TRAINING UPDATE

Lab Location:	GEC, SGAH & WAH	**Date Distributed:**	11/4/2014
Department:	QA & Mgmt	**Due Date:**	11/30/2014
		Implementation:	**12/1/2014**

DESCRIPTION OF PROCEDURE

Name of procedure:
Mid-Cycle Inspection Process GEC.QA227, SGAH.QA892, WAH. QA891 v0
Description of change(s):
New SOP that describes the process for mid-cycle CAP inspections This SOP will be implemented on December 1, 2014

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

Approved draft for training

Non-Technical SOP

Title	**Mid-Cycle Inspection Process**	
Prepared by	Leslie Barrett	Date: 10/23/2014
Owner	Cynthia Bowman-Gholston	Date: 10/23/2014

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

This procedure describes the process to perform and document responses for the College of American Pathologists (CAP) mid-cycle self-inspection.

2. SCOPE

This procedure applies to CAP mid-cycle self-inspections.

3. RESPONSIBILITY

All laboratory management and quality assurance (QA) personnel must have knowledge of and comply with this procedure.

4. DEFINITIONS

QD – Quest Diagnostics
ADV – Adventist Healthcare
CAP – College of American Pathologists

5. PROCEDURE

A. Inspection Preparation

1. The Medical Director and Regional Lab Director assign inspectors
2. The assigned QA specialist downloads the custom checklists from the CAP website and creates the summary spreadsheet for findings. See example in addendum A.
3. The Medical Director and Regional Lab Director select inspection dates. The assigned QA specialist creates an inspection schedule or timeline.

B. Inspect

1. Using the checklist, inspect the assigned area(s) per routine CAP guidelines
2. Record the location of the supporting documentation for each applicable checklist requirement. When referencing procedures or policies, include the title (SOP numbers vary within our sites). This information must be captured electronically on the checklist.
3. Record deficiencies and recommendations on the summary spreadsheet.
4. Submit all required documentation to the designated QA specialist by the due date.

C. Preparation of Draft Responses

1. All findings are transcribed onto a summary spreadsheet which is saved on the shared drive in a folder labeled appropriately by year. For example: G:\AHC_Lab\Quality Assurance\Regulatory Compliance\Inspections\CAP 2013Midcycle
    a. The spreadsheet contains the following elements
        - Checklist item and phase
        - Checklist question / statement
        - Inspector Comment/Observation
        - Corrective action
        - Attachments
        - Due date
        - Responsible person(s)
    b. Separate tabs are created for deficiencies for each parent facility (QD or ADV, as appropriate)
    c. A separate tab is maintained for recommendations for ALL sites

2. A timeline for corrective actions is established by the Medical Director and Regional Lab Director.

3. Corrective action for each deficiency is determined by the section manager or supervisor. Actions may include creating or revising a procedure, staff training, administering a competency, etc. Other laboratory leaders and/or the QA team may serve as resources for determining appropriate corrective action.

4. The manager or supervisor documents the planned action on the summary spreadsheet.
    a. Any supportive documentation is listed as attachment(s).
    b. Draft responses are submitted to the designated QA specialist by the assigned due date.

5. The designated QA specialist
    a. Reviews draft responses and recommends edits as needed
    b. Tracks all responses to ensure deadlines are met

c. Emails draft response forms and the summary to the Medical Director by the due date.

6. The Medical Director will approve or reject responses. If rejected, the manager or supervisor must make the necessary corrections and re-submit the response form. This process is coordinated by the designated QA specialist.

7. The manager or supervisor is responsible for submitting all required supporting documentation prior to the due date.

8. If a decision is made to challenge a deficiency, clearly state that on the response sheet, and explain the reason for the challenge. Attach required documentation supporting the claim that your laboratory was in compliance prior to the inspection, including records of ongoing implementation dated prior to the inspection.

D. Completion Process

1. The final spreadsheet is reviewed by the medical director.
2. Any response that requires further clarification is directed back to the manager or supervisor for action and resolution.
3. When corrective action is finished, the spreadsheet is updated with completion dates.
4. The spreadsheet and supporting documentation may be printed as evidence that the mid-cycle inspection was completed.

6. RELATED DOCUMENTS

None

7. REFERENCES

N/A

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By

9. ADDENDA AND APPENDICES

Addendum A: Example of Summary Spreadsheet

Addendum A

Example of Summary Spreadsheet

Site	Section	Item #	Phase	Checklist Question	Inspector Comment/Observation	Corrective Action	Comments	Due	Responsible

Form revised 3/31/00