findings in a professional manner and ensure each issue is resolved promptly and documented appropriately Module 10: 10.3 Assure proper record retention, rotation to storage, and disposal according to protocol
Checklist Items  Laboratory Strengthening Checklist	Module 1: 3.1 Duty Roster And Daily Routine Does the laboratory have a duty roster that covers normal and after hours? 3.2 Organizational Chart and External/Internal Reporting Systems Is an organizational chart available that indicates the relationship between the laboratory and its parent organization? Module 2: 8.12 Are environmental conditions checked and reviewed accurately? 8.13. Have acceptable ranges been defined for all temperature- dependent equipment with procedures and documentation of action taken in response to out of range temperatures? 12.4 Is the physical work environment appropriate for testing? 12.6 Laboratory Storage Areas Is laboratory-dedicated cold and room temperature storage free of staff food items, and are patient samples stored separately from reagents and blood products in the laboratory refrigerators and freezers? 12.7 Is the work area clean and free of leakage & spills, and are disinfection procedures conducted and documented? 12.10 Waste Disposal Is sufficient waste disposal available and adequate? Is waste separated into infectious and non-infectious waste, with infectious waste autoclaved/incinerate? 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? Module 3 and 4: 7.9 Inventory Organization and Wastage Minimization Is First-Expiration-First-Out (FEFO) practiced? 7.10 Product Expiration Are all reagents/test kits in use (and in stock) currently within the manufacturer-assigned expiration or within stability? 12.11 Hazardous Chemicals Are hazardous chemicals / materials properly handled? Module 5: 5.1 Adherence to Proper Equipment Protocol Is equipment installed and placed as specified in the operator's manuals and uniquely labelled or marked? 5.6 Equipment Maintenance Records Is relevant equipment service information readily available in the laboratory? 5.10 Equipment Preventive Maintenance Is routine user preventive maintenance performed on all equipment and recorded according to

	manufacturer's minimum requirements? 5.11 Equipment Service Maintenance Is equipment routinely serviced according to schedule as per the minimum manufacturer recommendations by qualified and competent personnel and is this information documented in appropriate logs? 5.15 Manufacturer's Operator Manual Are the manufacturer's operator manuals readily available to testing staff and, available in the language understood by staff? Module 6: 1.6 Policy and SOPs Accessibility Are policies and SOPs easily accessible/ available to all staff and written in a language commonly understood by respective staff? 1.7 Policies and SOPs Communication Is there documented evidence that all relevant policies and SOPs have been communicated to and are understood and implemented by all staff as related to their responsibilities? 1.8 Document Control Log Are policies and procedures dated to reflect when it was put into effect, its location, when it was reviewed and when it was discontinued? 8.7 Documentation of Examination Procedures Are examination procedures documented in a language commonly understood by all staff and available in appropriate locations? 8.9 Quality Control Is internal quality control performed, documented, and verified for all tests/procedures before releasing patient results? 8.10 Quality Control Data Are QC results monitored and reviewed (including biases and Levy-Jennings charts for quantitative tests)? 11.4 Are quality indicators (TAT, rejected specimens, stock-outs, etc.) selected and tracked? 12.3 Is each individual workstation maintained free of clutter and set up for efficient operation? Module 7: 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? 12.2 Are the patient care and testing areas of the laboratory distinctly separate from one another? 12.5 Laboratory Access Is the laboratory properly secured from unauthorized access with appropriate signage? Module 8: 9.1 Test Result Reporting System Are test results legible, technically verified by an authorized person, and confirmed against patient identity? 9.2 Testing Personnel Are testing personnel identified on the result report or other records (manual or electronic)? 9.3 Report Content Module 9: 9.6 Authorities and Responsibilities Has the laboratory defined and implemented authorities and responsibilities for the management and use of the laboratory information system– paper based and electronic, including maintenance and modifications that may affect patient care. 10.1 Are all identified nonconforming activities/ work identified and documented adequately? Module 10:

	1.10 Data Files Are test results, technical and quality records, invalid or discontinued policies and procedures archived for a specified time period in accordance with national/international guidelines? 1.11 Archived Results Accessibility Is there an archiving system that allows for easy and timely retrieval of archived records and results? 9.5 Archived Data Labelling and Storage Are archived results (paper or data-storage media) properly labelled and stored in a secure location accessible only to authorized personnel?

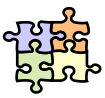
This activity is related to the following activities:	
	Module 1: Creating a Management Calendar Module 1: How Do You Assign Personnel to Tasks? Module 1: Process + Structure = Outcome

ACTIVITY AT-A-GLANCE				
Step		**Time**	**Resources**	**Key Points**
1	Explain how an efficient design impacts workflow	5 min		
2	Introduce the activity	5 min	Slide 1.25	
3	Construct the workstation (Module 1 only)	15 min	Refer to "Additional Items" Table	
4	Debrief the activity (Module 1 only)	5 min		
5	Conclude the activity (Module 1 only)	5 min		
	TOTAL TIME:	**35 min for Module 1**		
Repeat the following steps for each of the remaining modules (2-10)				
3	Construct the workstation	15 min/ module	Slides –see activity write-up Refer to "Additional Items" Table	
4	Debrief the activity	5 min/ module		
5	Conclude the activity	5 min/ module		
	TOTAL TIME:	**25 min for each remaining module (2-10)**		
The inclusion of the remaining modules (2-10) of this activity should be taught at the conclusion of each module. This activity provides an opportunity to reinforce key points and to indicate a transition between modules during the workshop.				
MULTIPLE-WORKSHOP OPTION: Any module's workstation activity can be presented independently, with the other module's elements in place prior to the presentation. Reinforce the other elements by briefly reviewing them.				

PROCESS

Preparation

- Obtain the necessary items prior to each module.
- Print the appropriate number of copies of handouts prior to each module. Unless otherwise specified, only one copy of the handout is required for this activity.
- Procure several cups, containers, and bottles of various sizes to represent the workstation items if you are unable to obtain supplies locally.
- Place an uncluttered, desk-sized table adjacent to the wall. The desktop will function as a makeshift laboratory workbench. Select an area in the classroom visible to all participants, where the desk can remain throughout training.
- Tape signs on the wall near the table designating the location of the store room, the supervisor's office, and the archival room. Below the store room sign, tape Handout 1: MSDS Sheet.
- Post a flipchart page entitled "The 6 S's of an Efficient Design" with the 6 S's (sort, straighten, shine, standardize, sustain, and safety) listed below. Tape the page near the desk for easy reference throughout the activity.
- Review the associated framework tasks and checklist items noted for each module in this activity. Develop links that relate the activity's physical workstation set-up with the manager's role in the development of standardized processes and procedures. See activity, *Process* + *Structure* = *Outcome* and apply that activity's key concepts at the individual workstation.



Step 1. Explain how an efficient design impacts workflow — 5 min

- Indicate that laboratory organization involves two designs: the overall laboratory and the individual workstation. When both areas are redesigned, it will impact laboratory workflow by:
  - Elimination of wasted effort, unnecessary movement, and unproductive time.
  - Removal of waste and the reduction of the potential to make errors.
- Provide a personal example to reinforce the previous statements. Throughout this activity, emphasize these concepts.
- Introduce and briefly explain the 6 S's regarding the workstation.
  - Sort - everything has its place.
  - Straighten - everything is in its place.
  - Shine – the work area is clean and uncluttered.
  - Standardize – the applicable policies, processes and procedures are developed and understood by staff.
  - Sustain – the required supplies, documents, and records, which support the workstation's functions, are available.
  - Safety – the work area is safe for personnel; the phlebotomy area is safe for patients

Step 2. Introduce the Activity — 5 min

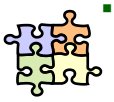
- Project Slide 1.25 to provide an overview of the activity.

- Indicate that throughout training, participants will assemble an organized and productive workstation with what has been learned from each module, beginning with an empty workbench.
- Emphasize that every lab manager is responsible for making certain workstations are well-organized in order to facilitate productivity and efficiency.
- Inform participants that connections to the *Laboratory Management Framework* and *Laboratory Strengthening Checklist* will be made throughout the activity to provide concrete directives toward the implementation of efficiency.

Step 3. Construct the workstation — 15 min per module

Module 1

- Place the cardboard box onto the table. Label it "Analyzer."
- Emphasize that principles extracted from this activity can be applied to any workstation in their laboratory. For example, in microbiology the workstation's focal point may be the biological safety hood area or the sink where the slides are stained.



- Explain that duties performed at this workstation must be clearly defined. The person designated from the duty roster is responsible for completing the defined tasks. Link this to the activity, *How Do You Assign Personnel to Tasks?* Tape Handout 2: Duties for Workstation to the wall behind the analyzer.
- Mention that electrical or masking tape may be used to tape off outlines of items needed at the workstation, i.e. stapler, scissors, etc. Demonstrate this idea.

Module 2

- Project Slide 2.13 to transition participants to this activity.

Waste disposal

- Place the bio-hazardous (infectious), routine (non-infectious), and sharps waste container in the appropriate places.
- Demonstrate how workstation set-up affects proper waste disposal.
  - Move the bio-hazardous waste container away from the workstation.
  - Place a glove on your hand while standing at the workstation.
  - Remove the glove while asking participants the likelihood of proper bio-hazardous (non-sharps) disposal if the receptacle is positioned away from the workstation.
  - Dispose of the glove into the sharps container.
  - Emphasize that even when staff members understands proper waste disposal, the convenience of the location will still influence behavior. Containers that are closest will be used, especially when one is busy. Ensuring proper waste disposal requires elements of engineering and enforcement.

Personal protective equipment (PPE)

- Place the appropriate PPE (gloves, masks, eye protection, etc.) near the analyzer without cluttering the testing area. When PPE is readily available staff members will better adhere to safety rules and practices.

- Place the bleach solution and gauze near the analyzer. Discuss the importance of preparing the bleach solution daily and the need to assign this task.

Documents and records

- Attach one copy of Handout 3: Temperature Chart in a convenient location on the wall.
- Display Slides 2.14 to 2.15.
  - Point out how each temperature includes the acceptable range.
  - Mention how the record serves as a visual reminder for workstation duties.
  - Point out how the disinfection of work surfaces is documented daily.
  - Facilitate a discussion on how others address temperature records and general workstation duties.
  - Point out documentation of active review by the manager. Link this to the *Creating a Management Calendar* activity.
  - Discuss how to monitor and review records.
- Demonstrate with the remaining temperature charts how to create a master copy and organize extra copies of records required at the workstation.
  - Label the folder, "Extra Copies."
  - Use a yellow highlighter and write "Master" on one temperature sheet.
    - A yellow highlighter does not show on photocopies.
    - When only this sheet remains, more copies must be made.
    - The "Master" should never be used.
  - Place the master and additional copies of temperature sheets into the folder.
  - Place the folder into a 'drawer' at the workstation. Label the drawer, "Extra Logs."

Electrical safety

- Place the jumbled ball of yarn or string in the testing area.
  - Discuss the need to keep the testing area clean and uncluttered.
  - Discuss electrical safety and placement of electrical cords.

Safety rules and practices

- Post Handout 4: Safety Signs near the workstation. Facilitate a discussion regarding the manager's responsibility to monitor staff adherence to safety rules and practices.

Module 3 and 4

- Project Slide 4.12 to transition participants to this activity.
- Explain the necessity of keeping a small quantity of supplies and consumables for testing. To maintain an uncluttered workstation, the bulk of the supplies should remain in the stock room.

Consumables

- Demonstrate how to restock the workstation.
  - Place the large bag with the consumable items and the large container labeled "Isopropyl Alcohol" below the posted sign, "Store Room."
  - Retrieve the bag and begin restocking the workstation.
  - Transfer the supplies into the small box so that the large bag is nearly

empty.
- Place the small, refilled box so that it is within reach and near the analyzer. It should not obstruct the test area.
- Return the bag to the stock room. Pause to check if additional inventory is available in the stockroom.
- Explain that inventory is too low upon inspection and your next step is to ensure an order has been placed (**sustain**).
- Discuss ways that staff members can verify that sufficient stock is available or on order

Hazardous Chemicals

- Demonstrate how to restock the workstation with a small quantity of hazardous chemical.
  - Retrieve the container from the store room and point to the MSDS sheet posted on the wall.
  - Choose a well ventilated area and pour a small quantity into the specimen cup. Label the cup appropriately.
  - Place the cup away from the analyzer to avoid heat. Mention that direct sunlight should also be avoided.
  - Return the hazardous chemical container to the store room and verify there is a sufficient supply for the future (**sustain**).
  - Elaborate on how to handle hazardous chemicals at the workstation.
- Discuss the need to verify expiration dates and lot numbers, as appropriate, when the workstation is restocked.

Module 5

- Project Slide 5.20 to transition participants to this activity.
- Place the specimen cups at the back of the desk away from the test area.
  - Explain these supplies are required to perform daily maintenance and should be within reach.
- Place the tool kit in a nearby area that does not obstruct the testing area.
- Tape the index card which has the equipment's detailed information to the analyzer.

Operator's manual

- Place the Operator's Manual binder by the instrument.
  - Indicate that based upon the manual's specifications, the analyzer's back fan area is too close to the wall and to prevent overheating, the analyzer needs to be repositioned.
  - Move the analyzer slightly forward.

Equipment Records

- Assemble the maintenance binder.
  - Place one copy of Handout 5: Maintenance Log, Handout 6: Reagent Log, and Handout 7: Corrective Action Log into the maintenance binder.
  - Place the paper labeled "Service Report" in the back of the maintenance binder.
    - Indicate if a calibration log is required, it should be placed into the maintenance binder.

- Create a "Master" copy (see Module 2) of each log and place it into the "Extra Copies" folder.

Instrument Print-outs

- Indicate that the 3-5 blank pieces of paper are instrument print-outs (system checks, etc).
  - Explain that print-outs should be retained and archived at the end of the month.
  - Demonstrate how to handle the print-outs by briefly reviewing and initialing the papers (**standardize**).
  - Turn the print-outs over and place them away from the immediate test area (i.e. at the back and far side of the desk) so that each paper has a designated spot on the desk (**sort**).
  - Indicate that by placing the daily print-outs face-down, the entire month will be in chronological order (**straighten**). At the end of the month, they will be collected along with all the completed logs for appropriate storage.
  - Mention that if QC print-outs are generated, they can be handled in a similar manner.
- Display Slides 5.21 to 5.25.
  - Point-out how ancillary equipment and safety equipment maintenance is documented.
  - Indicate that the criteria for stain acceptability should be defined in the SOP.
  - Point-out documentation of active review by the manager. Link this to the *Creating a Management Calendar* activity.
  - Discuss the visual cues before and after the morning workstation set-up routine in regards to the opened log binders and bottle of methanol.

Module 6

- Project Slide 6.36 to transition participants to this activity.
- Place the specimen cup of saline, indicating it is the proper specimen diluent for values exceeding linearity at this workstation.
- Tape the papers labeled 'Call List,' 'Reference Range List,' and Handout 8: Workstation Critical Value List on the wall at a convenient location so they can be seen by the operator of the workstation.
- Place any additional supplies onto the workstation. Ensure they do not clutter the working area.

Standard Operating Procedures (SOPs)

- Demonstrate how to have the workstation's SOP available at the workstation.
  - Place Handout 9: Signatory Cover Sheet Example into the binder labeled "SOP." Indicate the actual signed cover sheet is filed with the master document. Mention that document control will be covered in-depth during Module 10: Documents and Records.
  - Place Handout 10: Test-specific SOP Example into the same binder following the cover sheet.

Records

- Organize the additional records needed at the workstation.

  - Add to the maintenance binder previously placed next to the analyzer, one copy of the Handout 11: Daily QC Log, Handout 12: Levey-Jennings (L-J) Chart and, Handout 13: Quality Indicator Monthly Tally.
  - Create a "Master" copy of each log (see Module 2) and place it into the "Extra Copies" folder.

- Display Slides 6.37 to 6.41.
  - Discuss the various ways to create records to facilitate documentation.
  - Note how check marks can quickly document task completion.
  - Note how circles can quickly record qualitative result information.
  - Note how expected results are included, where appropriate. For some QC material, this information remains constant between lot numbers and can be incorporated into the record's template.
  - Discuss ways to validate and/or document the internal control area of a testing cassette.

Module 7

- Project Slide 7.23 to transition participants to this activity.

Pre-analytical processing errors

- Place one test tube rack next to the analyzer.
- Describe a scenario and facilitate a discussion.
  - Indicate that the workstation is fully stocked, organized, clean, and fully operational. All maintenance and QC was performed, acceptable and documented. It is now ready to analyze specimens.
  - Show the two red top tubes to the class. Ask participants, with a show of hands, if they believe this workstation can produce quality results on these specimens.
  - Place the first blood tube into the front of the rack. Explain this tube was obtained from the wrong patient.
  - Place the second tube into the front of the rack. Explain this specimen, though drawn on the correct patient, was refrigerated overnight without being centrifuged, and the nonhemolyzed serum was just recently separated from the cells.
  - Ask participants, with a show of hands, if this workstation is still capable of producing quality results on these specimens.
  - Emphasize "garbage in, garbage out."

Specimen workflow

- Display Slides 7.24 to 7.27.
  - Discuss the visual cues to facilitate specimen processing.
  - Suggest each workstation have a designated area to receive specimens.
  - Discuss visual cues to indicate a different ordering priority than routine.
  - Discuss ways participants can organize small batches received at the workstation.
- Demonstrate the workflow path within the workstation.
  - Place the EDTA tube into the test tube rack. Indicate the specimen has been delivered to the wrong workstation.

- Walk the EDTA tube to another part of the laboratory and mention how this disruption affects efficiency.
- Place the two red top tubes into the back of the rack. Indicate these specimens have been analyzed and reported and it is now the end of the day and specimens need to be stored.
- Move the rack containing the two red top specimens to another part of the classroom, the specimen storage area.
- Place an empty rack at the workstation to prepare for the next day.

Patient Safety

- Post Handout 14: Restricted Access Sign to the far side of the workstation set-up table. Facilitate a discussion about safety and confidentiality in the patient areas. Relate the previously conducted modules in this activity specifically to the phlebotomy area (i.e. biosafety, waste management, procedures). Consider addressing during the discussion:
  - If the current laboratory layout does not have a separate client areas, what are some ways a manger can take a poor design and make it better. How to advocate for a separate area.
  - How to organize the phlebotomy supplies so that the phlebotomist must never reach while performing the collection procedure.
  - How to organize collected specimens and deliver them to the appropriate workstation.

Module 8

- Project Slide 8.13 to transition participants to this activity.
- Place a copy of Handout 15: Report Form in the "Extra Copies" folder.
- Place 2 pens, one being red, in the 'drawer' of the workstation. Explain that all necessary pens, pencils, etc. should be available to record the test results as specified in the SOP.
- Place the binder labeled 'Logbook' to far side of the workstation. Note the workflow path you have created within the workstation for both the specimen and its requisition.
- Display Slides 8.14 to 8.21.
  - Discuss the visual clues used at the workstation. These cues indicate at which step within the workflow process for the specimen and the requisition.
  - Ask participants what cues are used in their own laboratory.

Module 9

- Project Slide 9.12 to transition participants to this activity.
- Place a copy of Handout 16: Occurrence Report in the "Extra Copies" folder.
- Explain that when an occurrence requires documentation, these copies should be handy.
- Walk a report (Handout 15: Report Form) from the workstation to another part of the classroom. Indicate the report is ready to be cross-checked and, if acceptable, released to the provider.

Module 10

- Project Slide 10.17 to transition participants to this activity.

Archival System

- Demonstrate the importance of an archival system.
    - Place the large, messy box labeled "Archive" in the designated archival area (under the posted "Archival Room" sign).
    - Ask for three volunteers and assign each one task.
        - Retrieve "Patient X's" test results needed to answer a provider's question or compare a previous result to validate the patient's current, but questionable, result.
        - File a Daily QC Log in the appropriate QC folder to archive records at the end of the month.
        - Retrieve a blank equipment maintenance log for the hematology analyzer to prepare for the next month.
    - Emphasize the wasted time, frustration, and confusion which occur when an archival system is not maintained.
    - Empty the remaining contents of the box.
    - Place all folders neatly into the empty box

Record rotation

- Demonstrate the handling of the workstation's records at the conclusion of the month.
    - Address those records that require supervisor's signature
        - Select a participant to act as Lead Tech.
        - Remove this month's logs, the temperature chart, and Daily Tally Log and place them on the "Lead Tech's desk" for review.
        - Instruct the lead tech to review and sign the records and then file them in the appropriate archival folder.
    - Address those records that can be archived directly.
        - Retrieve the instrument print-out piles and quickly page through them to ensure they are in chronological order.
        - Staple or paper clip the print-outs.
        - Place the instrument print-outs into the archival box.
- Prepare the workstation for the next month.
    - Remove sheets from the "Extra Copies" folder.
    - Write the next month and current year on each sheet and place them into their appropriate location.
    - Explain that the workstation is ready for tomorrow, the 1st of the month.
- Point-out Handout 14: Restricted Access Sign previously posted during module 7 of this activity. Facilitate a discussion regarding confidentiality, particularly if records are stored outside of the main laboratory

Step 4. Debrief the Activity 5 min

- Connect each module to the associated framework tasks and checklist items noted in the *Connection to Framework* table (page 3).

Step 5. Conclude the Activity 5 min

- Highlight and reiterate the key messages below.
- Make certain participants achieved the objectives of this activity.

KEY MESSAGES

- Use of the 6 S's provides a methodical approach to designing and engineering an efficient workstation.
- It is important to outline the duties for each workstation and to include policies, procedures, supplies, documents and records that must be readily available to achieve efficiency.
- A workstation's throughput is directly influenced by its organization and workflow design.

Can they:

- Identify the essential components needed to organize an efficient workstation?
- Integrate each module's lesson to better design and engineer an efficient workstation?

☑ ACTIVITY OBJECTIVES MET?

➢➢ Connections and Applications

Module 1

- The designated duties for the workstation provide a guide to the policies, processes, and procedures that must be developed and implemented (**standardized**).
- Assigned duties must be monitored and reviewed for compliance and acceptability. A defined laboratory hierarchy delineates this oversight and designates the authority to delegate this or portions of this responsibility.
- An organizational chart, outlining the hierarchical relationships between organizational areas, helps clarify workflow, reporting lines, and areas of responsibility.

Module 2

- Workstation set-up requires that everything has its place (**sort**). Consider the human factor when choosing its location. Remember that the PPE location will influence usage and compliance.
- The quality and selection of PPE provided will affect staff adherence to safety rules and practices. Scratched protective eyewear and ill-fitting lab coats or gloves will influence staff members non-compliance (**sustain**).
- To keep the work surfaces clean (**shine**), provide the bleach solution at the workstation so that it can be conveniently used. Soiled work surfaces will be more readily cleaned if the bleach is close by.
- Keeping the laboratory safe and clean is the responsibility of laboratory employees, not the housekeeping staff.
- When possible, always include what defines acceptability in a log. When the temperature's acceptable range is included, it allows staff to immediately determine if the result is acceptable or not. If this information elsewhere, it is time consuming and thus is easier to dismiss out-of-range results.
- When records are developed, consider elements to be included into the template in order to reduce the amount which must be written while still fulfilling the documentation needs of that record (**standardize**).
- In the decision to consolidate temperature checks into one record vs. to separate the individual components into several records, take into account workflow routines and laboratory layout.
- Document the active review of records (**sustain**). If it is performed at the end of the month, then include the review date and initial. If it is performed weekly, record each event.

➢➢ Connections and Applications

Modules 3 and 4

- The flap ripped from an empty box can serve as a quick reminder to follow-through on an inventory matter at the first available opportunity.
- A Material Safety Data Sheet (MSDS), prepared by the manufacturer, provides information on the safe use, handling, potential hazards, disposal, and proper response in the event of an emergency. MSDS can be requested from the manufacturer, vendor, or retrieved from the internet.
- When possible, consider the purchase of smaller, pre-packaged containers that contain hazardous chemicals so that each individual container is a suitable size to keep at the workstation. This eliminates the need to transfer the chemical into an inappropriate secondary container and reduces the possibility of a safety or health incident which might occur during this step.
- Restock the workstation at the end of the day to ensure the area is ready for the laboratory's busiest time period, the morning set-up and testing.

Module 5

- The life expectancy and acceptable operational performance of equipment will be prolonged when equipment is placed according to the manufacturer's criteria, and maintenance is performed based upon the manufacturer's recommended schedule.
- Daily maintenance will be more readily performed and documented by staff if all needed supplies and records are available at the workstation.
- If the instrument print-outs do not include the operator's identification, then the operator should initial them. Initialing identifies who performed, reviewed, and determined acceptability.
- Emphasize the visual cues used at the workstation. For example, an opened maintenance binder can signify the daily maintenance and QC are in progress. QC print-outs next to the L-J chart can indicate the data points still need to be plotted.
- Retain the ancillary equipment manuals either near the equipment or inserted in a central binder.
- Include ancillary equipment when equipment information is consolidated - including date of purchase.
- Customize operator's manuals to meet your laboratory needs. For example, if the photograph, accompanying the monthly sensor cleaning, does not adequately pinpoint the sensor's location, draw an arrow onto the photograph. If helpful hints are provided during the manufacturer's training session, write them onto the page's margin.
- Always keep a copy of the instrument's current set-up parameters and calibration factors readily available in the event they need to be reentered during troubleshooting.
- Each piece of equipment should have a file or "Book of Life," which contains documents and records that must be retained for the life of the instrument.

Module 6

- Ensure all needed documentation and records are available at the workstation. Any additional steps that require staff to leave the workstation for a central location may be viewed as an inconvenience. Compliance increases with ease of availability. Immediate documentation reduces interruptions during testing and avoids instances where staff forgets to document at a later time.
- Discordant or repeat test rates can easily be tracked by a tally on a slip of paper, which is later transferred to the appropriate record.

➢➢ Connections and Applications

- Explain how each workstation can document QA information. Under the "QA Indicator" column on the "Quality Indicator Monthly Tally", each workstation can record this immediately. At the end of the month the data can be transferred to a Balanced Scorecard to reflect overall laboratory operations.
- Supplies should be placed at the workstation to reduce repetitive motion. For example, if a pipette is needed to aliquot a portion of the sample, then the pipette tips should be placed on the dominant hand side to prevent reaching across the test area.
- Aliquots, such as saline or dH2O for dilutions or maintenance purposes, should be changed frequently to prevent deterioration and contamination. The entire contents should be discarded. Never pour fresh into old. Aliquots should always be labeled with the opened date and in-use expiration date. Ensure the storage container is acceptable.
- The QC records required at the workstation must support the assigned duties. For example, if one duty is to verify the sterility of new media, then a record must be developed to document this.
- If lot numbers do not change frequently, consider documentation of the number and expiration date in only one area of the record so that staff do not need to write this onto the log daily.
- When using a checkmark system to document record activity, ensure the checkmarks are complete so they can not be mistaken for random marks on the log.
- Point-of-Care (POC) devices provide results. Therefore, internal and external QC platforms should be developed.
- Each POC device in use should have its own QC and maintenance log. The log should identify the device by its serial number.

Module 7

- The pre-analytical workstations serve as the specimens' point of entry into the lab (phlebotomy) or another lab (referral lab specimen processing). Errors occurring at these workstations will carry over into the analytical and post analytical phases of testing.
- Quality Control is not sufficient to achieve quality in the laboratory. Processes must be planned, monitored and managed throughout all phases of laboratory service.
- Applicable policies, procedures, records, and supplies are required for every workstation -not just the analytical ones.
- Consider a designated area at each workstation to receive specimens from the phlebotomy workstation (**sort**). If additional specimen processing is required such as centrifugation or mechanical rocking choose an area adjacent to that equipment.
- Not only should workflow be considered throughout the whole laboratory, but it should also be considered within each workstation. The logical workflow for receiving, analyzing, and resulting should be determined in order to maintain an organized direction and provide consistent visual cues to increase efficiency (**standardize**).
- Ensure that staff members understand which test requests correspond to which workstation. The wrong test request received at that workstation wastes time, causes delays in the test process, and disrupts the testing workflow at the workstation initially receiving the incorrect request. If a specimen is shared between workstations, determine which workstation should initially receive it.
- Consider the use of verbal or non-verbal cues to signify a different testing

➢➢ Connections and Applications

priority. For example, specimens placed separately from the majority of specimens can easily signify a different test priority.

Module 8

- Emphasize the visual cues used at the workstation that indicate the specimen and requisition step in the workflow path.
- Post critical values to provide an easy reference if/when samples require result verification by repeat testing.
- An organized workstation facilitates another staff member who might cover for an unexpected or planned absence during a shift. This is much easier when the person who requires coverage is organized and thoughtful in regard to how the workstation is set up.
- Extra copies of the result/requisition form should be available at the workstation in the event they need to be rewritten because of contamination or recording errors. A laboratory policy should be created for such instances since the rewritten form would no longer posses the provider's authorized signature.
- Positive AFB results must be written in red ink, while negative results are written in blue or black ink.

Module 9

- Occurrence forms available at the workstation encourage staff members to utilize this report. A blank form can be used to write a few notes that can serve as a visual reminder to complete the form at the first available opportunity.

Module 10

- Instrument print-out tapes should be retained as part of a record retention plan. An empty blood culture bottle box and internal packaging material, originally used to separate the bottles during shipment, provides a handy way to store the day's rolled-up tape (**straighten**).
- Documents and records not stored in an organized and easily retrievable manner will result in wasted time later spent looking for the appropriate documents or records (**sort and sustain).**
- A manger should always have a spare key to unlock the record storage area.

Handout 1: MSDS Sheet

MATERIAL SAFETY DATA SHEET

SECTION 1. Product and Company Identification
70% ISOPROPYL ALCOHOL

Product Code:	HH-70% ISO ALCO
Product Name:	70% ISOPROPYL ALCOHOL
Reference #:	77845
Manufacturer Information	
Company Name:	XYZ Companies, Inc.
Emergency Contact:	713.414.321.789
Chemical Family:	Alcohol Mixture

SECTION 3. Hazardous Identification

Emergency Overview

No data available.

Route(s) of Entry: Inhalation? Yes , Skin? Yes , Eyes? Yes , Ingestion? Yes

Potential Health Effects (Acute and Chronic)

No data available.

Signs and Symptoms Of Exposure

Early to moderate CNS depression may be evidenced by giddiness, headache, dizziness and nausea; in extreme cases, unconsciousness, respiratory depression and death may occur.

Medical Conditions Generally Aggravated By Exposure

Pre-existing eye and/or skin irritation, respiratory, and/or digestive disorders.

Section 4. First Aid Measures

Emergency and First Aid Procedures

INHALATION = Remove victim to fresh air and provide oxygen if breathing is difficult. Obtain medical attention.

SKIN CONTACT = Flush skin with plenty of water. If irritation occurs, seek medical attention.

INGESTION = Do not give liquids if victim is unconscious or drowsy. Otherwise give no more than 2 glasses of water and induce vomiting. Obtain medical attention.

EYE CONTACT = Immediately flush eyes with plenty of water for at least 15 minutes. Obtain medical attention.

Hazard Ratings:	
Health:	**1**
Flammability:	**3**
Reactivity:	**NA**
Special Hazard:	**NA**

Minimal:	0
Slight:	1
Moderate:	2
Serious:	3
Extreme:	4

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Date Created	09/08/1994

Handout 2: Duties for Workstation

Hematology & CD4	
Daily Tasks	**Weekly, Monthly, or As-Needed Tasks**
▪ Inspect work area ▪ Adhere to safety practices; ensure all needed safety equipment is available ▪ Organize work area for the day's workload ▪ Perform all daily maintenance on analyzer and document in log ▪ Perform daily analyzer system checks; verify acceptability and document ▪ Perform daily QC; verify acceptability and document ▪ Perform assigned testing, validation, and interpretation ▪ Aliquot specimens properly as needed ▪ Troubleshoot and document corrective action on all invalid or discordant results ▪ Notify and document all panic values ▪ Record results in the log book ▪ Store specimens in proper place and temperature; discard specimens that exceed retention time ▪ Document and record QA indicators and occurrences ▪ Ensure proper disposal of waste ▪ Clean and disinfect work area ▪ Perform daily and as-needed microscope maintenance and document ▪ Restock work area with all needed supplies for the next day	▪ Perform analyzer weekly, monthly, and as-needed maintenance ▪ Perform, verify, and document calibration as needed ▪ Analyze and report EQA testing ▪ Change stain as needed and verify its performance ▪ Perform basic troubleshooting activities and document ▪ Contact customer service, document call, and monitor until resolved ▪ Issue repair orders and monitor until service is completed ▪ Monitor performance of new lots ▪ Review supplies and reagents needed at the workstation; update stockroom as needed ▪ Ensure sufficient workstation logs are available for the next month; provide blank logs at the end of month ▪ Ensure analyzer's toolkit is up-to-date ▪ Observe other members and provide feedback and cross-train as needed ▪ Review and sign-off on all SOPs for the workstation and overall laboratory policies

Handout 3: Temperature Chart

ENVIRONMENT & TEMPERATURE CHART

month/year _____

DAY	ROOM TEMP.	ROOM HUMIDITY	REAGENT REFRIG.	FREEZER	TIME CLOCK	WORK SURFACES	INITIALS
	acceptable range: (18 - 30'C)	acceptable range: (20-85%)	acceptable range: (3 - 6'C)	acceptable range: (< 0'C)	date/time verified	cleaned with 10% fresh bleach sol'n or Sanicloth	
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
15							
16							
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18							
19							
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21							
22							
23							
24							
25							
26							
27							
28							
29							
30							
31							

MAINTENANCE SCHEDULE

During Normal Operating Hours
- temperatures recorded
- stamp current tally log verifying correct date/time
- benches & phleb area wiped start/end of shift, immed after visible contamination

As Needed and Documented Under Action
- defrosting /internal cleaning of freezer/ refrig

Annually
- verify thermometer accuracy/acceptability

Date: **Corrective Action** **Initials:**

Handout 4: Safety Signs

Handout 4: Safety Signs

Handout 5: Maintenance Log

Clinic Laboratory

Maintenance Log

SN# AJ33055

Month/Year

		Daily							Weekly			Comments
		Startup	Waste	Background	Reproducibility	QC (L, N, H)		Shutdown	Extended	Rinse	Wipe	As Needed/Non Scheduled
Date	Tech		O.K.	Count		Performed	Plotted	1 hour	Clean	Flow Cell	Instrument	Maintenance
1												
2												
3												
4												
5												
6												
7												
8												
9												
10												
11												
12												
13												
14												
15												
16												
17												
18												
19												
20												
21												
22												
23												
24												
25												
26												
27												
28												
29												
30												
31												

Initial/check mark indicates value within instrument limits; maintenance procedure performed as required.

Handout 6: Reagent Log

Clinical Laboratory

Reagent Log

	Diluent			Rinse			Hgb Lyse			WBC Lyse			Fixative			
Today's Date	Lot #	Exp Date	Opened Exp Date 90 days	Lot #	Exp Date	Opened Exp Date 3 months	Lot #	Exp Date	Opened Exp Date 3 months	Lot #	Exp Date	Opened Exp Date 8 months	Lot #	Exp Date	Opened Exp Date same as exp date	Initials

Handout 7: Corrective Action Log

Corrective Action Log

Date:	Action Performed:	Initials:

Handout 8: Workstation Critical Value List

Chemistry Critical Value List

Test	Critical Low Value	Critical High Value
Amylase		> or = 300 U/L
Calcium	< 1.75 mmol/L	> 3.0 mmol/L
Creatinine Kinase (CK)		> 300 U/L
Creatinine		> 707 umol/L
Glucose	< 2.8 mmol/L	> 22.2mmol/L
Phosphorus	< 0.49 mmol/L	
Potassium	<3.0 mmol/L	> 6.5 mmol/L
Sodium	< 120 mmol/L	> 155 mmol/L
Total Bilirubin		> 171 umol/L (older than 5 days) > 307umol/L (0 – 5 days)
Uric Acid	< 89 umol/L	> 708 umol/L

Handout 9: Signatory Cover Sheet Example

Cape Clinic Medical Facility
Department of Clinical Laboratory

Document:	
Creatinine in Serum by IL 300 Plus Analyzer Procedure	
Approved by:	*Date:*
H. Grady Hines, PhD, MT (ASCP^i)	*June 1, 2008*

Prepared by:	*Date Adopted:*	*Supersedes Document:*
Anne Lugo, MT (ASCP^i)	*June 4, 2008*	Creatinine by Spectrophotometer Procedure

Date Reviewed:	*Date Revised:*	*Initials:*
November 30, 2008		*HH*
November 21, 2009		*HH*
December 05, 20XX		*HH*

Distribution:
#1 Master File
#2 Chemistry Department
#3 IL 300 Plus Analyzer Workstation

Handout 10: Test –specific SOP Example

Creatinine in Serum by IL 300 Plus Analyzer Procedure

Test Summary:
Creatinine is produced as a waste product through the conversion of creatine to phosphocreatine. Because most of the creatinine is produced in the muscles, the amount of creatinine is proportional to the patient's muscle mass. Serum creatinine is useful in the evaluation of kidney function and in monitoring renal dialysis.

Principle:
Creatinine is measured as a fixed timed chemical reaction using picrate (Jaffe reaction) in an alkaline environment to form an orange-red product. The increase in absorbance at 510 nm due to the orange-red complex is proportional to the creatinine concentration in the sample.

Specimen Handling and Preparation:
Serum is the specimen of choice. The serum may be stored for 1 day at 2-8'C.

Quality Control:
SeraChem 1 and SeraChem 2 are used for quality control. Both controls will be run each day of use and anytime new reagent, regardless of lot number, is added to the system throughout the day. If testing extends longer than 8 hours, this will be deemed as a second shift and both controls must be analyzed.

SeraChem Preparation

1. Gently tap bottle on counter top. Remove cap and slowly remove stopper without spilling its contents
2. Add 5.0 ml of dH_20 and replace stopper
3. Gently swirl reconstituted material until all lyophilized contents are dissolved.
4. Label reconstitution date on bottle. This information will be needed when preparing frozen aliquots
5. Allow material to sit for 30 minutes at 15-30'C, periodically swirling bottle during this time.
6. Gently invert bottle several times before removing any portion.

SeraChem Storage and Stability

- Unreconstituted material is stable at 2-8'C until expiration date indicated on label
- Reconstituted material is stable for 5 days at 2-8'C .Frozen aliquots are stable (-20'C) for 2 weeks. Frozen aliquots may not be refrozen.

SeraChem Expected Results

Refer to the "Value Table" enclosed in each kit for result information. Select the IL 300 table and choose the umol/L row to determine manufacturer's range, SD, and mean. After the observed mean and SD are calculated from parallel testing, those values will be used.

SeraChem Testing

Before testing, always gently invert the bottle or thawed aliquot. Control material can be tested either in the 'Sample' area or in the 'Std/Ctrl' area. Reagent blanking (RBL) should be performed with running QC.

Evaluation of SeraChem Results

- Review results for acceptability or the presence of flags in the 'Calibration Results' menu after each quality control run. If any result is unacceptable (flagged), begin troubleshooting. Patient results may not be reported until QC is acceptable for the test.
- Each week, review the Levey-Jennings Charts for both levels of SeraChem. Look for trends or shifts and take corrective action where appropriate.

Handout 11: Daily QC Log

DAILY Q.C. LOG

Clinitek 100 serial # S34A7
Multistix 10 SG:
lot #: ____________
exp. date ____________

Chek-Stix Combo Pak:

Positive Control
lot # ____________
exp. date ____________

Negative Control
lot # ____________
exp. date ____________

EXPECTED	*negative*	neg	neg	neg	1.010 - 1.025	6.0 - 7.0	neg	0.2 - 1	neg	neg	neg	
RESULTS	*positive*	trace - 250	pos	trace - 80	1.000 - 1.015	8.0 - 9.0	trace- 100	2.0 - 8.0	pos	mod - large	trace-moderate	
	units	mg/dl		mg/dl			mg/dl	EU/dl				
Date	**Control**	**Glu**	**Bili**	**Ket**	**S.G.**	**pH**	**Prot**	**Urobili**	**Nit**	**Blood**	**Leuk**	**Initials**
	negative				1.0							
	positive				1.0							
	negative				1.0							
	positive				1.0							
	negative				1.0							
	positive				1.0							
	negative				1.0							
	positive				1.0							
	negative				1.0							
	positive				1.0							
	negative				1.0							
	positive				1.0							
	negative				1.0							
	positive				1.0							
	negative				1.0							
	positive				1.0							
	negative				1.0							
	positive				1.0							

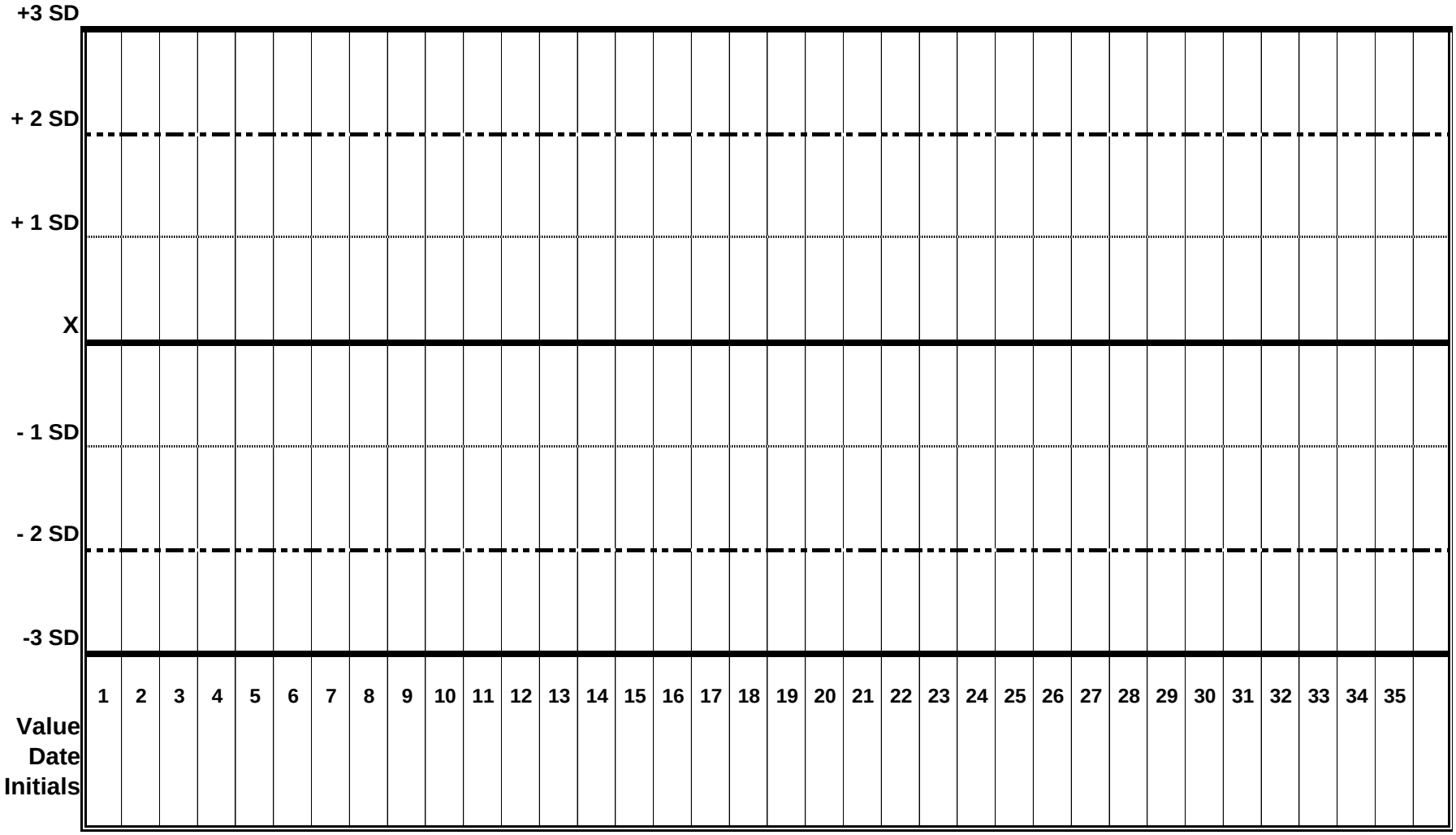
Handout 12: Levey-Jennings (L-J) Chart

Clinic Laboratory

L-J Chart for Control XYZ

Date From: _____ **Date To:** _____ **Analyte** _____

Lot # _____ **Exp Date** _____



Handout 13: Quality Indicator Monthly Tally

Quality Indicator Monthly Tally

month/year _____

DAY	FBC	Diff	Peripheral Smear	Malaria	CD4	QA INDICATOR
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
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23						
24						
25						
26						
27						
28						
29						
30						
31						
Total						

Handout 14: Restricted Access Sign

Handout 15: Report Form

Cape Clinic Laboratory

Lab #:
Drawn by:
Report Date/Time: Collected Date/Time:

Hematology

[ ] CBC [ ] see attachment Tech initials:

Results		Adult Normal Values		
	WBC	♂ 3.3 - 10.0	♀ 3.4 – 9.8	x10⁹/ul
	RBC	4.35 - 5.9	3.69 – 5.13	x10⁶/ul
	HGB	13.7 - 16.7	11.7 – 14.5	g/dl
	HCT	40.5 - 49.7	34.1 – 44.3	%
	MCV	79.7 – 92.0	81.5 – 96.7	fl
	MCH	26.1 – 33.3	26.5 – 33.5	pg
	MCHC	32.2 – 35.0	31.9 – 35.3	g/dl
	RDW	11.6 – 14.4		%
	PLT	140 - 440		x10⁹/ul

[ ] Differential Tech initials:

		Adult Normal Values
	Neutrophils	45 – 66%
	Bands (Neutrophilic)	1 – 12%
	Lymphocytes	20 – 40%
	Atypical Lymphocytes	0 – 2%
	Monocytes	4 – 10%
	Eosinophils	1 – 6%
	Basophils	0 – 2%
	Other	

RBC Morphology [ ] Normal Morphology

	Anisocytosis	Morphology Terms 1 = Slight 2 = Moderate 3 = Marked
	Microcytosis	
	Macrocytosis	
	Hypochromia	
	Poikliocytosis	

Chemistry

[ ] Basic [ ]Comprehensive [ ] LFT [ ] Lipid Tech initials:

	Result	Normal (M / F)		Result	Normal (M / F)
[ ] GLUC		3.9 – 5.8 mmol/l -fasting	[ ] ALT		< 41 / < 31 U/L
[ ] UREA		2.5 – 6.4 mmol/L	[ ] AST		< 37 / < 31 U/L
[ ] Na		136 - 145 mmol/L	[ ] ALP		53 – 128 / 42 – 98 U/L
[ ] K		3.5 – 5.3 mmol/L	[ ] CK		38 – 171 / 26 – 145 U/L
[ ] Cl		98 - 110 mmol/L	[ ] LDH		230 – 460 U/L
[ ] CREAT		62–115 / 53 -97 umol/L	[ ] AMY		27 – 102 U/L
[ ] URIC ACID		208– 430 / 155 - 360 umol/L	[ ] CALCIUM		2.15 – 2.50 mmol/L
[ ] T- PROT		64 – 83 g/L	[ ] PHOS		0.87–1.45 mmol/L
[ ] ALBUMIN		35 – 52 g/L	[ ] CHOL		3.6 – 5.7 mmol/L
[ ] T-BILI		5.1 – 20.5 umol/L	[ ] TRIG		< 2.26 mmol/L
[ ] D-BILI		0.0 – 3.4 umol/L	[ ] HDL-C		0.78 – 1.94 / 0.85–2.38 mmol/L
[ ] GGT		< 55 / < 38 U/L	[ ] calc LDL-C		< 1.71 – 5.44 / 1.48–5.80 mmol/L

Additional Test Requests

Additional In-House Testing

Tech initials:

				Normal Values
[ ] Urine Pregnancy	POS		NEG	N/A
[ ] CRP	POS		NEG	NEG
[ ] Malaria Rapid	POS		NEG	NEG
[ ] RPR	WEAK REACTIVE	REACTIVE	NON REACTIVE	NON REACTIVE
[ ] KOH			Source:	
[ ] Saline Prep				
[ ] Gram Stain				

CCMS Urinalysis

[ ] Tech initials:

		Normal Values
	Color	N/A
	Appearance	N/A
	Urobilinogen	<16 umol/L
	Glucose	Negative (mmol/L)
	Bilirubin	Negative (ummol/L)
	Ketones	Negative (mmol/L)
	Specific Gravity	1.005 – 1.030
	Blood	Negative
	pH	5.0 – 8.0
	Protein	Negative (g/L)
	Nitrite	Negative
	Leukocytes	Negative

[ ] Microscopic Tech initials:

	WBC/HPF	Crystals:
	RBC/HPF	
	EPI-renal/HPF	Casts/LPF:
	EPI-squamous /HPF	
	Bacteria	Trichomonas / Yeast / Parasite:
	Mucus	

Quality Assurance

Date Requested: ___/___/____ Ordering Doctor : _____

[ ] Routine [ ] Stat [ ] Waiting [ ] Fasting [ ] Non-Fasting

QA Review:

Date: ___/___/___ Comments:_____

Doctor Signature: _____

Patient Information

Name (surname, first): _____

D.O.B.: _____/_____/_____ Age: _____ [ ] Male [ ] Female

Patient No.: _____ Diagnosis_____

Patient Contact Information:

Handout 16: Occurrence Report Form

Occurrence Report Form

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 _____

ACTIVITY What Would You Do? Cross-Cutting

PURPOSE:

In this activity, participants integrate laboratory management concepts learned from the ten training modules and apply them to case study scenarios.

