2015 Version

MODULE 5

Equipment Maintenance

SLMTA Trainer's Guide

Overview

MODULE 5. ROUTINE / PREVENTIVE MAINTENANCE OF EQUIPMENT

Performance Outcome

With satisfactory participation in the training and successful implementation of laboratory improvement projects, a participant's laboratory should achieve the following outcome:

- Equipment is functioning all the time to ensure uninterrupted and quality service

Checklist Items Supported by this Module

This module supports the requirements for the following items from the SLIPTA Checklist:

1.5, 2.1, 2.2, 5.1, 5.3, 5.5, 5.6, 5.7, 5.9, 5.10, 5.11, 5.12, 5.13, 5.14, 5.15, 8.9, 8.10, 9.2, 9.5, 10.1, 10.2, 10.3, 10.5

Learning Objectives (Management Tasks)

By the end of this module, participants should be able to perform the following management tasks:

1. Consolidate and post equipment service information (contact, service frequency & dates, etc.) at site
2. Ensure proper preventive maintenance (i.e., cleaning, proper shutdown) on instruments when used
3. Perform and record troubleshooting on malfunctioning equipment
4. Review and sign maintenance logs to ensure regular preventive maintenance and timely repairs
5. Take corrective actions or issue repair orders and record all issues
6. Follow up on all corrective action – see if equipment is properly functioning, observe for trends or determine training needs
7. Communicate to upper management equipment specifications and maintenance needs

What's in this Module?

ACTIVITY TITLE	PURPOSE	DURATION
Creating a Maintenance and QC Log	Instrument logs must be available to record proper equipment maintenance and quality control (QC). Using excerpts from an operator's manual, participants learn to create an instrument log.	1 hr 20 min
Making a Service Call	When instrumentation issues cannot be resolved, it becomes necessary to call the service number. In this role-play activity, participants learn how to make a service call, document it, and follow through until the issue is resolved.	35 min
	TOTAL ACTIVITY TIME:	**1hr 55 min**

Overview

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ACTIVITY Creating a Maintenance and QC Log Module 5

PURPOSE:

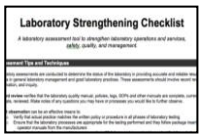
Instrument logs must be available to record proper equipment maintenance and quality control (QC). Using excerpts from an operator's manual, participants learn to create an instrument log.

RESOURCES FOR FACILITATOR:

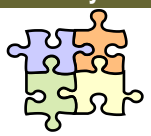
- ❑ PowerPoint slides: 5.6 to 5.14
- ❑ Tape, flipchart and markers

RESOURCES FOR PARTICIPANT:

- ❑ Handout 1: Reflotron Operator's Manual Excerpts (501)
- ❑ Handout 2: Suggested Format for Maintenance/QC Log (502)
- ❑ Handout 3: Sample Maintenance/QC Log (503)
- ❑ Worksheet: Creating a Maintenance/ QC Log (504)
- ❑ Job Aid 1: Documents and Records (505)
- ❑ Job Aid 2: Monthly Analyzer Review (506)
- ❑ Job Aid 3: Equipment Inventory Form (507)

This activity supports the following laboratory management tasks and SLIPTA checklist items	
Management Tasks 	1.9 Create a work plan and budget based on personnel, test, facility, and equipment needs. 5.1 Consolidate and post equipment service information. 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 5.7 Communicate to upper management equipment specifications and maintenance needs.
Checklist Items 	1.5 Laboratory Policies and Standard Operating Procedures Are policies and/or standard operating procedures (SOPs) for laboratory functions, technical and managerial procedures current, available and approved by authorized personnel? (Laboratory equipment; Calibration of Equipment; Validation and Verification of examination procedures / Equipment) 2.1 Routine Review of Quality and Technical Records Does the laboratory routinely perform a documented review of all quality and technical records? 2.2 Management Review Does the laboratory management perform a review of the quality system at a management review meeting at least annually? 5.3 Equipment and Method Validation/Verification and Documentation Are all equipment and methods validated/verified on-site upon installation and before use and is documented evidence available? 5.5 Equipment Record Maintenance Is current equipment inventory data available for all equipment in the laboratory? 5.6 Equipment Maintenance Records Is relevant equipment service information readily available in the laboratory? 5.9 Equipment Calibration and Metrological Traceability Protocol 5.10 Equipment Preventive Maintenance Is routine user preventive maintenance performed on all equipment and recorded according to manufacturer's minimum requirements?

	5.11 Equipment Service Maintenance Is equipment routinely serviced according to schedule as per the minimum manufacturer recommendations by qualified and competent personnel and is this information documented in appropriate logs? 5.15 Manufacturer's Operator Manual Are the manufacturer's operator manuals readily available to testing staff and, available in the language understood by staff? 8.9 Quality Control Is internal quality control performed, documented, and verified for all tests/procedures before releasing patient results? 8.10 Quality Control Data Are QC results monitored and reviewed (including biases and Levy-Jennings charts for quantitative tests)? 9.2 Testing Personnel Are testing personnel identified on the result report or other records (manual or electronic)? 9.5 Archived Data Labelling and Storage Are archived results (paper or data-storage media) properly labelled and stored in a secure location accessible only to authorized personnel?

This activity is related to the following activities:	
	Cross-Cutting: Workstation Set-up Module 1: Creating a Management Calendar Module 1: How Do You Assign Personnel to Tasks? Module 5: Making a Service Call Module 6: Using Standard Operating Procedures Module 10: Why Was the Outdated Version Used?

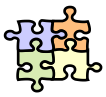
ACTIVITY AT-A-GLANCE				
Step		**Time**	**Resources**	**Key Points**
1	Explain why instrument records are important	15 min	Slides 5.6 to 5.10 Job Aid 1 Job Aid 2 Job Aid 3	
2	Introduce the activity	10 min	Slides 5.11 to 5.12 Handout 1	
3	List the individual steps for creating a log	20 min	Worksheet Handout 1	
4	Conduct the activity	15 min	Worksheet Handout 1	
5	Debrief the activity	15 min	Slides 5.13 to 5.14 Handout 2 Handout 3	
6	Conclude the Activity	5 min		
	TOTAL TIME:	**80 min**		

PROCESS

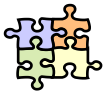
Preparation

Overnight Homework: Assign the reading of Job Aid 1: Documents and Records and Handout 1: Reflotron Operator's Manual Excerpts on the night prior to the activity.

Step 1. Explain why instrument records are important — 15 min



- Project Slides 5.6 to 5.10 to introduce the activity and to discuss the various documents and records required for equipment management. Indicate how records provide evidence of the completion of scheduled tasks and troubleshooting clues. Link this concept to *Making a Service Call* and *Workstation Set-up* activities. In addition, records can be used as an advocacy tool to communicate operational needs with upper management regarding frequent or extended down-times.
- Distribute or refer participants to Job Aid 1: Documents and Records. Ask participants what equipment they use that has predefined maintenance and calibration requirements. Ensure the discussion includes ancillary equipment.



- Distribute or refer participants to Job Aid 2: Monthly Analyzer Review. Emphasize that it is the manager's responsibility to ensure the tasks are completed, acceptable and documented by the assigned personnel. Managers must schedule time to perform this review and document when it was performed. Link this concept to activities - *How Do You Assign Personnel to Tasks?* and *Creating a Management Calendar* activities.
- Distribute or refer participants to Job Aid 3: Equipment Inventory Form. Emphasize that a manager is accountable for all equipment at their site. A complete inventory equipment list will assist with scheduling maintenance performed by outside service providers and with budgeting/forecasting equipment needs.

Step 2. Introduce the activity — 10 min

- Project Slides 5.11 to 5.12 to provide an overview of the activity and a picture of the instrument.
- Indicate that some instrument operator's manuals include record templates. In cases where templates are not provided or require modifications in order to match the laboratory procedures, records will need to be created.
- Explain that logs can easily be created or adapted from the information found in the operator's manual. Emphasize that an equipment log can be created for any instrumentation using the information found in the operator's manual.
- Indicate that participants will use excerpts from the operator's manual to create a maintenance and QC log for the Reflotron for the following two analytes: bilirubin and creatinine. Explain the maintenance for the Reflotron is minimal; therefore they can combine the maintenance and QC log into one document.
- Ask participants to read Handout 1: Reflotron Operator's Manual Excerpts. Allow 5 minutes to review this handout.

Step 3. List the individual steps for creating a log — 20 min

- Write on a flipchart "Step 1 Common Elements." Define "common elements" as any items applicable to any method or test. Ask participants to provide common elements needed in each log. List the responses on a flipchart. Some common elements include the staff member's initials, the date performed, the title of the log, an area to document supervisor's review, and the document control number.
- Write on a flipchart "Step 2 Scheduled Tasks." and create the following table:

Daily	Weekly	Monthly	As-Needed

- Inform participants that the laboratory performs 80 test measurements each week to assist them with determining the instrument's cleaning schedule. Ask participants for responses to complete the table based upon their reading of Handout 1: Reflotron Operator's Manual Excerpts. The completed table should appear as follows:

Daily	Weekly	Monthly	As-Needed
QC	Clean Optical Check		

- Write on a flipchart, "Step 3 List of Materials." Ask participants to list the materials required to perform the scheduled tasks. Write the responses on the flipchart. Discuss the common elements associated with the required materials that must be included in the log, such as lot numbers and expiration dates.
- Write on a flipchart, "Step 4 Inserting Materials into Table." Add the material list to the scheduled task table so that it appears as follows:

Daily	Weekly	Monthly	As-Needed
QC (Precinorm U: exp date, lot number) Test Strips (Bilirubin: exp date, lot number) (Creatinine: exp date, lot number)	Clean Optical Check (Check: exp date, lot number)		

- Suggest various ways to document the expiration and lot number information on a log.
  - If this information changes frequently, then it should be entered on a daily basis.
  - If this information changes infrequently, then it may be sufficient and more user-friendly to note this information in one area of the log. Emphasize that if this format is chosen, it must be communicated to staff that they are still responsible for verifying that the current lot number and the opened /manufacturer's expiration date correspond to the log's information.

- Distribute or refer participants to Worksheet: Creating a Maintenance/QC Log. Point out at the bottom of the worksheet is the optical check, QC material, and test strip specifications.
- Write on a flipchart, "Step 5 Acceptability of Tasks." Ask participants how acceptability will be determined for the scheduled tasks. Write the responses on the flipchart. Responses should include documentation of task completion and verification that the recorded values are within the specified range. Suggest ways participants can include information that assists staff members to quickly determine acceptability. For this activity, including the QC range for each analyte and the optical check range for each wavelength on the document would facilitate interpreting acceptability for the obtained values when recorded.

Step 4. Conduct the activity — 15 min

- Instruct participants to work in pairs (groups of 2) for 15 minutes.
- Inform participants to create a log for the material currently in-use for 2 analytes, bilirubin and creatinine.
- Provide assistance and coaching as participants create their log.

Step 5. Debrief the activity — 15 min

- Project Slide 5.13 and refer participants to Handout 2: Suggested Format for Maintenance/QC Log. Discuss the following areas:
  - Suggest that the notes section may serve as the reagent log or corrective action log depending upon the record needs for the workstation.
  - Note the log's title and how that title would be referenced in the instrument's SOP for documenting maintenance and QC. Link this to the *Using Standard Operating Procedures* activity.
  - Note the document control number in the lower right hand corner. A log template is a document since it is an established format for recording and reporting information. The template becomes a record once information is entered. Link this concept to the *Why Was the Outdated Version Used?* Activity.
- Project Slide 5.14 and refer participants to Handout 3: Sample Maintenance/QC Log. Discuss the following areas:
  - Emphasize that the QC's values should be based upon the laboratory's observed mean and standard deviation and not directly from the QC material's package insert.
  - Emphasize that the supervisor who reviews must verify acceptability of all values for each day in accordance to the schedule, or note some corrective action performed. Depending upon the level of managerial oversight needed, the review frequency may change. In this handout, the supervisor chose to perform a weekly review, which was documented each time.
  - Ask participants what issues they would address when reviewing this log? How would they handle and document the actions taken? Issues noted: No corrective action noted on the 1st for unacceptable QC values; LS consistently applies too much sample to the test strip; QC values for the 6th and 9th were not recorded)

Step 6. Conclude the Activity 5 min

- Point out that with the creation of this log, participants have the ability to create any record needed for their laboratory.
- Highlight or reiterate the key messages below.
- Make certain participants achieved the objectives for this activity.

KEY MESSAGES

- Records must be created to document the equipment's scheduled tasks.
- The operator's manual is a resource for either manufacturer's suggested templates or information to create and/or modify existing templates.
- The record formats must support the specific laboratory processes used at the site for all equipment.

Can they:

- Create a maintenance and QC log with the use of the manufacturer's instructions?
- Recognize elements of a record necessary to fully document the completion of scheduled tasks?

ACTIVITY OBJECTIVES MET?

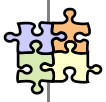
Connections and Applications

- An equipment management plan ensures instruments, equipment, and devices function as required to produce accurate and reliable patient test results used in patient care.
- If equipment has defined maintenance or calibration from either the manufacturer or accrediting organization, then it must be included into the equipment management plan. This includes ancillary equipment, such as pipettes, heat blocks, incubators, refrigerators, and centrifuges.
- The performance of proper equipment maintenance and calibration extends the life of the equipment.
- Always obtain an operator's manual or guide with each equipment acquisition.
- Each piece of equipment in the laboratory needs to have a unique identification number such as manufacturer's serial number, facility organizational tag, or laboratory defined identification number.
- Maintenance, QC, and calibration plans need to include:
  - Schedule of tasks to be performed.
  - Instructions (SOPs or operator's manuals) for the performance of each task.
  - Records of the tasks' results which document:
    - the tech who performed the task
    - interpretation of acceptability
    - follow-through when not acceptable
    - retention of records
- For extensive and detailed tasks, a laboratory may choose to reference in their SOPs the manufacturer's procedure, located in the operator's manual. However, the SOP must still include written instructions for how to record results and perform follow-up actions
- For simple instrumentation, logs can be combined into one record. As the equipment becomes more complex, the creation of separate logs to fully document the predefined tasks is necessary.
- It is necessary to retain some records for the life of the instrument, whereas

➢➢ Connections and Applications

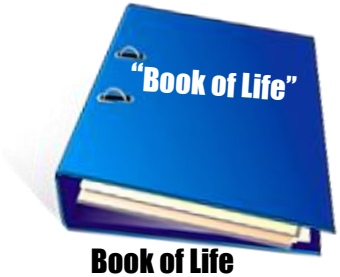
other records may be destroyed after a specified retention time. One must be familiar with the facility, country, or accrediting organization's record retention schedule to determine record retention requirements.

- Job Aid 2: Monthly Analyzer Review can assist a supervisor as they review the analyzer's workstation at the end of the month and prepare for the upcoming month.
- Job Aid 3: Equipment Inventory Form can assist a supervisor to consolidate all equipment information. Based upon the service frequency and last date of service, the supervisor can populate their management calendar to ensure the vendor or the facility's biomedical engineer performs all necessary service as required. Link this concept to *Creating a Management Calendar* activity.



Job Aid 1: Documents and Records

Managing Your Equipment's Documents and Records



Book of Life

Compile a Book of Life for each piece of equipment that has a predefined schedule for calibration or maintenance. It should contain all information regarding the equipment and it should be retained for the life of the equipment.

A Book of Life contains:

- Equipment Inventory Sheet (see below)
- Service Contract Information
- Vendor's Installation Records
- Laboratory's Validation Plan and Records
- Calibration, Maintenance and Service Schedules
- Manufacturer Notification Inserts and Alerts

Equipment name	Model and Serial Number
Manufacturer's Information: ○ Name ○ Address ○ Sales and technical support personnel's name and contact information ○ Service and support contact numbers	Facility or Laboratory Identification Number
	Location
	Purchase Date
	Installation Date
	Validation Date
	Placed into Service Date
	Decommission Date
	Removal Date

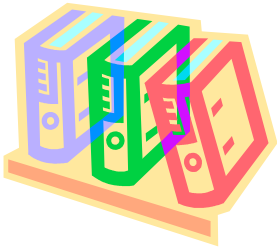
Equipment Inventory Sheet

Records

Retain records of scheduled tasks and troubleshooting and documentation of supervisor reviews, or any items specified by accrediting organization or facility/country policy.

Records you should keep include:

- Maintenance Records
  - o Reagent Log
  - o Maintenance Log
  - o Quality Control (QC) Log
  - o QC Charts
  - o Corrective Action Log
- Calibration Records
- Establishing Acceptable Range for QC Material Records
- Service or Repair Records
- External Peer QC Comparison Results and Corrective Action
- Proficiency Testing (PT) Results and Corrective Action
- Decommission Records
- Removal Records



Documents

Documents provide guidance or work instructions for performing/recording equipment activities. They should be readily accessible to staff.

Documents you should keep include:

- Operator's Manual
- Standard Operating Procedures (SOPs)
  - o Equipment
  - o Applicable Tests
- Expendable Parts List

Job Aid 2: Monthly Analyzer Review

Monthly System's Review of Analyzer

	Activity	Performed
Record Review		
1	Each day of use, daily maintenance performed, acceptable, documented and initialed	
2	Weekly, monthly, periodic maintenance performed as scheduled, acceptable, documented and initialed	
3	Storage temperatures for reagents acceptable, documented and initialed	
4	Each day of use, QC performed, acceptable, documented and initialed	
5	Every discrepancy for acceptable performance have a corresponding entry on the corrective action log	
6	Corresponding service report for every on-site visit	
7	Instrument print-outs to be retained (QC, System Function Checks) available for each day of use	
Reagents (includes reagents, controls and calibrators)		
1	Reagent Log is current	
2	Reagents are marked with date of receipt	
3	Reagents currently on analyzer have in-use date and in-use expiration date (if different) and match with reagent log	
4	No reagents (stored or in use) are expired	
5	Sufficient stock of reagents	
6	Reagents are stored properly	
Tool Kit		
1	Stocked with parts	
2	All tools are present	
Data Management		
1	All back-up archival information performed	
2	Records are stored according to retention schedule	
3	Sufficient logs available for next month	
Additional		
1	All ancillary equipment records contributing to the testing process are current	
2	Operator's manual available at workstation	
3	Contact information is up-to date	
4	Review routine service schedule (instrument and ancillary equipment) performed by either the facility's engineer or vendor. Schedule accordingly next on-site service date.	

Review Performed By: _____ **Date:** _____

Job Aid 3: Equipment Inventory Form

LABORATORY EQUIPMENT INVENTORY FORM

Hospital Name _____ **Date:** _____

Manufacturer	Equipment Name	Serial #	Manufacturing / Supply Date	Condition	How often does it need servicing?	Last service date	Service Provider	Service Provider Phone	Service Provider Address

Handout 1: Reflotron Operator's Manual Excerpts

Components of the Reflotron Plus System

Reflotron Plus

The Reflotron Plus is an in vitro diagnostic device designed for the quantitative determination of clinical chemistry parameters using Reflotron test strips. It works on the principle of reflectance photometry and ensures rapid and reliable results while being simple to use.

Reflotron Tests

The Reflotron tests are test strips designed for the specific determination of important clinical chemistry parameters. On the back of each Reflotron test strip there is a magnetic strip containing all test- and lot-specific data.

Reflotron Precinorm U

Control material for checking the performance of the Reflotron system.

Reflotron Clean and Check

Used for cleaning and checking the optical system.

Cleaning and Checking for Reflotron Plus

Cleaning the instrument

Clean the Reflotron Plus after 100 test measurements (or every 7 days if weekly testing volume is less than 100).
Improper (excessive) application of samples can make it necessary to carry out cleaning at considerably shorter intervals!

Cleaning Procedure

1. Open the flap to clean the measuring chamber.
2. Lift the black shield forward as far as it will go.
3. Clean the upper heater using an alcohol-moistened wipe (Reflotron Clean)
4. Hold the black shield forwards and pull upwards
5. Wipe the transporter, especially the lower heater and the magnetic head
6. Check the correct position of the lower heater
7. Return the black shield to its original position.
8. Leave the instrument to dry for at least 10 minutes with the measuring chamber flap open.
9. Close the flap.

After every cleaning operation, the optical system of Reflotron Plus should be checked using **Reflotron Check.**

Handout 1: Reflotron Operator's Manual Excerpts

Checking the optical system with Reflotron Check

Reflotron Check is designed for checking the optical system of Reflotron Plus.

Optical System Check Procedure

1. Turn the Reflotron Plus on.
2. After the warming-up, the instrument displays "READY".
3. Lift up the flap on the measuring chamber.
4. Take a **Reflotron Check** strip out of the container and insert it in the test strip holder. Close the test strip container at once to protect its contents from dust.
5. Insert the control strip
6. Holding the strip horizontally, place the front of the strip on the heater and push forwards.
7. Push the strip forward until it locks into place.
8. Close the flap.
9. Check the three results against the three ranges printed on the label to see if the optical system is working accurately. If one or more of the three results obtained lie outside the specified range, repeat the measurement with a new control strip.

Evaluating the Reflotron Check Values

Reflotron Plus measures the amount of light diffusely reflected by the strip at each of the three wavelengths (642 nm, 567 nm, and 951 nm) and displays the reflectance values per mil (‰).

The check values must lie between the minima and maxima specified on the label, x being the target value (mean). If one or more values are outside the confidence limits, proceed as follows:

- clean the transporter and the heaters
- repeat the measurement with an unused dust-free control strip.

If the values now lie within the specified confidence limits, the system can be used.

Handout 1: Reflotron Operator's Manual Excerpts

Performing Quality Control for Reflotron Plus

Performing daily quality control

Reflotron Precinorm U is designed for checking the performance of the Reflotron Plus. *Control sera should be handled as potentially infectious materials.*

Control Reconstitution and Analyzing Procedure

1. Open the **Reflotron Precinorm U** bottle, carefully avoiding any loss of lyophilized material and, in accordance with the package insert, add exactly the amount of distilled water specified using a suitable pipette.
2. Close the bottle carefully and dissolve its contents completely by occasionally swirling and inverting the bottle. Wait until the stated reconstitution time has elapsed.
3. The solution is then used for the analysis as a sample.
4. Compare the result with the values specified in the table supplied with the control material. If it lies outside the specified confidence limits, proceed as follows:
   - Check the expiry date of the test strips and the lyophilized or reconstituted control material.
   - Check that you are handling the pipette (or applicator) and the test correctly.
   – Clean the measuring chamber.
   – Check the performance of the optical system with **Reflotron Check**.
   – Repeat the test with the control serum.

excerpts taken from Reflotron Plus Operator's Manual. Roche Diagnostics, November 2007
Permission granted for use May 5, 200

Worksheet: Creating a Maintenance/QC Log

Reflotron Check: lot number 1234 expiration date January 15, 20XX

		Min	Mean (x)	Max
Reference Value for	**642 nm**	630	640	650
	567 nm	631	641	651
	951nm	622	632	642

Reflotron Precinorm U: lot number A231 expiration date April 15, 20XX

Reference Value for	Mean (x)	Range
Bilirubin	15 umol/L	14.5 - 15.5 umol/L
Creatinine	60 umol/L	55 - 65 umol/L

Bilirubin Test Strip
lot number B32 expiration date May 30, 20XX

Creatinine Test Strip
lot number C84 expiration date June 30, 20XX

Handout 2: Suggested Format for Maintenance/QC Log

Reflotron Plus Maintenance and QC Log

Month _____ Optic Check lot number _____ exp date _____ Precinorm U lot number _____ exp date _____ Bilirubin Test Strips lot number _____ exp date _____ Creatinine Test Strips lot number _____ exp date _____

Year _____

Date	Initials	Clean	Optic Check			Precinorm U		Notes
			642 nm	567 nm	951nm	Bilirubin (umol/L)	Creatinine (umol/L)	
		acceptable range						

Supervisor Review/Date: _____

Reflotron Plus Analyzer M/QC: #1-October 8, 20XX

Handout 3: Sample Maintenance/QC Log

503

Reflotron Plus Maintenance and QC Log

Month March | Optic Check lot number 1234, exp date 15/1/20XX | Precinorm U lot number A231, exp date 15/4/20XX | Bilirubin Test Strips lot number B32, exp date 30/05/20XX | Creatinine Test Strips lot number C84, exp date 30/06/20XX

Year 20XX

Date	Initials	Clean	Optic Check			Precinorm U		Notes
			642 nm	567 nm	951nm	Bilirubin (umol/L)	Creatinine (umol/L)	
		acceptable range	*630 - 650*	*631 - 651*	*622 - 642*	*14.5 - 15.5*	*55-65*	
1/3/20XX	TJ					14.3	55	
2/3/20XX	AM	✓	632	633	628	15.1	62	
3/3/20XX	LS					14.9	57	
4/3/20XX	AM					15.8	68	excessive serum noted on holder, cleaned transporter
4/3/20XX	AM	✓	640	639	631	14.8	61	performed check, repeated QC; check & QC acceptable
5/3/20XX	AM					15.2	60	
6/3/20XX	TJ							
7/3/20XX	AM					14.8	60	
8/3/20XX	BW					14.7	63	
9/3/20XX	TJ					15.2		
10/3/20XX	TJ					15.1	61	
11/3/20XX	BW	✓	641	639	632	14.8	60	new bottle Optic; same lot number
12/3/20XX	BW					14.6	58	
13/3/20XX	LS					14.8	59	
14/3/20XX	AM					15.7	67	excessive serum noted on holder, cleaned transporter
14/3/20XX	AM	✓	640	641	630	15.1	59	performed check, repeated QC; check & QC acceptable
15/3/20XX	BW					14.7	63	

Supervisor Review/Date: CCL 7/3/20XX CCL 14/3/20XX

Reflotron Plus Analyzer M/QC: #1-October 8, 20XX

ACTIVITY Making a Service Call — Module 5

PURPOSE:

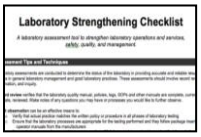
When instrumentation issues cannot be resolved, it becomes necessary to call the service number. In this role-play activity, participants learn how to make a service call, document it, and follow through until the issue is resolved.

RESOURCES FOR FACILITATOR:

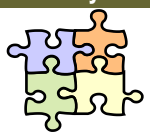
- ❑ PowerPoint slides: 5.16 to 5.19
- ❑ A small box to represent a manufacturer's tool kit
- ❑ A light bulb used in an instrument
- ❑ Tape, flipchart and markers
- ❑ Tool 1:Troubleshooting Steps Performed
- ❑ Tool 2: Calendar

RESOURCES FOR PARTICIPANT:

- ❑ Handout : L-J Chart (508)
- ❑ Worksheet: Corrective Action Log (509)
- ❑ Job Aid: Making a Phone Call (510)

This activity supports the following laboratory management tasks and SLIPTA checklist items	
Management Tasks 	5.3 Perform and record troubleshooting on malfunctioning equipment 5.5 Take corrective actions or issue repair orders and record all issues 5.6 Follow up on all corrective action – see if equipment is properly functioning, observe for trends or determine training needs
Checklist Items 	1.5 Laboratory Policies and Standard Operating Procedures Are policies and/or standard operating procedures (SOPs) for laboratory functions, technical and managerial procedures current, available and approved by authorized personnel? (Identification and Control of Nonconformities; Corrective Action; Laboratory Equipment; Laboratory Contingency Plan) 5.1 Adherence to Proper Equipment Protocol Is equipment installed and placed as specified in the operator's manuals and uniquely labelled or marked? 5.5 Equipment Record Maintenance Is current equipment inventory data available for all equipment in the laboratory? 5.6 Equipment Maintenance Records Is relevant equipment service information readily available in the laboratory? 5.7 Defective Equipment Waiting for Repair Is defective equipment, waiting for repair not used and clearly labelled? 5.11 Equipment Service Maintenance Is equipment routinely serviced according to schedule as per the minimum manufacturer recommendations by qualified and competent personnel and is this information documented in appropriate logs? 5.12 Equipment Malfunction - Response and Documentation Is equipment malfunction resolved by the effectiveness of the corrective action program and the associated root cause analysis? 5.13 Equipment Repair Monitoring and Documentation Are repair orders monitored to determine if the service is completed? Does the laboratory verify and document the equipment is in proper working order before being put it back into service? 5.14 Equipment Failure - Contingency Plan Is there a functional back-up system that prevent interruption of lab services? 8.10 Quality Control Data Are QC results monitored and reviewed (including

	biases and Levy-Jennings charts for quantitative tests)? 10.1 Are all identified nonconforming activities/ work identified and documented adequately? 10.2 Root Cause Analysis Is documented root cause analysis performed for non-conforming work before corrective actions are implemented? 10.3 Is corrective action performed and documented for non-conforming work? 10.5 Preventive Actions Are documented preventive actions implemented and monitored for their effectiveness?

This activity is related to the following activities:	
	Module 1: Creating a Management Calendar

ACTIVITY AT-A-GLANCE				
Step		**Time**	**Resources**	**Key Points**
1	Introduce the activity	1 min	Slide 5.16	
2	Describe the role-play scenario	5 min	Slide 5.17 Handout Worksheet Tool 1	
3	Accept the service call from volunteer #1	10 min	Handout Worksheet Job Aid	
4	Transition to volunteer #2	1 min		
5	Accept the service call from volunteer #2	10 min	Worksheet Wall Calendar (from Tool 2)	
6	Debrief the activity	5 min	Slides 5.18 to 5.19	
7	Conclude the Activity	3 min		
	TOTAL TIME:	**35 min**		

PROCESS

Preparation

- Label the box, "Tool Kit" and place the instrument bulb inside it.
- Post Tool 1: Troubleshooting Steps Performed or recreate it onto a flipchart sheet so that participants can easily refer to it.
- Print-out Tool 2: Calendar to create a 'Wall Calendar.' Tape this calendar to the wall near where the activity will be facilitated. If the calendar sheets from the activity, *Creating a Management Calendar*, are still posted, you may use those calendar sheets.
- Read the basic role play scenario (Steps 2-5). The facilitator will play the role of the customer service representative.

Step 1. Introduce the activity — 1 min

- Project Slide 5.16 to introduce the activity. Explain that this role-play activity involves calling the service number.
- Ask for two volunteers to play the role of a laboratory technologist.

Step 2. Describe the role-play scenario — 5 min

- Project Slide 5.17 and refer participants to Handout: L-J Chart and Worksheet: Corrective Action Log.
- Indicate that the technologist assigned to the CY Chemistry Analyzer workstation began performing basic troubleshooting steps for creatinine after obtaining the 1 3s rule failure (Handout 1 -first data point plotted for June 2nd). No significant change was observed with the other analytes. All instrument checks were acceptable. Refer participants to the list of troubleshooting steps performed (Tool 1: Troubleshooting Steps Performed) by the technologist
- Indicate the laboratory technologist (first volunteer) decided to call the customer service number after basic troubleshooting steps did not address the creatinine issue (Handout 1 -second data point plotted for June 2nd).
- Ask the participants to document a description of the problem on Worksheet.
- Select a participant to read aloud their documentation to the class. Inquire from the class if any additional information should be added to make the entry complete. Facilitate a discussion surrounding what constitutes adequate documentation for an instrument's action log.

Step 3. Accept the service call from volunteer #1 — 10 min

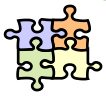
- Ask the volunteer to call you (the service representative) and describe the problem.
- Orchestrate the role play as follows:
  - Explain that based upon the problem's description, this analyte is the most sensitive to the fluctuations in the detector source. The bulb is approaching the end of its lifespan and needs to be replaced. If the bulb is not replaced, then other less sensitive analytes will also be affected in the near future.

  - Hand volunteer #1 the box that contains the bulb and ask the volunteer if a spare bulb is available at their site.
  - Ask the volunteer to replace the bulb, perform the system checks, and run QC. If the problem continues, he/she should call customer service back.
  - Indicate that because a spare bulb was available in the tool kit, the technologist was able to replace the bulb. All checks and QC were acceptable. Emphasize the importance of keeping a well-stocked tool kit.
- Ask the participants to document a description of the service call/problem resolution on Worksheet: Corrective Action Log.
- Select a participant to read aloud their documentation to the class. Inquire from the class if any additional information should be added to make the entry complete.
- Refer participants to Job Aid: Making a Phone Call with the focus on the section, *When Making A Service Call*. Discuss how to obtain a reference number for the service call and the importance of documenting the date, time and the name of the representative.

Step 4. Transition to volunteer #2 — 1 min

- Indicate that while the technologist was replacing the bulb, he/she noticed that the screws holding the bulb holder in place showed some wear and corrosion. Not sure if this observation may present a future problem, the technologist decided to call customer service.

Step 5. Accept the service call from volunteer #2 — 10 min

- Ask volunteer #2 to call you (the service representative) and mention the reference number logged previously.
- Orchestrate the role play activity so that you (the service representative) indicate a new bulb holder will be sent to the site. The laboratory should receive this item in seven to ten days. Upon receipt, the laboratory should contact customer service for phone assistance with replacing the part.
- Ask the participants to document a description of the service call/problem resolution on Worksheet: Corrective Action Log.
- 
  Facilitate a discussion regarding how a manger can ensure follow-through on this replacement part using the 'Wall Calendar.' Link the scheduling of this follow through to the activity, *Creating a Management Calendar*.
- Indicate that in the interim, the functionality of the analyzer was affected by the defective bulb holder and the back-up procedure was used until the part arrived. Facilitate a discussion regarding how to document when the back-up procedure is used.

Step 6. Debrief the activity — 5 min

- Ask the class if the documentation and the calendar entry are sufficient for them to discern what actions have occurred and what actions will be forthcoming in their laboratory. Emphasize the difficulty incurred when documentation is insufficient or incomplete.
- Project Slides 5.18 to 5.19. Discuss the importance of the equipment

service information (serial number, model number and customer service number) and its immediate availability at the workstation. Emphasize the importance of keeping the tool kit well stocked and complete.

Step 7. Conclude the Activity 3 min

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

KEY MESSAGES

- Any corrective action taken must be documented into the equipment's action record, and it should include a description of the problem and all steps taken to resolve the issue.
- It is important to document the date, time, representative's name, and the next steps when the customer service number is called.
- Corrective action is not complete until the issue is fully resolved and the equipment functions properly.

Can they:

- Document a description of the problem, the corrective action taken, and the events of the service calls?
- Reference the documented information to ensure follow-through action until the issue is resolved?

ACTIVITY OBJECTIVES MET?

➢➢ Connections and Applications

- The corrective action log should be specific for an instrument and include the serial and model number as well as any other facility identification number.
- Ensure the documentation on the corrective action log is complete so that continuous follow-through can occur even if the initial staff member who reported and documented the problem is not available. Specific action steps should be noted along with the success of the steps in the problem's resolution.
- Supervisors should communicate with staff what constitutes acceptable documentation on the action log. The Job Aid: Making a Phone Call posted by a phone could serve as a friendly reminder for the staff.
- Always request a confirmation or reference number from customer service for the issue being logged with them. This confirmation number can serve as a thread connecting the previous call's documentation in the event the issue remains unresolved.
- When the supervisor reviews the equipment's records cross referencing the corrective action log should indicate why the entries are incomplete (i.e. due to instrument downtime). By the documented reference to the back-up procedure that was in effect on the action log, the supervisor can determine why the daily maintenance was not performed or documented for those days on the primary instrument.
- Always conspicuously post the customer service number so that staff can locate it quickly. Time spent locating this information causes delays. Post this information either on the instrument, writing it on the inside cover of the operator's service manual, or both. Be consistent for all instruments so that staff readily knows where to quickly locate this information.
- Keep a copy of the service contract for the equipment to determine what items and services are covered and the expected turn-around time for delivering them. The contract should state the acceptable response time for phone support, including callback time, and on-site support.
- Instrument down-time should be tracked as a quality indicator. Some service contracts provide replacement or loaner equipment if the issue is chronic or remains unresolved. Even though vendors should maintain a service history according to the equipment's serial number, the laboratory's records and reports will be the records forwarded to the hospital's upper management to support their case for replacement or a higher level of action.
- The instrument tool kit contains both expendable parts and tools to complete preventative maintenance. A list of items to be included with the toolkit is frequently listed in the operator's manual. Contents of the toolkit should be periodically checked to assure it remains well-stocked and complete.
- Even though the focus of this activity is not quality control, discussions involving QC may occur during the activity. Areas to highlight are as follows:
    - Quality control monitors and detects changes in the analytical performance of the test system.
    - An instrument should not be calibrated until a problem is understood and calibration is deemed appropriate and necessary.
    - Calibrate an instrument when addressing accuracy.
    - Always correct precision issues before addressing accuracy issues.

Tool 1: Troubleshooting Steps Performed

Troubleshooting Steps Performed Prior to Calling Customer Service

1. Verified exp date, lot #, on-board & stability of creatinine reagent
2. Reviewed creatinine reagent & calibration logs
3. Reviewed instrument maintenance logs
4. Primed creatinine reagent & verified no bubbles present in line
5. Cleaned creatinine reaction cup & stirrer
6. Reanalyzed creatinine QC - rule failure 2 $_{2s}$ and 10x

Tool 2: Calendar

Monday	Tuesday	Wednesday	Thursday	Friday	Sat/Sun
	1	2	3	4	5/6
7	8	9	10	11	12/13
14	15	16	17	18	19/20
21	22	23	24	25	26/27
28	29	30	31		

