TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	2/5/2019
Department:	Mgmt & QA	**Due Date:**	2/28/2019
		Implementation:	**2/19/2019**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Proficiency Test Results Evaluation SGAH.QA21 v5

Survey Near Miss Evaluation AG.F430.1

Description of change(s):

Header: updated facility

Section 5: delete references to flow charts in part E.1, add note of Other code in E.3; add near miss form in F.2; add medical quality reporting to I

Section 6: add near miss form

Section 7: update QD policy

Section 9: update addenda A, delete flow charts

This revised SOP will be implemented on February 19, 2019

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

Non-Technical SOP

Title	**Proficiency Test Results Evaluation**	
Prepared by	Leslie Barrett	Date: 12/29/2009
Owner	Cynthia Bowman-Gholston	Date: 12/29/2009

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**

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TABLE OF CONTENTS

1. PURPOSE

Proficiency testing results are used to:

- Determine the quality of the laboratory performance
- Compare performance with peer groups
- Utilize the results as an educational and evaluative tool for employees and/or instrument/reagent performance.

2. SCOPE

All clinical laboratory staff involved in specimen testing is required to participate in proficiency testing.

3. RESPONSIBILITY

A. Laboratory Medical Director
Provides final review of all aspects of proficiency testing (PT) in Clinical Laboratory departments.

B. Laboratory Services Director
Review of PT results and ensures any required follow-up

C. Technical Supervisors
Provide primary review and evaluation received PT evaluations, and timely investigation and corrective action, as necessary.

D. Quality Assurance staff
Track routing of results to verify timely completion and thoroughness of investigation.

E. Staff technologists and technicians
Review PT evaluation as a mechanism for continuing education.

4. DEFINITIONS

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

CAP – College of American Pathologists

LAP – Laboratory Accreditation Program of CAP

Survey Error Investigation and Corrective Action Report (SEICAR) – a form used to document the investigation and corrective actions taken to proficiency testing non-conformances

Graded Result – a result that the proficiency agency has formally evaluated for acceptability against a peer group or all method results using defined evaluation criteria

Near-miss – a graded result that was close to non-conformance (± 2.5 SDI or greater) but the PT provider still determined as acceptable. Near misses must be investigated to evaluate future risk and to correct existing problems before an actual non-conformance occurs.

Ungraded Result – a result that the proficiency agency has not formally evaluated for acceptability (e.g., lack of participant consensus, peer groups that are too small for statistical evaluation, results reported using '<' or '>', and educational challenges).

Standard Deviation (SD) – a measurement of the dispersion of data around the mean. The SD decreases as variation decreases.

Standard Deviation Index (SDI) – a statistical tool that describes how far a single proficiency testing result is from the target value (in SDs).

5. PROCEDURE

A. Result Communication Prohibition

- **Intra- or inter-laboratory communication regarding PT materials or results is prohibited until the PT provider has formally evaluated the results.** (Questions regarding the administration of the PT program or material integrity may be directed to the Laboratory Director, designee, or PT provider, but communications or discussions concerning PT results are prohibited.)
- Refer to the QA procedure 'Procedure for handling Inappropriate Referral or Proficiency Materials or Inter/Intra laboratory Communication of Proficiency Test Information' for additional details.

