

## TRAINING UPDATE

**Lab Location:**  
**Department:**

GEC, SGMC & WAH  
Technical Mgmt & QA

**Date Distributed:**

8/28/2015

**Due Date:**

9/1/2015

**Implementation:**

**9/1/2015**

## DESCRIPTION OF PROCEDURE

**Name of procedure:**

**Intermittent Testing GEC.QA237, SGAH.QA921, WAH.QA913 v0**

**Description:**

This is a new SOP to describe the process for handling intermittent patient testing.

It is needed to meet CAP requirements.

**This SOP and Form will be implemented on September 1, 2015**

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

**Approved draft for training (version 0)**

Non-Technical SOP

<b>Title</b>	<b>Intermittent Testing</b>	
<b>Prepared by</b>	Leslie Barrett	Date: 8/6/2015
<b>Owner</b>	Cynthia Bowman-Gholston	Date: 8/6/2015

<b>Laboratory Approval</b>		
<b>Print Name and Title</b>	<b>Signature</b>	<b>Date</b>
<i>Refer to the electronic signature page for approval and approval dates.</i>		
Local Issue Date:		Local Effective Date:

<b>Review:</b>		
<b>Print Name</b>	<b>Signature</b>	<b>Date</b>

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**1. PURPOSE**

This procedure describes the process for how to handle intermittent patient testing.

**2. SCOPE**

This procedure applies to tests performed intermittently; i.e. tests are taken out of production for a time and then brought back into production.

**3. RESPONSIBILITY**

The technical supervisor is responsible for ensuring compliance with this procedure.

**4. DEFINITIONS**

None

**5. PROCEDURE**

A. A test is considered to be taken out of production when both of the following conditions are met:

1. Patient testing is not offered AND
2. Proficiency Testing (PT) or alternative assessment, as applicable, is suspended.

B. When a test is put back into production, the following requirements must be met:

1. Reinstate PT or alternative assessment performed within 30 days prior to restarting patient testing.

Note: If a PT challenge is not offered during the 30-day period prior to restarting patient testing, an alternative assessment of the test is performed. The laboratory must participate in the next scheduled PT event.

2. Complete method performance specifications verified, as applicable, within 30 days prior to restarting patient testing
3. Ensure that competency has been assessed for analysts within 12 months prior to restarting patient testing

C. Documentation

1. Prior to re-instatement of intermittent tests, a validation plan must be prepared and approved by the Medical Director.
  - a. The Equipment and Process Validation Protocol form is utilized to describe the performance specifications to be validated.
  - b. The plan must include the requirements specified in section B above.
2. Upon approval, the validation and assessment are performed and documented using routine SOPs (refer to Related Documents)
3. The Technical Supervisor and Medical Director review the data and approve/disapprove via electronic document control system.

**6. RELATED DOCUMENTS**

QA procedures

- Process and Equipment Validation Protocol
- Laboratory Method Validation Protocol, QA procedure
- Competency Assessment
- Proficiency Test Handling and Result Submission
- Proficiency Test Results Evaluation
- Internal Proficiency Testing Policy
- Equipment and Process Validation Protocol form (AG.F204)

**7. REFERENCES**

Laboratory General Checklist. College of American Pathologists, Laboratory Accreditation Program, Northfield, IL 60093

**8. REVISION HISTORY**

Version	Date	Reason for Revision	Revised By	Approved By

**9. ADDENDA AND APPENDICES**

N/A