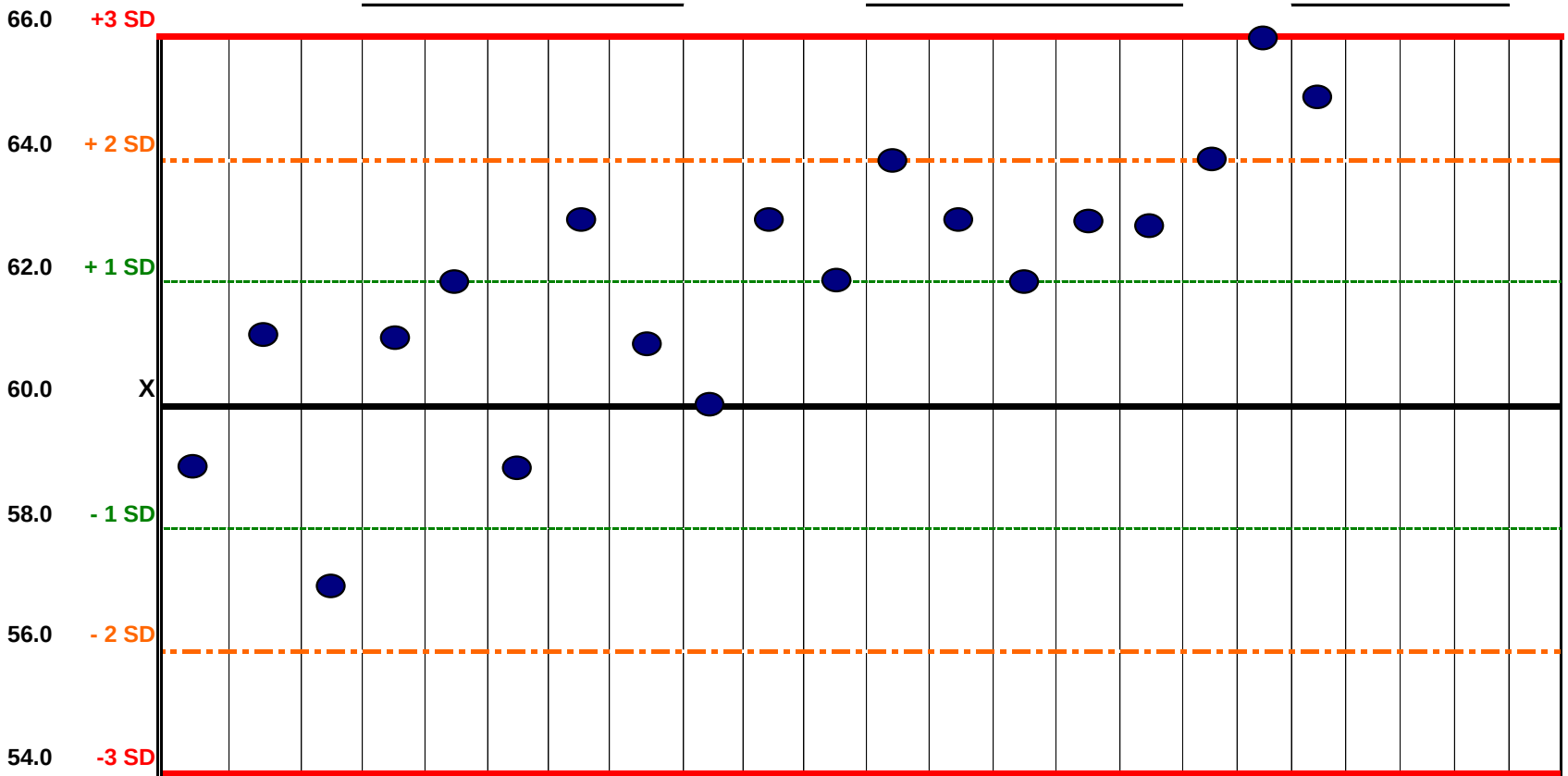
Handout: L-J Chart

Clinic Laboratory

L-J Chart for Control XYZ

Date From: 17/05/XX **Date To:**

Analyte Creatinine (umol/L) **Lot #** N854 **Exp Date** 30/11/XX



	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	24
Value	59	61	57	61	62	59	63	60	62	63	62	64	63	62	63	63	64	66	65				
Date	17/5	18/5	19/5	20/5	21/5	22/5	23/5	24/5	25/5	26/5	27/5	28/5	29/5	30/5	30/5	31/5	1/6	2/6	2/6				
Initials	AM	LC	AM	AM	AM	LC	ZB	AM	AM	LC	AM	LC	AM	LC	LC	AM	AM	ZB	ZB				

Worksheet: Corrective Action Log

CY Chemistry Analyzer Corrective Action Log

Model # XYZ

SN# AJ25055

Date:	Action Performed:	Initials:

Job Aid: Making A Phone Call

Making A Phone Call 510

When Making A Service Call

Make sure you have the following information:

- Instrument model
- Instrument serial number
- Description of the problem
- Actions already taken
- Appropriate contact information
  - –Direct service contact number
  - –Laboratory number for service technician to return calls

At the end of the call, you should know:

- Date/time of the call
- Person with whom you spoke
- Next steps to be taken
- When (timeframe) steps will be taken
- Note date for follow-up on management calendar

TIPS

Make sure you have the correct number
Speak clearly and courteously
Gather all the information before the call
Have a pen ready to write down information
Always document the call afterwards

When Calling About An Order

Be ready to describe the problem with the order:

- Missing item?
- Wrong item?
- Wrong amount?
- Expiry date too close?
- Damaged product?
- Unacceptable condition?

After the call, document:

- Reason for the call
- Date/time of the call
- Person with whom you spoke
- Corrective action (what was promised, when will it take place, etc.)