RESOURCES FOR FACILITATOR:

- ❑ PowerPoint slides: reference activity write-up for slide numbers

RESOURCES FOR PARTICIPANT:

- ❑ Handout : Case Study Scenarios (XC 29)

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

Management Tasks

Module 1:
- 1.3 Prioritize and assign work according to personnel skill level, workloads, and completion timeframe
- 1.6 Meet with staff individually to communicate expectations, provide feedback, coaching, or on-the-job training to ensure competency and productivity
- 1.8 Maintain and update personnel records (training, certification, competency assessment)

Module 2:
- 2.3 Monitor staff adherence to safety rules & practices
- 10.1 Maintain a library of documents (policies, guidelines, SOPs, references, etc.); review and update annually

Module 3:
- 3.4 Enforce good stock management practices (proper storage, stock cycling, inspection of incoming orders, etc.)

Module 4:
- 1.13 Communicate to upper management regarding personnel, facility, and operational needs
- 4.1 Accurately evaluate needs for equipment, supplies and reagents taking into consideration past patterns, present trends, and future plans

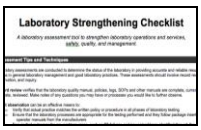
Module 5:
- 5.2 Ensure proper preventive maintenance (i.e., cleaning, proper shutdown) on instruments when used
- 5.4 Review and sign maintenance logs to ensure regular preventive maintenance and timely repairs
- 6.7 Review records of environmental checks & QC trends to assess impact on testing and take corrective action

Module 6:
- 6.12 Enroll in EQA program, monitor results, and take corrective actions
- 6.13 Periodically observe/assess accuracy of staff performance and take corrective action

Module 7:
- 7.3 Enforce good specimen handling and processing practices
- 9.3 Consult with clients regarding specimen quality, test results and findings in a professional manner and ensure each issue is resolved promptly and documented appropriately

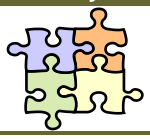
Module 8:
- 8.2 Cross-check test reports against test request to ensure completion of all tests

Module 9:

	9.3 Consult with clients regarding specimen quality, test results and findings in a professional manner and ensure each issue is resolved promptly and documented appropriately 9.4 Conduct customer satisfaction survey to identify areas for improvement Module 10: 10.1 Maintain a library of documents (policies, guidelines, SOPs, references, etc.); review and update annually 10.2 Maintain integrity, organization, and confidentiality of records (client test results, specimen transfer logs, maintenance logs, inventory logs, etc.)
Checklist Items  Laboratory Strengthening Checklist	Module 1: 3.1 Duty Roster And Daily Routine Does the laboratory have a duty roster that covers normal and after hours? 3.5 Personnel Filing System Are records of personnel maintained? 3.6 Laboratory Staff Training Is there a system for training? Module 2: 1.6 Policy and SOPs Accessibility Are policies and SOPs easily accessible/ available to all staff and written in a language commonly understood by respective staff? 1.7 Policies and SOPs Communication Is there documented evidence that all relevant policies and SOPs have been communicated to and are understood and implemented by all staff as related to their responsibilities? 3.7 Staff Competency Assessment and Retraining Is there a system for competency assessment? 12.12 Handling of Sharps Are 'sharps' handled and disposed of properly in 'sharps' containers that are appropriately utilized? 12.18 Post Exposure Prophylaxis Are post-exposure prophylaxis policies and procedures posted and implemented after possible and known exposures? 12.19 Are adverse incidents or injuries from equipment, reagents, occupational injuries, medical screening or illnesses, documented and investigated? 12.21 Laboratory Safety Officer Is a trained safety officer designated to implement and monitor the safety program in the laboratory, including the training of other staff? Module 3: 7.4 Inventory Control Does the lab maintain records for each reagent and consumable that contributes to the performance of examinations? 7.7 Laboratory Inventory System 7.9 Inventory Organization and Wastage Minimization Is First-Expiration-First-Out (FEFO) practiced? 7.10 Product Expiration Are all reagents/test kits in use (and in stock) currently within the manufacturer-assigned expiration or within stability? Module 4: 7.1 Inventory and Budgeting System Is there a system for accurately forecasting needs for supplies and reagents? 7.5 Budgetary Projections Are budgetary projections based on personnel, test, facility and equipment needs, and quality assurance procedures and materials? 11.3 Communication System on Laboratory Operations Does the laboratory communicate with upper management regularly regarding needs for continual improvement? Module 5: 2.1 Routine Review of Quality and Technical Records Does the laboratory routinely perform a documented review of all quality and technical records?

	5.10 Equipment Preventive Maintenance Is routine user preventive maintenance performed on all equipment and recorded according to manufacturer's minimum requirements? 8.7 Documentation of Examination Procedures Are examination procedures documented in a language commonly understood by all staff and available in appropriate locations? 8.12 Are environmental conditions checked and reviewed accurately? Module 6: 3.7 Staff Competency Assessment and Retraining Is there a system for competency assessment? 8.14. Does the laboratory participate in interlaboratory comparison program or alternative assessment systems for all tests? Module 7: 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? (Advisory Services; Resolution of Complaints and Feedback) 4.1 Advice and Training by Qualified Staff Do staff members with appropriate professional qualifications provide clients with advice and/or training regarding required types of samples, choice of examinations, repeat frequency, and interpretation of results? 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? Module 8: 9.6 Authorities and Responsibilities Has the laboratory defined and implemented authorities and responsibilities for the management and use of the laboratory information system– paper based and electronic, including maintenance and modifications that may affect patient care. 10.1 Are all identified nonconforming activities/ work identified and documented adequately? Module 9: 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? 9.6 Authorities and Responsibilities Has the laboratory defined and implemented authorities and responsibilities for the management and use of the laboratory information system– paper based and electronic, including maintenance and modifications that may affect patient care. 10.1 Are all identified nonconforming activities/ work identified and documented adequately? Module 10: 1.3 Document and Information Control System Does the laboratory have a system in place to control all documents and information from internal and external sources? 1.4 Document and Records Is there a list that details all documents used in the quality management system indicating their editions and distribution? 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? (Ethical Conduct; Identification and Control of Nonconformities; Corrective Action)

	1.8 Document Control Log Are policies and procedures dated to reflect when it was put into effect, its location, when it was reviewed and when it was discontinued? 9.5 Archived Data Labelling and Storage Are archived results (paper or data-storage media) properly labelled and stored in a secure location accessible only to authorized personnel? 12.5 Laboratory Access Is the laboratory properly secured from unauthorized access with appropriate signage?

This activity is related to the following activities:	
	None

ACTIVITY AT-A-GLANCE				
Step		**Time**	**Resources**	**Key Points**
1	Introduce the activity and the case scenario	2 min	Slides –see activity write-up Handout	
2	Conduct the case discussion and reporting	10 min		
3	Debrief the case scenario	5 min		
4	Facilitate the second case scenario (Modules 1, 7, 8, 9, 10)	10 min	Slides –see activity write-up Handout	
5	Conclude the Activity	3 min		
	TOTAL TIME:	**20- 30 min/ module**		

PROCESS

Preparation

- Review the case study scenario(s) that pertain to the module described in Handout: Case Study Scenarios.
- Review the associated framework tasks and checklist items noted for each module.

Note: Consider teaching the applicable scenario(s) at the conclusion of each module. This activity provides an opportunity to reinforce key points and to indicate a transition between modules during the workshop.

Step 1. Introduce the activity and the case scenario 2 min

- Project the following Slides to provide an overview for this activity and introduce the first scenario:

Slides 1.57 to 1.58	Module 1	Slides 6.42 to 6.43	Module 6
Slides 2.16 to 2.17	Module 2	Slides 7.28 to 7.29	Module 7
Slides 3.14 to 3.15	Module 3	Slides 8.22 to 8.23	Module 8
Slides 4.13 to 4.14	Module 4	Slides 9.13 to 9.14	Module 9
Slides 5.26 to 5.27	Module 5	Slides 10.18 to 10.19	Module 10

- Refer participants to Handout: Case Study Scenarios. Emphasize to participants that they are the manager of this laboratory and must address each scenario from a managerial perspective.
- Divide the class into groups of 4-5.
- Indicate each group must select a spokesperson to represent their group's answers. Ensure different spokespersons are chosen throughout this cross-cutting activity
- Indicate each group has 5 minutes to discuss the scenario.

Step 2. Conduct the case discussion and reporting 10 min

- Allow participants to discuss and brainstorm about appropriate management approaches.
- Ask each group to take turns reporting their responses to the class. The report should be brief - less than 2 minutes.
- **(Optional** – if time is constrained)- Select one group to present the scenario. Allow the other groups to add thoughts or comments.

Step 3. Debrief the case scenario 5 min

- Discuss and summarize the responses while making connections to the framework tasks and checklist items.
- Ask participants how their approach would have differed prior to this training.

Step 4. Facilitate the second case scenario 10 min

- Request participants to remain in their groups and select a different spokesperson.
- Project the following Slides to introduce the second scenario:

Slide 1.59	Module 1
Slide 7.30	Module 7
Slide 8.24	Module 8
Slide 9.15	Module 9
Slide 10.20	Module 10

- Repeat steps 2 and 3.

Step5. Conclude the Activity 3 min

- Highlight or reiterate the key messages.
- Make sure participants achieved the objectives of this activity.

KEY MESSAGES

- Laboratory documents contain policies, processes, and procedures that provide explicit information for staff and details what work is to be done, and how to handle and perform the work.
- Managers need to ensure that policies, processes, and procedures are in place and staff is trained to follow them.
- Documentation and follow-through are essential for managing laboratory operations.

Can they:

- Integrate the module's lessons and apply them to the case scenario?
- Propose specific steps to address the scenario?

ACTIVITY OBJECTIVES MET?

➢➢ Connections and Applications

Module 1:

First Scenario

- Operator's manuals should be customized to meet your laboratory's needs. For example, if the photograph in the manual that accompanies the monthly sensor cleaning does not adequately pinpoint the sensor's location, an arrow should be drawn on the photograph. Likewise, during the manufacturer's training session if helpful hints are provided, write them onto the page's margin.
- Attendance records for manufacturer-provided service training should be included in each staff member's personnel file.
- Weekly staff meetings provide a perfect opportunity to present the information learned from a training seminar.

Second Scenario

- Efficiency or inefficiency at the start of the day will cascade through and affect the remainder of the day. It is therefore important to communicate and monitor start of shift tasks and their expected time for completing them.

Module 2:

- Criteria defining expectations and acceptable behavior should be stated in the policies and procedures; otherwise, holding staff members accountable is difficult.
- A revision of an approved document is an element of document control. Documentation for revisions include: notation of the revision date on the document, replacement of all obsolete versions with the current document, and documentation of staff notification.
- Selection of safety engineered devices should include staff member input when exploring safety device options such as safety needle devices.

Module 3:

- Managers must bridge the gap between skills/knowledge and staff's behavior/attitude. Even if personnel understand the concept of First-Expiry-First-Out (FEFO), busy staff members will absently grab the first item. Organize the storeroom to facilitate the desired behavior.

Module 4

- Advocacy includes documentation to support your needs and requests.

Module 5

- Criteria outlined in laboratory documents serve as the basis for competency assessment.
- A manager must clarify responsibilities, communicate expectations, and point out consequences for failing to meet these expectations.

Module 6

- EQA survey material is an excellent resource to assess competency as long as the survey is handled in the same manner as the patients' specimens. After the initial results are mailed, consider assigning the survey to all authorized testing personnel. Evaluating individual testing performance can be included with the personnel file as periodic assessment documentation.
- Save all EQA survey materials until after results are returned to assist with troubleshooting any responses graded as 'failed.'

Module 7

➢➢ Connections and Applications

First Scenario

- Seek input when developing policies and procedures that involve interaction between the laboratory and the other clinic areas or customers. Joint collaboration, tailored to the needs of all involved, will be more functional.

Second Scenario

- Consider developing patient information inserts to assist patients with the collection/submission of their samples. Use language that is easily understood by those unfamiliar with laboratory.

Module 8

First Scenario

- Determining the root cause of problems also applies to handling personnel. Never assume, but actively listen. Distraction from personal phone calls can range from concern over the safety of a loved one to plans for a night at the disco. The manager needs to address the impact of distractions; however, keep in mind the next steps chosen must support both the needs of the laboratory and the staff member.

Second Scenario

- An occurrence log allows managers to track trends or to recognize systematic problems.

Module 9:

First Scenario

- Always request that results given verbally are read back to ensure accuracy.

Second Scenario

- A clinician's handbook should include expected turn-around-times (TAT).
- The primary focus must be the patients' best interests (best outcome). Keep this focus in the forefront when reviewing suggestions and complaints.

Module 10

First Scenario

- A policy for document control must be developed. To avoid variations, the current document must be available to all staff members.

Second Scenario

- Customers must have trust in the laboratory product and how that product is handled.

Handout: Case Study Scenarios

What Would You Do?

Module	Case Scenario
1	You are the only staff member available to attend an in-service training seminar on instrument maintenance. You are responsible to train your coworkers using your notes from the training and the instrument operator's manual. List the steps you will take to assure the staff is fully trained. How will you document the training?
	After arriving at work at 8 AM, you already notice a long outpatient queue. By 8:30 AM, the queue is even longer and two workstation daily set-ups have not yet been completed. Both workstations have already received their first batch of patient specimens ready for analysis. You discover that the personnel assigned to the workstations are reading the morning newspaper. As the laboratory manager, how will you handle this situation?
2	A Phlebotomist reports that he stuck himself with a contaminated needle during a blood collection. Earlier in the month during his phlebotomy competency assessment, you noticed that he routinely recapped used needles. After providing feedback during the assessment, you noticed that the laboratory policy does not explicitly state that recapping of needles is prohibited. You decide not to document this finding on the assessment report. ▪ How will you handle this needle stick injury? ▪ How will you persuade management that the policy should include a statement about recapping needles? ▪ Management agrees that the policy should be changed. How will you make the changes and communicate this policy change to the staff? ▪ Three months later, you see the same phlebotomist recapping a used needle. How will you handle this situation?
3	You walk into the store room and see six cubes of diluent ready to expire next week. You know from the last order and physical inventory that this should not be the case. When you check the analyzer, you see the diluent currently in-use has an expiration date of six months from now. After reviewing the reagent log, you realize that the lot number with the longer expiration date has been used on the analyzer for the past several months. ▪ How will you handle the current situation? ▪ What steps will you take to prevent this situation from reoccurring? ▪ How will you monitor future inventory cycling of stock to ensure the corrective action is effective?
4	You recently received an inventory order of chemistry reagents. Your current refrigerator is so overcrowded that the controls can barely fit. You are also aware that your facility will extend hours and will add another ART clinic day. In light of these changes, you forecast a significant increase in the amount of reagents that will need to be ordered. This refrigerator will be unable to hold the required inventory. You need management to purchase another refrigerator before the next ordering cycle. ▪ What information can you provide management that will support your equipment request? ▪ What steps must you take to purchase this new refrigerator? ▪ Management explains they do not have available funds. What alternative solutions can you propose to address your upcoming situation?

Handout: Case Study Scenarios

Module	Case Scenario
5	Upon monthly review of the maintenance and temperature charts, it appears documentation was missed on most days. How will you address: ▪ The staff member who is responsible for performing and documenting the activities? ▪ The staff member who says they forgot or did not know it was expected? ▪ The staff member who explains that at the beginning of the month, the past month's charts were still posted and the new month's charts were not available?
6	You notice that only one staff member performs testing on EQA samples. In fact, the EQA survey was not performed last week because that staff member was on holiday. When you questioned the other staff members they explained they are uncomfortable performing EQA tests. During the same discussion, you discover that the staff member who usually performs the tests has been running the samples 5 times to make certain he has the correct result. You know patients' samples are not to be handled in this manner, and it does not reflect your testing process. How should you handle EQA surveys at your facility?
7	After hours, a clinician obtained a venipucture specimen from a small child. The clinician left the specimen in the laboratory without notifying the laboratory staff on call. The following morning you receive a call from the clinician who asks for the laboratory result. You find no documentation of a result or the receipt of this specimen. After searching, you find the specimen in the refrigerator grossly hemolyzed. ▪ How will you handle this situation? ▪ What steps will you take to prevent a reoccurrence of this situation?
	On Thursday, a patient submits 3 specimens collected during the previous week for AFB testing. None of the specimens are acceptable. You overhear the patient angrily yelling in the reception room that he did what he was told to do. After you clarify the procedure to the patient for recollection, you discover that during the patient's first visit, he was only given the cups with no further explanation. How will you handle this situation?
8	You cross-check results and notice several errors committed by the same staff member. Throughout the day, you notice this staff member preoccupied and distracted with personal phone calls. You feel this distraction is affecting the quality of his work. How will you handle this situation?
	You receive a call from the nurse who indicates that another urine pregnancy test was overlooked. From the occurrence log, you discover that your laboratory easily overlooks urine pregnancy tests when a routine urinalysis is ordered on the same specimen. How will you address this problem?

Handout: Case Study Scenarios

Module	Case Scenario
9	The laboratory scientist called a critical calcium result of 4.20 mmol/L to the nurse. The nurse wrote the verbal result as 2.40 mmol/L (reference value is 2.15 – 2.50 mmol/L) on a slip of paper. After the laboratory's report for this patient was delivered to the nursing unit, the provider noticed the calcium value previously written on a slip of paper did not match the value indicated on the laboratory report. The provider angrily stormed into the laboratory and demanded to know why the result was changed. Upon examination of the report, there was no documentation that a call was made. The nurse told the provider that the laboratory reported the wrong result. How will you handle this situation?
	From a customer satisfaction survey, the 2 most common complaints were: ▪ Why does it take so long to obtain the AFB microscopy report? ▪ The laboratory is too unreliable! There is never any prior notice when a test cannot be performed or significantly delayed because the instrument is broken. How will you address these two complaints?
10	You recently updated a policy to prevent the reoccurrence of a serious issue. Later in the month, the same situation occurred again resulting in a serious injury to a patient. When you questioned the staff member, you discovered he/she only had access to the old version of the policy that did not reflect the updated changes. You realize there are several copies of this policy, but you cannot recall where they are all located. What actions can you take in managing your documents and records?
	You have heard rumors that patients in your community are hesitant to come to your facility because of confidentiality issues. ▪ What actions do you take to ensure the confidentiality of the laboratory results? ▪ When asked, how will you assure your patients that the laboratory maintains confidentiality?

ACTIVITY Planning Improvement Projects – Master Class Cross-Cutting

PURPOSE:

Actual measurable laboratory improvement is the desired outcome of this program. In this small-group learning activity, each participant receives one-on-one coaching in turn to develop an individualized implementable plan for his/her improvement project.

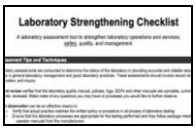
STOP DO NOT conduct this activity until you have completed Using the Improvement Method activity, Managing Performance – The Balanced Scorecard activity, and the specific activity related to the chosen improvement project!

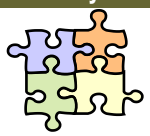
RESOURCES FOR FACILITATOR:

- ❑ PowerPoint slides XC.41 – XC.44
- ❑ Tool 1: Selecting Improvement Projects
- ❑ Tool 2 - Improved IP Plan [Sample Rejections]
- ❑ Flip Chart & Markers

RESOURCES FOR PARTICIPANT:

- ❑ Handout 1: IP Plan [Sample Rejections] (XC 12.01)
- ❑ Handout 2 - IP Plan [Turn Around Time] (XC 12.02)
- ❑ Handout 3 - IP Plan [Stock Outs] (XC 12.03)
- ❑ Handout 4 - IP Plan [Equipment Maintenance] (XC 12.04)
- ❑ Handout 5 - IP Plan [Customer Complaints] (XC 12.05)
- ❑ Handout 6 – Sample Rejection Log (XC 12.06)
- ❑ Handout 7 - TAT Monitoring Form (XC 12.07)
- ❑ Handout 8 - Stock Control Bin Card (XC 12.08)
- ❑ Handout 9 - Equipment Maintenance Data Collection Tool (XC 12.09)
- ❑ Handout 10 - Customer Survey Questionnaire (XC 12.10)
- ❑ Worksheet: Quality Improvement Project Plan (XC 30)
- ❑ Job Aid 1: Improvement Project Report Format (XC 31)
- ❑ Job Aid 2: Improvement Project PowerPoint Template (XC 32)
- ❑ [OPTIONAL] Job Aid 3 - IP Reporting Example - Equipment Maintenance (XC 33)
- ❑ [OPTIONAL] Job Aid 4 - IP Reporting Example - Inventory management (XC 34)

This activity supports the following laboratory management tasks and SLIPTA checklist items	
Management Tasks 	1.12 Develop and implement lab improvement plans based on best practices and feedback from staff, patients, customers, quality indicators, and external assessment
Checklist Items 	11.2 Quality Management System Improvement Measures Does the laboratory identify and undertake continual quality improvement projects? 11.4 Are quality indicators (TAT, rejected specimens, stock-outs, etc.) selected and tracked? 11.5 Is the outcome of the review of quality indicators used to improve lab performance? 11.6 Are the actions taken checked and monitored to determine the effectiveness of improved quality of lab performance?

