CROSS-CUTTING

SLMTA Participant's Manual

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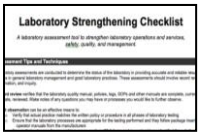
NOTE: Print this document single-sided and in color if possible.

ACTIVITY SUMMARY SHEET

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.

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

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.

SELF-ASSESSMENT

Can you:

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

For this activity, you will need:

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

Specimen Flow Process Table[XC 01]

	Step	What happens?	Who is 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

	Step	What happens?	Who is 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

Tips: Using Process Mapping to Improve Your Laboratory[XC 02]

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

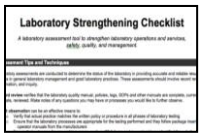
Step 8. Begin the Plan-Do-Check-Act (PDCA) Cycle to assess effect of changes

ACTIVITY SUMMARY SHEET

ACTIVITY	Using the Improvement Method	Cross-Cutting

PURPOSE:

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.

This activity supports the following laboratory management tasks and accreditation preparedness 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 	1.4 Laboratory Policies and Standard Operating Procedures Are policies and standard operating procedures (SOPs) for laboratory functions current, available and approved by authorized personnel? (Resolution of Complaints, Identification and Control of Nonconformities, Preventive Action, Continual Improvement,, Internal Audits) 2.3 Annual Review of Quality Management Systems Does the laboratory management annually perform a review of all quality systems at a management review meeting? 2.4 Quality Management System Improvement Measures Does the laboratory identify and undertake quality improvement projects? 6.2 Audit Recommendations and Action Plan & Follow up Are recommendations for corrective/preventive actions made based on audit findings; is an action plan developed with clear timelines and documented follow-up? 10.2 Is non-conforming work reviewed and submitted for troubleshooting and cause analysis? 11.2 Are quality indicators (TAT, rejected specimens, stock outs, etc.) selected, tracked, and reviewed regularly to monitor laboratory performance and identify potential quality improvement activities? 11.3 Are the outcomes of internal and external audits, PT, customer feedback and all other information derived from the tracking of quality indicators used to improve lab performance? 11.4 Is the outcome of the action taken checked and monitored to determine the effectiveness of improved quality of lab performance?

KEY MESSAGES

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

SELF-ASSESSMENT

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?

For this activity, you will need:

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

Management Scenarios[XC 02.1]

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.

Quality Improvement Project Plan[XC30]

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:

_____

_____

SECTION B: Action Plan

I. Identified problem: _____

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

_____

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

Action item	Responsible Person	Timeline	Signature

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

V. Results of element measured at baseline _____

VI. Acceptable results (target for this measure) _____

VII. Data Collection

How will the data be collected? _____

Who is responsible for collecting data? _____

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

How often will the data be collected? _____

How often will the data be reviewed?_____

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

_____

DO

IMPLEMENT Action Plan

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

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

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

Monitor how the plan is being executed.

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

CHECK

Was change effective? _____

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

_____

_____

Unexpected Observations:

_____

_____

ACT

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

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

PLAN-DO-CHECK-ACT (Next Cycle)

Plan & Implement Cycle II of Improvement Project:

Proposed date to begin Cycle II of improvement project _____

Signature of Reviewer _____ Date _____

Laboratory Director _____ Date _____

Sample Rejections XC 02.3

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*

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

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 _____

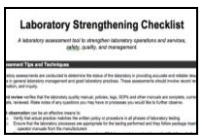
ACTIVITY SUMMARY SHEET

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.

This activity supports the following laboratory management tasks and accreditation preparedness 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 	1.9 Data Files Are test results and technical and quality records archived in accordance with national/international guidelines? 2.4 Quality Management System Improvement Measures Does the laboratory identify and undertake quality improvement projects? 4.4 Evaluation Tool and Follow up Is there a tool for regularly evaluating client satisfaction and is the feedback received effectively utilized to improve services? 5.15 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 assessment)? 7.15 Laboratory Testing Services Has the laboratory provided uninterrupted testing services, with no disruptions due to stock outs in the last year or since last assessment? 8.13 Does the laboratory participate in external Proficiency Testing (PT) or exercise an alternative performance assessment system when appropriate? 9.3 Test Result Records Are test results recorded in a logbook or electronic record in a timely manner? 11.1 Are graphical tools (charts and graphs) used to communicate quality findings and identify trends? 11.2 Are quality indicators (TAT, rejected specimens, stock outs, etc.) selected, tracked, and reviewed regularly to monitor laboratory performance and identify potential quality improvement activities? 11.3 Are the outcomes of internal and external audits, PT, customer feedback and all other information derived from the tracking of quality indicators used to improve lab performance? 11.4 Is the outcome of the action taken checked and monitored to determine the effectiveness of improved quality of lab performance?

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.

SELF-ASSESSMENT

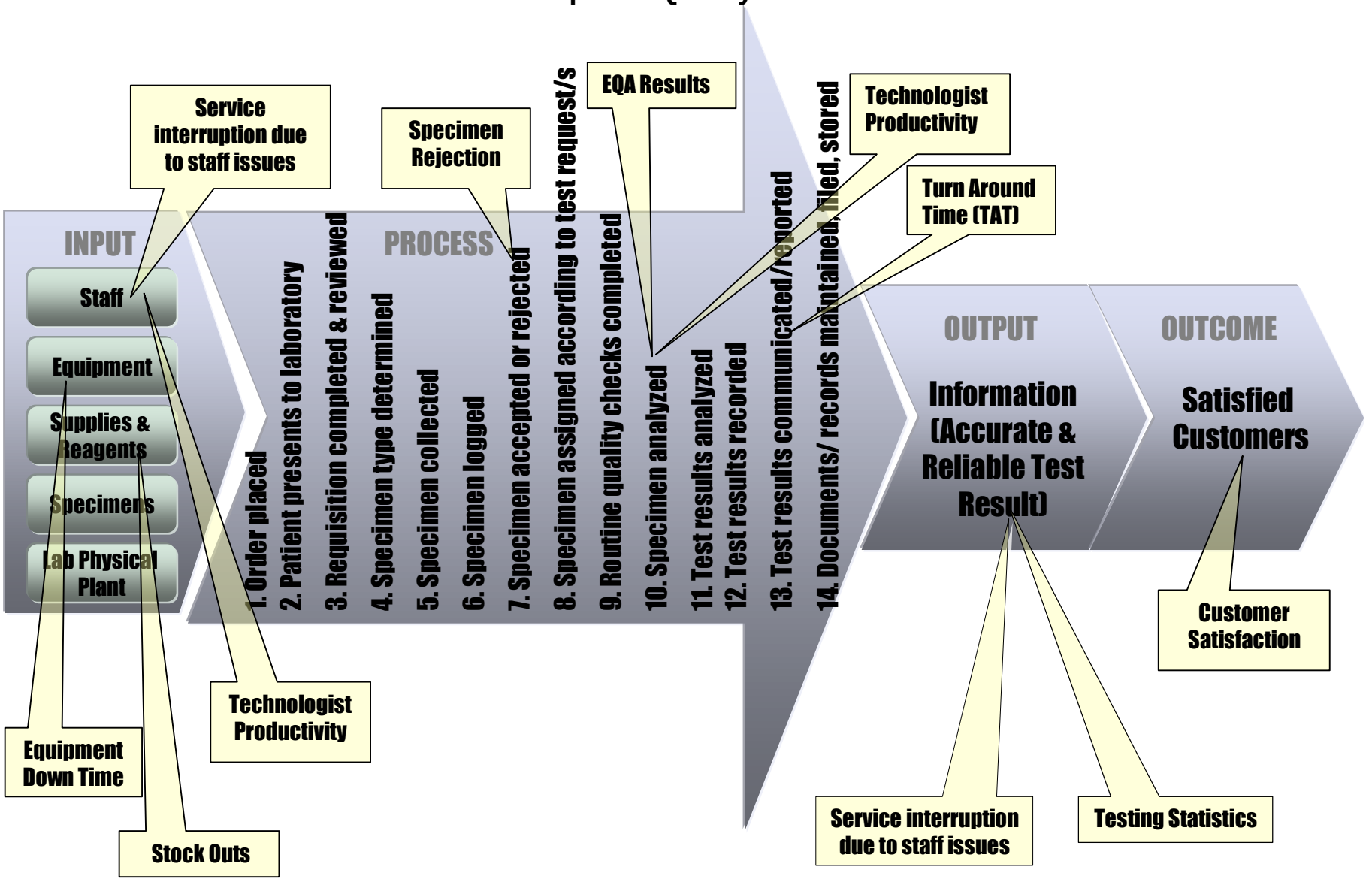
Can you:

