TRAINING UPDATE

Lab Location:	GEC, SGAH & WAH	**Date Distributed:**	5/21/2013
Department:	All staff	**Due Date:**	6/30/2013
		Implementation:	**6/1/2013**

DESCRIPTION OF PROCEDURE

Name of procedure:

Planned Deviation Process GEC / SGAH / WAH.QA47 v000

Planned Deviation Documentation AG.F235.000

Description of change(s):

New SOP and form to document approval and notification when we are unable to follow our standard procedure for a particular test or process.

The SOP was presented at general lab staff meetings in May.
It is being reviewed on MTS to assure that all staff are informed and aware of the SOP.

This SOP was implemented on June 1, 2013

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

Approved draft for training all sites (version 000)

Non-Technical SOP

Title	**Planned Deviation Process**	
Prepared by	Leslie Barrett	Date: 4/8/2013
Owner	Cynthia Bowman-Gholston	Date: 4/8/2013

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

To provide a process to document the approval and notification of planned deviations from standard operating procedures and processes.

2. SCOPE

The planned deviation process formally documents excursions from standard procedures and processes before they are initiated.

3. RESPONSIBILITY

The Medical Director or designee is responsible for review and approval of the planned deviation process.

The Supervisor is responsible for documenting the planned deviation process.

Laboratory staff are responsible for adhering to standard testing procedures without deviation unless a planned deviation process has been approved by the Medical Director or designee. Staff are required to sign the planned deviation document to acknowledge both its onset and termination.

4. DEFINITIONS

Deviation: the departure of a process or system from established procedures, guideline or standards

Planned deviation: a departure of a process or system from established procedures, guideline or standards approved and documented BEFORE the deviation has occurred

Process: set of interrelated resources and activities that transform inputs into outputs

Procedure: specific way to perform an activity

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Standard operating procedure (SOP): detailed work instructions on how to perform a task

5. PROCEDURE

1. The Supervisor or designee must request a planned deviation from a procedure or process
   a. Complete a Planned Deviation Documentation form (see appendix)
   b. Specify the procedure and description of the deviation (*example*: 'utilize previously tested patient sample as a negative control for mono testing')
   c. Document the reason for the deviation request (*example*: 'delay in shipment of control from manufacturer')

2. The Supervisor or designee must obtain approval
   a. Submit the completed Planned Deviation Documentation form to the Medical Director for approval signature.
   b. Verbal approval can be given if the Medical Director is not onsite.
      - Document the date and time verbal approval was given
      - Obtain signature upon director's return
   c. Supervisor signs and inserts planned deviation start date.

3. The Supervisor or designee must obtain staff signatures
   a. Staff who perform the specified test / process must record name and tech code, signature and date to document notification of deviation
   b. At the conclusion of the deviation, staff must sign and date the 'End deviation' column

4. Final signed documentation will be maintained in the QA office, with the recall notifications.

5. Blood Bank deviations are documented on the Pathologist Consultation form.

6. RELATED DOCUMENTS

Pathologist Consultation, Blood Bank form

7. REFERENCES

N/A

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By

Form revised 3/31/00

9. ADDENDA AND APPENDICES

Planned Deviation Documentation (see Attachment Tab of Infocard)

Quest Diagnostics

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

Planned Deviation Documentation

Procedure:				
Reason for Deviation:				
Medical Director or Designee:			Date:	
Supervisor:			Date:	
Deviation Start Date:			Deviation End Date:	
Testing Personnel Signatures	Start Deviation Signatures		End Deviation Signatures	
Printed Name/Code	Signature	Date	Signature	Date