This activity is related to the following activities:	
	Cross-cutting: Using the Improvement Method Cross-cutting: Managing Performance – the Balanced Scorecard and Extensions

ACTIVITY AT-A-GLANCE				
Step		**Time**	**Resources**	**Key Points**
PHASE I				
1	Explain Improvement Projects	5 min	Slide XC.41	
2	Discuss how to Create a Robust IP Plan	15 min	Handout 1 Tool 2 Handout 6	
3	Introduce the Activity (Improving a Poor IP Plan)	5 min	Slide XC.42 Handout 2 Handout 3 Handout 4 Handout 5	
4	Monitor the Activity	30 min		
5	Debrief the Activity	25 min	Handout 7 Handout 8 Handout 9 Handout 10	
PHASE II				
6	Prepare for the Master Class	30 min	Tool 1 Worksheet Overnight Homework	

ACTIVITY AT-A-GLANCE				
Step		**Time**	**Resources**	**Key Points**
PHASE III				
7	Conduct the Master Class	60 min	Slide XC.43	
8	Debrief the Activity	10 min	Job Aid 1 Job Aid 2 Job Aid 3 Job Aid 4	
9	Conclude the Activity	5 min	Slide XC.44	
	TOTAL TIME:	**3 hr 05 min**		

PROCESS

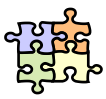
Preparation

This activity has three phases, to be delivered over two separate days.

Day 1	Phase I	Learning how to create a sound IP Plan - Activity Steps 1 to 5
	Phase II	Preparing for the Master Class and overnight homework – Activity Step 6
Day 2	Phase III	Master Class – Activity Steps 7 - 9

For Workshop #1, all three phases are facilitated. For successive workshops, only Phase II and Phase III are facilitated

- Select the improvement projects. Consult Tool 1: Selecting Improvement Projects for a set of projects to select from. Prepare the IP assignment handouts modeling after the four examples in Tool 1 (Workstation Set-up, Safety Audit, SOP Development, and Internal Audit).
- Consider additional improvement projects (not listed in Tool 1) specific to a country or facilities based on:
    - Results of SLMTA baseline assessments and internal audits
    - Findings from SLMTA follow up visits
    - General problems from the entire laboratory network e.g. EQA failures, equipment breakdowns
- Inform participants that they can also implement an additional improvement project of their choice as long as the project is based on an identified problem within the laboratory operations. That project, like any other, will be discussed and agreed with the facilitator during the Master Class.
- Ensure that the chosen improvement project be aligned with activities covered during the workshops before. For example, the *Customer Service* activity should be facilitated prior to assigning an improvement project to monitor customer satisfaction. However, this should not necessarily stop the chosen project, as long as there is a discussion and agreement with the supervisor.
- Schedule the Master Class on the day prior to the close of the workshop to allow sufficient time to answer any questions about the improvement projects.



- Refer to *Managing Performance – The Balanced Scorecard* activity or individual indicator activities for specific improvement project plans, examples, and data collection sheets.
- Prepare the facilitators to assure that there is a clear understanding of the parameters of the projects, including what, when, how, and where to monitor. Make sure that facilitators understand the structure of the master class – individual attention for each person in turn, with the other participants listening & learning.
- Prior to the Master Class (Phase III), divide participants into groups and assign facilitators. If facilitators will be the one conducting the follow-up visits, group participants with the facilitator who will follow them up. It is suggested that 4 participants be assigned to each facilitator. Alternatively, a list of project names with associated facilitators can be posted and the participants may sign up for the class / facilitator that match his/her chosen project.

Overnight Homework: Participants plan how they will implement the

improvement project by completing the Plan section of Worksheet 1: Quality Improvement Project Plan on the night prior to the Master Class. Remind participants that a detailed plan (following examples given in Tool 1) must be completed for each of the Improvement Projects after the Master Class. They can select additional Improvement Projects not assigned as long that is in agreement with the facilitator.

Step 1. Explain Improvement Projects (IP) 5 min

- Project Slide XC.41.
- Provide participants with an overview of the improvement project process. Inform participants that they will be responsible for completing improvement projects in their own lab. The in-country laboratory team will monitor these projects. A report of the progress made and lessons learned will be required at the next workshop session or after a predetermined interval.
- Emphasize that to be able to demonstrate improvement or not, there must be ***2 data points, the baseline and final results***. The difference or no difference between the two will demonstrate improvement or lack thereof. Using the PDCA's Plan phase, the data collected must be able to address the problem, aim and objectives of the problem.
- State that it must be clear from their Improvement Project what problem was identified, what data was collected to identify the problem (baseline), what improvements were implemented to address the problem and what results were obtained at completion of the improvements
- Indicate that the project chosen be of a wider scope that yields improvements in several areas related to the problem being resolved. One way is to look at how many questions from the checklist does the project cover. However, the scope of the projects can be widened as participants gain more confidence in selection and implementing improvement projects.
- Provide the class an overview of this activity. In Phase I of this activity, participants will learn to create a sound IP plan. In Phase II, participants will receive the IP assignments and work as an overnight homework to complete the plans for each IP assigned. In Phase III, a master class with a facilitator/coach will clarify the details, yielding an implementable plan.

Step 2. Discuss How to Create a Robust IP Plan 15 min

- Refer participants to Handout 1: IP Plan [Sample Rejections].
- Indicate that this was a plan from another participant and the class will help improve it. Remind participants of the PDCA Cycle wall poster - if still on the wall, point to it.
- Generate discussions by asking open-ended questions as follows. Facilitate a discussion so that the necessary details will be brought out. Refer to Tool 2 - Improved IP Plan [Sample Rejections] for example.
  - Review the identified problem statement. Does it clearly define what the problem is? Are you able to identify the "WHAT" "WHEN" "WHO" and "WHERE"?
  - Is the aim SMART (Specific, Measurable, Achievable, Realistic, and Time)? Rejection is to be reduced from what to what by when.
  - Look at the element to be measured. Will it be helpful for the laboratory just to know how many samples have been rejected? If 200, so what? Is it not better to know that 200 samples were rejected and 130 of them were

from Male Medical ward or from Clinic Y? Of these 130 from Medical Ward, 90 were because they were clotted. Collection of such baseline data will help the lab understand the problem better, hence be able to come up with possible solutions that are likely to eliminate the root cause.

- Is the target of "very low" measurable? How low will be low and what will be considered close to zero? If there is more than 1 staff in sample reception, responsibility to "all staff" might be too open. In as much as all staff in sample reception must be involved, there must be a specific person who is overally responsible for that activity. Such accountability increases the chance of implementation.

- Distribute or refer participants to Handout 6 – Sample Rejection Log. Indicate that this is an example of a data collection tool for sample rejection. For the improvement project that the participant select, such data collection tools might be required.
- Indicate to participants that this is how each one of their plans will be reviewed in the Master Class. The review of their plans will be done in groups, hence all must participate, in the same way as above, in helping their colleague refine their plan and make it implementable.

Step 3. Introduce the activity (Improving a Poor IP Plan) 5 min

- Project Slide XC.42 to introduce the activity.
- Divide participants into four groups and assign each group one of the four poor IP plans (below).
  - Handout 2 - IP Plan [Turn Around Time]
  - Handout 3 - IP Plan [Stock Outs]
  - Handout 4 - IP Plan [Equipment Maintenance]
  - Handout 5 - IP Plan [Customer Complaints]

Step 4. Monitor the activity 30 min

Provide assistance and coaching as needed.

Step 5: Debrief the activity 25 min

- Ask each group to present its improved plan (3 minutes per group). Facilitate a discussion as necessary after each presentation to ensure all key points are covered.
- Distribute or refer participants to the following sample data collection tools. Comment on each and highlight how they can be used in relation to the IP plans given in the activity.
  - Handout 7 - TAT Monitoring Form
  - Handout 8 - Stock Control Bin Card
  - Handout 9 - Equipment Maintenance Data Collection Tool
  - Handout 10 - Customer Survey Questionnaire
- Emphasize that a data collection tool helps to objectively collect data as shown in the activity examples.

Step 6. Prepare for the Master Class — 30 min

- Distribute the IP assignment handouts you have created (Tool 1 and any others created) and Worksheet: Quality Improvement Project Plan (one sheet for each IP assigned).
- Explain Improvement Projects assignment.
- Assign participants to facilitators.
- Ask participants to complete the homework overnight by completing the Plan section of Worksheet for each IP.

Step 7. Conduct the Master Class — 60 min

- Project Slide XC.43. If possible, place each group in a separate section of the room.
- Each participant is allowed 15 minutes of individual time. Each individual plan will be reviewed. The facilitator will determine if the plan is sound, if the details are well thought out, and if the participant understands the concepts. The others in the group will listen to the discussion and learn from each other's situations and can participate as well in refining the plan.

Step 8. Debrief the activity — 10 min

- Distribute or refer participants to Job Aid 1: Improvement Project Report Format. State that each participant will be required to produce a full write up of their improvement project. Briefly explain the report format highlighting the subheadings. Where participants have no access to computers, the same must be done in handwritten form
- Distribute or refer participants to Job Aid 2: Improvement Project PowerPoint Template In addition to the IP Report, each participant must summarize the report into a 10-minute PowerPoint presentation. The participant will use the summarized PowerPoint in the next workshop. Where participants have no access to computers, the same must be done in handwritten form
- [OPTION] Distribute sample IP reports (Job Aid 3 - IP Reporting Example - Equipment Maintenance and Job Aid 4 - IP Reporting Example - Inventory management) for further illustration.
- At the end of the training, remind participants of the three improvement projects. Specify the time lines for starting, conducting, and for completing the project.
- Clarify whom and how the participants should contact if there are questions regarding the projects.
- Assign the in-country laboratory team the responsibility for monitoring the progress on the projects. Inform the participants of the dates for the 2 follow up visits.
- Assure participants that their assigned facilitators will always be available to assist them in this process.

Step 9. Conclude the Activity — 5 min

- Link to *Managing Performance – the Balanced Scorecard* activity and *Using the Improvement Method* activity. Highlight or reiterate the key messages below.
- Project Slide XC.44. Remind participants that lab improvement benefits patient care. The patient is the focus of the health care system!
- Make sure participants achieved objectives of the activity.

KEY MESSAGES

- Data collection is an important part of laboratory improvement.
- Planning an improvement project requires thinking through the specific details.
- Individuals learn from each other regarding planning an improvement project.
- Improvement projects require supervisory visits with significant support.

Can they:

- Collect Data to assess laboratory operations?
- Plan an improvement project?
- Implement an improvement project?

ACTIVITY OBJECTIVES MET?

Tool 1: Selecting Improvement Projects

Listed below are Improvement Projects (IP) by workshop that you can select from. Once selected, a detailed plan of implementation must be developed using Worksheet: Quality Improvement Project Plan. Four examples of IP assignments are provided in this tool: Workstation Set-up, Safety Audit, SOP Development, and Internal Audit.

Activity	Improvement Project	What is to be measured
Workshop #1		
Balanced Scorecard	Monitor one of the Quality Indicators presented in this activity	Chosen Quality Indicator
Floor Plan Activities	Re-design your laboratory layout	Show before and after layout (or pictures). List the number of changes made to the layout or measure by way of improved TAT before and after.
Competency Assessment	Design a competency assessment program for the laboratory and conduct some assessments	Number of staff competent on each procedure
Workstation Set-up See example	Improve workstation set-up	Availability of required items and documentation of each workstation. See example
Workshop #2		
Safety Audit See example	Conduct a safety audit using the Safety section of the Checklist	Improvement of score for the Safety section of the Checklist
Inventory Management	Introduce an inventory management system: monitor consumption, calculate minimum stock / reorder levels, stock counts, reagent inventory list, review of suppliers and list of preferred suppliers	Stock outs, number of supplies with stock cards, number of stock with documented minimum stock or re-order level, consumption rate and stock counts, number of orders tracked and inspected on receipt, number of supplier reviews and preferred supplier list created
Equipment	Equipment maintenance and service	Number of days and times (weekly, bi-weekly, monthly, etc.) equipment maintained by user as per manufacturers requirements, measure of equipment down time, number of equipment serviced on time, number of records of after service checks

Tool 1: Selecting Improvement Projects

Activity	Improvement Project	What is to be measured
Documentation See example	Improve documentation (Policies, SOPs, quality logs and checklists) in the laboratory	Number of policies available vs. required by WHO AFRO SLIPTA checklist question 1.3. Number of SOPs available vs. required by the laboratory plus listed on question 1.3 of the WHO SLIPTA checklist. See example
Workshop #3		
Quality Control	Monitor running of IQC	Number of days IQC run and reviewed by tester. Number of L-J charts plotted as the IQC is done. Number of corrective actions done for failed IQC. Number of IQC logs and L-J charts reviewed by supervisor.
External Quality Assurance	Monitor performance and documentation of EQA	Number of tests enrolled on EQA vs tests done in the lab, EQA pass rate (analytes done vs. passed), EQA submitted on time. Documentation of (i) receipt of EQA material (who received, when and in what condition) (ii) date tested and results submitted and by whom (ii) review of results, corrective action and review of corrective actions by supervisor
Specimen Management	Monitor specimen rejection	Specimen rejection rates, number of specimens rejected by sample type, test, source e.g. which ward, reason for rejection
Referral Specimens	Monitor results of referral specimens	Number of tests referred, tracking of referral results and TAT, reviews of referral logbook.
Customer Service	Customer satisfaction survey	Customer Satisfaction Survey results, follow up actions
Internal Audit See example	Conduct an internal audit using the WHO AFRO SLIPTA checklist sections 1-11	Improve of the checklist score. Document action plans with timelines and tasks assigned to personnel. Track number of non conformities (YES, Partial and NOs) from baseline to final

Tool 1: Selecting Improvement Projects

Compulsory Activities

These are projects that are not extensive enough to be considered a SLMTA IP. These will be assigned as "compulsory activities" i.e. all participants must implement these in addition to the selected IP.

- Laboratory Organization - "Sort / Straighten / Shine / Standardize / Sustain" an area of the laboratory:
  - The storeroom
  - One workstation (e.g., the phlebotomy area)
  - The office
  - The records
  - Remove non-functioning equipment from the laboratory
- Duty Roster
- Management Calendar
- Equipment Master list/Inventory

Tool 1: Selecting Improvement Projects

IP: Workstation Set-up

Workstation Set-up: Improving workstation set up

1. Discuss and explain the IP in a team meeting. Document the minutes
2. Create an initial listing of every analytical workstation in your laboratory as follows, for example FBC workstation, CD4 workstation, sample reception workstation, sample referral workstation, TB microscopy screening, TB staining station…..Fill these in column 1 of the data collection tool below
3. List all the equipments associated with each work station e.g. CD4 workstation: FACS Count. Also include ancillary equipments within that workstation e.g. for CD4 workstation: blood mixer, printer, 2-8°C Fridge. Fill these in column 2 of the data collection tool below
4. Assign specific individuals specific workstations to work on for the IP.
5. For baseline data, complete columns 3. If the item is in place e.g. maintenance log indicate by marking column under Y (YES). If the item does not apply e.g. QC log in the sample collection area indicate N/A in any of the columns Y or N.
6. Count the number of Y (YES) and N (NO) for each item e.g. SOPs: Yes = 12, NO = 28
7. Add up the number of Y and N for all items e.g. if Service Stocker = 15 Yes, small parts = 0 YES, book of life = 2 YES……total YES = 15 + 0 + 2 + …. …. = 17 YES (baseline)

Data Collection Tool

Work-station	Equipment + Ancillary Equipment	Uniquely Identified		Service Sticker		SOP		QC Log		Maintenance Log		Backup Plan		Small parts		Competency Assessment checklist		Book of Life		User Manual		Quality Docs Reviewed	
		Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N
Automated FBC	Sysmex K21																						
	Coulter Act 5																						
	Blood Rotator																						
Totals (Y or N)																							

8. Report baseline data at the next team meeting
9. Assign tasks to be completed to specific individuals within certain workstations with timelines for completion. See example below

Deficiency Identified	Cause or Reason for the Deficiency	Proposed Corrective Action	Action Plan					
			Task to be completed	Who is responsible	By When	Review 1	Review 2	Review 3
			1)					
			2)					
			3)					
			1)					
			2)					

Tool 1: Selecting Improvement Projects

10. Review the progress of the IP monthly. Indicate progress of the assigned tasks under review 1 to 3.
11. At the end of the IP (1-2 weeks before next workshop), collect final data using the same data collection tool
12. Add up the total Y and N for each item and for all items as given in steps ?//
13. Compare baseline and final data
14. For areas still not improved, discuss how these will be improved.
15. Complete another action item for the incomplete tasks as in the above action plan
16. Prepare report to present at the workshop

This improvement project supports the following SLIPTA checklist items:

1.3 Are policies and standard operating procedures (SOPs) for laboratory functions current and available and approved by an authorized person?

1.4 Are policies and SOPs easily accessible / available to all staff?

1.5 Is there documentation that all staff have read and understood the policies and SOPs that relate to their responsibilities in the laboratory?

2.2 Does the laboratory supervisor routinely perform a documented review of all quality records?

2.3 Does the laboratory identify and undertake quality improvement project?

2.4 Does the laboratory communicate with upper management regularly regarding personnel, facility, and operational needs?

3.5 Are personnel files present? *: Periodic Performance Review- including observation, competency assessment, coaching/feedback, on-the job training.*

5.3 Is current equipment inventory data available on all equipment in the laboratory?

5.4 Is relevant equipment service information readily available in the laboratory?

5.6 Is routine calibration of laboratory equipment – including pipettes, centrifuges, balances, and thermometers – scheduled, indicated on the equipment, and verified?

5.7 Is routine preventative maintenance performed on all equipment and recorded according to SOPs?

5.9 Is stock of expendable parts present on site?

5.12 Are there back-up procedures for equipment failure?

5.13 Are the equipment manufacturer's operator manuals readily available to testing staff?

9.2 Have acceptable ranges been defined for all temperature dependent equipment with procedures that detail what to do when temperatures are out of range?

9.10 Are SOPs for specific testing present and easily accessible at the workbench?

9.11 Is internal quality control (IQC) performed, documented, and reviewed prior to release of patient results?

9.12 Is the laboratory result report(s) in a standard form determined to be acceptable in consultation with clients?

9.18 Does the laboratory participate in a Proficiency Testing (PT) scheme or inter-laboratory comparison?

10.2 Are out-of-control runs reviewed and submitted to troubleshooting and cause analysis?

Tool 1: Selecting Improvement Projects

IP: Safety Audit

Safety Audit: Implementing, conducting and improving performance on safety audit

*The **ISO 15190:2003(E) states that** "Safety is the primary consideration; cost is of secondary importance"*

Steps

1. Discuss the IP in the team meeting. Document the minutes
2. Using Section 12 of the WHO SLIPTA checklist or any other safety audit checklist approved by the Lab, perform a Safety Audit.
3. List all areas identified as deficient or noncompliant from the safety audit findings. Specify if the deficiency applies to all areas of the laboratory or only to specific sections of the laboratory. E.g. "the Lab does not have suitable chairs" instead of " Hematology and bleeding room have chairs that are absorbent to fluids, hence not suitable for lab use"
4. Present the audit findings to the laboratory staff and upper management. Document the minutes for these meetings.
5. Propose corrective actions for all identified areas that include an action plan developed with clear timelines. The proposed corrective action should be based upon the cause or reason for the deficiency. See table below

Deficiency Identified	Cause or Reason for the Deficiency	Proposed Corrective Action	Action Plan					
			Task to be completed	Who is responsible	By When	Review 1	Review 2	Review 3
			1)					
			2)					
			3)					
			1)					
			2)					

1) Document all corrective and follow-up actions taken.
2) Review the action plans at after each due date and document progress or proposed new dates.
3) Perform the final safety audit at the end of the IP
4) List the audit findings and action items as done at baseline
5) Review the findings
   - Which areas were able to be sustained?
   - Is there need to train the rest of the staff in the newly introduced and sustained areas?
   - Which areas persisted as non conformities and why? What is the plan for the Lab to resolve these?
6) Compile a report to report at the next SLMTA workshop

This improvement project supports the following SLIPTA checklist items:

A ll Questions under Section 12 of the checklist

Tool 1: Selecting Improvement Projects

IP: Documentation

Documentation: Improving documentation in the Laboratory

The clause below refers to documentation and document control from ISO 15189
Clause: 4.3.1. *The laboratory shall define, document and maintain procedures to control all documents and information (from internal and external sources) that form its quality documentation. A copy of each of these controlled documents shall be archived for later reference and the laboratory director shall define the retention period. These controlled documents may be maintained on any appropriate medium – including, or not, paper.*
National, regional and local regulations concerning document retention could apply.

Data Collection Tool

#	Document (SOP/Policy/Works station Tasks/Log/checklist etc)	In Place (Yes/No)			
		Baseline Yes/No	Comment (Draft, authorized, expired, read by all staff)	Final Yes/No	Comment (Draft, authorized, expired, read by all staff)

Steps

1. Discuss the IP in the team meeting
2. Assign all sections to:
   - Make a list of all activities and tests conducted in their section

   <u>SOPs</u>
   - Using the data collection tool above, list the SOPs needed for each of the procedures and activity listed
     - E.g. In Chemistry, activities include: Chemistry testing using Selectra junior Analyzer: ***SOP for chemistry analysis using Selectra Junior***
     - Maintenance of Selectra Junior: ***SOP for Maintenance of Selectra Junior***
     - Training Plan

   <u>Training Plans</u>
     - Training plan for each test or workstation listed above

   <u>Logs</u>
   - Maintenance logs for Selectra Junior, centrifuge
   - Temperature logs for fridge, freezer and room
   - Cleaning of room and bench surfaces logs
   - Quality Indicator monitoring logs

   <u>Checklists</u>
   - Competency Assessment checklists for chemistry testing using Selectra Junior

NOTE: Do this for all sections of the laboratory, including sample reception, sample referral, cross check areas, store room, phlebotomy.