- 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?

For this activity, you will need:

- ❑ 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)

Process Map with Quality Indicators XC 05



Balanced Scorecard XC 06

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

Quality Indicator Monthly Summary – A Case Study XC 07

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									

Quality Indicator Quiz XC 08

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*

Quality Indicator Investigation Worksheet XC 09

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?	

Monthly Laboratory Report Example[XC10]

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 Determe 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

QUALITY INDICATOR MONTHLY SUMMARY TEMPLATE[XC 11]

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									

Quality Improvement Project Plan[XC30]

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:

_____

_____

SECTION B: Action Plan

I. Identified problem: _____

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

_____

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

Action item	Responsible Person	Timeline	Signature

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

V. Results of element measured at baseline _____

VI. Acceptable results (target for this measure) _____

VII. Data Collection

How will the data be collected? _____

Who is responsible for collecting data? _____

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

How often will the data be collected? _____

How often will the data be reviewed?_____

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

_____

DO

IMPLEMENT Action Plan

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

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

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

Monitor how the plan is being executed.

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

CHECK

Was change effective? _____

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

_____

_____

Unexpected Observations:

_____

_____

ACT

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

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

PLAN-DO-CHECK-ACT (Next Cycle)

Plan & Implement Cycle II of Improvement Project:

Proposed date to begin Cycle II of improvement project _____

Signature of Reviewer _____ Date _____

Laboratory Director _____ Date _____

ACTIVITY SUMMARY SHEET

ACTIVITY 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.

This activity supports the following laboratory management tasks and accreditation preparedness 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:

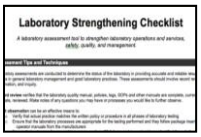
- 6.6 Review discordant rates and determine appropriate action
- 6.7 Review records of environmental checks & QC trends to assess impact on testing and take corrective action
- 6.10 Customize site-specific SOPs as needed

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 Workload, Schedule and Coverage Do work schedules show task assignments & coordination of work for adequate lab staff coverage? 3.2 Duty Roster And Daily Routine Are daily routine work tasks established, assigned (duty roster and workstation assignments/tasks), monitored and supervised by qualified professional staff, and which indicates that only authorized personnel perform specific tasks? 3.3 Organizational Chart and External/Internal Reporting Systems Are lines of authority and responsibility clearly defined for all lab staff, including the designation of a supervisor and deputies for all key functions? Module 2: 8.11 Are environmental conditions are checked and reviewed accurately? 8.12 Have acceptable ranges been defined for all temperature- dependent equipment with procedures and documentation of action taken in response to out of range temperatures? 10.2 Is non-conforming work reviewed and submitted for troubleshooting and cause analysis? 12.4 Is the physical work environment appropriate for testing? 12.6 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 Is sufficient waste disposal available and is waste separated into infectious and non-infectious waste, with infectious waste autoclaved, incinerated, or buried? 12.12 Are 'sharps' handled and disposed of properly in 'sharps' containers that are appropriately utilized? 12.16 Is personal protective equipment (PPE) easily accessible at the workstation and utilized appropriately and consistently? Module 3 and 4: 7.12 Inventory Organization and Wastage Minimization Is First-Expiration-First-Out (FEFO) practiced? 7.14 Product Expiration Are all reagents/test kits in use (and in stock) currently within the manufacturer-assigned expiration dates or within stability? 12.11 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 labeled or marked? 5.4 Equipment Maintenance Records Is relevant equipment service information readily available in the laboratory? 5.7 Equipment Preventive Maintenance Is routine preventive maintenance performed on all equipment and recorded according to SOPs/log sheet? 5.8 Equipment Service Maintenance Is equipment routinely serviced according to schedule by qualified and competent personnel and is this information documented in appropriate logs? 5.13 Manufacturer's Operator Manual Are the equipment manufacturer's

	operator manuals readily available to testing staff, and where possible, available in the language understood by staff? 8.7 Is there a reagent logbook for lot number and dates of opening that reflects verification of new lots? Module 6: 1.5 Policy and SOPs Accessibility Are policies and SOPs easily accessible/ available to all staff and written in a language commonly understood by respective staff? 1.6 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? 1.7 Document Control Log Are policies and procedures dated to reflect when it was put into effect and when it was discontinued? 8.6 Is complete procedure manual available at the workstation or in the work area? 8.9 Is internal quality control performed, documented, and verified before releasing patient results? 8.10 Are QC results monitored and reviewed (biases, shifts, trends, and Levy-Jennings charts)? Is there documentation of corrective action when quality control results exceed the acceptable range in a timely manner? 10.4 Are discordant results tracked and appropriate corrective action taken? 11.2 Are quality indicators (TAT, rejected specimens, stock outs, etc.) selected, tracked, and reviewed regularly to monitor laboratory performance and identify potential quality improvement activities? 12.3 Is each individual workstation maintained free of clutter and set up for efficient operation? Module 7: 8.1 Are guidelines for patient identification, specimen collection (including client safety), labeling, and transport readily available to persons responsible for primary sample collection? 8.2 Are adequate sample receiving procedures in place? 12.2 Are the patient care and testing areas of the laboratory distinctly separate from one another? 12.5 Is the laboratory properly secured from unauthorized access with appropriate signage? Module 8: 9.3 Test Result Records Are test results recorded in a logbook or electronic record in a timely manner? 9.8 Test Result Report Is the laboratory result report(s) in a standard form determined to be acceptable by its customers? Module 9: 9.5 Result Cross-check System Is there a system for reviewing for transcription errors? 10.1 Are all laboratory-documented occurrence reports indicating the root cause of the problem(s) and corrective & preventive actions taken to prevent recurrence? Module 10: 1.3 Document and Records Are documents and records properly maintained, easily accessible and fully detailed in an up-to-date Master List? 1.9 Data Files Are test results and technical and quality records archived in accordance with national/international guidelines? 1.10 Archived Results Accessibility Are archived records and results easily retrievable in a timely manner? 2.2 Review of Quality and Technical Records Does the laboratory supervisor routinely perform a documented review of all quality and technical

	records? 9.6 Archived Data Labeling and Storage Are archived results (paper or data-storage media) properly labeled and stored in a secure location accessible only to authorized personnel?