B. Routing of Results/Evaluation

Step	Action
1	The College of American Pathologists (CAP) evaluates submitted results for each survey and returns an evaluation report and statistical participant summary and critique. This information is mailed to the facility and available on the CAP website. CAP also sends email notices to the CLIA site CAP administrators as soon as website results are published. • A QA specialist or designee will assess the evaluations for failures and near misses. • CAP documents good or acceptable at the far right of each result. o If the qualitative result is deemed acceptable, no action is required. o If the quantitative result is deemed acceptable and the SDI is less than 2.5, no action is required. o If a result is deemed unacceptable, a SEICAR is required. o If the quantitative result is greater than or equal to 2.5, the supervisor must review and document the "Near Miss" findings. • For CAP evaluations that reflect unacceptable results (failure or near-miss), the PDF evaluation will be emailed to the Technical Supervisor to begin the investigation. Refer to sections E, F and H as applicable.
2	The **Technical Supervisor, QA specialist or designee** will route the hard-copy evaluation and critique to Laboratory leadership (Technical Supervisor, Medical Director, Laboratory Services Director – see Responsibility section).
3	Results will be reviewed and evaluated within two weeks. Proficiency testing results must be signed by the Technical Supervisor/Manager, Medical Director, Services Director or designee(s), and the QA specialist or designee.
4	The supervisor will document the investigation of any unsatisfactory PT results or results that do not agree with the majority of respondents on a Survey Error Investigation and Corrective Action Report (SEICAR). (Refer to section E)
5	Corporate Medical Quality also requires that any result deemed "near miss", must be investigated. • Graded results that meet the PT provider's acceptance criteria are evaluated internally to detect "near-misses" for each analyte. Near-misses are opportunities to detect and correct problems before an actual miss occurs. Near-misses are not counted as PT non-conformances. • If a near-miss is detected, the investigation/corrective actions (if required) must be documented. • PT results are initially assessed visually, using SDIs, charts or other tools provided on the PT report. It is not necessary to perform near-miss calculations for every PT challenge, just the challenges that visually appear to meet the near-miss criteria. • Refer to Section F for investigation and documentation process.

Step	Action
6	Refer to Section H if a challenge is ungraded due to one of the following: • Routinely ungraded analyte/result • Educational challenge • Lack of participant consensus • Results submitted after cut-off date • Results not submitted • Appropriate method code was not submitted
7	All documentation is returned to QA staff for filing.

C. Staff Feedback/Continuing Education

Step	Action
1	PT materials consisting of photomicrographs are reviewed by the Medical Director and used as a Continuing Education resource.
2	The Analyte Scorecard on the CAP website will be posted periodically for staff.
3	Continuing education credits are available online from CAP for selected surveys. Participant summary, including site-specific CAP numbers and kit numbers are available at each site. Participation is voluntary.

D. Proficiency Testing Exception Summary (PTES)

Step	Action
1	A Proficiency Testing Exception Summary (PTES) is issued by CAP if the performance of an analyte falls below the LAP's acceptable criteria for PT.
2	This report is designed to ensure the monitoring of PT performance for purposes of CAP and CLIA certification. PTES notification will be issued for regulated analytes (analytes that CLIA requires PT) that are reported to the Centers for Medicaid Medicare Standards (CMS), regulated analytes that are not reported to CMS; and non-regulated analytes.
3	CAP mails the PTES reports to the Medical Director and or a designated QA specialist, who delivers them to the appropriate supervisor for resolution. The PTES packet includes instructions for responding to the PT exception, an exception response form, and a summary of scores for the previous four PT testing events.

E. Survey Error Investigation and Corrective Action Report (SEICAR)

Step	Action
1	The process for investigation of PT failures is defined and includes the following analysis: • Assess what went wrong. Is there a problem? • How did we identify the problem or exclude it? • Outline steps followed during investigation. QC review, patient data, technolo performance, etc. • What steps will be taken to prevent a recurrence?