Tool 1: Selecting Improvement Projects

3. Include all SOPs and Policies from **Question 1.3** on the WHO AFRO SLIPTA checklist.
4. For each document, indicate under comments section whether it is:
   - In place or not?
   - In draft form?
   - Authorized?
   - Expired?
5. After listing all the documents count how many:
   - Are supposed to be in place?
   - Are in place?
6. For those in place how many are:
   - In draft?
   - Expired? or
   - Read by all staff?
7. After collecting baseline data, present to lab team. Document minutes.
8. List improvements that need to be put in place. Formulate an Action Item table

Deficiency Identified	Cause or Reason for the Deficiency	Proposed Corrective Action	Action Plan					
			Task to be completed	Who is responsible	By When	Review 1	Review 2	Review 3
			1)					
			2)					
			3)					
			1)					
			2)					

9. Continue monitoring the progress of the project by reviewing monthly
10. At the end of the project timeline, collect final data using the same data collection tool 1-2 weeks before next workshop
11. Compare baseline and final data results. If there are still some outstanding action items or new ones, list the action items as done at baseline
12. Compile a report to report at the next SLMTA workshop

All documents produced must follow the laboratory document control system. i.e. the document must have:

- Document control number
- Version number
- Author
- Authorizer
- Effective date
- Date of retrieval
- Laboratory name/ministry of health
- Page numbers

All documents must be listed on the document Master list

Tool 1: Selecting Improvement Projects

This improvement project supports the following SLIPTA checklist items:

1.1 Is there a system or procedure for document & record control and retention?
1.2 Are documents & records properly maintained, easily accessible and indicated on an up-to-date Master List?
1.3 Are policies and standard operating procedures (SOPs) for laboratory functions current, available, and approved by an authorized person?
- ✓ *Each testing procedure performed including QC guidelines, acceptability, what to do if QC is out of range*
- ✓ *Equipment Maintenance*
- ✓ *Specimen Collection & Processing*
- ✓ *Specimen pre- and post-test storage*

1.4 Is there documentation that all staff have read and understood the policies and SOPs that relate to their responsibilities in the laboratory?
1.5 Is there a system for competency assessment of staff (both new hires and existing staff) and does it include planning and documentation of retraining and reassessment, when indicated?
1.9 Are invalid or discontinued policies and procedures removed from use and retained according to schedule?
3.6 Does the laboratory have adequate training policies, procedures, and/or training plan, including cross training within the laboratory team, one-on-one mentoring, and/or off-site external training
4.2 Is there a laboratory handbook for clinicians' use that includes information on services offered, quality assurance, laboratory operations, sample collection and transport, and agreed turnaround times, etc.?
5.7 Is routine preventative maintenance performed on all equipment and recorded according to the SOPs?
5.12 Are there back-up procedures for equipment failure?
9.10 Are SOPs for specific testing present and easily accessible at the workbench?
- ✓ *Does the SOP include procedures that ensure specimen integrity and prevent mixing of samples?*
- ✓ *Is intermixing of test kit contents from different lot numbers prohibited, unless otherwise specified?*
- ✓ *Where appropriate, it there a procedure for performing grading and reporting microscopic examinations?*

Tool 1: Selecting Improvement Projects

IP: Internal Audit

Internal Audit: Implementing, conducting and improving performance on internal audits

Quoted below is the ISO 15189 Clause on internal audit
"4.14.1 *In order to verify that operations continue to comply with the requirements of the quality management system, internal audits of all elements of the system, both managerial and technical, shall be conducted at intervals defined by the system itself. The internal audit shall progressively address these elements and emphasize areas critically important to patient care."*

Data Collection Tool

Section 1: Documentation							
	Baseline			**Final**			**Comment**
	Y	**P**	**N**	**Y**	**P**	**N**	
Is there a SOP on how to conduct Internal Audit?							
Is there a person trained in conducting internal audits (Manager, Quality Manager or someone else)?							
Is there an internal audit checklist							
Section 1: Total Marks							
Section 2: The Audit							
	Baseline			**Final**			
Total Internal Audit Marks							
Total number of conformities (YES)							
Total number of Partials (P)							
Total number of non conformities (NO)							

Steps

1. Discuss the IP in the team meeting.
2. Set action items relate to the IP. Some of the action items will have specific activities to be dome to achieve the action item e.g. if there is no internal audit SOP
   - Action Item: Quality Officer to write SOP
   - Activities:
     - QA Officer draft SOP
     - Supervisor review SOP
     - QA Officer train staff on SOP
3. Using the internal audit checklist perform an internal audit.
4. List all areas identified as deficient or noncompliant from the internal audit findings. Specify if the deficiency applies to all areas of the laboratory or only to specific sections of the laboratory. E.g. instead of saying "Lab not performing IQC consistently but say CD4 section not performing IQC on the FACS Count"

Tool 1: Selecting Improvement Projects

5. Present the audit findings to the laboratory staff and upper management. Document the minutes for these meetings.
6. Propose corrective actions for all identified areas that include an action plan developed with clear timelines. The proposed corrective action should be based upon the cause or reason for the deficiency

Deficiency Identified	Cause or Reason for the Deficiency	Proposed Corrective Action	Action Plan					
			Task to be completed	Who is responsible	By When	Review 1	Review 2	Review 3
			1)					
			2)					
			3)					
			1)					
			2)					

1) Document all corrective and follow-up actions taken.
2) Review the action plans at after each due date and document progress or proposed new dates.
3) Perform the final internal audit at the end of the IP
4) List the audit findings and action items as done at baseline
5) Review the findings
   - Which areas were able to be sustained?
   - Is there need to train the rest of the staff in the newly introduced and sustained areas?
   - Which areas persisted as non conformities and why? What is the plan for the Lab to resolve these?
6) Compile a report to report at the next SLMTA workshop

Tool 2: Improved IP Plan [Sample Rejections]

Sample Rejections

PLAN

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:

Observed high sample rejection rate. There have been an increased number of complaints from clinicians regarding no results available due to laboratory rejecting unsatisfactory samples for testing.

II. Collect Baseline Data:

What data will be collected? *Sample rejection rate*

Method - How will the data be collected? *Number of samples rejected will be counted and rejection rate calculated. Results will be analyzed by reason and ward/clinic. Samples rejected will be recorded as they are rejected.*

Who is responsible for collecting data? *Sample receiving staff and laboratory testing personnel*

What are the tools/forms/checklists to be used? *The revised Sample Rejection Log Document #GEN-FRM-001*

Over what period of time will the data be collected? *21 May through 15 June 20xx (4 weeks)*

When will the data be reviewed? *15 June 20xx*

III. Analyze the baseline data:

What is wrong? _____

Where is it happening? _____

When is it happening? _____

Who is involved? _____

IV. Identify possible causes:

Poor sample collection technique (will revisit causes once baseline data is analyzed)

V. Propose possible solutions:

Resend instructions on proper sample collection techniques to all sites (will revisit once baseline data is analyzed)

Tool 2: Improved IP Plan [Sample Rejections]

SECTION B: Action Plan

I. Identified problem:

Unable to perform testing due to the receipt of unsatisfactory specimens. Further clarification still pending until baseline data is analyzed.

II. AIM Statement (overall goal of this project) *To reduce sample rejection percentage to below 2% by 1 September 20xx*

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

Action item	Responsible Person	Timeline	Signature
Revise Sample Rejection Log to include location, rejection reason, test requested	*Tech 1*	*19 May 20xx*	
Adopt #GEN-FRM-001 and distribute to laboratory sample receiving areas	*Quality Officer*	*21 May 20xx*	
Staff meeting to present IP project	*Laboratory Manager*	*23 May 20xx*	
Review Specimen Rejection criteria, policy and procedure and update as needed	*Quality Officer*	*1 June 20xx*	
Review specimen collection procedures and update as needed	*Quality Officer*	*8 June 20xx*	
Resend instruction on proper sample collection techniques to all sites	*Tech 2*	*12 June 20xx*	
Analyze sample rejection rates by sending sites	*Quality Officer*	*15 June 20xx*	
Present summary of baseline analysis to improvement team	*Quality Officer*	*18 June 20xx*	

IV. Select and Define ELEMENT TO BE MEASURED (to monitor effectiveness of implemented actions) *The % of samples rejected*

$$\frac{\text{Number of samples rejected}}{\text{Total number of samples received}} \times 100\% = \%\text{ of samples rejected}$$

V. Results of element measured at baseline _____

VI. Acceptable results (target for this measure) *rejection rate less than 2%*

Tool 2: Improved IP Plan [Sample Rejections]

VII. Data Collection

How will the data be collected? *Samples rejected will be recorded as they are rejected at sample reception and at any stage of testing.*

Who is responsible for collecting data? *Sample receiving staff and laboratory testing personnel*

What are the tools/forms/checklists to be used? *The revised Sample Rejection Log Document #GEN-FRM-001*

How often will the data be collected? *At the end of the work shift, the sample receptionist will deliver the completed logs to the Quality Officer's office.*

How often will the data be reviewed? *Rejection log will be reviewed weekly by the Quality Officer*

How often will the data be analyzed to monitor effectiveness of implemented actions? *An analysis will be performed every 2 weeks by the Quality officer*

Handout 1: IP Plan [Sample Rejections]

Sample Rejections

PLAN

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:

There have been an increased number of complaints from clinicians on no result returns due to lab rejecting unsatisfactory samples. Yesterday, a nurse from the ward yelled at the receptionist for rejecting most of her samples

II. Collect Baseline Data:

What data will be collected? *Records of samples rejected will be collected from the sample register at the reception*

Method - How will the data be collected? *Count the number of samples rejected*

Who is responsible for collecting data? *Sample reception staff*

What are the tools/forms/checklists to be used? *Sample registers*

Over what period of time will the data be collected? *Daily as samples are rejected*

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: *The wards deliver samples that are no good*

V. Propose possible solutions: *The wards should deliver good samples for testing*

Handout 1: IP Plan [Sample Rejections]

SECTION B: Action Plan

I. Identified problem: *Too many samples being rejected*

II. AIM Statement (overall goal of this project) *To reduce the number of rejected samples*

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) *Total number of samples rejected*

V. Results of element measured at baseline _____

VI. Acceptable results (target for this measure) *Very low numbers (almost zero) of rejected samples.*

VII. Data Collection

How will the data be collected? *Records of samples rejected will be collected from the sample register at the reception.*

Who is responsible for collecting data? *Sample reception staff*

What are the tools/forms/checklists to be used? *Sample registers*

How often will the data be collected? *We will continue to collect data until the numbers are lower than the baseline.*

How often will the data be reviewed? _____

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

_____

Handout 2: IP Plan [Turn Around Time]

Turn Around Time

PLAN

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:

Doctors complained about poor quality and delayed reporting on hemoglobin and malaria smear results. The Maternal-Child Health Clinic is unable to treat their patients in a timely fashion.

II. Collect Baseline Data:

What data will be collected? *The times of all laboratory samples*

Method - How will the data be collected? *The turnaround time (TAT) of samples will be recorded by tracking time samples come into the laboratory and the time results are released*

Who is responsible for collecting data? *Sample reception staff*

What are the tools/forms/checklists to be used? *Sample registers*

Over what period of time will the data be collected? *One week*

When will the data be reviewed? *The following week*

III. Analyze the baseline data:

_____

IV. Identify possible causes:

_____

V. Propose possible solutions:

_____

_____

Handout 2: IP Plan [Turn Around Time]

SECTION B: Action Plan

I. Identified problem: *Poor turnaround time*

II. AIM Statement (overall goal of this project) *To reduce TAT to limits acceptable for our clients (patients and clinicians)*

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

Action item	Responsible Person	Timeline	Signature
Create a new log	*Quality Officer*	*Next week*	

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

The TAT of samples received in the laboratory during working hours

V. Results of element measured at baseline _____

VI. Acceptable results (target for this measure) *Good TAT*

VII. Data Collection

How will the data be collected? *The TAT of hematology samples will be recorded by tracking time samples come into the hematology area and the time results released*

Who is responsible for collecting data? *Hematology Staff*

What are the tools/forms/checklists to be used? *The newly created log*

How often will the data be collected? *Daily as samples are received and results released*

How often will the data be reviewed? *At the end of each work day*

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

Handout 3: IP Plan [Stock Outs]

Stock Outs

PLAN

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:

Irregular results (i.e. sometimes LFTs are done and sometimes they are not done) Impromptu provision of information if services are not available. This inconsistency of services is due to reagent and consumable stock outs and use of expired stock by laboratory

II. Collect Baseline Data:

What data will be collected? *Record number of stock outs and number of expired reagents in use*

Method - How will the data be collected? *Counting stock outs and expired reagents*

Who is responsible for collecting data? *Quality Officer*

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: _____

IV. Identify possible causes: *Central supply does not send us what we need*

V. Propose possible solutions: *Ensure there is a stock card for each reagent and consumable.*

Handout 3: IP Plan [Stock Outs]

SECTION B: Action Plan

I. Identified problem: *Many reagent and consumable stock outs and use of expired stock by the laboratory*

II. AIM Statement (overall goal of this project) *To reduce number of stock outs and use of expired reagents*

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) *Stock outs and use of expired reagents*

V. Results of element measured at baseline _____

VI. Acceptable results (target for this measure) *Reduced stock outs and number of expired reagents in use*

VII. Data Collection

How will the data be collected? *Record number of stock outs and number of expired reagents in use*

Who is responsible for collecting data? *All staff; Staff must capture information as they use reagents and when they cannot find what they want in the store room.*

What are the tools/forms/checklists to be used? *No tools to be in place to use*

How often will the data be collected? *Daily as each time a staff member visits the store room*

How often will the data be reviewed? *With each order received from central supply*

How often will the data be analyzed to monitor effectiveness of implemented actions? *With each order received from central supply*

Handout 4: IP Plan [Equipment Maintenance]

Equipment Maintenance

PLAN

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:

Service engineer indicated the frequent breakdowns of the analyzers have been due to maintenance not being performed.

II. Collect Baseline Data:

What data will be collected? *Retrospective study of maintenance logs*

Method - How will the data be collected? *For each log located, the number of tic marks will be counted*

Who is responsible for collecting data? *Lead tech from each department*

What are the tools/forms/checklists to be used? *Maintenance logs from previous months*

Over what period of time will the data be collected? *As many logs that can be located*

When will the data be reviewed? _____

III. Analyze the baseline data: _____

IV. Identify possible causes: *Staff not doing maintenance*

V. Propose possible solutions: *Have a staff meeting and tell staff to do maintenance*

Handout 4: IP Plan [Equipment Maintenance]

SECTION B: Action Plan

I. Identified problem: *Poor maintenance of equipment*

II. AIM Statement (overall goal of this project) *To improve equipment maintenance*

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

Action item	Responsible Person	Timeline	Signature
Ensure staff has necessary logs	*Lead tech*	*soon*	

IV. Select and Define ELEMENT TO BE MEASURED (to monitor effectiveness of implemented actions) *Levels of performance of equipment performance*

V. Results of element measured at baseline _____

VI. Acceptable results (target for this measure) *Good equipment maintenance documentation*

VII. Data Collection

How will the data be collected? *Records of equipment maintenance over a period of time*

Who is responsible for collecting data? *All staff*

What are the tools/forms/checklists to be used? *Maintenance logs*

How often will the data be collected? *Daily*

How often will the data be reviewed? *Monthly*

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

Handout 5: IP Plan [Customer Complaints]

Customer Complaints

PLAN

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:

Hospital administration wanted to know why the majority of doctors were requesting patients to have investigations carried out by an external laboratory.

II. Collect Baseline Data:

What data will be collected? *See Data Collection under Section B*

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? *Doctors are not satisfied with laboratory services.*

Where is it happening? _____

When is it happening? _____

Who is involved? _____

IV. Identify possible causes:

_____

_____

_____

V. Propose possible solutions:

There is a need for doctors and laboratory staff to have regular meetings.

Handout 5: IP Plan [Customer Complaints]

SECTION B: Action Plan

I. Identified problem: *Doctors complaining too much.*

II. AIM Statement (overall goal of this project) *To improve relationship between laboratory and doctors.*

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

Action item	Responsible Person	Timeline	Signature
Talk with doctors *Schedule meetings*			

IV. Select and Define ELEMENT TO BE MEASURED (to monitor effectiveness of implemented actions) *Doctor's complaints to the laboratory.*

V. Results of element measured at baseline *Staff feels it is very high.*

VI. Acceptable results (target for this measure) *Reduced doctors' complaints*

VII. Data Collection

How will the data be collected? *By speaking to doctors during their breaks*

Who is responsible for collecting data? *Laboratory staff on duty for that day*

What are the tools/forms/checklists to be used? *Customer satisfaction survey used by the hospital from last year's survey of hospital clients*

How often will the data be collected? *During break times of tea and lunch until the number of responses required I achieved*

How often will the data be reviewed? *At the end of break times*

How often will the data be analyzed to monitor effectiveness of implemented actions? *At the end of break times*

Handout 6: Sample Rejection Log

Sample Rejection Log

Month_____ **Year**_____

Facility	Condition of Specimen							
	Clotted	Unlabeled Sample	Form with no sample	Insufficient	Grossly haemolysed	Sample too old	Others	Total
Total								

Handout 7: TAT Monitoring Form

LABORATORY SERVICES	Turnaround Times Monitoring Form	Effective Date:
Written by Camilla Letsota	Document #: Version: 1	Approved by:

Turnaround Times Monitoring Form

Section_____ **Test**_____

#	Date & Day	Lab ID/Patient Name	Sample Reception		Testing Bench		Processing (e.g. pippeting for CD4, creating worklist for FBC)		Testing (e.g. time on results printout)		Result Dispatching		Time (hrs)
			Date	Time In	Date	Time In	Date	Time In	Date	Time	Date	Time out	
	Indicate time elapsed above each arrow		→		→		→		→				
	Indicate time elapsed above each arrow		→		→		→		→				
	Indicate time elapsed above each arrow		→		→		→		→				
	Indicate time elapsed above each arrow		→		→		→		→				
	Indicate time elapsed above each arrow		→		→		→		→				

Handout 7: TAT Monitoring Form

LABORATORY SERVICES	Turnaround Times Monitoring Form	Effective Date:
Written by Camilla Letsota	Document #: Version: 1	Approved by:

DIRECTIONS for USE:

1. **SELECTION of SAMPLES for TAT MONITORING**
   Select 5 samples per day for a week every month to track. The samples selected should span the whole day e.g. one from the first samples of the day and one from the last samples received, the rest interspaced in between.
2. **NUMBER (#)**
   Record the sequence number of the samples selected for TAT monitoring. If following 12 specimens for TAT monitoring (with 3 pages of TAT monitoring tables) the far left column will, in sequence, be populated with #'s 1-12.
3. **DAY & DATE**
   Record the day of the week and date that the samples selected for monitoring were collected.
4. **LAB ID/PATIENT NAME**
   Record the Lab ID and/or patient name for the samples selected for monitoring.
5. **SAMPLE RECEPTION**
   Record the date the sample was received. Record the specific time received (e.g., 10:07)
6. **TESTING BENCH**
   Record the date the sample arrived at the testing bench. Record the specific time received.
7. **PROCESSING**
   Record the date the pre testing processing of the sample started. Record the specific time processing began (e.g., the time that pippeting for CD4 testing began or the time the worklist is created for FBC testing).
8. **TESTING**
   For automated tests, record the date and time on the results printout. For manual testing, record the date and time when actual testing is done.
9. **RESULT DISPATCHING**
   Record the date the results were dispatched. Record the time the results were dispatched.
10. **TIME**
    To determine the TAT, summarize above each arrow the time elapsed between the steps/stages represented in the table (see example below). Start by determining the amount of time elapsed between the 'Time In' at sample reception and the 'Time In' at the testing bench.
    Add the times above the arrows from left to right. The resulting sum should be recorded in the column marked "Total Time".

Handout 7: TAT Monitoring Form

LABORATORY SERVICES	Turnaround Times Monitoring Form	Effective Date:
Written by Camilla Letsota	Document #: Version: 1	Approved by:

COMPLETED EXAMPLE

#	Day & Date	Lab ID/Patient Name	Sample Reception		Testing Bench		Processing		Result Dispatching		Total Time (hrs)
			Date	Time In	Date	Time In	Date	Time In	Date	Time out	
1	**06/05/09** (Wednesday)	*Lab ID or Patient Name*	**06/05/09**	**10:03**	**06/05/09**	**13:25**	**07/05/09**	**12:30**	**08/05/09**	**11:00**	**48hrs 25mins**
	Indicate above each arrow the time taken from one stage to the next		**3hrs 22min** →		**22 hrs 55mins** →		**22 hrs 30min** →				

Handout 8: Stock Control Bin Card

Stock Control Bin Card

Item Description: _____ **Reorder Stock Level:_____**

1. **Consumption Rate = Total** number of items issued or used.
2. **Reorder level** = When items reach the reorder level, a new order should be placed

Date	Quantity Received	Lot Number	Expiry Date	Rec. From/Issued to	Quantity Issued	Discarded Expired Stock	Balance	Monthly Stock Count	Consumption Rate	Signature

Reviewed by: _____ Date: _____

Handout 9: Equipment Maintenance Data Collection Tool

Equipment Maintenance Data Collection Tools

Daily Maintenance Data Collection Tool

DAILY MAINTENANCE						
Equipment name	Average No. of Days maint done/month (A)		Average No. of testing days/month (B)		AV % (A/B x 100)	
	Baseline	Final	Baseline	Final	Baseline	Final
FACS Calibur						
Sysmex 21N						
Pentra 80						
Pentra 60						

Engineer Scheduled Service Maintenance Data Collection Tool

Equipment	Was Service Done				Was Service done on time				Date of next service
	Baseline		Final		Baseline		Final		
	Yes	No	Yes	No	Yes		Yes	No	
FACS Calibur									
Sysmex KX21									
PENTRA 60									
PENTRA 80									

Handout 10: Customer Satisfaction Questionnaire

Customer Survey Questionnaire

As part of service improvement efforts, your local Laboratory _____ is conducting a Customer Satisfaction Survey. Your Local laboratory intends to use this information to identify areas that need improvement in order to give laboratory services the highest quality at all times. This will enable you to give timely and accurate diagnosis, monitoring and treatment of patients.

Please take a few minutes to complete this survey. Your valuable opinion will be treated with highest confidentiality. Refusal to complete this survey will not in any way affect your position or result in victimization. For any questions, please contact your local laboratory:

Thank you for your cooperation. Your opinion is greatly appreciated.

Date: …….. Profession of Respondent: .....

Clinic/Hospital name with ward.....

Laboratory where samples are sent: …….....

Please rate our services by marking with an X as either Excellent, Good, Average, Below Average or Poor. Where the statement does not apply to your facility, indicate by marking with an X under Not Applicable.

	Excellent >90%	Good >80%	Average >70	Below Average <60	Not Applicable
CD4 Count results turnaround times					
DNA PCR results turnaround times					
Viral Load results turnaround times					
Chemistry results turnaround times					
Hematology results turnaround times					
Cytology turnaround times					
Histology turnaround times					
Microbiology AFBs results turnaround times					
Microbiology TB culture turnaround times					
Microbiology General turnaround times					
Blood Transfusion turn around times					
Processing of urgent requests					

Handout 10: Customer Satisfaction Questionnaire

Communication of critical results to the clinic or ward					
Communication of rejected samples to the ward/clinic.					
Communication of reason for rejection to the ward/clinic					
Communicating of changes that affect testing (reagent stock outs, machine breakdowns, new tests)					
Courtesy when speaking face to face					
Courtesy when speaking on the phone					
Courtesy of clinical laboratory staff					
Explanation of tests, tests results and result interpretation when asked.					
Availability of staff in the laboratory to attend to questions and queries					
Availability of staff on the phone to attend to questions and queries					
SAMPLE REQUEST AND TRANSPORTATION					
Sample transport system from clinic to Laboratory					
The design of the sample request form					
The information that comes with result reports to aid interpretation (reference ranges, interpretations, explanations)					
Diagnostic accuracy (results reflecting clinical status of patient)					
Reliability of results					

In your own opinion, what is the major problem in laboratory services?

……..

……..

……..

==========THANK YOU========

Worksheet: Quality Improvement Project Plan

Quality Improvement Project Plan

PLAN

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:

_____

_____

Worksheet: Quality Improvement Project Plan

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?

_____

Worksheet: Quality Improvement Project Plan

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 _____

Jod Aid 1: Improvement Project Report Format

Job Aid: Improvement Project Report Format

Make a project write up (in Microsoft word if computer is available or handwritten using the following format. The report becomes the Laboratory own record of improvement projects conducted

1.0 Introduction

1. A brief description of the quality indicator or element being investigated
2. What led the lab to selecting the project
3. What you intend to achieve out of the project (Aim and Objectives) e.g.

