Strengthening Laboratory Management Toward Accreditation

Module 5: Routine/Preventative Maintenance of Equipment

Key Message ...

My lab maintains equipment to provide uninterrupted service.

Desired Outcome

Equipment functioning all the time to ensure uninterrupted and quality service.

Laboratory Equipment

Well maintained equipment is critical to the operations of any laboratory

- Assures testing is accurate and reliably available for patient care needs
- Prevents instrument failures and prolongs life of the instrument



No patient results should be reported until:

- Maintenance is performed, acceptable and documented
 - Daily maintenance procedures
 - System checks
- Quality control is performed, acceptable, and documented

Tasks

- 5.1 Consolidate and post equipment service information at site
 - Contact
 - Service frequency
 - Dates
- 5.2 Ensure proper preventative maintenance on instruments when used
 - Cleaning
 - Proper shutdown

 5.4 - Review and sign maintenance logs to ensure regular preventative maintenance and timely repairs

Not documented, not done!

Creating a Maintenance and QC Log

Module 5: Routine/Preventative Maintenance of Equipment

Operator's Manual

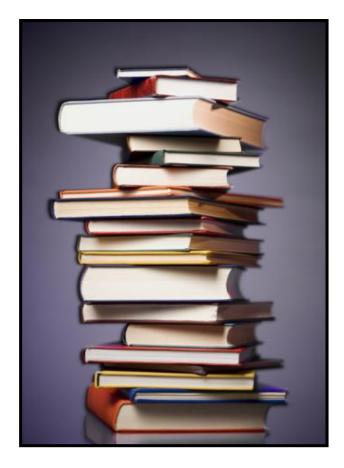
- Preventative maintenance procedures and schedules are indicated
- Frequently includes maintenance logs that can be photocopied
- Step-by-step instructions are provided to perform maintenance, system checks and basic troubleshooting.
- Explanation of error codes and alerts

Standard Operating Procedures (SOPs)

- Current
- Easily accessible at the workbench
- Available for all tests performed
- Customized to reflect site-specific instructions
- Provide step-by-step instructions

Instrument Records

- Maintenance Logs
 - Daily
 - Weekly
 - Monthly and Periodic
 - Calibration
 - Corrective Action
 - Quality Control Logs
- Service Logs



Reagent Log

- Documents the reagents on-board
- Should include:
 - Opened date
 - Manufacturer's expiration date
 - Lot number
 - On-board expiration date
 - Initials

Activity: Creating a Maintenance and QC Log

Purpose

To create an instrument log

What will you need?

- <u>Handout 1</u>: Reflotron Operator's Manual Excerpts
- <u>Worksheet</u>: Creating a Maintenance/QC Log

What will you do?

Work in pairs (groups of 2)

- Read <u>Handout 1</u>
- Create a Maintenance and QC log (<u>Worksheet</u>) for the Reflotron based on information supplied in the <u>Handout 1</u>



15 minutes

Roche Reflotron Plus



Photograph from <u>Reflotron Plus Operator's Manual</u>. Roche Diagnostics, November 2007 Permission granted for use May 5, 2009

Suggested Format Example

Reflotron Plus Maintenance and QC Log											
Month		Optic Check	Precinorm U			Bilirubin Test	Strips	Creatinine Test Strips			
Year		lot number	lot number			lot number		lot number			
		exp date	exp date			exp date		exp date			
								<u> </u>			
Date	Initials	Clean	Optic Check				norm U	Notes			
			642 nm	567 nm	951nm	Bilirubin (umol/L)	Creatinine (umol/L)				
	acc	eptable range									

Supervisor Review/Date:

Reflotron Plus Analyzer WQC: #1-October 8, 20XX

Applied Log Example

			Reflotro	on Plus Maint	enance 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	date <u>15/1/20XX</u> exp d		the $15/4/20XX$ exp dat		5/30/20XX	exp date $6/30/20XX$	
Date Initials		Clean	Optic Check		Precir	norm U	Notes		
			642 nm	567 nm	951nm	Bilirubin (umol/L)	Creatinine (umol/L)		
	acc	eptable range	630 - 650	631 - 651	622 - 642	14.5 - 15.5	55-65		
1/3/20XX	TT					14,3	55		
2/3/20XX	AM	\checkmark	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 transporte	
4/3/20XX	AM	\checkmark	640	639	631	14.8	61	performed check, repeated QC; check & QC acceptable	
5/3/20XX	AM					15.2	60		
6/3/20XX	ΤŢ								
7/3/20XX	AM					14.8	60		
8/3/20XX	BW					14.7	63		
9/3/20XX	TT					15,2			
10/3/20XX	ΤŢ					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 transporte	
14/3/20XX	AM	\checkmark	640	641	630	15.1	59	performed check, repeated QC; check \mathcal{E}_{T} QC acceptable	
15/3/20XX	BW					14.7	63		

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

CL 7/3/20XX CCL 14/3/20XX

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

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
 - Determine training needs
- 5.7 Communicate to upper management equipment specifications and maintenance needs

Activity: Making a Service Call

Purpose

To make a service call, document it, and follow-through until the issue is resolved.

What will you need?

- Handout: L-J Chart
- Worksheet: Corrective Action Log

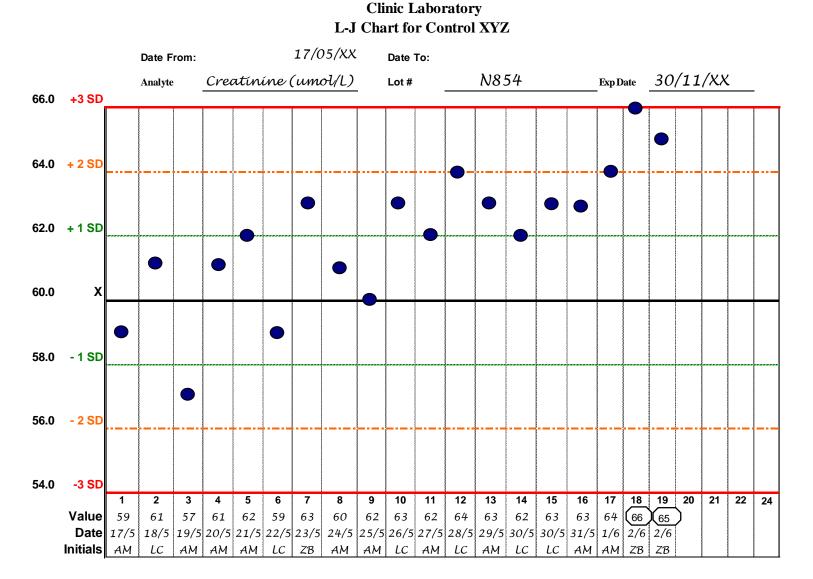
What will you do?

- Review the <u>Handout</u> to understand the instrumentation issue presented in the scenario
- Document the corrective action on the <u>Worksheet</u>
- Role-play calling the instrument's service contact number.



25 minutes

Levey-Jennings (L-J) Chart



Module 5: Routine/Preventative Maintenance of Equipment

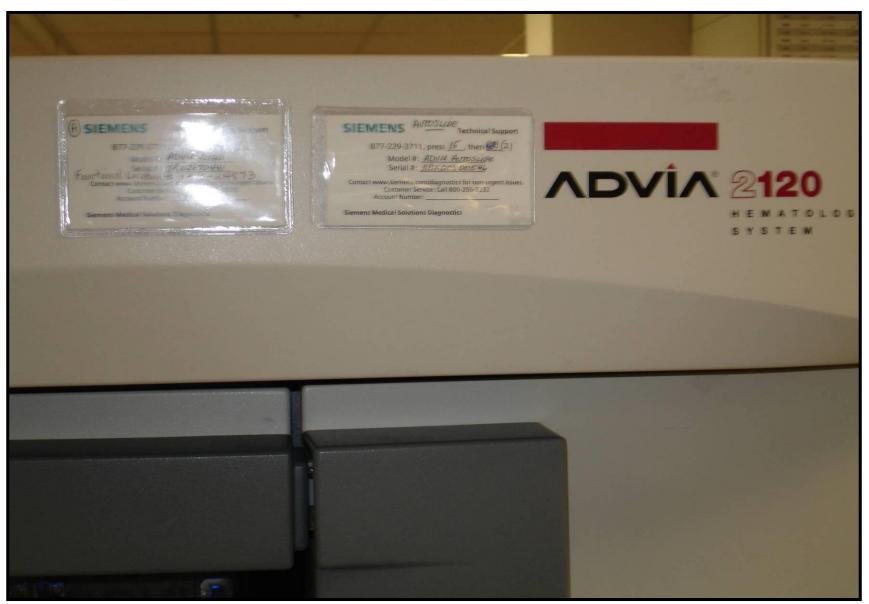


Photo from Cape Regional Medical Center

Tool Kits

- Provided by manufacturer
- Includes specific tools to perform maintenance and troubleshooting
- Stores commonly needed spare parts (bulbs, filters, probes, and tubing)



Photo from Cape Regional Medical Center

Activity: Workstation Set-up

Purpose

To create and organize an efficient and productive workstation using elements developed from each module.

What will you need?

Laboratory Accreditation Preparedness Checklist

What will you do?

- Participate in the classroom's discussion
- Integrate key concepts from earlier activities



15 minutes

Information and Supplies at the Instrument's Workstation

- Operator's manual
- SOP for the analyzer
- Supplies to perform maintenance and testing
- Instrument logs
- Toolkit
- Contact information
- Supplies (gloves, waste receptacle)
- Extra Reagents (if space permits)



Photo from Cape Regional Medical Center

MICROSCOPE WORKSTATION MONTHLY MAINTENANCE LOG

		IVI	ICRUSCUP							_OG	
month/year	May 2	20XX	_							Reviewed by / date:	
Chemtreck Wright Stain						КОН		NaCl		AM 4/5/XX AM 11/5/XX	
lot #	WS0845A		-		lot #	SA#73	-	SA#1123		AM 18/5/XX	
exp date	e <u>12/09/XX</u>		-		exp date	13/07/XX	<u>-</u>	21/06/XX	<u>.</u>	<i>T</i> // · · · · / · /	
DAY	WRIGHT STAIN		CENTRIFUGES	EYE WASH STATION	WORK SURFACES	10% ł	КОН	0.9% NaCl		MICROSCOPE	INITIALS
	no ppt/ quality O.K. (each day of use)	changed (weekly)		checked & flushed; caps cleaned with 10% bleach (weekly)	cleaned with 10% fresh bleach sol'n (daily)	no ppt or contam. (each day of use)	changed (weekly)	no ppt or contam. (each day of use)	changed (weekly)	oil removed with lens paper, 10x objective in position, light source off, covered (after each day of use)	
1	\checkmark				\checkmark					\checkmark	RSM
2	\checkmark				✓	\checkmark	\checkmark	\checkmark	✓	\checkmark	RSM
3	\checkmark	 ✓ 			\checkmark	\checkmark				\checkmark	TΥ
4	\checkmark				\checkmark	\checkmark		\checkmark		\checkmark	TΥ
5			\checkmark	\checkmark	\checkmark					\checkmark	RSM
6			•	•	· •	\checkmark				~	RSM
7	\checkmark				· •					· · · · · · · · · · · · · · · · · · ·	RSM
8	▲ ✓				× ✓	~		\checkmark	~	↓ ✓	RSM RSM
-	✓ ✓	\checkmark			✓ ✓	•	•	v	•	✓ ✓	
9	•	~			-						LLC
10					 ✓ 					✓ ✓	RSM
11	~		✓		✓	~		\checkmark		✓	RSM
12	✓			~	✓	~				~	TΥ
13	\checkmark				\checkmark	\checkmark				\checkmark	LLC
14	\checkmark				\checkmark					\checkmark	RSM
15	\checkmark	 ✓ 			\checkmark					\checkmark	RSM
16	\checkmark				\checkmark					\checkmark	RSM
17	\checkmark	İ.			\checkmark	\checkmark	✓	✓	\checkmark	\checkmark	RSM
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20	✓				✓	✓		\checkmark		\checkmark	ΤΥ
Date:		•	•				2	•	1	<u></u>	Initials:
16/05XX			ced mícros	•							RSM
19/05/XX biomed engineer checked rpm's and timer on centrifuge; service report filed										ΤY	

Ancillary Equipment

Require Periodic Maintenance and Service

- Maintenance logs
- Service orders
- Replacement parts and supplies

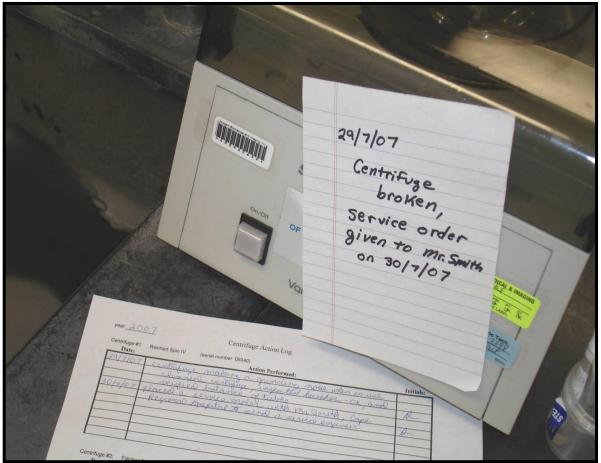


Photo from Cape Regional Medical Center



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Activity: What Would You Do?

Purpose

To integrate the module's lessons and apply them to the case scenario.

What will you need?

Handout: Case Study Scenarios

What will you do?

Divide into groups of 4-5

- Select a spokesperson for your group
- Formulate specific action steps to address the scenario from the <u>Handout</u>.
- The group's spokesperson presents the proposed steps during the 2 minute class report.



5 minutes

What Would You Do?

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?

Tasks

- Consolidate and post equipment service information at site
- Ensure proper preventative maintenance on instruments when used
- Review and sign maintenance logs to ensure regular preventative maintenance and timely repairs
- Perform and record troubleshooting on malfunctioning equipment
- Take corrective actions or issue repair orders and record all issues
- Follow-up on all corrective action
- Communicate to upper management equipment specifications and maintenance needs