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 you:

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

SELF-ASSESSMENT

For this activity, you will need:

- ❑ 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)

MATERIAL SAFETY DATA SHEET (MSDS) XC 13

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

Generated	11/07/2007
Revision	11/07/2007
Supersedes Revision	04/08/2007
Date Created	09/08/1994

Duties for Workstation XC 14

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

XC 15

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							
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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

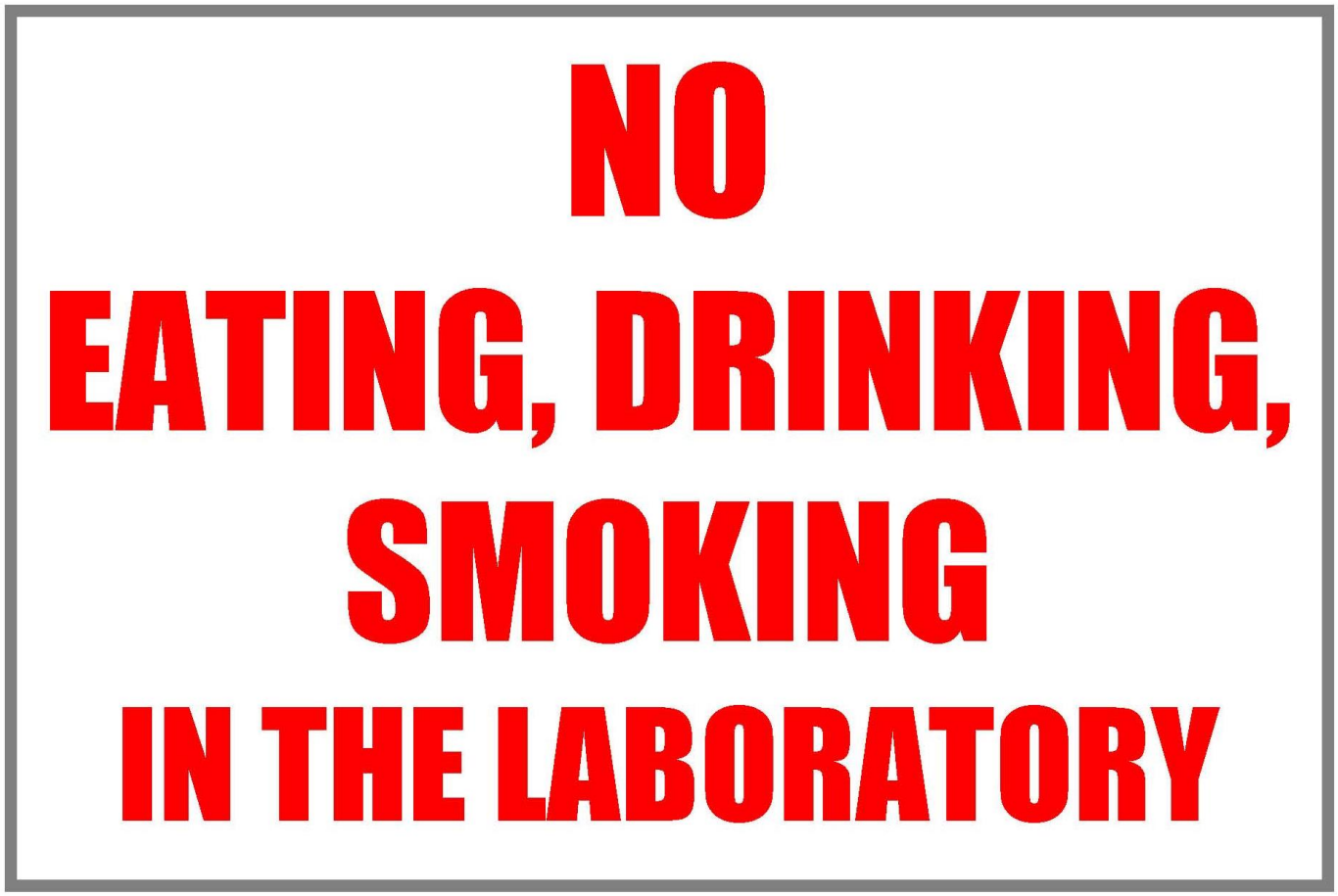
Annually

verify thermometer accuracy/acceptability

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

Safety Signs[XC 16]

Safety Signs[XC 16]



Laboratory Management

XC 17

Clinic Laboratory

Maintenance Log

SN# AJ33055

Month/Year

		Daily							Weekly			Comments
Date	Tech	Startup	Waste O.K.	Background Count	Reproducibility	QC (L, N, H) Performed	QC (L, N, H) Plotted	Shutdown 1 hour	Extended Clean	Rinse Flow Cell	Wipe Instrument	As Needed/Non Scheduled 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.

XC 18

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

XC 19

Corrective Action Log

Date:	Action Performed:	Initials:

Chemistry Critical Value List XC 20

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

Signatory Cover Sheet Example[XC 21]

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

Test-specific SOP Example XC 22

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 Levy Jennings Charts for both levels of SeraChem. Look for trends or shifts and take corrective action where appropriate.

