TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	5/23/2018
Department:	Mgmt, QA & Core Leads	**Due Date:**	6/20/2018
		Implementation:	**6/13/2018**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Unannounced Inspection Process SGAH.QA29 v5

This has been converted to a system SOP

Description of change(s):

Section 3: Added Responsibility Titles
Section 4: Added definitions
Section 6: Added Corporate SOP
Section 9: Updated Attachments A, B and C

This revised SOP will be implemented on June 13, 2018

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

Non-Technical SOP

Title	**Unannounced Inspection Process**	
Prepared by	Leslie Barrett	Date: 11/13/2009
Owner	Cynthia Bowman-Gholston	Date: 11/13/2009

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**

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TABLE OF CONTENTS

1. PURPOSE

This procedure defines a process to prepare for unannounced inspections by regulatory agencies.

2. SCOPE

This procedure applies to all laboratory staff, upon inspection by the following agencies:

- AABB (American Association of Blood Banks)
- CAP (College of American Pathologists)
- CMS (Centers for Medicare and Medicaid Services) - CLIA Program
- FDA (Food and Drug Administration)
- TJC (The Joint Commission)
- NRC (Nuclear Regulatory Commission)
- OSHA (Occupational Safety and Health Administration)
- State or Local Agencies
- MQA (Medical Quality Assessments - formerly CQA)

3. RESPONSIBILITY

The laboratory management team is responsible for duties and tasks assigned within this procedure.

The **Laboratory Director** is responsible for the approval of the initial document and any subsequent revisions.

The **Laboratory Director or Designee** is responsible for recurring review of this document.

4. DEFINITIONS

Corporate Departments: Medical Regulatory Affairs (MRA), Legal, Corporate Quality Assessment (CQA), Environmental Health and Safety (EHS).

Immediate Notification: Notification to the required Corporate Departments on the same business day or if after hours on the next business day.

Non-Routine Inspection: Any inspection that is not part of the license renewal process, e.g., a communication based on a patient complaint to an agency referenced above.

Routine Inspection: Any inspection (announced or unannounced) that is conducted by a state, federal, accrediting or other regulatory agency for the purpose of license or accreditation renewal

5. PROCEDURE

Prior to the Inspection

1. For each area of the lab, identify primary and back-up staff that will have knowledge of procedures, policies, and location of key documents (e.g., QC, PT, QM, training and competency, instrument validation, AMR records).
2. Identify inspection day tasks and assign primary and backup staff for each task (see attachment A)
3. Develop a phone list of primary and backup staff to contact upon the arrival of the inspection team. List should include medical director, lab director, all management team and QA team members, technical specialist and POC Sr. MT. If the lab needs additional FTEs on the day of the inspection, a list of staff who has previously indicated the ability to work on short notice should be contacted immediately.
4. Store onsite documents and records in a central location so that they are easily accessible during the inspection. Ensure that relevant staff knows how to locate or retrieve the documents and records.
5. Identify options for workspace that can be used by the team. Space can either be in the laboratory, in an area designated for clerical/administrative services, or elsewhere in the institution that is convenient to the lab.
6. If the inspection team has to travel from site to site, develop maps and identify possible modes of transportation in the event the team has not previously made arrangements.
7. Train all staff so that they are familiar with the Checklists and the inspection process. Familiarize staff on what to expect. Unannounced inspections should be an on-going agenda item at lab meetings to increase communication and provide preparedness updates.

Inspection Day

1. On the day of an unannounced routine inspection or when notified by the regulatory agency, if advanced notice is received, the Laboratory must immediately notify MQA (for laboratory performance) or EHS (for safety). Refer to the policy *Notification of*

Federal and State Agency Laboratory Performance Investigations, Inspections, Complaints or Adverse Media for additional details.

2. Results of the routine inspection must be sent to MQA (for laboratory performance) or EHS (for safety) as applicable.
3. Activate the inspection day task list and refer to it as necessary during the day. Refer to attachments A and B.
4. Assemble required documents and materials. Refer to attachment C

6. RELATED DOCUMENTS

Records Management Process, Transfusion Service, Blood Bank Procedure
Retention of Records and Materials, Laboratory policy
Notification of Federal and State Agency Laboratory Performance Investigations, Inspections, Complaints or Adverse Media, QA Procedure

7. REFERENCES

CAP Unannounced Inspection Tips for Labs, College of American Pathologists, 4/27/07.

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SOP QA210.001		
000	3/26/2010	Attachments updated	L. Barrett	C. Bowman
001	7/25/2012	Attachments updated	L. Barrett	C. Bowman
002	3/4/2014	Section 5: Removed prepare annotated checklists for each section. Section 9: Updated Attachments A. B and C Footer: version # leading zero's dropped due to new EDCS in use as of 10/7/13.	C. Bowman	C. Bowman
3	4/11/2016	Section 5: Removed develop process for off-site records and showing video. Section 6: Added lab policy Section 9: Updated Attachments A, B and C	L. Loffredo L. Barrett	C. Bowman-Gholston
4	5/2/2018	Header: Added other sites Section 3: Added Responsibility Titles Section 4: Added definitions Section 6: Added Corporate SOP Section 9: Updated Attachments A, B and C	L. Barrett C. Bowman-Gholston	C. Bowman-Gholston

9. ADDENDA AND APPENDICES

Attachment A: Inspection Day Tasks
Attachment B: Notification and Contact List
Attachment C: Document Location chart

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Attachment A

Inspection Day Tasks

Task/Role	SGAH Primary Staff/ Extension #	Backup Staff/ Extension #	WAH Primary Staff/ Extension #	Backup Staff/ Extension #
Designated central contact for the inspection	Operations Director 240-826-6095 (office) 240-620-3413 (cell)	Sr. QA Specialist 240-826-6553	Operations Director 301-891-6238 240-620-3413 (cell)	QA Specialist 301-891-6308
1. Secure workspace for the inspection team	SGAH Lab Conference Room	Sr. QA Specialist 240-826-6553	WAH Lab Conference Room	QA Specialist 301-891-6308
2. Greet the inspection team at the reception desk and lead them into the lab or to the workspace	Operations Director – Day 240-826-6095 Group Lead Evening/Night- 240-826-6286	Group Lead – Day 240-826-6286	Core Lab Supervisor – Day 301-891-5681 Group Lead Evening/Night - 301-891- 5880	Group Lead – Day 301-891-5880
3. Assess workflow/FTE situation; make appropriate modifications as necessary	Group Lead – 240-826-6286	2nd Group Lead – 240-826-6433	Group Lead – 301-891-5880	Tech in Charge or Sr. MT – Day 301-891-5880
4. Make appropriate phone calls to notify that inspection team has arrived (attachment B)	QA Specialist 240-826-6553	Administrative Asst.	QA Technologist 301-891-6308	Technical Supervisor 301-891-5681
6. Arrange for food and beverages—coffee/water/drinks and lunch	Send to On Site Cafeteria.	Technical Supervisor and/or member of Mgmt Team	Send to On Site Cafeteria.	Technical Supervisor and/or member of Mgmt Team
7. Arrange for off-site records to be delivered	Supervisor	Group Lead 240-826-6286	Supervisor	Group Lead 301-891-5880
8. Arrange for tour of laboratory	Operations Director	Senior member of Mgmt Team or Technical Supervisor	Operations Director	Senior member of Mgmt Team or Technical Supervisor

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Attachment B

Notification and Contact List

Shady Grove Medical Center

- QA Director – Quest Diagnostics, Baltimore – 410-536-1501
- VP, Quality – 240-826-6393
- VP Ancillary Services – 240-826-6061

Washington Adventist Hospital

- QA Director – Quest Diagnostics, Baltimore – 410-536-1501
- VP, Quality – 301-891-5221
- VP Ancillary Services – 301-891-5458

Medical Quality Assessment (Linda Lowe) – 513-236-6294

Executive Director CCPL Capital Choice Pathology Laboratory – 301-206-2579

Attachment C

Document Locations

Record	WAH	SGMC	GEC
QC – Core lab	Current month at workbench, past months and previous year in Lab Conference Room	Current month at workbench, past months and previous year on bookshelves in the lab.	On shelves in lab
QC – Micro	Current month at workbench, past months and previous year in Lab Conference Room	Binder above workbench	On shelves in lab
PM – Core lab	Current month at workbench, past months and previous year in Lab Conference Room	Binders on bookshelves within the lab.	On shelves in lab
PM – Micro	Current month at workbench, past months and previous year in Lab Conference Room	Binders on shelves within the lab.	NA
Calibrations	Chemistry - Current year on bookshelves in lab; Previous year in Lab Conference Room	Binders on bookshelves within the lab.	On shelves in lab
Linearity	Lab Conference Room	Core Laboratory shelves	On shelves in lab
Validations	On electronic document control system	On electronic document control system	On electronic document control system
Correlations	Lab Conference Room	Core Laboratory shelves	On shelves in lab
Pipette calibration	Lab Conference Room	Core Laboratory shelves	On shelves in lab
Thermometer, Timer, Centrifuge checks	Lab Conference Room	Core Laboratory shelves	On shelves in lab
SOPs - lab copy	Each department	Each department	Each workstation
SOPs - retired versions	On electronic document control system	On electronic document control system	On electronic document control system
Prof Testing	QA office (2yrs)	QA office (2yrs)	In Lab (2 yrs)
Employee Personnel files	Secure office	Secure office	At SGMC
Competency	QA office file	QA office file	QA file, SGMC
Training	QA office file	QA office file	QA file, SGMC
PI / QA	QA office file	QA office file	QA office, SGMC
Safety SOP manual	Core Lab Bookshelf	Core Laboratory shelves	GEC Laboratory shelves
Safety Documents	Lab Conference Room	QA office	SGMC QA office
POC Documents	POC office	Shelf above POC computer	On shelves in lab
For **Blood Bank record** storage refer to Records Management Process, Transfusion Service			

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