

## TRAINING UPDATE

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

**Date Distributed:** 11/19/2015  
**Due Date:** 11/30/2015  
**Implementation:** 12/1/2015

### DESCRIPTION OF PROCEDURE REVISION

**Name of procedure:**

**Internal Proficiency Testing Policy GEC / SGAH / WAH.QA18 v2**  
**Internal Proficiency Testing by Referee Lab Worksheet AG.F185.1**  
**Internal Proficiency Testing by Direct Observation Worksheet AG.F186.1**

**Description of change(s):**

**SOP:**

Section 3: update job title  
Section 4: update PT database  
Section 5: remove chart with alternative listing  
Section 6: forms moved from section 9

**FORMS:** update logo & SG facility name

**The revised SOP and Forms will be implemented on December 1, 2015**

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

Approved draft for training (version 2)

Non-Technical SOP

<b>Title</b>	<b>Internal Proficiency Testing Policy</b>	
<b>Prepared by</b>	Leslie Barrett	Date: 7/20/2009
<b>Owner</b>	Cynthia Bowman-Gholston	Date: 7/20/2009

<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 an alternate system to assess the accuracy and precision of laboratory results for analytes not evaluated with commercially available Proficiency Testing (PT) materials.

### **2. SCOPE**

Applies to any analyte or test without commercially available Proficiency Testing (PT) materials.

### **3. RESPONSIBILITY**

- Test performance is rotated among all staff.
- Specimen procurement, coordination of testing and evaluation of results are the responsibility of each section Supervisor.
- The supervisor or QA staff enters results in the PT database.
- The QA ~~senior specialist supervisor~~ is responsible for content and review of this procedure.

### **4. DEFINITIONS**

**Proficiency Testing (PT)** – A means to determine that test methods are performing as expected through outcomes for predetermined standards.

**PT database**– Excel spreadsheet utilized to track ~~all aspects of~~ external and internal Proficiency Testing, including:

- Applicable survey descriptions and codes
- Ship date, if applicable
- Receipt date
- Due date for results to be submitted

- Actual date results are submitted
- Date CAP evaluation of results is received, if applicable
- ~~Participating techs~~
- ~~Number of results/tests performed~~
- ~~Number of results/tests correct~~
- ~~Calculated percent of correct results~~
- Explanation of variances/failures

## 5. PROCEDURE

### A. General Information

1. For analytes not evaluated through the College of American Pathologists (CAP) or another approved PT provider, an internal system of assessment will be performed at a minimum of twice per year.
2. Internal PT complements the external PT program by:
  - a. Ensuring the quality of the laboratory performance for all testing.
  - b. Providing blind samples to challenge staff performance.
3. Laboratory leadership will perform appropriate documentation and review of results. The procedure and evaluation of results are defined within the specific laboratory sections.
4. This internal assessment may use the following methods:
  - a. Exchange samples with another accredited laboratory.
  - b. Use split specimens and send to a reference laboratory.
  - c. Blind testing of specimens with known results.
  - d. For labile specimens have multiple technologists perform analysis.
  - e. Direct observation of test performance.

### B. Testing Instructions

1. The laboratory initiating the testing is the “performing” lab. The laboratory that repeats the test is the “referee” lab.
2. Only one testing challenge is required per event, but more challenges may be performed at the supervisor’s discretion.
3. The test is performed and results recorded by the performing lab on the Internal Proficiency Testing by Referee Lab Worksheet (see attached). The specimen, or preferably an aliquot of the specimen, and worksheet are forwarded to the referee lab.
4. The referee lab performs the testing and records results. If testing is performed at SGMC or WAH, any discrepancies must be brought to the attention of the referee laboratory supervisor.
5. For assessment by direct observation, document performance for each person observed on the competency assessment form. One half of all testing personnel will be evaluated every six months. A summary of observations will be compiled on the internal Proficiency Testing by Direct Observation Worksheet (see attached). Include the number of observations performed and the number assessed as acceptable. Attach copies of the competency assessment forms.

**C. Evaluation of Results**

1. The performing lab supervisor reviews the PT results.
  - a. Utilize the Total Allowable Error (TEa) for quantitative tests.
  - b. Performance expectations established by method validation or manufacturer’s studies, or national performance standards may be utilized if applicable.
2. The performing lab also investigates any discrepancies. Investigation should include, but is not limited to, repeat testing, review of Quality Control and Training/Competency records, Preventative Maintenance records, SOP, and previous patient results. Additional testing and consultation with the technical manager and the medical director may be necessary to resolve test result discrepancies.
3. All results including discrepancy investigations are routed to the section manager and medical director for review and signature. Refer to Proficiency Test Results Evaluation procedure.
4. A copy of the result and ALL supporting documentation is filed in the CAP survey notebook(s). The supervisor or QA tech enters these results in the PT database.

~~**D. Alternate Proficiency Testing: Tests and PT Method**~~

<b>Test</b>	<b>Referee Site WAH</b>	<b>Referee Site SGAH</b>	<b>Referee Site Reference Lab</b>	<b>Blind Testing/Multiple Technologists</b>	<b>Direct Observation</b>
<b>Phlebotomy</b>					
<b>Bleeding Time</b>	<b>Phlebotomy supervisor or designee</b>	<b>Phlebotomy supervisor or designee</b>			<b>X</b>

**6. RELATED DOCUMENTS**

- Proficiency Test Handling and Result Submission
- Proficiency Test Results Evaluation
- Competency Assessment
- Internal Proficiency Testing by Referee Lab Worksheet (AG.F185)
- Internal Proficiency Testing by Direct Observation Worksheet (AG.F186)

**7. REFERENCES**

- CAP Laboratory General Checklist ([www.cap.org](http://www.cap.org)).

**8. REVISION HISTORY**

<b>Version</b>	<b>Date</b>	<b>Reason for Revision</b>	<b>Revised By</b>	<b>Approved By</b>
		Supersedes SOP QA003.004		
000	8/13/12	Section 5: correct form titles added to Part B Section 6: update titles Section 9: update title, add Direct Observation form	L. Barrett	C. Bowman
001	10/26/15	Section 3: update job title Section 4: update PT database Section 5: remove chart with alternative listing Section 6: forms moved from section 9 Footer: version # leading zero's dropped due to new EDCS in use as of 10/7/13.	L. Barrett	C. Bowman

**9. ADDENDA AND APPENDICES**

None

~~Internal Proficiency Testing by Referee Lab Worksheet (see Attachment tab of Infocard)~~

~~Internal Proficiency Testing by Direct Observation Worksheet (see Attachment tab of Infocard)~~

### Internal Proficiency Testing by Referee Lab

Performing Lab completes this section	
Analyte: _____ Methodology: _____	
Date of Original Result: _____	
Date Sent for PT: _____	
Site of Original Result (Performing Lab): <input type="checkbox"/> SGMC <input type="checkbox"/> WAH <input type="checkbox"/> GEC	
Referee Lab for PT: <input type="checkbox"/> SGMC <input type="checkbox"/> WAH <input type="checkbox"/> GEC <input type="checkbox"/> Reference Lab <input type="checkbox"/> Pathologist	
Tech(s) Performing PT : _____ _____	
Performing Lab Results:   	
Referee Lab completes this section	
Date Rec'd: _____	
Date tested: _____	
Results: _____	Tech: _____
Evaluation: <input type="checkbox"/> PASS <input type="checkbox"/> FAIL	
Corrective Action Plan for Failures (to be completed by performing lab):     	

**Supervisor:** \_\_\_\_\_

**Date:** \_\_\_\_\_

**Administrative Director:** \_\_\_\_\_

**Date:** \_\_\_\_\_

**QA Specialist:** \_\_\_\_\_

**Date:** \_\_\_\_\_

**Lab Medical Director:** \_\_\_\_\_

**Date:** \_\_\_\_\_

### Internal Proficiency Testing by Direct Observation

**Test / Analyte:** \_\_\_\_\_ **Methodology:** \_\_\_\_\_

Site (Performing Lab): <input type="checkbox"/> SGMC <input type="checkbox"/> WAH <input type="checkbox"/> GEC
Date(s) of observation:
Tech(s) / Staff performing PT:
Direct observation performed by:
Summary data:  # of observations performed: _____ <i>(attach copies of completed worksheets)</i>  # of observations correct: _____  Reviewed by: _____
Results: <input type="checkbox"/> PASS <input type="checkbox"/> FAIL
<b>Corrective Action Plan (for failures):</b>          

**Supervisor:** \_\_\_\_\_

**Date:** \_\_\_\_\_

**Administrative Director:** \_\_\_\_\_

**Date:** \_\_\_\_\_

**QA Specialist:** \_\_\_\_\_

**Date:** \_\_\_\_\_

**Lab Medical Director:** \_\_\_\_\_

**Date:** \_\_\_\_\_