DAILY Q.C. LOG XC 23

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							

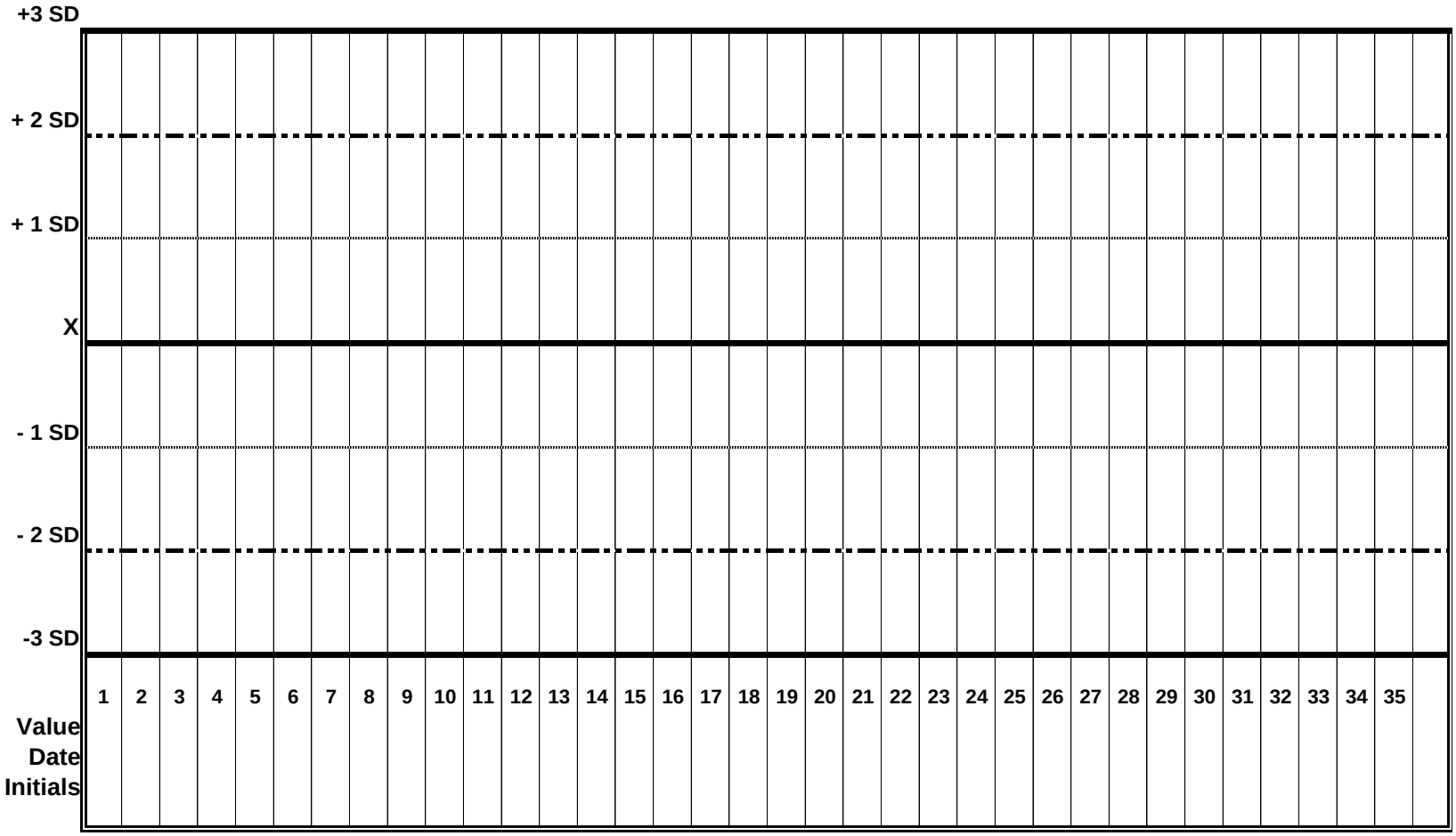
XC 24

Clinic Laboratory

L-J Chart for Control XYZ

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

Lot # _____ **Exp Date** _____



Quality Indicator Monthly Tally[XC 25]

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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18						
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23						
24						
25						
26						
27						
28						
29						
30						
31						
Total						

Restricted Access Sign[XC 26]

Report Form XC 27
Cape Clinic Laboratory

Lab #:
Collected Date/Time:
Drawn by:

Hematology

[ ] CBC **Tech initials:**

Results	Adult Normal Values			
	WBC	M/ 3.3 - 10.0	F/ 3.4 – 9.8	x10^3/ul
	RBC	4.35 - 5.9	3.69 – 5.13	x10^6/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		x10^3/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**
	Microcytosis	1 = Slight
	Macrocytosis	2 = Moderate
	Hypochromia	3 = Marked
	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
[ ] Glucose Result by Glucometer	4.1 – 5.9 mmol/l -fasting		

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:

Occurrence Report Form XC 28

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 SUMMARY SHEET

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.

This activity supports the following laboratory management tasks and accreditation preparedness 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

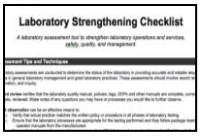
Module 5:
- 5.2 Ensure proper preventive maintenance (i.e., cleaning, proper shutdown) on instruments when used
- 5.4 Review and sign maintenance logs to ensure regular preventive maintenance and timely repairs
- 6.7 Review records of environmental checks & QC trends to assess impact on testing and take 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 Workload, Schedule and Coverage Do work schedules show task assignments & coordination of work for adequate lab staff coverage? 3.2 Duty Roster And Daily Routine Are daily routine work tasks established, assigned (duty roster and workstation assignments/tasks), monitored and supervised by qualified professional staff, and which indicates that only authorized personnel perform specific tasks? 3.5 Personnel Filing System Are Personnel Files present? 3.7 Laboratory Staff Training Does the laboratory have adequate training policies, procedures, and/or training plans, including cross-training within the laboratory team, one-on-one mentoring, and/or off-site external training? Module 2: 1.5 Policy and SOPs Accessibility Are policies and SOPs easily accessible/ available to all staff and written in a language commonly understood by respective staff? 1.6 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? 3.6 Staff Competency Assessment and Training Is there a system for competency assessment of personnel (both new hires and existing staff) and does it include planning and documentation of retraining and reassessment, when indicated? 12.12 Are 'sharps' handled and disposed of properly in 'sharps' containers that are appropriately utilized? 12.18 Are post-exposure prophylaxis policies and procedures posted and implemented after possible and known exposures? 12.19 Are occupational injuries, medical screening or illnesses documented in the safety occurrence log? 12.21 Is a trained safety officer designated to implement and monitor the safety program in the laboratory, including the training of other staff? Module 3: 7.7 Inventory Control System Is an inventory control system in place? 7.10 Inventory Control System – Stock Counts Are stock counts routinely performed? 7.12 Inventory Organization and Wastage Minimization Is First-Expiration-First-Out (FEFO) practiced? 7.14 Product Expiration Are all reagents/test kits in use (and in stock) currently within the manufacturer-assigned expiration dates or within stability? Module 4: 2.5 Communications System on Laboratory Operations Does the laboratory communicate with upper management regularly regarding personnel, facility, and operational needs?

	5.14 Communication on Effectiveness of Quality Management System Are equipment specifications and maintenance needs routinely communicated to upper management? 7.1 Inventory and Budgeting System Is there a system for accurately forecasting needs for supplies and reagents? 7.4 Budgetary Projections Are budgetary projections based on personnel, test, facility and equipment needs, and quality assurance procedures and materials? Module 5: 2.2 Review of Quality and Technical Records Does the laboratory supervisor routinely perform a documented review of all quality and technical records? 5.7 Equipment Preventive Maintenance Is routine preventive maintenance performed on all equipment and recorded according to SOPs/log sheet? 8.6 Is complete procedure manual available at the workstation or in the work area? 8.11 Are environmental conditions are checked and reviewed accurately? Module 6: 3.6 Staff Competency Assessment and Training Is there a system for competency assessment of personnel (both new hires and existing staff) and does it include planning and documentation of retraining and reassessment, when indicated? 8.13 Does the laboratory participate in external Proficiency Testing (PT) or exercise an alternative performance assessment system when appropriate? Module 7: 1.4 Laboratory Policies and Standard Operating Procedures Are policies and standard operating procedures (SOPs) for laboratory functions current, available and approved by authorized personnel? (Resolution of Complaints) 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 Are guidelines for patient identification, specimen collection (including client safety), labeling, and transport readily available to persons responsible for primary sample collection? 8.2 Are adequate sample receiving procedures in place? Module 8: 9.5 Result Cross-check System Is there a system for reviewing for transcription errors? 10.1 Are all laboratory-documented occurrence reports indicating the root cause of the problem(s) and corrective & preventive actions taken to prevent recurrence? 10.2 Is non-conforming work reviewed and submitted for troubleshooting and cause analysis? Module 9: 9.5 Result Cross-check System Is there a system for reviewing for transcription errors? 4.4 Evaluation Tool and Follow up Is there a tool for regularly evaluating client satisfaction and is the feedback received effectively utilized to improve services? 10.1 Are all laboratory-documented occurrence reports indicating the root cause of the problem(s) and corrective & preventive actions taken to prevent recurrence?

	10.2 Is non-conforming work reviewed and submitted for troubleshooting and cause analysis? Module 10: 1.2 Document and Information Control System Does the laboratory have a system in place to control all documents and information (internal and external sources)? 1.3 Document and Records Are documents and records properly maintained, easily accessible and fully detailed in an up-to-date Master List? 1.4 Laboratory Policies and Standard Operating Procedures Are policies and standard operating procedures (SOPs) for laboratory functions current, available and approved by authorized personnel? (Identification and Control of Nonconformities, Corrective Action, Patient Confidentiality) 1.7 Document Control Log Are policies and procedures dated to reflect when it was put into effect and when it was discontinued? 9.6 Archived Data Labeling and Storage Are archived results (paper or data-storage media) properly labeled and stored in a secure location accessible only to authorized personnel? 12.5 Is the laboratory properly secured from unauthorized access with appropriate signage?

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 you:

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

SELF-ASSESSMENT

For this activity, you will need:

- ❑ Handout : Case Study Scenarios (XC 29)

Case Study Scenarios XC 29

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?

Module	Case Scenario
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?
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?

Module	Case Scenario
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?
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. You feel certain the implemented change will prevent any future happenings. 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 they 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?

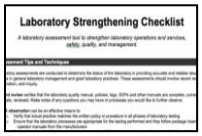
ACTIVITY SUMMARY SHEET

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.

This activity supports the following laboratory management tasks and accreditation preparedness 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 	2.4 Quality Management System Improvement Measures Does the laboratory identify and undertake quality improvement projects? 11.2 Are quality indicators (TAT, rejected specimens, stock outs, etc.) selected, tracked, and reviewed regularly to monitor laboratory performance and identify potential quality improvement activities? 11.3 Are the outcomes of internal and external audits, PT, customer feedback and all other information derived from the tracking of quality indicators used to improve lab performance? 11.4 Is the outcome of the action taken checked and monitored to determine the effectiveness of improved quality of lab performance?

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 you:

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

SELF-ASSESSMENT

For this activity, you will need:

- ❑ 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)

IP Plan [Sample Rejections] XC 12.01

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*

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?

_____

IP Plan [Turn Around Time] XC 12.02

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:

_____

_____

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*

IP Plan [Stock Outs] XC 12.03

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.*

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*

IP Plan [Equipment Maintenance] XC 12.04

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*

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*

IP Plan [Customer Complaints] XC 12.05

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.

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*

Sample Rejection Log XC 12.06

Month_____ **Year**_____

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

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

Turnaround Times Monitoring Form XC 12.07

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		→		→		→		→				

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

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".

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

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 →**				

Stock Control Bin Card XC 12.08

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: _____

Equipment Maintenance Data Collection Tools XC 12.09

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									

Customer Survey Questionnaire XC 12.10

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					

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========

Quality Improvement Project Plan[XC30]

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:

_____

_____

SECTION B: Action Plan

I. Identified problem: _____

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

_____

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

Action item	Responsible Person	Timeline	Signature

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

V. Results of element measured at baseline _____

VI. Acceptable results (target for this measure) _____

VII. Data Collection

How will the data be collected? _____

Who is responsible for collecting data? _____

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

How often will the data be collected? _____

How often will the data be reviewed?_____

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

_____

DO

IMPLEMENT Action Plan

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

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

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

Monitor how the plan is being executed.

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

CHECK

Was change effective? _____

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

_____

_____

Unexpected Observations:

_____

_____

ACT

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

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

PLAN-DO-CHECK-ACT (Next Cycle)

Plan & Implement Cycle II of Improvement Project:

Proposed date to begin Cycle II of improvement project _____

Signature of Reviewer _____ Date _____

Laboratory Director _____ Date _____

Improvement Project Report Format XC 31

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.

IP Reporting PowerPoint Template XC 32

1

Project Title

Participant Name

2

INTRODUCTION

3

AIMS & OBJECTIVES

- Aim
- Objectives

4

METHODOLOGY

5

METHODOLOGY

6

RESULTS

7

CONCLUSION

RECCOMMENDATIONS

9

8

CHALLENGES

10

ACKNOWLEDGEMENTS

EQUIPMENT MAINTENANCE DOCUMENTATION AT XXXXX LABORATORY XC 33

By

XXXXXXX

August 2010

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

Table of Contents

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

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 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
- 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 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.

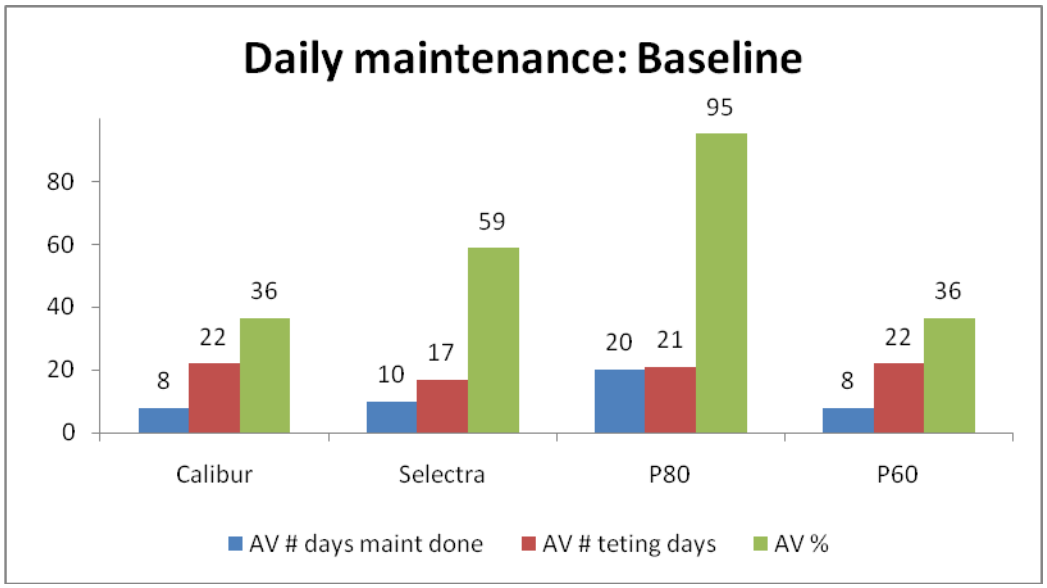


Figure 1: Average daily maintenance

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%

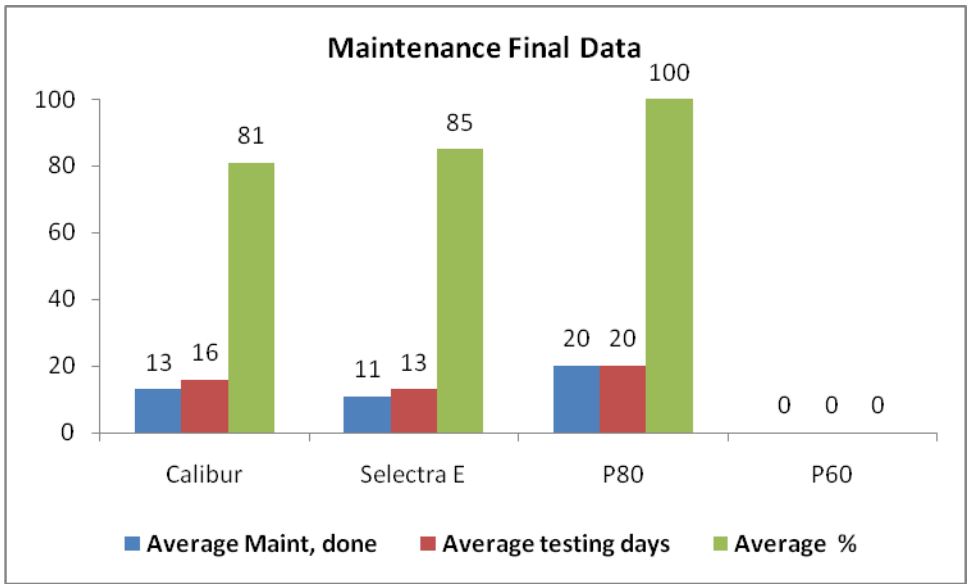


Figure 2: Maintenance final data

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.

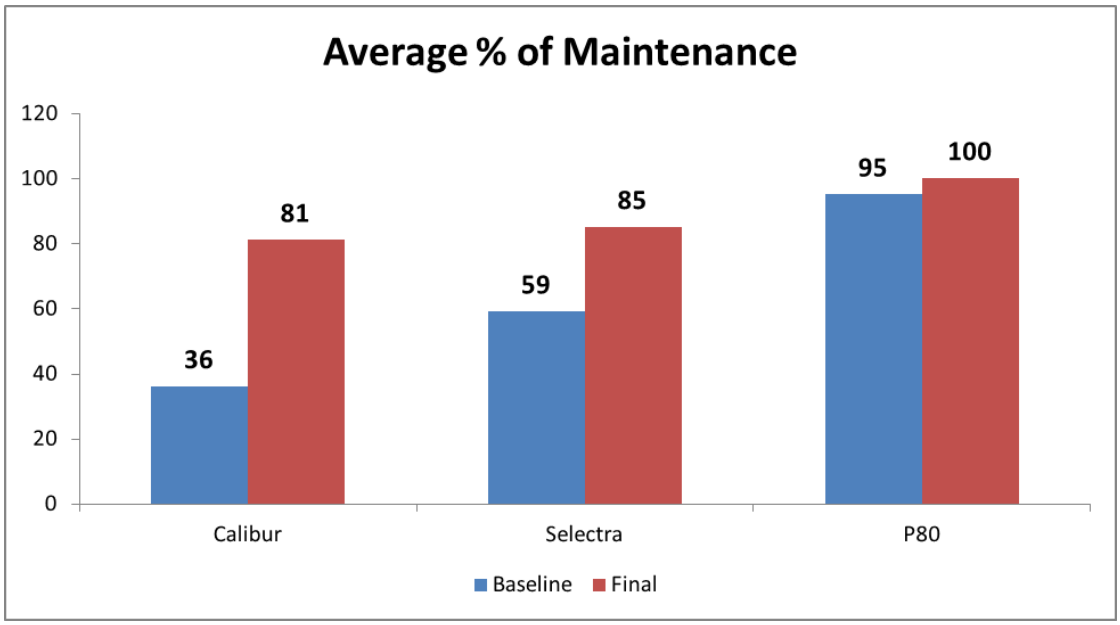


Figure 3: Average Maintenance January to July 2010

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.

4.2 Weekly Maintenance

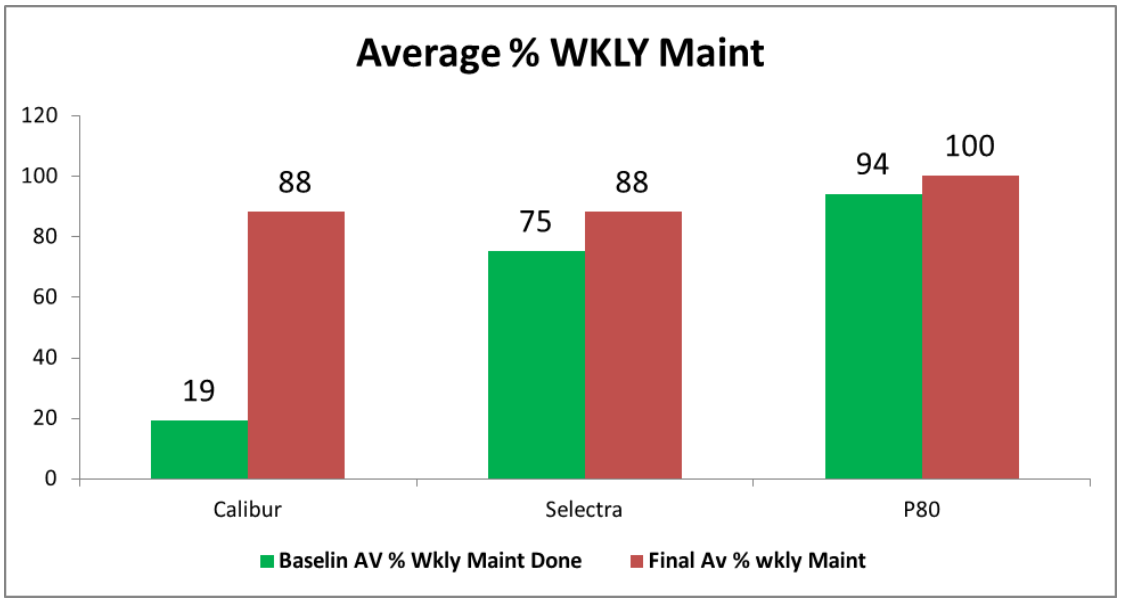


Figure 4: Average weekly maintenance

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

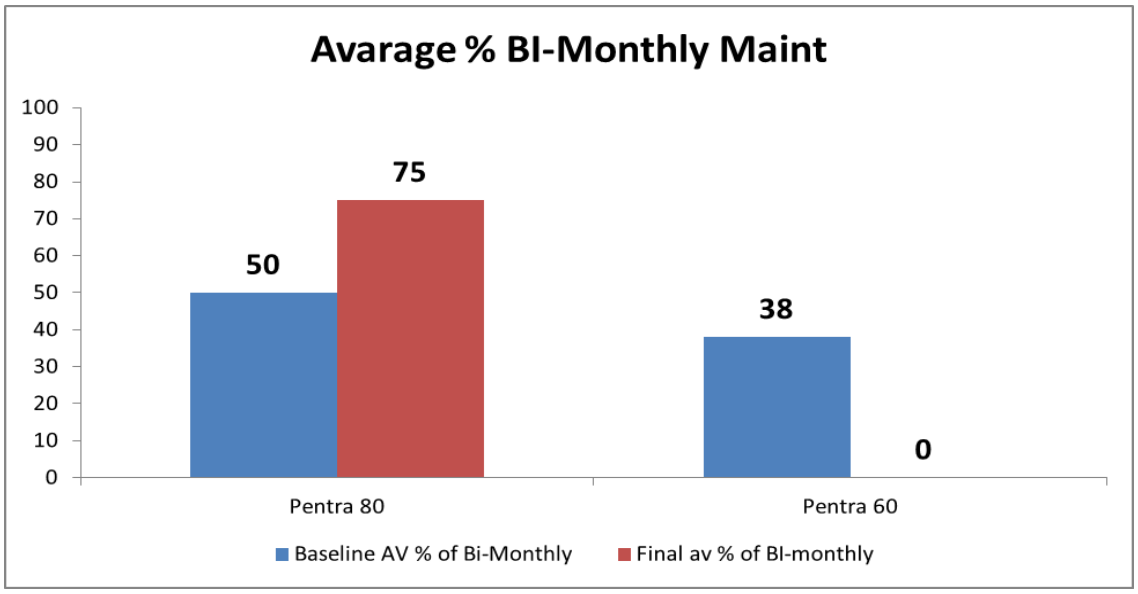


Figure 5: Average Bi-Monthly Maintenance

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

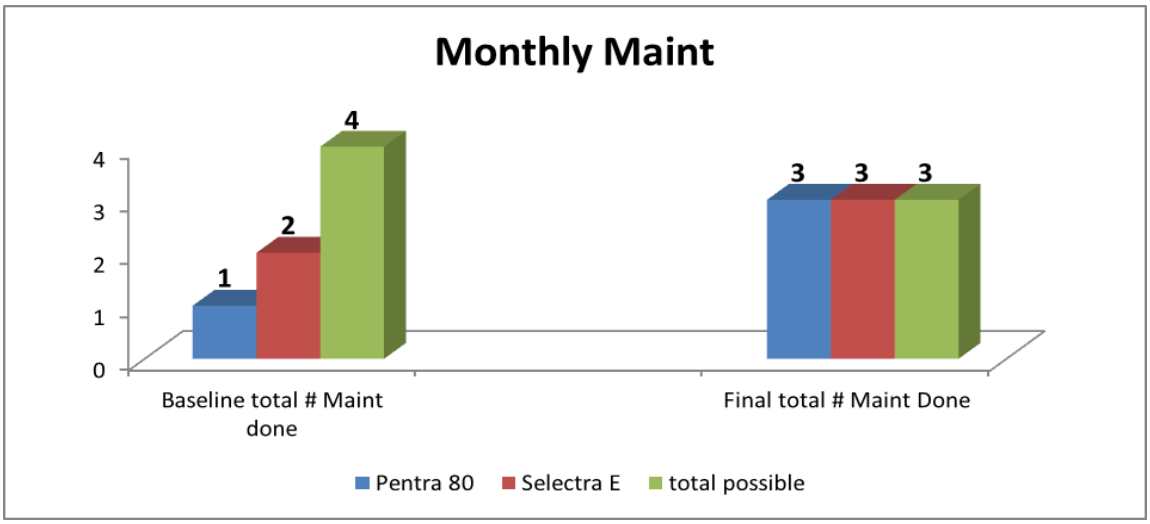


Figure 6: Monthly Maintenance

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.

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.

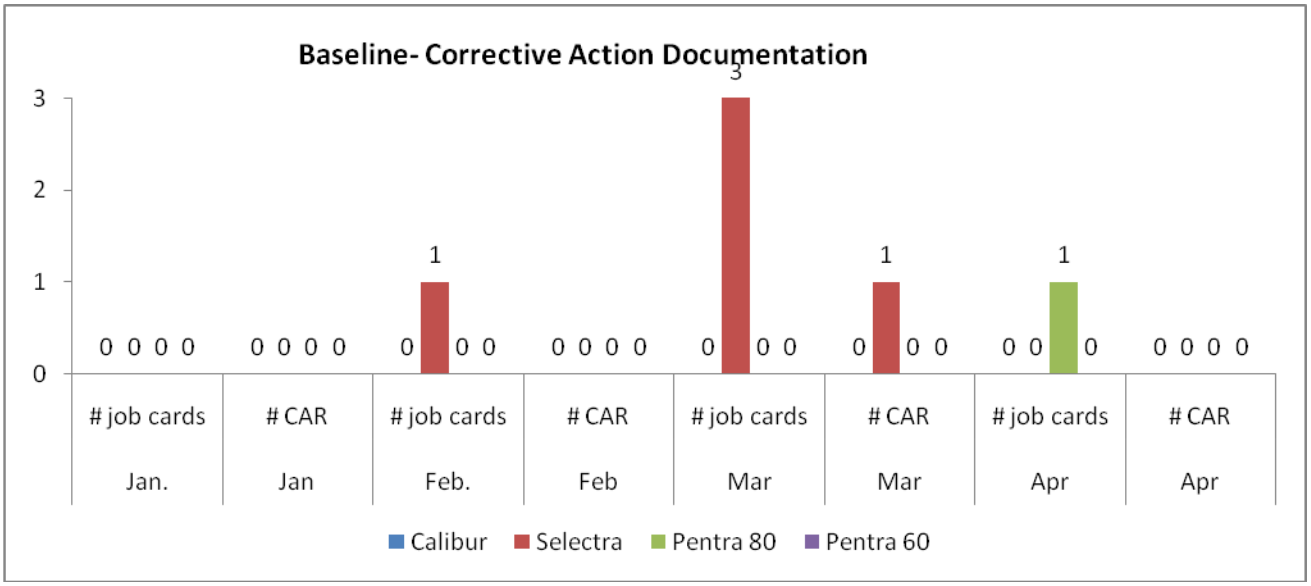


Figure 7: Corrective Action Documentation

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.

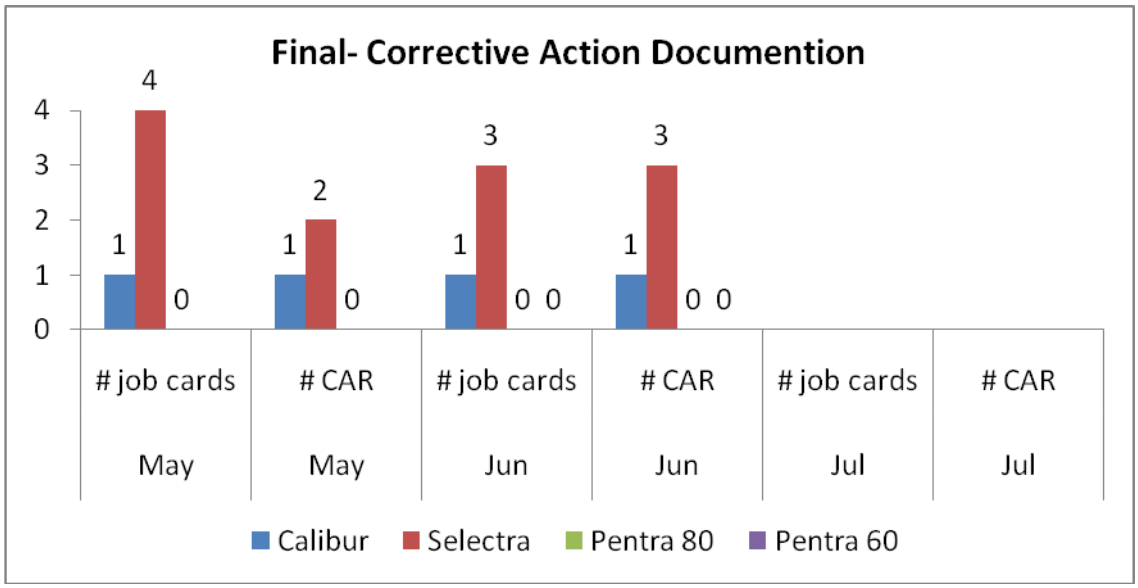


Figure 8: Corrective action documentation Final

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.

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

IP Reporting Example - Inventory management XC 34

1

IMPROVING INVENTORY MANAGEMENT

2

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.

3

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

4

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.

5

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.

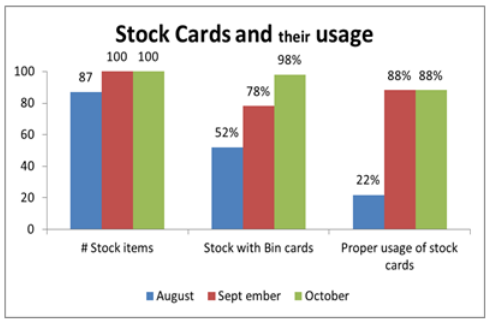
6

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

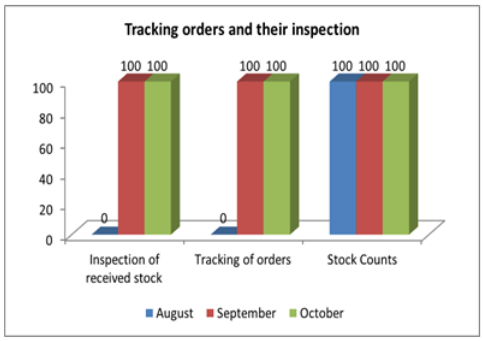
7

RESULTS



8

RESULTS



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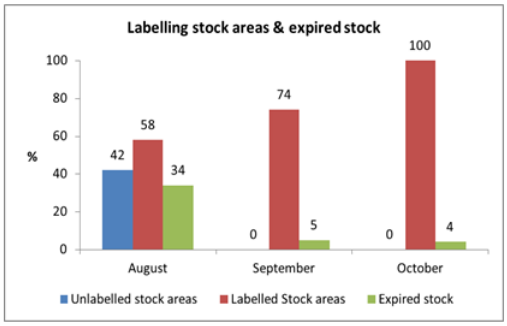
RESULTS



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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

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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

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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

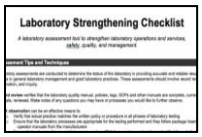
ACTIVITY SUMMARY SHEET

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.

This activity supports the following laboratory management tasks and accreditation preparedness 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 	2.4 Quality Management System Improvement Measures Does the laboratory identify and undertake quality improvement projects? 11.2 Are quality indicators (TAT, rejected specimens, stock outs, etc.) selected, tracked, and reviewed regularly to monitor laboratory performance and identify potential quality improvement activities? 11.3 Are the outcomes of internal and external audits, PT, customer feedback and all other information derived from the tracking of quality indicators used to improve lab performance? 11.4 Is the outcome of the action taken checked and monitored to determine the effectiveness of improved quality of lab performance?

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 you:

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

SELF-ASSESSMENT

For this activity, you will need:

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

Peer Grading Sheet[XC 35]

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 SUMMARY SHEET

ACTIVITY Using the Checklist to Improve the Laboratory — Cross-Cutting

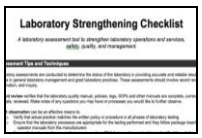
PURPOSE:

The Laboratory Accreditation Preparedness 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.

This activity supports the following laboratory management tasks and accreditation preparedness 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 	2.4 Quality Management System Improvement Measures Does the laboratory identify and undertake quality improvement projects? 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 Are quality indicators (TAT, rejected specimens, stock outs, etc.) selected, tracked, and reviewed regularly to monitor laboratory performance and identify potential quality improvement activities?

KEY MESSAGES

- The Laboratory Accreditation Preparedness 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.
-

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 Laboratory Accreditation Preparedness Checklist to objectively evaluate a laboratory?
- Understand how the Checklist is used to improve laboratories in the effort toward accreditation?

☑ ACTIVITY OBJECTIVES MET?

For this activity, you will need:

- ❑ Laboratory Accreditation Preparedness 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)

Using the Checklist[XC36]

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

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

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		

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		

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		

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

Quality Improvement Project Plan[XC30]

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:

_____

_____

SECTION B: Action Plan

I. Identified problem: _____

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

_____

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

Action item	Responsible Person	Timeline	Signature

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

V. Results of element measured at baseline _____

VI. Acceptable results (target for this measure) _____

VII. Data Collection

How will the data be collected? _____

Who is responsible for collecting data? _____

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

How often will the data be collected? _____

How often will the data be reviewed?_____

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

_____

DO

IMPLEMENT Action Plan

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

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

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

Monitor how the plan is being executed.

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

CHECK

Was change effective? _____

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

_____

_____

Unexpected Observations:

_____

_____

ACT

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

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

PLAN-DO-CHECK-ACT (Next Cycle)

Plan & Implement Cycle II of Improvement Project:

Proposed date to begin Cycle II of improvement project _____

Signature of Reviewer _____ Date _____

Laboratory Director _____ Date _____

Using the Checklist (Completed)[XC37]

Inputs				
Checklist Item	**Policies & Procedures**	**Inputs**	**Observe**	**Ask**
1.4, 2.1, 2.3, 3.1-3.3, 3.5-3.7, 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?
1.4, 1.6, 8.6		Specimen	(See specimen flow process table below)	
1.4, 2.1, 2.3, 5.1-5.15, 12.8, 12.15		Equipment	(See specimen flow process table below – Analysis step) Biosafety cabinet; Refrigerators with specimens & reagents stored separately	
1.4, 2.1, 2.3, 7.1-7.15, 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?

Inputs				
Checklist Item	**Policies & Procedures**	**Inputs**	**Observe**	**Ask**
1.4, 2.1, 2.3, 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	
1.1, 1.4-1.8, 3.7, 12.9	SOPs for all laboratory activities; Training P/P	Policies / Procedures	SOPs – Present, easily accessible, Signed by all staff; Procedures dated & retained	
1.1-1.10, 9.1-9.7	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;	

Specimen Flow Process				
Checklist Item	**Policies & Procedures**	**Step In Process**	**Observe**	**Ask**
1.1, 1.4-1.6, 4.2, 8.2	Verbal Orders	Order Placed	Laboratory Handbook	Clinicians – Do you know lab hours of operation, how to collect & transport specimens properly, expected TAT, etc.?
1.4, 1.5, 8.1, 8.2, 8.6, 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.
1.4, 1.5, 8.1, 8.2, 8.6	Guidelines for Patient ID, Specimen collection, labeling, transport	Requisition reviewed by Laboratory staff	SOP; Requisition	
1.4, 1.5, 8.1, 8.2, 8.6		Specimen type determined for collection	SOP	
1.4, 1.5, 8.1-8.3, 12.3	Guidelines for Patient ID, Specimen collection, labeling, transport & storage;	Specimen collected	SOP; Workstation Set-up	
1.4, 1.5, 8.2, 8.13	SOP for specimen handling	Specimen logged	SOP, Specimen Register	
1.4, 1.5, 2.2, 8.2	Specimen rejection	Specimen accepted or rejected	SOPs; Documented management review;	
1.4, 1.5, 8.2-8.4, 8.13	Specimen Storage, Referral & Packaging; Urgent requests	Specimen assigned according to test request	TAT & process times; Specimen Storage – racks, refrigerator; Specimen referral log;	
1.4, 1.5, 2.2, 3.2-3.4, 3.6,	SOPs for QA.	Routine quality	Documented management review;	How do you verify

Specimen Flow Process				
Checklist Item	**Policies & Procedures**	**Step In Process**	**Observe**	**Ask**
3.7, 8.6-8.13, 10.1-10.4, 11.1-11.4	Quality Manual	checks completed	Temp Charts – review, ranges, corrective action; QC Log – monitored, occurrence reports, corrective actions, & preventive measures; Discordant rates review; Reagent Log; Graphical Charts	your QC results?
1.4, 1.5, 1.7, 2.2, 2.3, 3.2, 5.1-5.13, 5.15, 7.9, 7.14, 8.6, 11.1, 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?
1.4, 1.5, 8.6, 8.9-8.13, 10.3, 10.4, 11.1-11.4		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;	How do you verify your QC results? Are laboratory results analyzed and verified prior to release? If so, who is authorized to release

Specimen Flow Process				
Checklist Item	**Policies & Procedures**	**Step In Process**	**Observe**	**Ask**
			Graphical chart review;	laboratory reports?
1.4, 1.5, 8.5, 8.6, 9.1-9.5, 11.1	Clerical Errors; Referral Specimen P/P	Test results recorded	SOP; Result report – legible, personnel ID, timely, traceable equipment; Referral log	
1.4, 1.5, 8.4-8.6, 9.8	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?
1.2-1.5, 1.7-1.10, 8.6, 9.6, 9.7	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?

Management Evaluation				
Checklist Item	**Policies & Procedures**	**Step In Process**	**Observe**	**Ask**
2.1-2.5, 3.3, 7.4, 7.5, 8.9, 8.11, 8.13, 9.8, 10.1-10.4, 11.1-11.4		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?
5.14		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?