	• Was patient care affected? The process applies to each analyte missed (graded or ungraded). ~~The flowcharts in Addenda B may be utilized to assist in the investigation process.~~
2	A SEICAR form is required to document and code this process. **The draft SEICAR must be routed for approval within 30 days.**
3	The technical supervisor or designee will: • Lead the investigation process. • Interview involved staff members. • Review all records associated with the batch(es) that contained the proficiency testing specimen(s). These records include but are not limited to: test records, worksheets, instrument preventive maintenance records, calibration records (instruments, pipettes, centrifuge, etc.), daily/weekly/monthly QC records, the Survey Companion Form, the proficiency survey result reporting form, participant summary, and previous PT results. • Request retesting the sample, if it's available and document the results on the SEICAR. The proficiency agency may be contacted to obtain additional specimen for evaluation (additional fee may apply). Document on the SEICAR if no specimen is available for retesting. **Note**: In the case of an event failure, the evaluation must include a mechanism to demonstrate the test is currently performing acceptably • List all issues identified during the record review on the SEICAR in the area entitled "Review of Testing Records." Determine if any of the listed issues caused or contributed to the proficiency miss or near-miss. From this information, ~~and using the Survey Error Investigation Flow Charts (Addendum B~~), assign an error code (Addendum A) to the non-conformance. **Note**: If error code 'Other' (E1 or E2) is chosen, contact the Medical Quality Assessment (MQA) support manager for assistance with further investigation. • Determine the root cause of the non-conformance. • Determine if the PT miss(es) could have any impact on patient samples tested before, during or after the failed PT event. Make necessary corrective action for patient impact. • Define the required corrective action(s) taken to correct the problem and record this information on the SEICAR. The corrective actions must include effective date(s). • Define what steps/actions are required to prevent recurrence of this non-conformance. • Define the monitoring steps/actions that may be required to ensure the corrective action is maintained over time. • Complete the SEICAR. The completed form, CAP evaluation report and any accompanying letters and documentation will be given to the Medical Director and Operations Director for review, approval and signature. • If approved by the Medical Director and Services Director the report will then be signed by the Technical Supervisor. • If the report is not approved, the supervisor will make appropriate revisions

	and return to the Medical and Services Directors for review and approval. • Completed documentation is returned to Hospital QA staff for signature and filing.
4	Hospital QA staff will retain a copy of the signed SEICAR with the CAP PT results. Refer to Section I for additional details.

F. Near Miss Investigation

Step	Action
1	The process for investigation of a near miss includes • Evaluation of testing vs. submitted result • Evaluation of QC • Repeat sample testing, if applicable • Previous survey failures, if applicable • Assessment of the review • If errors are detected, complete a SEICAR including root cause and corrective action documentation.
2	The investigation is documented on the Near Miss Evaluation report and attached to the CAP summary report. All documentation is reviewed by the Services Director and Medical Director. SEICAR is also completed if errors are detected.

G. Maryland Department of Health

Step	Action
1	A letter may also be received from the Maryland Department of Health requesting documentation/explanation of a proficiency testing failure.
2	The same process, corrective action form, and response will be supplied to the State of Maryland.
3	Written responses are submitted to the Services Director and the Medical Director for review and signature.
4	Responses are sent to the State of Maryland via certified return receipt requested, US mail.
5	A copy of the response letter is attached to the proficiency testing results and filed in the appropriate survey notebook. The certified mail receipt is attached to the letter.

H. Ungraded Challenges

Step	Action
1	The QA specialist or Technical supervisor will review the laboratory's result(s) and compare with those provided in the CAP critique or explanation booklet. The following criteria is utilized: Quantitative: For Peer Group Mean: ± 3 SDI Near Miss: ± 2.5 SDI For All Method Mean: ± 3 SDI Near Miss: ± 2.5 SDI

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	Semi-Quantitative: Six or fewer possible categories: Most frequent response ± 1 category More than six possible categories: Most frequent response ± 2 categories Qualitative: Agreement with majority response (>50% consensus) of peer group, all methods, or referee group If the above standards cannot be applied, the Laboratory Director or designee will evaluate the results using clinical judgment, medical usefulness, or equivalency. Results of this alternative evaluation as acceptable or unacceptable must be documented on the printed evaluation report.
2	The QA specialist or Technical supervisor will document the review and include an assessment of acceptability. • For results deemed unacceptable, a SEICAR will be completed following the steps outlined in Section E. • For near miss results, refer to Section F. All documentation is reviewed by the Services Director and Medical Director.

I. Records

Step	Action
1	A result summary is maintained in an Excel spreadsheet. The QA staff logs the date results are received.
2	Completed and signed SEICARs may be electronically scanned, saved and hyperlinked to the PT Nonconformance database. The report is saved on the G-drive using the following pathway: G:\CHYDept\AHC_Lab\Quality Assurance\Proficiency Testing\Problem Reports_pdf files
3	The QA specialist reports CAP survey failure error codes to Medical Operations and Quality for graded results only: a) Upon completion of the CAP survey failure investigation or at least monthly, report the Error Code to Corporate Medical Operations and Quality via the External Proficiency Exception Data Folder on the Quest Diagnostics Share Drive (\\Qdcns0001\projects\External Proficiency Exception Data) b) Open the External PT Exceptions Excel file for the Baltimore laboratory. • On the "CAP" tab, locate the line for the test non-conformance. • In the "QD Exception Code" column, the laboratory will select the appropriate exception code from the drop-down list. • With this selection, the program will automatically enter the "QD Exception Type" and "QD Exception Description". • In cases where more than one error code is identified for a failure, report the single most significant error on the spreadsheet.
4	All survey documentation maintained for the duration outlined in the ~~Quest Diagnostics~~ record retention policy.

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6. RELATED DOCUMENTS

- Proficiency Test Handling and Result Submission, QA procedure
- Procedure for handling Inappropriate Referral or Proficiency Materials or Inter/Intra laboratory Communication of Proficiency Test Information, QA procedure
- Internal Proficiency Testing Policy, QA procedure
- Retention of Records and Materials, Laboratory policy
- Survey Error Investigation and Corrective Action Report (AG.F285)
- Survey Near Miss Evaluation (AG.F430)

7. REFERENCES

- Commission on Laboratory Accreditation Inspection Checklist, Laboratory General, Proficiency Testing section, College of American Pathologists, 325 Waukegan Road, Northfield, Illinois, 60093-2750.
- College of American Pathologists website, www.cap.org
- Quest Diagnostics *Policy for Review and Evaluation of Proficiency Test Results*, QDMOQ716

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SOP QA002.003		
000	5/7/2012	Section 5: B.3 & H.29 revised to match practice; C.9 revised to post CAP Analyte Scorecard Section 9: Update appendix A and addenda B&C	L Barrett	C Bowman
001	4/18/2014	Section 4: add SEICAR, graded / ungraded results, near miss Section 5: update near miss and ungraded criteria; remove CLIA detail; add detail for SEICAR process; replace Chantilly with Baltimore QA Section 6: add updated SEICAR form Section 9: update addenda A&B, add C&D Footer: version # leading zero's dropped due to new EDCS in use as of 10/7/13.	L Barrett	C Bowman
2	3/2/2015	Section 4: add SD and SDI, remove dry erase board Section 5: add email of failures, update near miss evaluation and ungraded challenge criteria, add online continuing education Section 9: remove near miss flow chart	L Barrett R SanLuis	C Bowman-Gholston
3	4/7/2017	Header: add other sites Section 4: remove CAP database Section 5: remove references to database, update continuing education process, extend SEICAR draft due date to 30 days	L Barrett	C Bowman-Gholston

Version	Date	Reason for Revision	Revised By	Approved By
4	1/31/2019	Header: update facility Section 5: delete references to flow charts in part E.1, add note of Other code in E.3; add near miss form in F.2; add medical quality reporting to I Section 6: add near miss form Section 7: update QD policy Section 9: update addenda A, delete flow charts	L Barrett	C Bowman-Gholston

9. ADDENDA AND APPENDICES

A. Survey Nonconformance Error Codes
B. ~~Proficiency Testing Result Evaluation Flowchar~~t – delete since codes have changed
C. Approved Proficiency Testing Agencies

