

TRAINING UPDATE

Lab Location: GEC, SGMC & WAH
Department: Mgmt, QA

Date Distributed: 5/6/2016
Due Date: 5/12/2016
Implementation: 5/12/2016

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:
Unannounced Inspection Process GEC / SGAH / WAH.QA29v4
Description of change(s):
<p>Section 5: Removed develop process for off-site records and showing video.</p> <p>Section 6: Added lab policy</p> <p>Section 9: Updated Attachments A, B and C</p> <p>This revised SOP will be implemented on May 12, 2016</p>

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

Approved draft for training (version 4)

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
<i>Refer to the electronic signature page for approval and approval dates.</i>		
Local Issue Date:		Local Effective Date:

Review:		
Print Name	Signature	Date

TABLE OF CONTENTS

1. PURPOSE.....	2
2. SCOPE	2
3. RESPONSIBILITY.....	2
4. DEFINITIONS.....	2
5. PROCEDURE.....	2
6. RELATED DOCUMENTS	3
7. REFERENCES	3
8. REVISION HISTORY.....	3
9. ADDENDA AND APPENDICES.....	3

1. PURPOSE

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

2. SCOPE

This procedure applies to all laboratory staff.

3. RESPONSIBILITY

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

The Senior QA Specialist is responsible for the content and periodic review of this procedure.

4. DEFINITIONS

None

5. PROCEDURE

Prior to the Inspection

1. Identify primary and back-up staff for each area of the lab, who 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, ~~managing director~~, lab director, all management team and QA team members, technical specialist and POC Sr MT. ~~lab manager and section head supervisors~~. 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 ~~also be available~~ be contacted immediately.
4. ~~Develop a process for timely retrieval of off-site records, such as personnel training records and initial instrument/method validation studies.~~ 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. ~~Show the video that is included with the reapplication process to reinforce the general CAP approach to inspections and~~ 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. Activate the inspection day task list and refer to it as necessary during the day. Refer to attachments A and B.
2. 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](#)

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

9. ADDENDA AND APPENDICES

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

Form revised 3/31/00

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	Sr. QA Specialist 240-826-6553	Operations Director 301-891-6238	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 - 301-891-5149	Group Lead – Day 301-891-5149
3. Assess workflow/FTE situation; make appropriate modifications as necessary	Group Lead – 240-826-6286	2 nd Group Lead – 240-826-6433	Group Lead – 301-891-5147	Tech in Charge or Sr. MT – Day 301-891-5149
4. Make appropriate phone calls to notify that inspection team has arrived (attachment B)	Sr. QA Specialist 240-826-6553	Administrative Asst.	QA Technologist 301-891-6308	Technical Supervisor 301-891-6587
6. Arrange for food and beverages—coffee/water/drinks and lunch	Administrative Asst.	Technical Supervisor and/or member of Mgmt Team	Administrative Asst.	Technical Supervisor and/or member of Mgmt Team
7. Arrange for off-site records to be delivered	Administrative Asst.	Group Lead 240-826-6286	Administrative Asst.	Group Lead 301-891-5149
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

Form revised 3/31/00

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

- Director of Quest Diagnostics Baltimore Business unit – 410-536-1725
- VP, Quality – 301-891-5221
- VP Ancillary Services – 301-891-5458

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 Op director’s office	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 Op director’s office	Binder above workbench	On shelves in lab
PM – Core lab	Current month at workbench, past months and previous year in Op director’s office	Binders on bookshelves within the lab.	On shelves in lab
PM – Micro	Current month at workbench, past months and previous year in Op director’s office	Binders on shelves within the lab.	NA
Calibrations	Chemistry - Current year on bookshelves in lab; Previous year in Op Director’s office	Binders on bookshelves within the lab.	On shelves in lab
Linearity	Op Director’s office	Core Laboratory shelves	On shelves in lab
Validations	On electronic document control system	On electronic document control system	On electronic document control system
Correlations	Op Director’s office	Core Laboratory shelves	On shelves in lab
Pipette calibration	Op Director’s office	Core Laboratory shelves	On shelves in lab
Thermometer, Timer, Centrifuge checks	Op Director’s office	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
Employee Personnel files	Operations Director’s office	Operations Director’s office	At SGMC
Competency	QA office file	QA file	QA file, SGMC
Training	QA office file	QA file	QA file, SGMC
PI / QA	QA office	QA office	QA office, SGMC
Safety SOP manual	Core Lab Bookshelf	Core Laboratory shelves	On shelves in lab
Safety Documents	Op Director’s office	QA office	QA office, SGMC
POC Documents	POC office	Shelf above POC computer	On shelves in lab
For Blood Bank record storage refer to Records Management Process, Transfusion Service			