MODULE 5

Equipment Maintenance

SLMTA Participant's Manual

TABLE OF CONTENTS

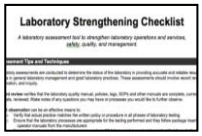
NOTE: Print this document single-sided and in color if possible.

ACTIVITY SUMMARY SHEET

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.

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?

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 you:

- 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?

SELF-ASSESSMENT

For this activity, you will need:

- ❑ 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)

Reflotron Operator's Manual Excerpts[501]

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 forwards 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.**

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.

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, 20

Reflotron Plus Maintenance and QC Log[502]

Month _____ Year _____

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 _____

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

Supervisor Review/Date: _____

503

Reflotron Plus Maintenance and QC Log

Month March | Optic Check | Precinorm U | Bilirubin Test Strips | Creatinine Test Strips

Year 20XX | lot number 1234 | lot number A231 | lot number B32 | lot number C84

exp date 15/1/20XX | exp date 15/4/20XX | exp date 30/05/20XX | exp date 30/06/20XX

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

Creating a Maintenance / QC Log[504]

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

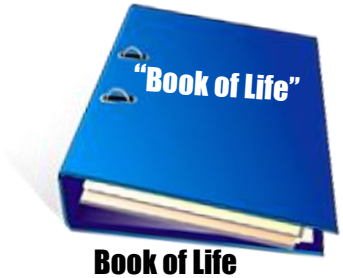
Reference Value for	**Mean (x)**	**Range**
Bilirubin	15 umol/L	14.5 - 15.5 umol/L
Creatinine	60 umol/L	55 - 65 umol/L

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

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

505

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

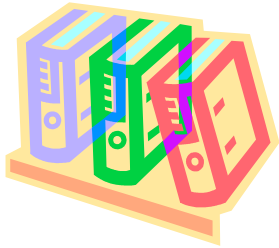
Equipment Inventory Sheet

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

Monthly System's Review of Analyzer[506]

	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:** _____

LABORATORY EQUIPMENT INVENTORY FORM[507]

Hospital Name _____ **Date:** _____

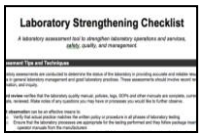
Manufacturer	Equipment Name	Serial #	Manufacturing / Supply Date	Condition	How often does it need servicing?	Last service date	Service Provider	Service Provider Phone	Service Provider Address

ACTIVITY SUMMARY SHEET

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.

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?

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.

SELF-ASSESSMENT

Can you:

- 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?

For this activity, you will need:

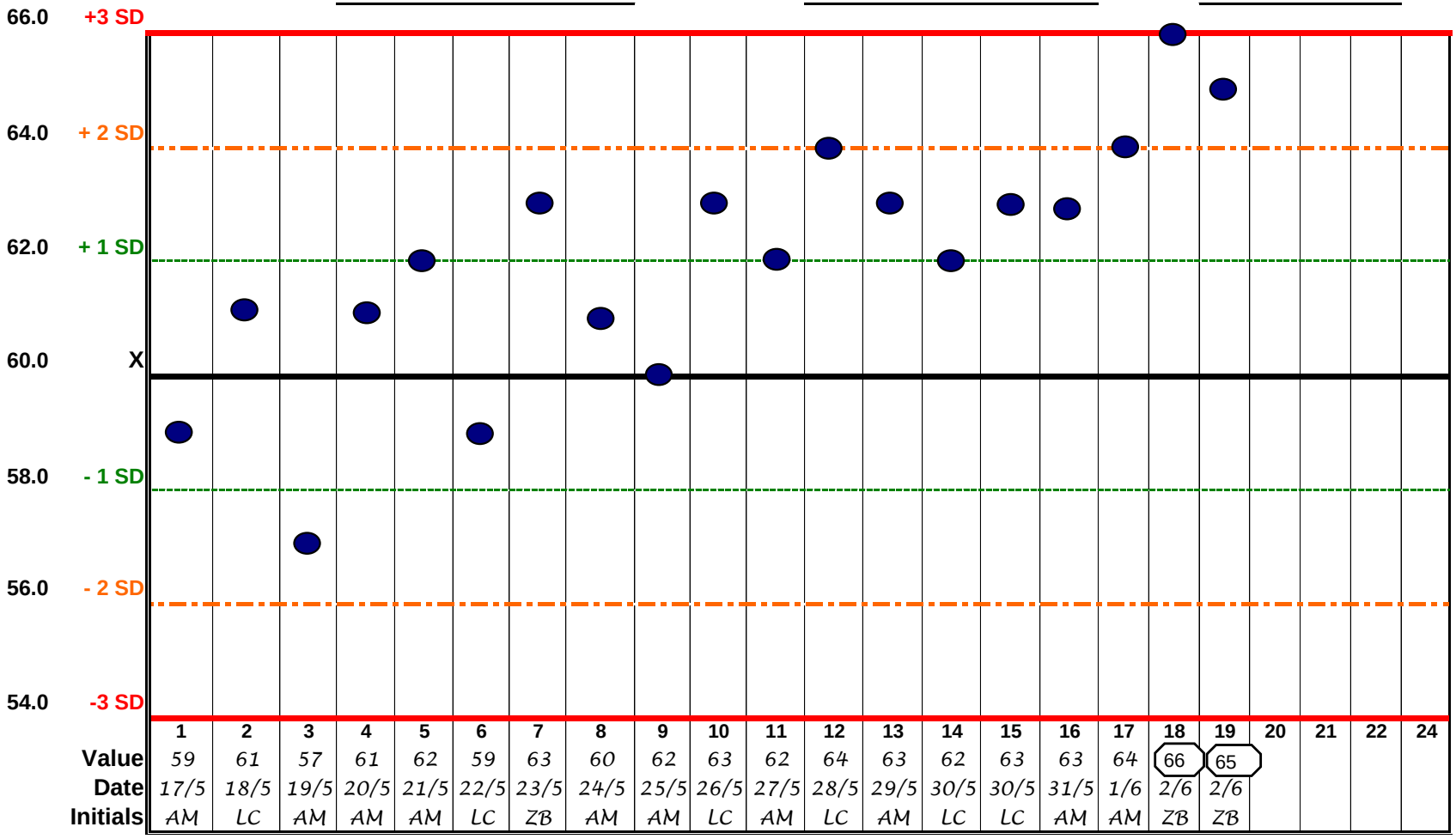
- ❑ Handout : L-J Chart (508)
- ❑ Worksheet: Corrective Action Log (509)
- ❑ Job Aid: Making a Phone Call (510)

L-J Chart[508]

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				

CY Chemistry Analyzer Corrective Action Log[509]

Model # XYZ

SN# AJ25055

Date:	Action Performed:	Initials:

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.)