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Addendum A

Survey Non-conformance Error Key

Error Category	Error Description	Error Code
PT Material	Was proficiency testing material received in the laboratory within an appropriate time after shipment?	PT1
	Were proficiency testing materials received at the appropriate temperature?	PT2
	Were proficiency materials tested within stability limits?	PT3
	Were your results graded in the appropriate peer group based on the method reported on the result form?	PT4
	Have you ruled out a problem with specimen matrix?	PT5
Specimen Handling	Were Survey specimens prepared/reconstituted as indicated in the Kit Instructions?	S1
	Were Survey specimens stored as indicated in the Kit Instructions?	S2
	Were any special instructions for PT Handling performed as indicated in the Kit Instructions or by the test/instrument manufacturer?	S3
	Were the correct tests performed and reported on the correct vial of proficiency testing material?	S4
Procedural	Was the written test procedure followed?	P1
	Were the reagents prepared and stored according to procedure?	P2
	Were the reagents within their open stability acceptable range?	P3
	Was culture media prepared and stored per manufacturer's instructions?	P4
	Was staining performed and interpreted correctly?	P5
	Were dilutions performed correctly?	P6
	Were calculations performed correctly?	P7
	Was the test result reaction(s) or data interpreted correctly according to the SOP?	P8
	For microbiology specimens, were the local procedures effective/adequate for recovery or identification of the expected organism?	P9
	Is the sensitivity of the method adequate to detect the expected result?	P10
Analytical	Was the most recent calibration acceptable, within established stability limits, and without bias at the time proficiency testing was performed?	A1
	Does a review of the past proficiency testing results indicate evenly distributed data without bias?	A2
	Was the intended result within the measuring range for the instrument?	A3
	Was instrument maintenance performed on schedule?	A4
	On the day of testing, were Quality Control results acceptable and without bias?	A5
	Prior to and on the day of PT testing, were Quality Control results free from shifts or trends?	A6
	Does a review of instrument and reagent records indicate that there were no related instrument or reagent problems noted prior to or after the proficiency testing was performed?	A7

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Error Category	Error Description	Error Code
Analytical	Was the patient result distribution appropriate and free from carryover or contamination?	A8
	Was the result reaction or data interpreted correctly by an instrument or software?	A9
	Were microscopic examinations interpreted correctly?	A10
	Were cells/organisms on photomicrograph or slide identified correctly?	A11
	Were macroscopic examinations interpreted correctly?	A12
Clerical	Was the result correctly transcribed from the instrument read-out or report?	CL1
	Was the correct instrument/method/reagent reported on the result form?	CL2
	Do the units of measure match between the result form and the instrument results?	CL3
	Was the result reported with the correct decimal place(s)?	CL4
	Does the result reported on the result form match the result found on the proficiency testing evaluation report?	CL5
	Did the laboratory submit survey results by the agency deadline (i.e., on-line or fax to CAP or other provider)?	CL6
	Were all pages of the report form submitted (i.e., on-line, mailed or faxed to agency?	CL7
Other	**NO** root cause is identified for Graded Survey Results	E1
	NO root cause is identified for Near Miss or Ungraded results	E1
	The laboratory is able to identify the source of error but the error is not listed in the section above	E2

Addendum B

External Proficiency Programs

Approved for Accuracy Evaluations by Alternative Performance Assessment

Agency	Telephone Number
College of American Pathologists (CAP)	(800) 323-4040
Accutest, Inc.	(800) 665-2575
American Association of Bioanalysts (AAB)	(800) 234-5315
American Proficiency Institute (API)	(800)333-0958
New York State Department of Health	(518) 474-8739
Puerto Rico Proficiency Testing Service	(787) 274-6827
WSLH	(800) 462-5261

Other CLIA Approved Proficiency Programs

Agency	Telephone Number
American Academy of Family Physicians (AAFP)	(800) 274-7911
California Thoracic Society (CTS)	(714) 730-1944
Medical Laboratory Evaluation Program (MLE)	(800) 338-2746
Commonwealth of Pennsylvania	(610) 280-3464

Adventist HealthCare

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

SURVEY NEAR MISS EVALUATION

Department: Test Name:
Survey Agency: Survey Name:

Route the completed Near Miss Evaluation with the Survey Evaluation Report

Test / Analyte	PT Spec. ID	Original Result	Mean	SDI	Survey Acceptability Range (Low-High)	Repeat Result	Repeat Result SDI

	Yes	No	N/A	Comments
Clerical error	☐	☐	☐	
Previous failures	☐	☐	☐	
Testing repeated	☐	☐	☐	
QC Review:				
Any bias or trends	☐	☐	☐	
Peer comparison OK	☐	☐	☐	
Instrument Review:				
Calibration OK	☐	☐	☐	
Maintenance OK	☐	☐	☐	
Assessment:				
☐ No further action required at this time, test performance is acceptable.				
☐ Issue detected, complete full SEICAR.				

Completed by: Date:

Additional comments: