Quest Diagnostics

TRAINING UPDATE

Lab Location:	GEC, SGAH & WAH	**Date Distributed:**	1/7/2013
Department:	Core	**Due Date:**	2/4/2013

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Equipment Records and Repair GEC.L31, SGAH.L34, WAH.L33 v2

Description of change(s):

Reason for Revision
Section 5: specify electrical checks, replace Equipment Malfunction Report with logs, change service department to Biomedical Engineers, and add retention of records. Section 6: add logs Section 9: remove form

Document your compliance with this training update by taking the quiz in the MTS system.

Approved draft for training all sites (version 002)

Non-Technical SOP

Title	**Equipment Records and Repair**	
Prepared by	Leslie Barrett	Date: 6/4/2009
Owner	Robert SanLuis	Date: 7/12/2010

Laboratory Approval		
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		
Local Issue Date:	Local Effective Date:	

12 month (or new) management review and approval: Signature acknowledges SOP version remains in effect with NO revisions.		
Print Name	**Signature**	**Date**

Form revised 3/31/00

TABLE OF CONTENTS

1. PURPOSE

Equipment records are maintained in the Laboratory to document validation, calibration and preventive maintenance for all equipment. Equipment repair records are retained to ensure that all equipment is performing according to the specifications for each piece of equipment.

2. SCOPE

Applies to all equipment used for clinical laboratory testing.

3. RESPONSIBILITY

All Laboratory staff must be:

- trained to properly utilize any equipment applicable to the job function
- knowledgeable of the process for reporting and repairing equipment that malfunctions

Designated staff are trained and perform required validation, calibration and preventive maintenance as specified.

Managers and supervisors are responsible for ensuring compliance with this procedure.

4. DEFINITIONS

QC – Quality Control
PM – Preventive Maintenance

5. PROCEDURE

A. Installation of Equipment:

1. Installation of equipment is done by the Vendor and/or Biomedical Engineers department. Arrange a date and time for equipment installation prior to equipment use.
2. Biomedical Engineers will perform any electrical installation and checks, as well as calibration, if necessary.
3. Prior to patient use, perform and record any equipment calibrations and preventive maintenance (PM) or quality control (QC) according to manufacturer's directions.

B. Equipment Repair:

1. Any equipment that fails calibration, leaks, smokes, or is defective in any way must be removed from service.
2. If patient testing is in progress, it must be evaluated for conformance with standards. If in doubt, seek guidance from the Group Lead, Supervisor, Lab Director or Medical Director.
3. Contact Biomedical Engineers for equipment repairs that are beyond routine PM done by the Laboratory staff. Any repairs beyond the scope/ability of Biomedical Engineers are performed by the manufacturer. If the repair is related to an electrical problem, the service person must document ground and leakage checks.
4. Document equipment issues and/or downtime on the appropriate Maintenance and Repair Downtime Action Log and the Bench Pass Down log. ~~Complete the Equipment Malfunction Report form~~
5. Equipment Repair records are obtained quarterly from Clinical Engineering and retained in the Laboratory section's equipment records file/manual or analyzer service manual.

C. Equipment Returned After Repairs:

1. Record date 'returned to service' on any applicable QC/PM logs.
2. ~~Provide Equipment Malfunction Report form to service person to document electrical check if applicable.~~
3. Perform QC, calibration and function checks as necessary after repairs to verify equipment is functioning prior to patient/donor/component testing or processing.
4. Notify Supervisor or Group Lead of any equipment QC, calibration or function check failures.
5. Retain all repair records in the appropriate file / notebook.

D. Equipment Removed Permanently from Service:

Record the date equipment is removed from service and final disposition on the appropriate form.

6. RELATED DOCUMENTS

Process for Complying with FDA Regulations Requiring Device User Facilities to Report MDR Reportable Events, QA procedure
Maintenance and Repair Downtime Action Log
Laboratory Bench Pass Down Log

7. REFERENCES

College of American Pathologists, General Laboratory Inspection checklist, (most current version)

Form revised 3/31/00

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SOP L043.000		
000	7/12/2010	Updated owner	L. Barrett	L. Loffredo
001	12/5/2012	Section 5: specify electrical checks, replace Equipment Malfunction Report with logs, change service department to Biomedical Engineers, and add retention of records. Section 6: add logs Section 9: remove form	L. Barrett	R. SanLuis

9. ADDENDA AND APPENDICES

None

~~Equipment Malfunction Report (see Attachment Tab of Infocard)~~

Form revised 3/31/00