TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	1/20/2017
Department:	All staff	**Due Date:**	2/14/2017
		Implementation:	**2/14/2017**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Equipment Records and Repair SGAH.L34 v4

Note: this has been converted to a system SOP

PM Inspection Report for Refrigerators and Freezers AG.F366.0

Equipment Service Report AG.F367.0

Description of change(s):

SOP -

Section 5: replace Biomed with entity or company, specify repair records are provided, update disposal

Section 6: add centrifuge & corporate SOP, add PM/repair forms

FORMS –

New forms used to document repairs & service to equipment

The revised SOP and FORMS will be implemented on February 14, 2017

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

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

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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 is 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 contracted company ~~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~~ Electrical installation and checks will be performed by the entity / company providing that service.
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. Utilize instrument specific forms or PM Inspection Report for Refrigerators and Freezers as appropriate.
5. Detailed information and requirements for centrifuges can be found in the SOP Centrifuge Use, Maintenance and Function Checks.

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 the Vendor or contracted company ~~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.
    - Laboratory staff will provide an Equipment Service Report. The entity performing the repair must complete it.
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 maintained in the appropriate file / notebook. ~~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:

1. Record the date equipment is removed from service and final disposition on the appropriate form.
2. The Quest corporate SOP for disposal, transfer or sale of equipment and applicable forms are available on the Quest intranet at: http://questnet1.qdx.com/Business_Groups/test_the_specimen/Instrument_Inventory.htm

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
Centrifuge Use, Maintenance and Function Checks, QA procedure
Maintenance and Repair Downtime Action Log (AG.F61)
Laboratory Bench Pass Down Log (AG.F47)
TIC Pass Down Log (AG.F128)
PM Inspection Report for Refrigerators and Freezers (AG.F366)
Equipment Service Report (AG.F367)
Quest Diagnostics *Instrument Disposal Process*, QDNO700

7. REFERENCES

All Common and General Laboratory checklists, College of American Pathologists, Laboratory Accreditation Program, Northfield, IL 60093, www.cap.org

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

Form revised 3/31/00

002	4/24/2014	Section 5: add requirement for validation, add detail to required documentation for downtime Section 9: 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
3	1/4/2017	Header: add other sites Section 5: replace Biomed with entity or company, specify repair records are provided, update disposal Section 6: add centrifuge & corporate SOP, add PM/repair forms	L. Barrett	R. SanLuis

9. ADDENDA AND APPENDICES

None

Quest Diagnostics™

□ Germantown Emergency Center
□ Washington Adventist Hospital
□ Shady Grove Medical Center

PM INSPECTION REPORT - REFRIGERATORS/FREEZERS/PLATELET ROTATORS

Date Performed:

EQUIPMENT INFORMATION			
Description		Model Number	
Manufacturer		Serial Number	

TASKS PERFORMED							
	Yes	No	NA		Yes	No	NA
Unit Exterior Inspection				**Refrigeration Inspection**			
Properly located				Check/clean condenser motor/blade			
Clean outside of unit				Check/clean condenser coil/filter			
				Check/clean condenser fan			
Outer & Inner Door Inspection				Clean compressor compartment			
Door latch				Compressor mounting hardware			
Door switch				Mechanical hardware secure			
Door gasket				Tubing & insulation			
Door hinges				Check/clean evaporator coil			
Outer door alignment & seal				Check/clean evaporator fans			
Door heaters				Evaporator fan guards in place			
Inner door hinges & latches				Crankcase heater operation			
				Defrost operation			
Electrical system inspection				Pressure controls			
Tighten electrical connections				Drain pan & line			
Guards & shields in place							
Amperage draw compressor				**Chamber Interior Inspection**			
Amperage draw motors in range				Shelving & brackets			
Proper voltage to unit				Product load distribution			

Comments:

Performed By: _____ Date: _____

Reviewed By: _____ Date: _____

Quest Diagnostics™

□ Germantown Emergency Center
□ Shady Grove Medical Center
□ Washington Adventist Hospital

Equipment Service Report

Description		Date	
		Model Number	
Manufacturer		Serial Number	

Problem:

Solution:

Cost:

Comments:

Performed By: _____ Date: _____

Reviewed By: _____ Date: _____