   Aim: To measure satisfaction level of Clinicians served by Lab X customers and improve all areas of satisfaction to at least 80% by July 2011

   Objectives

   To measure customer satisfaction levels of lab X clients (Doctors, nurses, patients) using a survey questionnaire

   To improve all areas of satisfaction to above 80% as measured by the survey questionnaire by July 2011

2.0 Methodology

1. Where was the project being conducted?
2. How was the IP conducted (data collection methods, data collection tools, frequency of collection and who was collecting and how the data will be analyzed)
3. What improvements were implemented, by whom and how?
4. For how long was the project conducted?

3.0 Results

1. Describe the results: Baseline and final
2. Analysis of the results baseline and final

4.0 Conclusion

1. What are/is the conclusion(s) based on results

5.0 Challenges

6.0 Recommendations

For Reporting in the next workshop, summarize your improvement project into a 10 minutes presentation (power point or handwritten). Use the summary for presenting during the IP reporting class in the next workshop. See attached example.

Jod Aid 2: Improvement Project PowerPoint Template

IP Reporting PowerPoint Template

Project Title

Participant Name

1

METHODOLOGY

4

INTRODUCTION

2

METHODOLOGY

5

AIMS & OBJECTIVES

- Aim
- Objectives

3

RESULTS

6

Jod Aid 2: Improvement Project PowerPoint Template

7 CONCLUSION	9 RECCOMMENDATIONS
8 CHALLENGES	10 ACKNOWLEDGEMENTS

Jod Aid 3: IP Reporting Example - Equipment Maintenance

EQUIPMENT MAINTENANCE DOCUMENTATION AT XXXXX LABORATORY

By
XXXXXXX
August 2010

This project was completed in partial fulfillment of the Strenthening Laboratory Towards Accreditation Training



Jod Aid 3: IP Reporting Example - Equipment Maintenance

Table of Contents

Jod Aid 3: IP Reporting Example - Equipment Maintenance

ACKNOWLEGEMENTS
I would like to acknowledge and express my gratitude to the following people for their magnificent support and contributions to my project:
Mr. XXXXXX (for generously sharing his wisdom), co-workers, XXXXXX, XXXX and XXXXXXXX

Jod Aid 3: IP Reporting Example - Equipment Maintenance

1.0 INTRODUCTION

Preventative maintenance refers to a series of actions that are performed on either a time-based schedule or a schedule based on that of machine-run-time. These actions are designed to detect, preclude, or mitigate degradation of a system (or its components)

A yearly preventative maintenance service plan on the system is preferred and should be in the form of service contract. When properly done, maintaining the equipment will save money and help the equipment last longer. The goal of a preventative maintenance approach is to minimize system and component degradation and thus sustain or extend the shelf life of the equipment.

Dirt is the biggest enemy in mechanical systems. During preventative maintenance, certain parts that can cause trouble when dirty are cleaned to keep the equipment running smoothly and efficiently. Another benefit is that problems can be discovered before serious damage is done so appropriate measures can be taken before a complete breakdown.

As part of quality, each time the equipment is maintained or serviced, appropriate documentation has to be done e.g. job cards and logging on the preventative maintenance log. These logs also need to be reviewed regularly and the reviews documented. At Motebang laboratory, documentation of equipment maintenance has appeared as one of the non-conformities in a number of assessments done to date.

2.0 AIM

To improve equipment maintenance documentation of major instruments namely: FACS Calibur, Selectra E, Pentra XL 80 and Pentra 60 to an average of at least 80% for the period of May-July.

2.1 Objectives

1. To improve equipment maintenance documentation of FACS Calibur, Selectra E, Pentra 80 and Pentra 60 analyzers
2. To review maintenance logs for FACS Calibur, Selectra E, Pentra 80 and Pentra 60 analyzers

3.0 METHODOLODY

Every morning after maintenance was done, equipment maintenance sheets were checked for proper maintenance and documentation. Equipment maintenance sheets were reviewed every month. The following were used

3.1 Equipment maintenance log sheets

Equipment maintenance log sheet is designed in such a way that it reflects daily, weekly, BI-Monthly, monthly and as needed maintenances. Therefore, the number of times daily, weekly, BI-monthly and monthly maintenances were performed was counted. The total number of days that maintenance was

Jod Aid 3: IP Reporting Example - Equipment Maintenance

performed was divided by the total number of working days for that month and converted to a percentage. The period considered for baseline data was January to April 2010. Public holidays and the days indicating machine breakdown were not counted in the denominator as long as it was documented on maintenance log sheet. Whenever machine breakdown and holidays were not indicated on the log, those days were counted in the total number of working days for that month; e.g. if maintenance was done for 12 days and the number of working days for that month was 20, and there are no indications on the log for any holidays or breakdowns then the percentage was calculated as 12/20 x 100 = 60%. However, if for the same month of 20 working days there are indications on the log of 2 days holidays and 3 days equipment breakdown the total number of working days becomes 20-5=15. Therefore percentage becomes 12/15x100=80.

3.2 Equipment Maintenance Log Review Form

Every maintenance log is reviewed every month. The number of logs reviewed with evidence (documentation) of review by being signed, dated with comments or use of a maintenance review form were counted.

3.3 Corrective Action Forms

Job cards were used to find out whether corrective action was performed for any equipment breakdowns or failures. For every job card, a corrective action report is expected. The number of corrective action forms was counted and compared with number of job cards for the period of January to April (for baseline data) and thereafter for the period of May to July.

3.4 Service Maintenance Job Cards

Job cards and 6 months preventative maintenance service plan were used to check whether service maintenance was performed. Service performance was indicated as performed if it was indicated on the job card. The previous job cards or the service information card kept on the machine with service dates were used to check if service was done on time

Corrective action implemented

- Equipment maintenance
    - Equipment maintenance had to be performed and documented as expected, e.g. daily, weekly, BI-Monthly, monthly and six monthly.
    - Signature had to appear on equipment log sheet to indicate the person who had done maintenance.
    - There had to be an indication on the log sheet for equipment breakdown, holidays and weekends, so that there was no gap on the log sheet.
    - Maintenance logs were checked daily by the supervisor to make sure that equipment maintenance was performed daily and documented

Jod Aid 3: IP Reporting Example - Equipment Maintenance

- Equipment maintenance log review
  - Equipment maintenance log review had to be done monthly by quality control officer or supervisor
  - Equipment maintenance review form had to be completed monthly by quality control officer or laboratory supervisor.
  - Signature, date and comment should appear on equipment maintenance review form as an indication that reviews was done.
  - Date of review was scheduled on management calendar.
- Corrective action reporting
  - corrective action report was done for each machine breakdown
  - the number of job cards was suppose to be equal to the number of corrective action reports
  - After each report of breakdown, laboratory supervisor was suppose to make immediate follow up for completed corrective action report form
  - How to use corrective action report form was discussed in a laboratory meeting with mentor
  - Job cards and corrective action report forms were suppose to be reviewed by quality control officer or supervisor monthly
  - Corrective action report review was scheduled on management calendar

4.0 RESULTS

4.1 Daily Maintenance

Table 1: Daily Maintenance

DAILY MAINTENANCE						
Equipment	**AV # Days maint done**		**AV # testing days**		**AV %**	
	Baseline	Final	Baseline	Final	Baseline	Final
Calibur	8	13	22	16	34	81
Selectra	10	11	17	13	58	72
P80	19	20	21	20	94	100
P60	8	-	22	-	44	-

Table 1 above shows the average number of days maintenance was done and an average number of testing days for the four instruments over the baseline period January to April and the final May to July. For baseline data Calibur was maintained for an average of 8 days in an average of 22 working

Jod Aid 3: IP Reporting Example - Equipment Maintenance

days which gives an average percent of 34 %. For final data maintenance was done for an average of 13 days in an average of 16 working days and an average percent is 34%. For Selectra the average number of days maintenance was done was 10 and the average number of working days was 17, giving 58%. For final data it was maintained for an average of 11 days with an average number of 13 working days giving 72%. For baseline data Pentra 80 was maintained for an average of 19 days in 21 working days, giving 94%. For final data maintenance was done for an average number of 20 days in an average of 20 working days giving 100%. For Pentra 60 baseline data shows 8 days to be an average number for maintenance and 22 average number of working days which gives average percentage of 44. There are no figures for final data because the machine was out of order and taken by the supplier to be fixed.

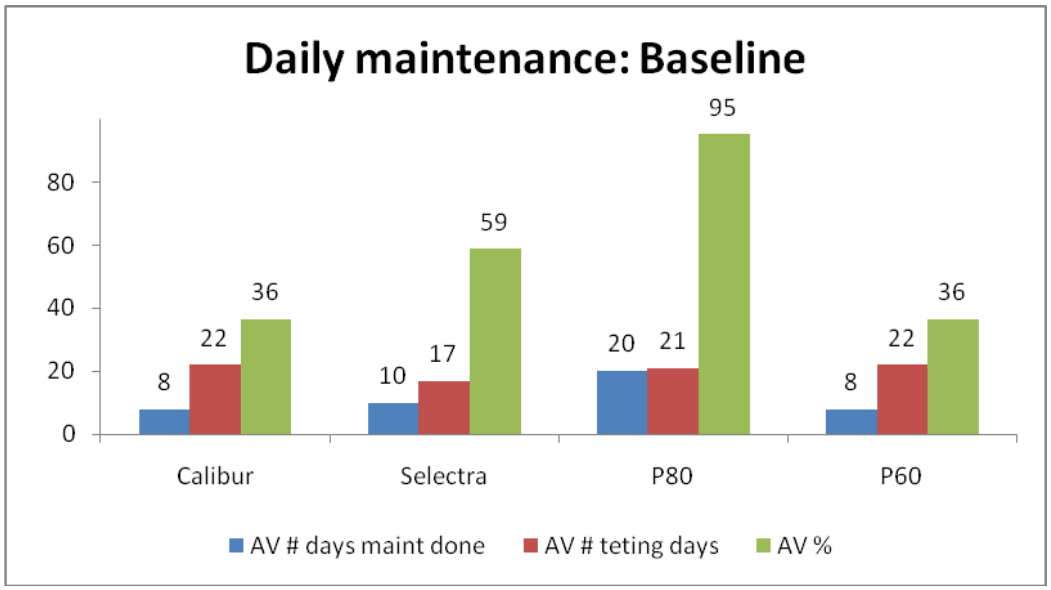


Figure 1: Average daily maintenance

Figure 1 above shows daily maintenance for the four instruments. The blue bar represents an average number of days maintenance was performed, the red bar represents an average number of testing days and the green one represents an average percentage. Histogram shows that Calibur maintenance was done for 8 days in an average of 22 testing days and that gives a percentage of 36%. If proper maintenance was done the bars were expected to be equal.

Selectra E maintenance was done for an average of 10 days and the number of testing days was 17, giving an average of 59%. Pentra 80 was maintained for an average of 20 days in 21 working days and that give the average percentage of 95%. Baseline data also shows that Pentra 60 maintenance was done and documented for an average of 8 days and an average testing days was 22, giving 36%

Jod Aid 3: IP Reporting Example - Equipment Maintenance

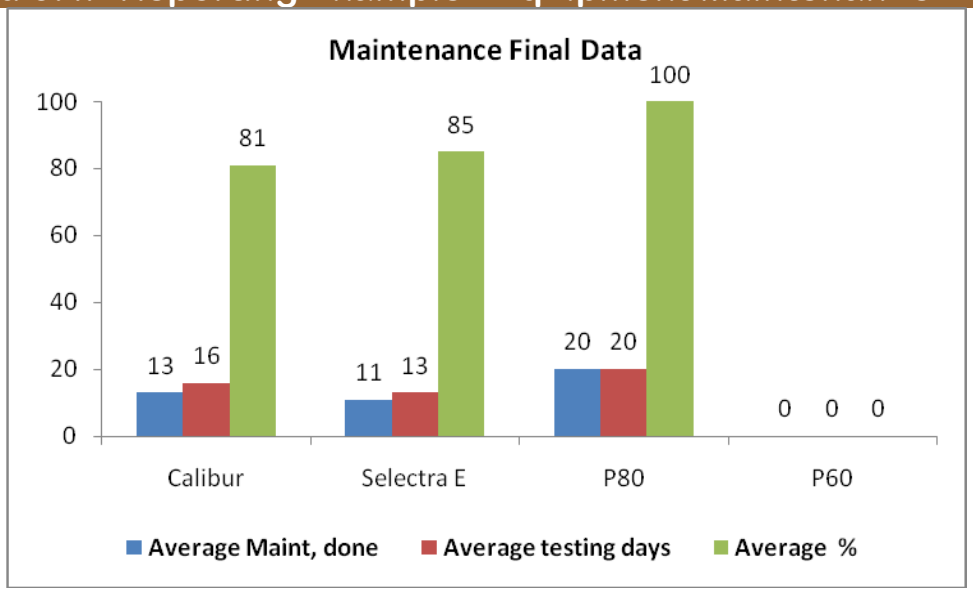


Figure 2: Maintenance final data

Figure 2 above shows Calibur average maintenance at 81%, Selectar E at 85% and Pentra 80 at 100%. The Pentra 60 was out of order.

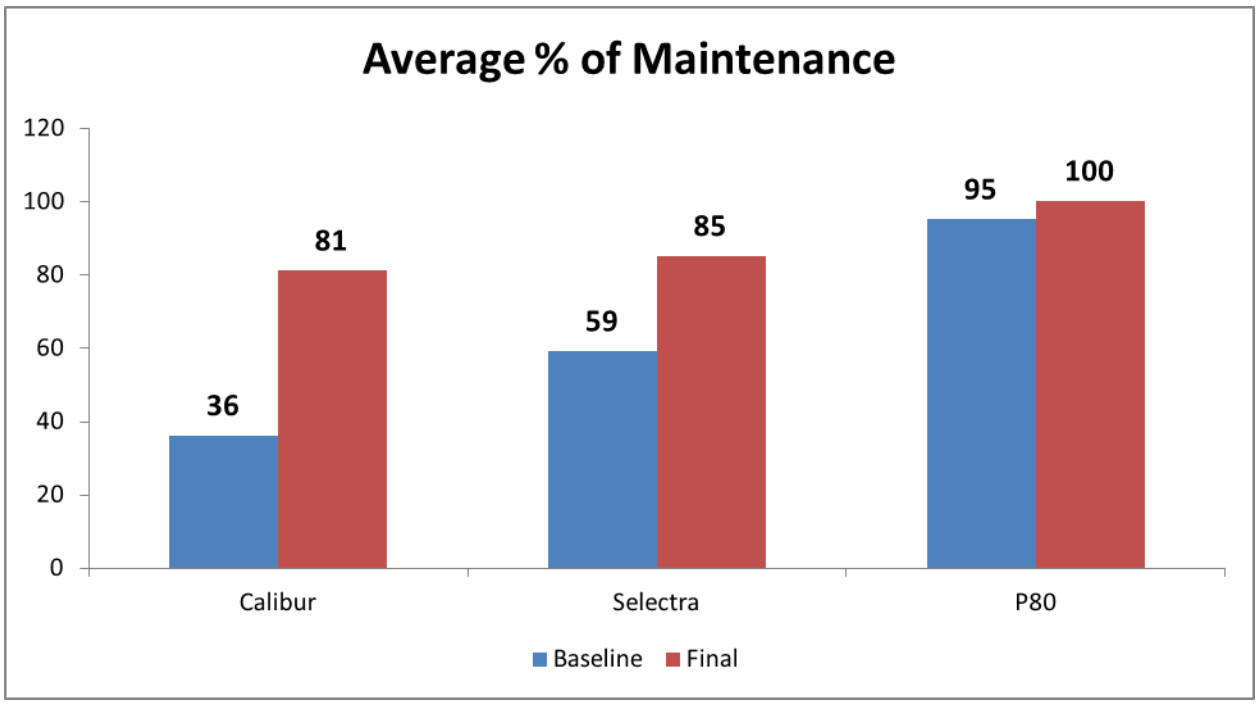


Figure 3: Average Maintenance January to July 2010

Figure 3 above shows an increase in average percentage of maintenance for calibur, Selctra E and Pentra 80, from 36% to 81%, 59% to 85% and 95% to 100% respectively. During the time period May to July, the Pentra 60 was out of order.

Jod Aid 3: IP Reporting Example - Equipment Maintenance

4.2 Weekly Maintenance

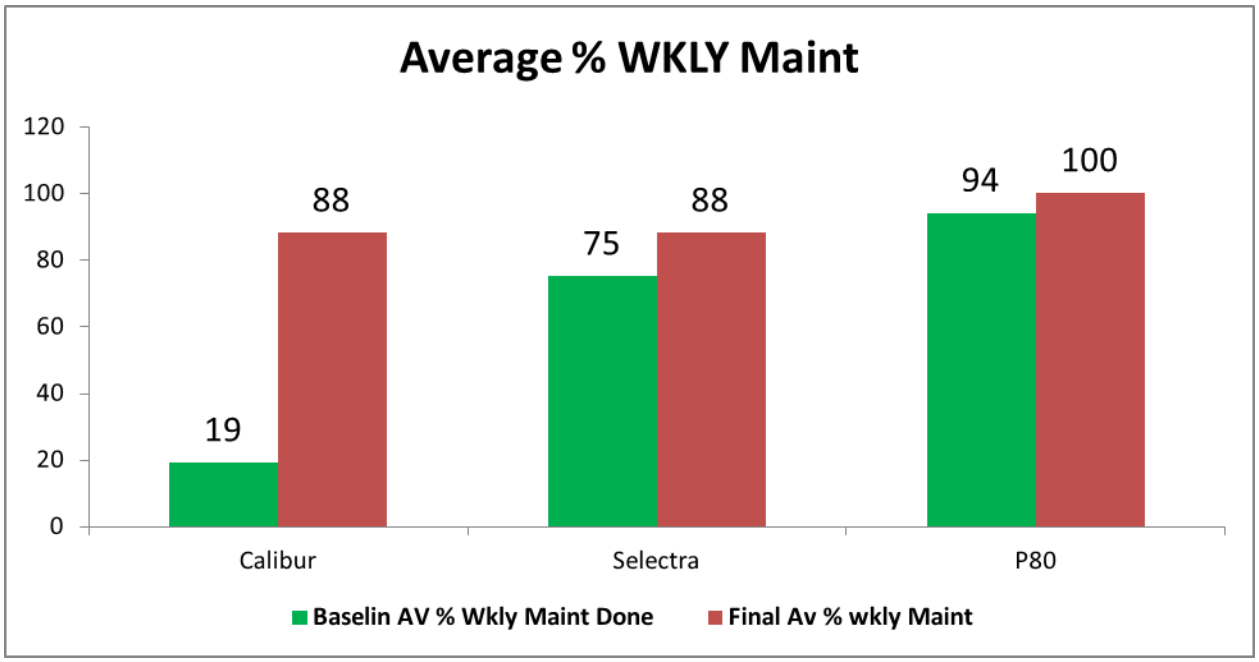


Figure 4: Average weekly maintenance

Figure 4 above shows comparison of average percentage of weekly maintenance. Green bar represents baseline data while red bar represents final data. For Calibur, the average percentage has increased from 19% to 88%, and above the expected 80%. For Selectra E percentage had increased from 75% to 88%, above 80%. For Pentra 80, it has increased from 94% to 100%, above the expected 80%.

4.3 Bi Monthly Maintenance

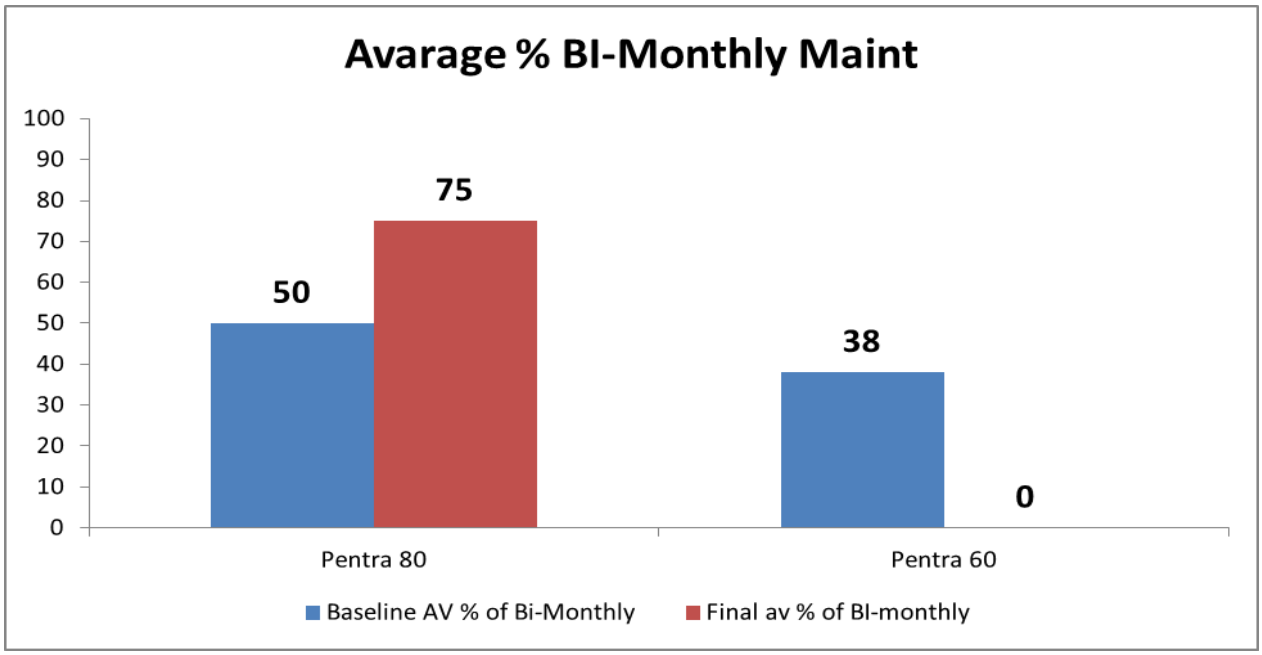


Figure 5: Average Bi-Monthly Maintenance

Jod Aid 3: IP Reporting Example - Equipment Maintenance

BI-Monthly maintenance is performed for only Pentra 60 and Pentra 80. Figure 5 above shows Bi-monthly maintenance for Pentra 80 and Pentra 60. For Pentra 60, only baseline data was collected because it was out of order between May and July. It shows that for baseline data percentage has increased from 50% to 75% for Pentra 80 even though it is below the expected 80%. For Pentra 60 baseline data shows a percentage at 36% far below expected 80%.

4.4 Monthly Maintenance

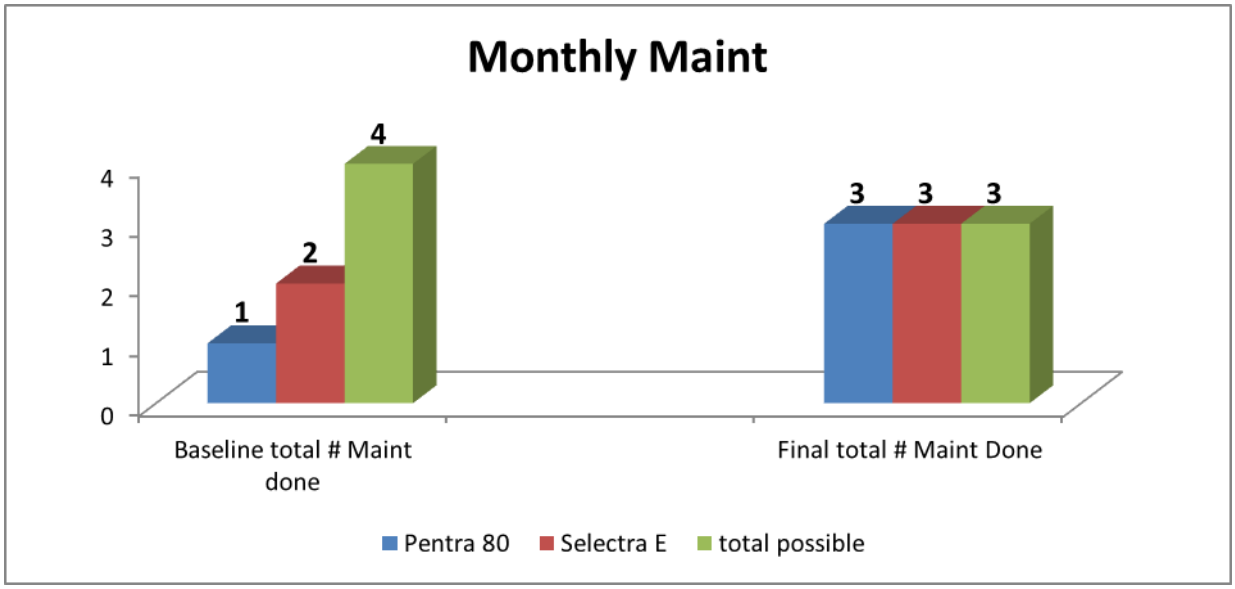


Figure 6: Monthly Maintenance

For baseline, out of the 4 possible maintenances expected, only one month indicates performance of monthly maintenance for Pentra 80. For Selectra E, 2 months indicate performance of monthly maintenance. Final data shows that for both machines monthly maintenance was performed for 3 months out of expected total of 3 months

4.5 Equipment Maintenance Log review

Table 2: Equipment Maintenance Log Review

Equipment	Jan	Feb	Mar	Apr	May	Jun	July
FACS Calibur	NR	NR	NR	NR	R	R	R
Selectra	NR	NR	NR	NR	R	R	R
PENTRA 60	NR	NR	NR	NR	R	R	R
PENTRA 80XL	NR	NR	NR	NR	R	R	R

NR : Not Reviewed R : Reviewed

Table 2 above shows that no equipment maintenance log review was done for all equipments between January and April. All equipment maintenance logs were reviewed between May and July.

Jod Aid 3: IP Reporting Example - Equipment Maintenance

4.6 Engineer Scheduled Service Maintenance

Table 3: Engineer Scheduled Service Maintenance

Equipment	Was Service Done		Was Service done on time		Date of next servise
	Yes	No	Yes	No	
FACS Calibur	✓	X	X	✓	September 2010
Selectra	✓	X	X	✓	September 2010
PENTRA 60	✓	X	X	✓	October 2010
PENTRA 80	✓	X	X	✓	October 2010

Engineer scheduled service maintenance was done for all the equipments. None of the equipments was serviced on time. For FACS Calibur and Selectra E the next service will be in September 2010 while for the Pentra 80 & 60 will be in October 2010.

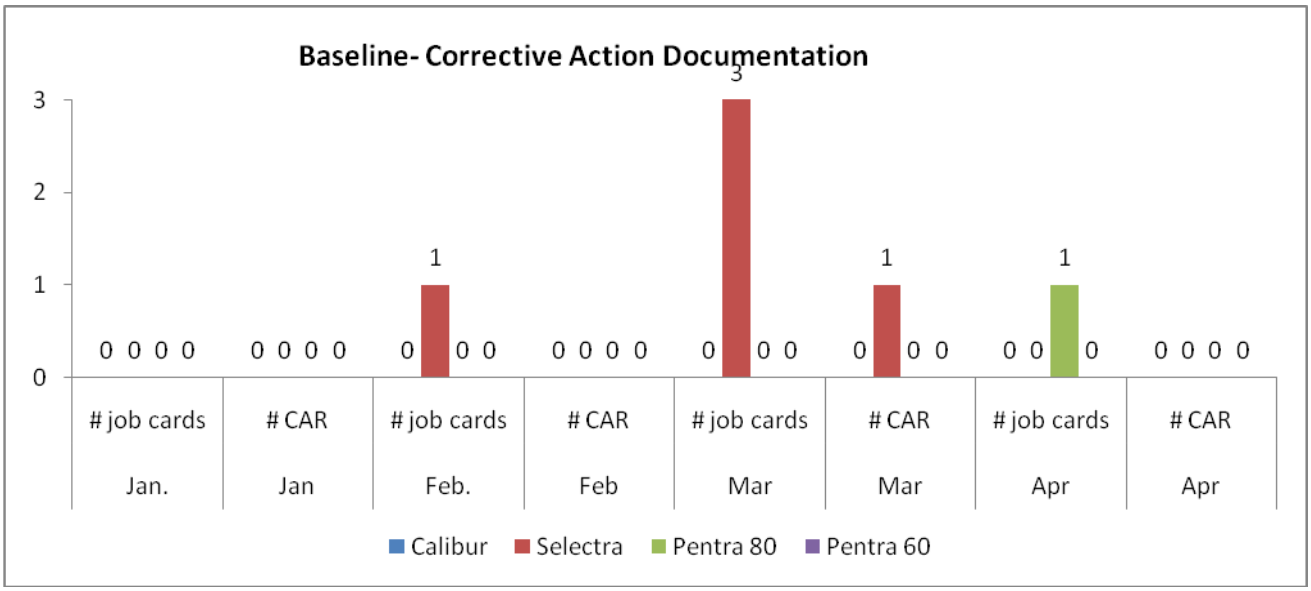


Figure 7: Corrective Action Documentation

The number of job cards indicates how many times each instrument was down. For every job card, there has to be a corrective action report done. There was no equipment breakdown for Calibur and Pentra 60 between January and April. Baseline data shows that only 2 instruments were down between January and April. Selectra was down once in February which is indicated by one job card. There was no corrective action done. It was down three times in March which is indicated by three job cards and only one corrective action was performed.

Jod Aid 3: IP Reporting Example - Equipment Maintenance

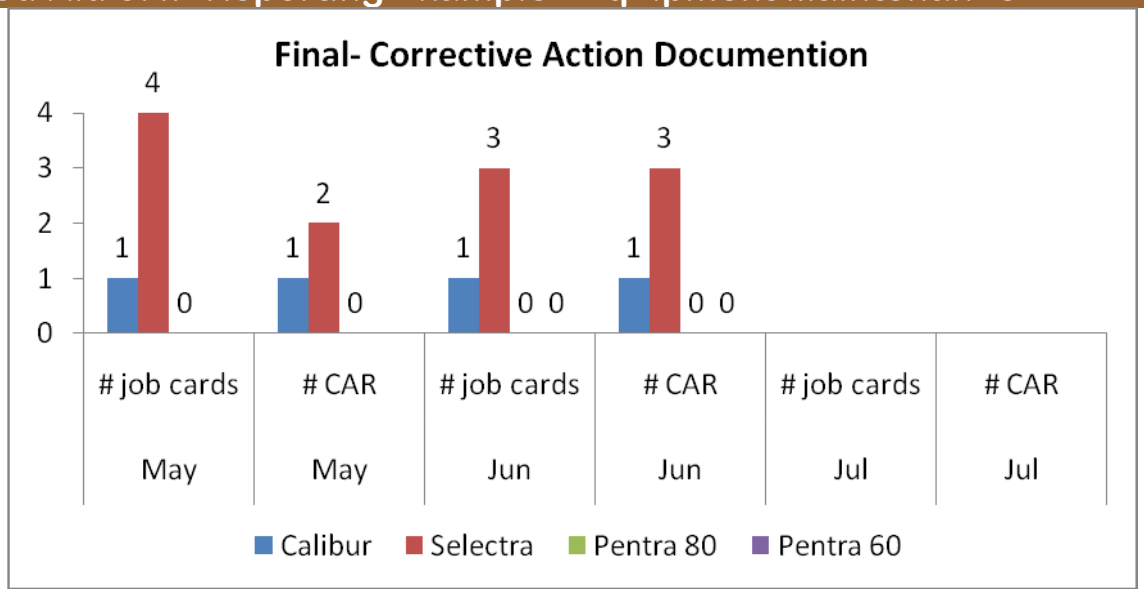


Figure 8: Corrective action documentation Final

There was equipment breakdown for Calibur in May and June and there was one corrective action report done for each month. Four job cards indicate that Selectra was down four times in May and only two corrective action reports were done. It was down three times in June and there were three corrective action reports done. There was no equipment breakdown for Pentra 80 between May and June. Pentra 60 was still out of order. Selectra E was out of order once in June and one corrective action was performed.

5.0 CONCLUSION

The objective of the project was to improve equipment documentation of the four analyzers by an average of at least 80%. Therefore for all types of equipment maintenance (daily, weekly, BI-Monthly, monthly and 6monthly), equipment maintenance log review and corrective action report followed up during the project, show a great success. There was significant improvement in equipment maintenance documentation because final data for daily maintenance showed that the average percentage for all the instruments was above 80%.

When comparing the average percentage of daily maintenance for baseline and final data, there was a significant percentage increase for all the equipment except Pentra 60. The percentage has increased from 36% to 81%, 58% to 85% and 95% to 100% for Calibur, Selectra and Pentra 80 respectively. This is due to proper equipment maintenance and documentation, for instance, there were very few gaps and holidays, weekends and equipment breakdown were indicated on the logs.

There was also improvement on weekly maintenance and its documentation because final data showed that an average percentage for all instruments was above the targeted 80%. There was percentage increase from 50% (baseline) to 75 %(final) for BI-Monthly maintenance for Pentra 80 even though it is below 80%. The few gaps identified for Pentra 80 for bi monthly maintenance were not identified early enough to allow for correction.

Jod Aid 3: IP Reporting Example - Equipment Maintenance

Baseline data shows that for monthly maintenance, out of a total possible of four maintenances per month, only one was done for Pentra 80 and two for Selectra. But final data shows an improvement because out of the total possible of three maintenances, three were done.

There was also an improvement on equipment maintenance log review because baseline data showed that no document was reviewed for all the instruments between January and April; but final data showed that between May and July, all equipment logs were reviewed for all the instruments.

Improvement could not be demonstrated for the engineer scheduled service maintenance. The scheduled maintenances were done before the project and the due dates for the next service are well after the project. However, data has been collected at baseline on whether maintenance was done on time. The last services were all not done on time. In this project the dates for the next service were noted to make sure the next services will be done on time

6.0 REFERENCES

Job Aid 4: IP Reporting Example - Inventory management

IP Reporting Example - Inventory management

IMPROVING INVENTORY MANAGEMENT

1

INTRODUCTION

- A sound Inventory Management include:
  - Elimination of time consumption
  - Reductions of number of vendors
  - Supplies accessibility
  - Usage of valid supplies
  - Reduction of stock outs.
- SLMTA assessments indicated a weakness in Inventory Management at Butha - Buthe Laboratory.

2

AIM & OBJECTIVES

AIM

To improve on Inventory Management and reduce stock outs to less than 5% by October 2010

OBJECTIVES

- To establish minimum stock level for all stock items
- To establish lead time for all stock items
- To establish consumption rate for all stock items
- To improve on usage of stock cards to >90%
- To inspection all supplies received and tracking all orders made

3

METHODOLOGY

- The project was discussed with the laboratory team in the scheduled laboratory meetings
- Baseline data was collected on the 13th August 2010.
- Final data was collected between 13th September and 13th October 2010.
- Baseline data was analyzed & findings were discussed with all staff at the meeting.

4

METHODOLOGY

- Improvements were suggested and implemented as listed below:
  - All items in stock were counted and noted.
  - Stock cards were created for all the stock items that did not have.
  - Stock cards were also monitored for proper usages.
    - Improperly used stock card had physical count and stock card balance not matching
  - Shelves were labeled according to how stock items were arranged.
  - A file was created for inspection of received stock using the "received inspection checklist"
  - Orders were tracked and documented using the "order tracking forms" for items ordered from Central Stores
  - The file was placed in the store room.
  - All staff members were shown how to use these forms
  - Final data was collected on the 14th October 2010 and presented to the laboratory team.

5

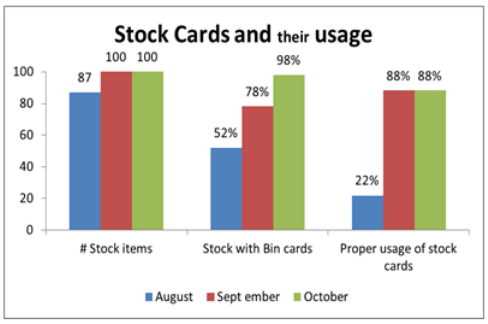
RESULTS

Item	Baseline (August)		Sept		Final	
	#	%	#	%	#	%
All stock terms	87		100		100	
No of stock cards available	45/87	52	78/100	78	98	98
No of stock counts	1/1	100	2/2	100	3/3	100
*Use of stock cards	10/45	22	69/78	88	88/100	88
Inspection of received stock	**0		1/1	100	2/2	100
Tracking of orders	**0		1/1	100	2/2	100
Bin cards with monthly consumption, lead time and minimum stock levels	0		0			
Labeled stock areas	51/87	58	74/100	74	100/100	100
Unlabeled stock areas	36/87	42	13/100	13	0	0
Number of expired reagents/ supplies discarded	30/87	34	5/100	5	4/100	4

6

Job Aid 4: IP Reporting Example - Inventory management

RESULTS



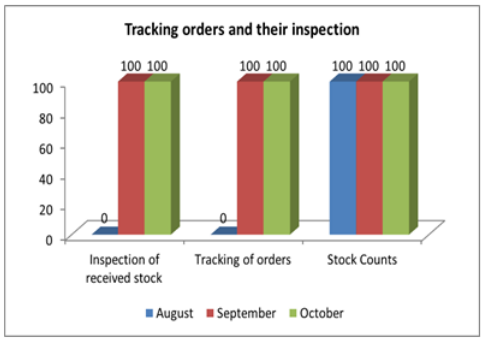
7

CONCLUSION

- The findings clearly indicate that there was improvement in all aspects of inventory management that this project concentrated on.
- Calculations of monthly consumption, minimum stock level, re-order level and quantity to order are essential tools which lead to smooth ordering processes

10

RESULTS



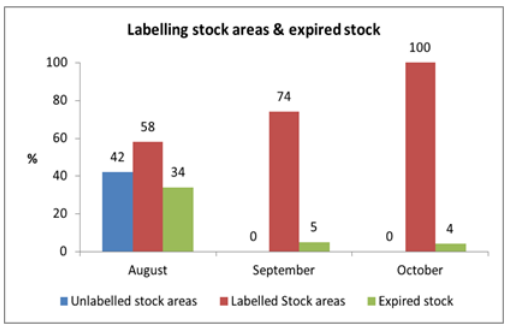
8

CHALLENGES

- Lack of proper inventory control at Central Stores made it difficult to
  - Calculate lead times and minimum stock levels
- The size of the store room is too small for the stock levels
- Some of the expired stock were not available from central Stores for replacement

11

RESULTS



9

RECOMMENDATIONS

- All laboratory staff should be trained in Inventory management
- Inventory management must be practiced at Central Stores as well
- Employment of basic data clerks in all District Laboratories will free technologists to do some of the work required by accreditation
- There should be a special Laboratory purchasing vote in a warrant to avoid delays in placing orders

12

Job Aid 4: IP Reporting Example - Inventory management

ACKNOWLEDGEMENTS I would like to express my sincere gratitude to Mr. XXXXXX for the guidance throughout the project and my colleagues for their support and participation in this project. 13	

ACTIVITY Reporting Improvement Projects — Cross-Cutting

PURPOSE:

Reporting improvement projects promotes reflection on accomplishments made, lessons learned, and challenges faced. This activity encourages participants to synthesize, summarize, and share this information, thereby building a learning network among in-country peers.

STOP DO NOT conduct this activity until both the Planning Improvement Projects – Master Class and Using the Improvement Method activities have been completed!

RESOURCES FOR FACILITATOR:

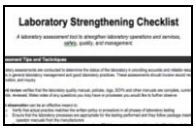
- ❑ PowerPoint slides: XC.45 to XC.46
- ❑ Tool: SLMTA Follow-up Visit Report
- ❑ Timer
- ❑ Timekeeping signs that indicate *3 minutes*, *1 minute*, and *timeout*
- ❑ (OPTIONAL) Prizes for labs with the highest accomplishments or best lessons learned
- ❑ Flipchart & markers

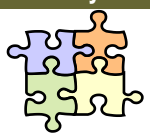
RESOURCES FOR PARTICIPANTS:

- ❑ Worksheet 2: Peer Grading Sheet (XC 35)

From the IP Planning Master Class:

- ❑ Worksheet 1: Quality Improvement Project Plan (XC 30)
- ❑ Job Aid 1: Improvement Project Report Format (XC 31)
- ❑ Job Aid 2: Improvement Project PowerPoint Template (XC 32)
- ❑ [OPTIONAL] Job Aid 3 - IP Reporting Example - Equipment Maintenance (XC 33)
- ❑ [OPTIONAL] Job Aid 4 - IP Reporting Example - Inventory management (XC 34)

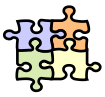
This activity supports the following laboratory management tasks and SLIPTA checklist items	
Management Tasks 	1.12 Develop and implement lab improvement plans based on best practices and feedback from staff, patients, customers, quality indicators, and external assessment
Checklist Items 	11.2 Quality Management System Improvement Measures Does the laboratory identify and undertake continual quality improvement projects? 11.4 Are quality indicators (TAT, rejected specimens, stock-outs, etc.) selected and tracked? 11.5 Is the outcome of the review of quality indicators used to improve lab performance? 11.6 Are the actions taken checked and monitored to determine the effectiveness of improved quality of lab performance?

This activity is related to the following activities:	
	Cross-cutting: Balanced Scorecard Planning Improvement Projects – Master Class Conducting Site Visits Module 2: What did we see on our site visits?

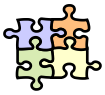
ACTIVITY AT-A-GLANCE				
Step		**Time**	**Resources**	**Key Points**
1	Introduce the activity	5 min	Slides XC.45 to XC.46 Job Aid 2 Worksheet 2 Timekeeper's Signs	
2	Conduct project reporting	5 min per participant	Tool Timekeeper's Signs	
3	Debrief the activity	10 min	Flipchart & Markers	
4	Conclude the activity	5 min		
	TOTAL TIME:	**20 min plus project reporting**		

PROCESS

Preparation



- Participants should have obtained a copy of the following worksheet and job aids from *Improvement Project Planning - Master Class* activity.
  - Worksheet 1: Quality Improvement Project Plan
  - Job Aid 1: Improvement Project Report Format
  - Job Aid 2: Improvement Project PowerPoint Template
  - [OPTIONAL] Job Aid 3 - IP Reporting Example - Equipment Maintenance
  - [OPTIONAL] Job Aid 4 - IP Reporting Example - Inventory management
- To keep the entire class engaged, consider asking participants to grade all presentations using Worksheet 2: Peer Grading Sheet.
- Assign a timekeeper to time the presentations. Position the timekeeper in a highly visible spot for the presenters to see.
- Prepare timekeeping signs as indicated.
- If prizes are to be awarded, assign a panel of judges. It is the best if these judges are the same people as those who visited the labs.
- Site Visits - Supervisors, coaches or facilitators should visit these labs in between workshops to provide support, as well as to check and validate progress, especially if prizes are to be awarded. Only projects that have been independently validated should be presented. Use the Tool: SLMTA Follow-up Visit Report for documentation. Use the total number of marks in the IP section of the form to grade the projects. Findings should also be documented photographically. Validation must precede reporting of a project. The participants should be coached on what to present in their reports to the class following the templates (Job Aid 1 and Job Aid 2) and the examples (Job Aid 3 and Job Aid 4) from *Improvement Project Planning - Master Class* activity. Link to Activities - *What Did We See on Our Site Visits?* and *Conducting Site Visits.*



Step 1. Introduce the activity 5 min

- Project Slides XC.45 to XC.46. Each laboratory has 10 minutes to report on their projects.
- Introduce the timekeeper, who will remind the presenters of time remaining by flashing the signs at *5- minute*, *3-minute*, *1-minute*, and *timeout* points.
- The presentation should be succinct and address all the questions in Job Aid 2.
- Remind participants that a failed project is as important as a successful project as long as they can articulate what lessons they have learned from that experience and what they will do differently next time so they will have a better chance of success.
- Direct participants to Worksheet 2: Peer Grading Sheet for peer grading. Remind presenters that they are being graded not only on the merits of their projects, but also on their ability to communicate to their peers.

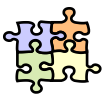
Step 2. Conduct project reporting — 5 min per participant

- Provide a brief comment following each participant's report. If any important points from the site visit were noted on Tool: SLMTA Follow-up Visit Report, share those points at this time. Note lessons that have general applicability to all the laboratories.
- Be as encouraging and positive as possible. It is important to create a friendly environment where people feel free to share their mistakes and discuss missteps.
- Ask probing questions, such as "How much did you improve?" or "How did you measure the improvement in turn-around time?"
- Praise laboratories that successfully implemented improvement projects.
- Help labs that failed to implement determine what they could do differently the next time

Step 3. Debrief the activity — 10 min

- Summarize common themes (e.g., shared challenges and solutions) and key lessons learned. Use flipchart & markers.
- Take time to correct mistakes or misunderstanding. It may be necessary to re-teach some topics that were not learned well.
- Since participants face similar challenges, encourage them to be each other's consultant. They can form a "learning network" and continue to share ideas after the workshop. Make sure they have everyone's cell number or e-mail address.
- Collect completed Worksheet 2. Use the grading sheets judiciously in concert with site visit reports, photos, and judge's opinions to grade the projects. If prizes are to be awarded, decide in advance how they will be distributed.

Step 4. Conclude the activity — 5 min



- Link to activities: *Improvement Project Planning – Master Class, What Did We See on Site Visits?* and *Conducting Site Visits*.
- Highlight or reiterate the key messages below.
- Make sure participants achieved objectives of the activity.

KEY MESSAGES

- Implementation of an Improvement Project requires an extensive plan, ongoing supervisory support, and result analysis.
- Reporting an improvement project provides an opportunity to gain experience synthesizing, summarizing, and presenting information publically.
- Distilling lessons learned and sharing the project with the class is an important opportunity to develop a peer-to-peer learning network, which imparts sustainability to the country's improvement culture.

Can they:

- Implement an improvement project?
- Clearly synthesize, summarize, and report the results and lessons learned from an improvement project?

☑ ACTIVITY OBJECTIVES MET?


1 Minute

Tool: SLMTA Follow-up Visit Report

SLMTA Follow-up Visit Report		
Date of Visit	Visit Details Workshop #:____ Follow-up visit #:____	Facilitator Name
Facility Name	SLMTA Trained Person	Title

I. Improvement Project

Improvement Project 1 Title: _____

Start Date: _____ End Date: _____

	Yes	No	Comments
Is the whole laboratory team involved in the improvement project?			
Has the baseline data been collected & cause analysis done. What was the data collected?			**Please rate progress** 0-5 (0=No baseline data & 5 excellent data present with cause analysis excellently done) **Score = _____**
Have positive improvements been implemented and if so, what are they?			**Please rate improvement from** 0-5 (0=Not implemented & 5 excellent improvements) **Score = _____**
Were improvements effective? Please describe.			**Please rate effectiveness from** 0-5 (0=Not effective & 5 very effective) **Score = _____**

Tool: SLMTA Follow-up Visit Report

I. Improvement Project

Improvement Project 2 Title: _____

Start Date: _____ End Date: _____

	Yes	No	Comments
Is the whole laboratory team involved in the improvement project?			
Has the baseline data been collected & cause analysis done. What was the data collected?			**Please rate progress** 0-5 (0=No baseline data & 5 excellent data present with cause analysis excellently done) **Score = _____**
Have positive improvements been implemented and if so, what are they?			**Please rate improvement from** 0-5 (0=Not implemented & 5 excellent improvements) **Score = _____**
Were improvements effective? Please describe.			**Please rate effectiveness from** 0-5 (0=Not effective & 5 very effective) **Score = _____**

Tool: SLMTA Follow-up Visit Report

I. Improvement Project

Improvement Project 3 Title: _____

Start Date: _____ End Date: _____

	Yes	No	Comments
Is the whole laboratory team involved in the improvement project?			
Has the baseline data been collected & cause analysis done. What was the data collected?			**Please rate progress** 0-5 (0=No baseline data & 5 excellent data present with cause analysis excellently done) **Score = _____**
Have positive improvements been implemented and if so, what are they?			**Please rate improvement from** 0-5 (0=Not implemented & 5 excellent improvements) **Score = _____**
Were improvements effective? Please describe.			**Please rate effectiveness from** 0-5 (0=Not effective & 5 very effective) **Score = _____**

Tool: SLMTA Follow-up Visit Report

II. Compulsory Activities

Indicate whether the following compulsory activities have been implemented. Activities are assigned after every workshop.

Activity	Yes	No	Comments
Follow Up Visit *If this is not 1st visit but a subsequent visit (e.g. 2and, 3rd etc.), check for continued implementation of these activities*			
1. Management Calendar			
2. Organization Chart			
3. Implement Duty Roster			
4. Conducting Staff Meetings			
5. Equipment Master list completed and maintained			
6. Supplies and reagents master list completed and maintained			
7. SOP and document master list completed and maintained			
8. Occurrence log implemented and maintained			
Previous IP(s) *Assess if improvements made with the previous IP(s) are still in place*			

Tool: SLMTA Follow-up Visit Report

III. SLMTA Tool Adoption Rate

SLMTA Tool Adoption Rate =

[Total # SLMTA Tools Used] ÷ [Total # SLMTA tools issued in the previous workshop(s)]

NOTE: From workshop 1 to workshop 3, the total number of tools issued increases.

	%	90-100%=5	80-89%=4	70–79%=3	60-69%=2	50-59%=1	0-50%=0
		Comments					
SLMTA Workshop 1							
SLMTA Workshop 2							
SLMTA Workshop 3							

IV. Quality Indicators

Are the following QI in place and being monitored?

	Yes	No	Comment
EQA			
Stock Outs			
Customer Complaints			
TAT			
Equipment Downtime			

Tool: SLMTA Follow-up Visit Report

V. Others

What coaching was provided during this visit?

Site visit summary report

Follow-up actions

Worksheet 2: Peer Grading Sheet

Please grade your fellow participants fairly on the following points. (Award 5 points for an excellent job, 4 points for a good job, 3 points for an average job, 2 points for a below average job, and 1 point for a poor job.)

Participant Name	Project Quality	Project Results	Challenges Surmounted	Lessons Learned	Presentation Quality

Project Quality Was the project clearly defined, planned in depth, and carried out as assigned?

Project Results Was the project implemented well, and completed by the due date? Did actual improvement occur in the laboratory? Was patient care improved?

Challenges surmounted Were challenges met and surmounted? Did the laboratory team show initiative and innovation in dealing with challenges?

Lessons Learned Did the laboratory team take the opportunity to learn lessons from difficulties, challenges, and presumed failures? Were those lessons shared?

Presentation Quality Did the person summarize his/her laboratory team's project well? Did they clearly articulate the project, results, challenges, and lessons learned? Were they short and to the point? Did they respect the time limit?

ACTIVITY Using the Checklist to Improve the Laboratory Cross-cutting

PURPOSE:

The SLIPTA Checklist serves several purposes, including:

- An objective tool to measurably assess laboratories
- An educational guidance document to show the way toward laboratory improvement
- A training monitoring tool

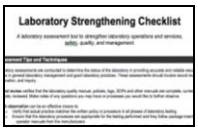
This activity allows participants to become familiar with the Checklist, to gain experience using it in an actual laboratory assessment, and to focus on using it to improve the laboratory.

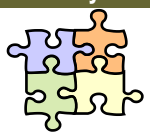
RESOURCES FOR FACILITATOR:

- ❑ PowerPoint slides: XC.47 to XC.73
- ❑ Flipchart & Markers

RESOURCES FOR PARTICIPANT:

- ❑ SLIPTA Checklist (001)
- ❑ Worksheet 1: Using the Checklist (XC 36)
- ❑ Worksheet 2: Quality Improvement Project Plan (XC 30)
- ❑ Job Aid: Using the Checklist (Completed) (XC 37)
- ❑ Pens

This activity supports the following laboratory management tasks and SLIPTA checklist items	
Management Tasks 	1.1 Develop and implement lab improvement plans based on best practices and feedback from staff, patients, customers, quality indicators, and external assessment
Checklist Items 	6.1 Internal Audits Are internal audits conducted at intervals as defined in the quality manual and do these audits address areas important to patient care? 11.2 Quality Management System Improvement Measures Does the laboratory identify and undertake continual quality improvement projects? 11.4 Are quality indicators (TAT, rejected specimens, stock-outs, etc.) selected and tracked?

This activity is related to the following activities:	
	Cross cutting: Process Mapping, Using the Improvement Method, Planning Improvement Projects - Master Class, Reporting Improvement Projects Module 2: Conducting a Safety Audit

ACTIVITY AT-A-GLANCE				
Step		**Time**	**Resources**	**Key Points**
1	Explore uses of the SLIPTA Checklist	5 min	Slides XC.47 to XC.50	
2	Conduct orientation to the SLIPTA Checklist	10 min	Checklist Slides XC.51 to XC.61	
3	Introduce the activity	10 min	Slides XC.62	
4	Conduct the activity	20 min	Checklist Worksheet 1 Slides XC.63	
5	Debrief the activity	10 min	Job Aid Flipchart & Markers	
6	Share laboratory assessment techniques	5 min	Slides XC.64 to XC.68	

ACTIVITY AT-A-GLANCE				
Step		**Time**	**Resources**	**Key Points**
7	Conduct orientation to the laboratory assessment visit	5 min	Slides XC.69 to XC.71	
8	Conduct laboratory assessment visit	4 hours	Checklist	
9	Debrief the laboratory assessment visit	1 hour	Worksheet 2 Slides XC.72	
10	Conclude the activity	5 min	Slides XC.73	
	TOTAL TIME:	**1 hour 5 min** **Plus Site Visits & Debrief**		

PROCESS

Preparation

- For laboratory assessment visit, make prior arrangements with the laboratory and arrange logistics for participants.
    - Select a laboratory comparable in size and complexity to the participant's own laboratory.
    - Assign facilitators and participants to groups.
    - Determine scope of the assessment (i.e., what sections of the checklist will be utilized).

Overnight Homework: Ask participants to review 1) the face page of the SLIPTA Checklist - "Assessment Implementation" and 2) the specific section to be assessed.

Overnight Homework: Ask participants to complete the PLAN section of the Improvement Project Plan following the site visit field trip.

Step 1. Explore uses of the SLIPTA Checklist — 5 min

- Project Slides XC.47 to XC.50. Open a discussion regarding practical uses of the Checklist as an assessment tool - in one's own or another's laboratory. Take participants suggestions and write on flipchart.

  SLIPTA Checklist Suggested Uses:
    - **Baseline Assessment:** Prior to training or efforts toward accreditation, a baseline assessment should be obtained. Improvement requires objective measurable data to verify.
    - **Supervisory visit / training follow-up:** Consider choosing one priority section for ongoing monitoring over several visits, assessing progress made at each visit.
    - Alternatively, the supervisor can monitor a different section on each visit, while the laboratory monitors all sections for the internal audit.
    - **Moving toward accreditation:** Perform an initial self-audit (baseline assessment) and select one, two, or three areas for initial focus. Set a goal to move to the next level of achievement over the next year of monitoring. Use the Checklist as a guidance document toward this goal. Repeat full assessment after one year to assess progress toward accreditation.
- In summary, assessment, monitoring, and guidance are all functions of the checklist.

Step 2. Conduct orientation to the SLIPTA Checklist — 10 min

- Project Slides XC.51 to XC.61.
- Orient the participants to the overall organization and layout of the Checklist, the scoring system, and the interconnectedness of the Checklist items.
- Ultimately, laboratory assessment asks the question, "How well does the laboratory perform its main function – providing clinically relevant, accurate,

reliable information that benefits the care of the patient?" The Checklist seeks to examine 12 areas of laboratory function objectively to answer this important question. All the tools and improvement projects must come together in the laboratory to improve these core functions of the laboratory. Therefore, the ultimate measure of laboratory function is assessed using the Checklist and reflected in the accreditation status of the laboratory.

Step 3. Introduce the activity - Map the checklist items 10 min

- Project Slide XC.62.
- Assign participants to form groups of 2-3 persons.
- Revisit the specimen flow process.
- Have participants review the Checklist.
- Assign each group two or three of the inputs, steps, or management review categories listed in the center column of Worksheet 1: Using the Checklist.
- Walk participants through a few Checklist items and show how these items can be mapped to the steps of the specimen flow process (inputs, or review items) located in the center column. Refer to Job Aid 1: Using the Checklist (Completed).
- Have the groups complete the left column (Checklist Items) for each assigned category.
- Inform participants that they will have 20 minutes to review the checklist and map the checklist items to the category of the specimen flow process assigned.

Step 4. Conduct the activity 20 min

- Project Slide XC.63.
- Monitor activity to assure understanding of the task and timely completion.

Step 5. Debrief the activity 10 min

- Ask the participants to post their Checklist item numbers on the flipchart when they have completed their task.
- Ask 2 or 3 groups to share their answers, reading the checklist items and showing how they relate to the category in the center column - specimen flow process steps, inputs, or review items.
- Make sure that the participants understand that the checklist items relating to a given category of the specimen flow process may be found in several sections of the checklist.
- Emphasize that one cannot just read the checklist items one by one as one completes an assessment. One must follow the specimen, making notes, and then completing the Checklist.
- Familiarization with the checklist prior to the assessment visit is necessary to the assessment process.
- Encourage participants to complete all categories of the specimen flow process on their own to fully appreciate the breadth and depth of the Checklist.
- Refer participants to Job Aid 1: Using the Checklist (Completed) for a completed Worksheet.

Step 6. Share laboratory assessment techniques 5 min

- Project Slides XC.64 – XC.68 - Share assessment techniques.
- Focus the discussion on the actual performance of an assessment.

  SLIPTA Checklist Implementation:
  - **Reading documents:** Are the policies, procedures, documents and records need in place?
  - **Observing Practices:** Do the laboratorians follow the policies and procedures that are in place?
  - **Asking questions: (**Refer to the face page of the SLIPTA Checklist for additional guidance regarding "Assessment Implementation".) Do not proceed through reading each question laboriously to the laboratorian. Asking general open-ended questions is likely to elicit broader responses that may cover several Checklist items.
  - **Assessment methods:** Three methods are noted. In this course, the approach which follows the specimen flow will be followed. One can ask to follow a single specimen **prospectively** in its flow around the laboratory, beginning with receipt of the sample and observing until the result is released to the referring clinician.
  - The assessment may begin with a review of the policies, procedures, manuals, personnel files, documentation, etc and then proceed to specimen flow.

Note: A complete assessor's training certification course on the Checklist is beyond the scope of this activity, and is indeed an entire workshop in itself. However, this does not preclude the use of this tool for self-audit, specific area-directed assessment, training follow-up and monitoring, and assessment in monitoring progress along the road to accreditation.

Step 7. Conduct orientation to the laboratory assessment visit 5 min plus homework

- On the day prior to site visit, post the site visit agenda - including time, date, teams (facilitators and participants), and checklist sections to be assessed.
-  Ask participants to review overnight: 1) the face page of the SLIPTA Checklist ("Assessment Implementation") and 2) the specific section to be assessed.
- Describe the logistics of the field trip, i.e. time to meet, where to meet, mode of transportation, any meal arrangements, etc.

Step 8. Conduct the laboratory assessment visit 4 hours

- Using the checklist, have participants walk through the assessment process with their facilitators.
-  Remind participants to complete Worksheet 2: Improvement Project Plan overnight.

Step 9. Debrief the laboratory assessment visit — 1 hour

- Project Slide XC.72. Set aside time upon returning from the site visits to debrief the assessment process.
- Have participants report significant assessment findings as directed using Worksheet 2: Quality Improvement Project Plan. Ask participants to present one deficiency noted, along with a plan to measure and improve this issue. Emphasize that what is important is to think about these deficiencies and the approach to improvement using the improvement model.
- Use these findings to explore the challenges encountered, questions raised, and lessons learned.

Step 10. Conclude the activity — 5 min

- Link to *Process Mapping* and *Conducting a Safety Audit* activities.
- Project Slide XC.73. Highlight or reiterate the key messages below.
- Make sure participants achieved objectives of the activity.

KEY MESSAGES

- The SLIPTA Checklist provides a standardized tool for objective evaluation of the laboratory. This tool can be utilized in various ways.
- Familiarization with the Checklist is necessary in order to use this tool in an actual laboratory assessment.
- Following the specimen is one recommended assessment technique.
- Assessment relies on reading policies and procedures, observing lab practices, and asking questions.
- Assessment reveals the gaps that must be surmounted to improve the laboratory and move toward accreditation.

ACTIVITY OBJECTIVES MET?

Can they:

- State the various uses for the Checklist.
- Become familiar with the Checklist, ordering the questions in reference to the specimen flow process?
- Use the SLIPTA Checklist to objectively evaluate a laboratory?
- Understand how the Checklist is used to improve laboratories in the effort toward accreditation?

Connections and Applications

Defining Questions For Laboratory Assessment

- How does the laboratory score on an objective assessment tool such as the SLIPTA Checklist, at baseline & at routine follow-up intervals?
- Does the checklist show improvement at the routine follow-up intervals?
- How does the individual competency of a laboratorian, given a particular procedure, compare with the pre-determined benchmark of acceptable performance?

Worksheet 1: Using the Checklist

Inputs				
Checklist Item	**Policies & Procedures**	**Inputs**	**Observe**	**Ask**
		Personnel		
		Specimen		
		Equipment		
		Supplies & Reagents		

Worksheet 1: Using the Checklist

Inputs				
Checklist Item	**Policies & Procedures**	**Inputs**	**Observe**	**Ask**
		Infrastructure		
		Policies / Procedures		
		Document & Record System		

Worksheet 1: Using the Checklist

Specimen Flow Process				
Checklist Item	**Policies & Procedures**	**Step In Process**	**Observe**	**Ask**
		Order Placed		
		Patient presents to laboratory		
		Requisition reviewed by Laboratory staff		
		Specimen type determined for collection		
		Specimen collected		

Worksheet 1: Using the Checklist

Specimen Flow Process				
Checklist Item	**Policies & Procedures**	**Step In Process**	**Observe**	**Ask**
		Specimen logged		
		Specimen accepted or rejected		
		Specimen assigned according to test request		
		Routine quality checks completed		
		Specimen analyzed		

Worksheet 1: Using the Checklist

Specimen Flow Process				
Checklist Item	**Policies & Procedures**	**Step In Process**	**Observe**	**Ask**
		Test results analyzed		
		Test results recorded		
		Test results communicated /reported		
		Documents & records maintained, filed & stored		

Worksheet 1: Using the Checklist

Management Evaluation				
Checklist Item	**Policies & Procedures**	**Step In Process**	**Observe**	**Ask**
		Management Reviews		
		Staff Meetings		
		Equipment		
		Internal Audit		

Job Aid: Using the Checklist (Completed)

Inputs				
Checklist Item	**Policies & Procedures**	**Inputs**	**Observe**	**Ask**
1.5, 3.1-3.7, 7.5, 12.16-12.21	Competency Assessment; Training Plan; Safety Manual	Personnel	Work Schedule, Workstation Assignment, Organogram, Personnel Files including occupational illness or injury & vaccination status; Training Plan; Safety training for laboratory staff & couriers & cleaners; Safety Plan, PEP,; Safety officer designated	To whom do you report directly? Are matters addressed & resolved when you report problems? What would you do in case of a chemical spill?
1.5, 1.7, 8.7		Specimen	(See specimen flow process table below)	
1.5, 5.1-5.16, 7.5, 9.9, 9.10, 12.8, 12.15		Equipment	(See specimen flow process table below – Analysis step) Biosafety cabinet; Refrigerators with specimens & reagents stored separately	
1.5, 2.1, 2.2, 7.1-7.12, 12.11	Forecasting & Procurement; Inventory P/P	Supplies & Reagents	SOPs, Forecasting & Procurement system, Review of S/R specifications, Manager review supply request forms; List of suppliers; Orders tracked, inspected & receipted; Inventory control system; Inventory records; Consumption records; Physical stock counts; Storage area – (See 7.11) FIFO, expired products disposed within expiry dates, Hazardous chemicals; Refrigerators – FIFO, within expiry dates; Stock outs;	Describe your inventory control system? How often are S/P specifications reviewed? How often do you perform a physical inventory count? How do you dispose of expired reagents / supplies? How many stock outs have you experienced in the last year?
1.5, 7.5, 12.1-12.7, 12.10-12.16, 12.18		Infrastructure	Laboratory Layout; Separation of client area & testing area; Signage; Waste disposal; Sharps; Fire Extinguisher; Safety Equipment; PEP Policy	
1.2, 1.5-1.9, 3.6, 12.9	SOPs for all laboratory activities; Training P/P	Policies / Procedures	SOPs – Present, easily accessible, Signed by all staff; Procedures dated & retained	

Job Aid: Using the Checklist (Completed)

Inputs				
Checklist Item	**Policies & Procedures**	**Inputs**	**Observe**	**Ask**
1.1-1.11, 9.1-9.5	Document & Record Control including preservation; Document & Record Master List	Document & Record System	Quality Manual, Safety Manual, D & R system – Policy on procedure creation, circulation, retention, & preservation;	

Job Aid: Using the Checklist (Completed)

Specimen Flow Process				
Checklist Item	**Policies & Procedures**	**Step In Process**	**Observe**	**Ask**
1.5-1.7, 4.1, 4.3, 8.3	Verbal Orders	Order Placed	Laboratory Handbook	Clinicians – Do you know lab hours of operation, how to collect & transport specimens properly, expected TAT, etc.?
1.5, 1.6, 8.1, 8.2, 8.7, 12.5	Guidelines for Patient ID, Specimen collection, labeling, transport;	Patient presents to laboratory	SOPs at reception, SOP signoff; Authorized Signage	Walk me through the path that a specimen would take from the time it enters the laboratory until the result is released to the clinician.
1.5, 1.6, 8.1, 8.2, 8.7	Guidelines for Patient ID, Specimen collection, labeling, transport	Requisition reviewed by Laboratory staff	SOP; Requisition	
1.5, 1.6, 8.1, 8.2, 8.7		Specimen type determined for collection	SOP	
1.5, 1.6, 8.1, 8.2, 8.4, 12.3	Guidelines for Patient ID, Specimen collection, labeling, transport & storage;	Specimen collected	SOP; Workstation Set-up	
1.5, 1.6, 8.2, 8.3, 8.14	SOP for specimen handling	Specimen logged	SOP, Specimen Register	
1.5, 1.6, 2.1, 8.3	Specimen rejection	Specimen accepted or rejected	SOPs; Documented management review;	
1.5, 1.6, 8.2-8.5, 8.14	Specimen Storage, Referral & Packaging; Urgent requests	Specimen assigned according to test request	TAT & process times; Specimen Storage – racks, refrigerator; Specimen referral log;	

Job Aid: Using the Checklist (Completed)

Specimen Flow Process				
Checklist Item	**Policies & Procedures**	**Step In Process**	**Observe**	**Ask**
1.5, 1.6, 2.1, 8.7-8.10, 8.12, 8.13, 10.1-10.5, 11.1, 11.4-11.6	SOPs for QA. Quality Manual	Routine quality checks completed	Documented management review; Temp Charts – review, ranges, corrective action; QC Log – monitored, occurrence reports, corrective actions, & preventive measures; Discordant rates review; Reagent Log; Graphical Charts	How do you verify your QC results?
1.5, 1.6, 1.8, 2.1, 2.2, 3.1, 5.1-5.16, 7.7, 7.9-7.11, 8.7, 8.11, 12.3, 12.4, 12.16	Specific Analyte SOPs; Equipment Validation; Equipment Backup; Grading Micro Exams	Specimen analyzed	SOP at workstation; SOP signoff; Procedures dated; Documented review of preventive maintenance & corrective action reports; Workstation assignments posted; Equipment placement; Equipment validated; **Equipment Information** - "Book of Life" – Operators manuals, Inventory, Service information & service records, repair orders, corrective action, calibration, preventive maintenance; Back up procedures; Non-functioning equipment removed; Workstation clean & safe; **Reagent Information** - FIFO, Expiry dates, consumption records; PPE	How often does your equipment go down? What happens when your equipment goes down? Has this lab provided uninterrupted service over the last year?

Job Aid: Using the Checklist (Completed)

Specimen Flow Process				
Checklist Item	**Policies & Procedures**	**Step In Process**	**Observe**	**Ask**
1.5, 1.6, 8.7, 8.9, 8.10, 9.6, 9.8		Test results analyzed	QC log review documented prior to release of patient results; QC results validated; Results cross-checked; Corrective action review; Discordant results review; Graphical chart review;	How do you verify your QC results? Are laboratory results analyzed and verified prior to release? If so, who is authorized to release laboratory reports?
1.5, 1.6, 8.6, 8.7, 9.1-9.4	Clerical Errors; Referral Specimen P/P	Test results recorded	SOP; Result report – legible, personnel ID, timely, traceable equipment; Referral log	
1.5, 1.6, 9.1-9.3, 9.6, 9.8, 9.9	Specimen Tracking, Result Reporting	Test results communicated /reported	SOPs, Referral Log, Test Report	Are clients happy with your reports? How do you know? Do you conduct any d\client satisfaction surveys?
1.10, 1.11, 9.5, 9.6, 9.8, 9.10	Lab Data Preservation	Documents & records maintained, filed & stored	Result archives / files storage; Record from the 12th of last month;	Please tell me how records are filed, maintained, & stored? Are there any precautions for preserving data in case of destruction?

Job Aid: Using the Checklist (Completed)

Management Evaluation				
Checklist Item	**Policies & Procedures**	**Step In Process**	**Observe**	**Ask**
2.1 – 2.4, 7.6, 11.3		Management Reviews	Work plan & Budget; Budgetary Projections; Review of Quality Records; Review Supply Requests; Quality Improvement Projects; Reports to upper management; Organogram; Review environmental checks; Review QC out-of-control, occurrence report, & cause analysis; Review discordant results; EQA result review, cause analysis, corrective action; Quality Indicators review; Client satisfaction review; Occurrence reports review with corrective & preventive action	What quality reviews are undertaken? To whom do you report? What information is submitted to upper management?
3.8		Staff Meetings	Minutes (See Checklist #3.8)	Are staff meetings held routinely?
7.5, 11.3		Equipment	Specification review; Report to upper management	How are your equipment needs reviewed and communicated to upper management?
6.1, 6.2		Internal Audit	Internal Audit with root cause analysis & corrective actions documented	How often is an internal audit conducted? What do you do with the information obtained from the internal audit?

Worksheet 2: Quality Improvement Project Plan

Quality Improvement Project Plan

PLAN

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:

_____

_____

Worksheet 2: Quality Improvement Project Plan

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?

_____

Worksheet 2: Quality Improvement Project Plan

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 _____