TRAINING UPDATE

Lab Location:	GEC, SGAH & WAH	**Date Distributed:**	6/9/2014
Department:	Core	**Due Date:**	6/30/2014
		Implementation:	**7/1/2014**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Equipment Records and Repair GEC.L31, SGAH.L34, WAH.L33 v3

Maintenance and Repair Downtime Action Log (AG.F61.2)

Description of change(s):

Section 5: add requirement for validation, add detail to required documentation for downtime
Section 6: add Validation Protocol and TIC log

Add instructions to the Action Log and column to indicate QC & Function Checks have been completed

This revised SOP will be implemented on July 1, 2014

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

Approved draft for training all sites (version 3)

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:	

Review:		
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. All new equipment must be validated. Refer to the procedure Process and Equipment Validation Protocol.
4. Prior to testing patient samples, 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 when the equipment fails, suspend testing and do not report patient results. Re-test samples on another instrument or by a different method, if applicable. Seek guidance from the Group Lead, Supervisor, Lab Director or Medical Director as needed.
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, the Bench Pass Down log and Tech In Charge (TIC) Pass Down log.
    - All documentation (instrument printouts, QC, calibrations, background checks, etc.) generated during the troubleshooting and repair process, must be retained in the designated location.
    - Retained documentation must include the failed attempts to fix the instruments or resolve the problem.
    - A complete and clear trail for anyone reviewing the instrument history is necessary. Documentation must include the date / time the instrument went down, all steps taken to resolve, and the date / time the instrument was placed back in service and patient testing was resumed.
5. All required QC, function checks and calibrations must be performed BEFORE the instrument or equipment is put back in service.
6. Equipment Repair records are available from Clinical Engineering.

C. Equipment Returned After Repairs:

1. Record date 'returned to service' on any applicable QC/PM logs.
2. Perform QC, calibration and function checks as necessary after repairs to verify equipment is functioning prior to patient/donor/component testing or processing.
3. Notify Supervisor or Group Lead of any equipment QC, calibration or function check failures.
4. 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
Process and Equipment Validation Protocol, QA procedure
Maintenance and Repair Downtime Action Log (AG.F61)
Laboratory Bench Pass Down Log (AG.F47)
TIC Pass Down Log (AG.F128)

7. REFERENCES

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

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
002	4/24/2014	Section 5: add requirement for validation, add detail to required documentation for downtime Section 6: add Validation Protocol and TIC log Footer: version # leading zero's dropped due to new EDCS in use as of 10/7/13.	L. Barrett	R. SanLuis

9. ADDENDA AND APPENDICES

None

Form revised 3/31/00

Quest Diagnostics

Maintenance and Repair Downtime
ACTION LOG

☐ Germantown Emergency Center
☐ Shady Grove Adventist Hospital
☐ Washington Adventist Hospital

Instrument Name: _____ **Serial Number:** _____

Retain all documentation (instrument printouts, QC, calibrations, background checks, etc.) in the appropriate location.
Perform all required QC, function checks, calibrations, etc. BEFORE placing instrument back into service for patient testing

Date	Time	Problem	Action Taken	Time of Service Call	QC & Function Checks complete?	Time Back in Service	Patient Impact Yes / Why? No / Why?	Tech

Weekly review:	Weekly review:	Weekly review:
Weekly review:	Weekly review:	Monthly review: