TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	5/9/2019
Department:	All staff except phleb	**Due Date:**	5/31/2019
		Implementation:	**5/23/2019**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Handling Inappropriate Referral of Proficiency Material or Inter/Intra-laboratory Communication of Proficiency Test Information SGMC.QA4001 v1

Description of change(s):

This is a 'new' SOP that replaces our previous NQA corporate version. It is very similar to the old SOP but has been converted to our local SOP format. A few minor changes were made:

- Deleted info that did not pertain to our labs
- Updated Addendum B by removing Chantilly info

Note: Annual training is required for this SOP

This revised SOP will be implemented on May 23, 2019

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

Non-Technical SOP

Title	**Handling Inappropriate Referral of Proficiency Material or Inter/Intra-laboratory Communication of Proficiency Test Information**
Prepared by	Leslie Barrett Date: 4/10/2019
Owner	Cynthia Bowman-Gholston Date: 4/10/0219

Local 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 and Title	**Signature**	**Date**

TABLE OF CONTENTS

1. PURPOSE

This document specifies the policy and procedure for the identification and handling of inappropriately communicated, submitted, tested or referred proficiency samples or information. Inappropriately submitted, tested or referred proficiency samples are defined as any proficiency test sample OTHER than those submitted by the local laboratory Quality Assurance Department for testing.

2. POLICY

In compliance with the Clinical Laboratory Improvement Amendments (CLIA) requirements 493.801 (b)(3), the College of American Pathologists (CAP) and specific state requirements, laboratories that perform tests on proficiency testing samples must not engage in any inter- or intra-laboratory communications about proficiency testing sample(s) until after the deadline for submission of data to the proficiency testing provider. **Quest Diagnostics' requirement is no communication / referral before formal evaluation of results by the proficiency testing provider.**

Laboratories with multiple testing sites or separate locations must not participate in **any** communications or discussions across sites/locations concerning proficiency testing sample results until after the date the results are formally evaluated by the Proficiency Testing (PT) provider. **Any laboratory that the Centers for Medicare and Medicaid Services (CMS) determines intentionally engaged in inter- or intra-laboratory communications regarding an active proficiency testing event before the deadline for submission of data to the proficiency testing provider may have its certification revoked for at least one year or be subject to civil money penalties.**

In compliance with CLIA requirements 493.801(b)(4), the laboratory must not send PT samples or portions of samples to another laboratory for any testing for which it is certified to perform in its own laboratory (even if the laboratory refers patient samples). **Any laboratory that the Centers for Medicare and Medicaid Services (CMS) determines intentionally referred its proficiency testing samples to another laboratory for analysis will have its certification revoked for at least one year.**

Any laboratory that receives proficiency-testing samples from another laboratory for testing must notify CMS of the receipt of such samples, even if the laboratory is owned or operated by Quest Diagnostics. Failure to notify CMS of receipt of inappropriate test orders will be subject to sanctions (including, but not limited to civil money penalties).

REMINDER:

- The laboratory must not knowingly accept or test any PT material from another laboratory prior to formal evaluation of results by the PT provider.
- The laboratory must not send any PT material to another laboratory for testing. (NOTE: PT material may be shared AFTER the PT provider has formally evaluated results).
- The Laboratory must **not** perform any testing on suspect PT material.
- Laboratory personnel must not engage in any inter- or intra-laboratory communications about proficiency testing sample(s) until formal evaluation by the proficiency testing provider.
- Laboratory personnel must not discuss any concerns about the assay, reagents or run containing a PT sample with another laboratory. They must contact their laboratory director or supervisor for advice; and NOT discuss the issue with another laboratory.
- Questions regarding proficiency testing material, testing or reporting must be directed to the PT provider.
- Laboratory personnel must immediately notify their Laboratory Director or designee of any concern about potential inappropriate handling of PT material or information.
- The Laboratory Director or designee must contact Quest Corporate Medical Regulatory Affairs for guidance regarding any suspect inappropriate handling of PT material or information.
- If the laboratory determines that it has received PT samples from another laboratory for testing, the Laboratory Director, in collaboration with Corporate Medical Regulatory Affairs, will provide appropriate notification to CMS and other regulators as required.
- The laboratory must sequester any suspect PT material or information received from another laboratory, site, or location.
- All staff (as appropriate for their job description) will be trained on this procedure:
  - Within 30 days of hire (including temporary employees)
  - Annually
  - Whenever changes are made to the policy or procedure

3. SCOPE

- This procedure applies to proficiency testing irrespective of regulated status of the analyte designated by CMS (e.g., regulated and non-regulated analytes).

- This procedure applies to all proficiency material irrespective of the provider (e.g., CAP, AAB, etc.).
- This procedure applies to all appropriate personnel (pre-analytical, analytical, and post-analytical; includes any staff involved in laboratory processes that receive or log-in samples, test or report results of proficiency testing samples or refer samples for testing as well as departments that communicate with clients) in all laboratories.

NON-COMPLIANCE WITH THIS SOP:

- The following may result in actions up to and including termination:
  - Knowingly **referring** a PT sample to another laboratory.
  - Knowingly **accepting** a PT sample from another laboratory.
  - Knowingly **engaging in any inter- or intra-laboratory communications** about proficiency testing sample(s) before formal evaluation of results by the proficiency testing provider.
- Failure to fully cooperate and be truthful in any investigation regarding suspected non-compliance with this policy may result in actions up to and including termination.

4. RESPONSIBILITY

- The **Laboratory Director** (CLIA license holder) is responsible for:
  - Approval and implementation of this SOP, and any subsequent revisions.
  - Ensuring the implementation of this SOP in all relevant departments.
  - Ensuring compliance with this SOP.
  - Providing the investigation and notification as appropriate to Corporate Medical Regulatory Affairs and CMS of any suspected or confirmed inappropriate Proficiency Material referral event or inappropriate PT inter- or intra-laboratory communication.
  - Directly contacting the client's Laboratory Director if suspect PT referral or communication has occurred.
- The **Laboratory Director** or designee is responsible for:
  - The recurring review of this procedure.
  - Ensuring appropriate handling of PT material.
- The **Department Supervisor/Manager** is responsible for implementing and ensuring compliance with this procedure in the pre-analytical and post-analytical department for which he/she is responsible.
- The **Technical Supervisor** is responsible for:
  - Implementing and ensuring compliance with this procedure in the analytical departments or laboratories for which he/she is responsible.
  - Ensuring documented training in his/her departments for all employees including new hires and those returning from FMLA (within 30 days of hire / return AND prior to handling PT samples).
- The **Laboratory Services Director** or designee is responsible for the maintenance of all documents and records associated with this procedure.

- The **Quality Assurance** department is responsible for ensuring annual PT compliance training and maintenance of all records associated with this procedure.

5. DEFINITIONS

- **CLIA:** Clinical Laboratory Improvement Amendments
- **CMS:** Centers for Medicare and Medicaid Services. The Centers for Medicare & Medicaid Services (CMS) regulate all laboratory testing (except research, forensic and SAMHSA drug testing) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments of 1988 (CLIA).
- **Proficiency Testing (PT):** The process that uses samples from a PT provider to demonstrate the laboratory's ability to provide accurate and reliable results in its patient testing system. The process incorporates elements of pre-analytical, analytical, and post-analytical areas. Educational challenges are to be handled the same way as routine proficiency testing.

6. IDENTIFICATION OF A SUSPECTED PROFICIENCY TEST REFERRAL FROM AN EXTERNAL LABORATORY

Laboratory staff MUST NOT ACCEPT proficiency sample(s) from another laboratory (including another Quest Diagnostics laboratory).

Laboratory staff MUST NOT TEST any proficiency sample(s) received from another laboratory (including another Quest Diagnostics laboratory).

- Any staff involved in pre-analytic, analytic, and post-analytic laboratory processes including employees that receive or log-in samples, test samples, report results or refer samples for testing as well as departments that communicate with clients (e.g., Specimen Processing, Technical Staff, and Client Services personnel) must use reasonable efforts to identify a proficiency test sample. This may be done through visual recognition, or through electronic capture in the laboratory's information system (where available), or any requisition, worksheet or manifest that may accompany a proficiency test sample.

Staff will take the following actions:

IF…	THEN…
A sample, requisition, worksheet, manifest or electronic order from any CLIENT or INTERNAL DEPARTMENT has any of the acronyms listed on the "Suspect Proficiency Sample" poster (QANQA319) in the patient name field OR Any of these acronyms displayed anywhere on the requisition or electronic order…. OR A patient name is coded and reflects any of	• **DO NOT** process the order • Sequester all suspect samples • Document the case on the "Suspect Proficiency Sample" Form (Addendum A) • Contact the section Supervisor, Manager, Group Lead, Laboratory QA specialist, or Administrative On-call Supervisor (See Section 9 for Supervisor/Manager Escalation Process)

IF…	THEN…
these acronyms (or similar acronyms or survey mailing descriptions e.g., SB-01) and has a two-digit number such as 01, 02, and 03….	
A sample type, sample integrity or result creates suspicion that the sample MAY be a PT sample…	• The department must immediately stop all testing on the suspect sample(s). • Sequester all available suspect sample(s). **AND** • Notify the department supervisor, manager, Laboratory Director, or QA (See Section 9 for Supervisor/Manager Escalation Process)
Upon review of a requisition or any electronic record any of the acronyms listed on the "Suspect Proficiency Sample" poster (QDNQA319) are in the patient name field OR The paper or electronic report has any of the acronyms listed above in the patient name field	Refer all relevant information to your supervisor. (See Section 9 for Supervisor/Manager Escalation Process)
At any time, when clarifying a test order or discussing a result, the client states or implies that the sample submitted is proficiency material	• **DO NOT** process the order • Sequester all suspect samples • Document the case on the "Suspect Proficiency Sample" Form (Addendum A) • Contact the section Supervisor, Manager, Group Lead, Laboratory QA specialist, or Administrative On-call Supervisor (See Section 9 for Supervisor/Manager Escalation Process)

- **Note:** Exceptions to this process are those samples submitted under an internal QA account for the laboratory's **own** proficiency testing to be tested on site.
- The "Suspect Proficiency Samples" Poster reminding staff of this requirement must be displayed prominently throughout the appropriate departments.

7. REFERRAL OF PROFICIENCY TEST TO ANOTHER LABORATORY

Laboratory staff MUST NOT REFER any portion of a proficiency test sample to another laboratory (including another Quest Diagnostics laboratory).

- If reflex testing would normally trigger referral of the patient sample to another laboratory for further testing, **the PT sample must <u>not</u> be referred** to another laboratory. Only the initial screening result generated by the enrolled laboratory can be tested and reported.
    - Addendum B describes the LIS rules implemented to prevent the reflex process.

- If an instrument or test is down and the laboratory is sending patient samples to another laboratory for testing, proficiency test samples that were scheduled for this test must not be

referred. **Only patient samples may be referred for testing.** Refer to Addendum C for the downtime process.
Note: When using panels / profiles to order PT, if any analyte or component in the panel is being referred to another laboratory, either temporarily or on an ongoing basis, the panel code may not be used. The individual analytes must be ordered separately.

8. COMMUNICATION ABOUT PROFICIENCY TESTING

Laboratory staff MUST NOT engage in either Intra- or Inter-laboratory communication about proficiency testing sample(s) before formal evaluation of results by the proficiency testing provider (including communication with another Quest Diagnostics laboratory).

- If you are employed at more than one laboratory you may not participate in the same active proficiency testing challenge at both facilities. Performing the same proficiency activity at multiple laboratory facilities is a violation of CLIA and accrediting organization requirements, and may result in loss of the employee's own licensure (if applicable) and the licensure of both laboratory facilities.
    - The employee is required to work with their supervisors at both facilities to ensure that: 1) intra- or inter-laboratory communication does not occur; 2) they are not actively participating in the same PT surveys at both facilities; and 3) they are participating in PT at each facility as required without overlap.

Staff will take the following actions:

IF…	THEN…
You are contacted by another laboratory (by any means of communication i.e., email, phone, text, verbal, etc.) to discuss an active proficiency test survey result.	Do not engage in any response to such a communication. Immediately contact your Supervisor, QA Department or Laboratory Director.
At any time, when clarifying a test order or discussing a result, the client states or implies that the sample submitted is proficiency material.	• **DO NOT** process the order • Sequester all suspect samples • Contact the section Supervisor, Manager, Group Lead, Laboratory QA specialist, or Administrative On-call Supervisor (See Section 9 for Supervisor/Manager Escalation Process)
You are employed at another laboratory	Work with your supervisors at both facilities to ensure that: 1. intra- or inter-laboratory communication does not occur; 2. you are not actively participating in the same PT surveys at both facilities; and 3. you are participating in PT at each facility as required without overlap.

9. SUPERVISOR/MANAGER ESCALATION

Whenever a department/shift supervisor, department manager, or Technical Supervisor is made aware of a potentially inappropriate submission, testing or referral of proficiency material s/he will:

- Initiate a "Suspect Proficiency Sample" form (Addendum A).
- Sequester all samples (maintaining sample stability).
- Contact Laboratory QA staff.
- Submit "Suspect Proficiency Sample" form to QA Department immediately.

10. QUALITY ASSURANCE INVESTIGATION

- All events where the laboratory suspects a PT sample may have been inappropriately submitted, tested of communicated must be documented on the "Suspect Proficiency Sample" form (Addendum A).
- Upon notification (via email, voice mail, LIS mail, etc.), QA will do the following:

Step	Action….	
1	Investigate the event by any or all of the following: • Review of the original requisition and samples. • Review of patient information provided (including Insurance information). • Check to see if there is an "active" PT survey in the lab for the same test(s). • Contact the client for order clarification and if appropriate (i.e., client claims sample is not PT), obtain a letter from the client describing what the sample is (e.g., correlation studies). • Other steps as needed.	
2	If it is determined that the sample is NOT proficiency material:	
	a.	Document reasons/supporting information on the "Suspect Proficiency Sample" form.
	b.	Contact the Supervisor that submitted the "Suspect Proficiency Sample" form and release the order for processing.
3.	If it is determined that the order is <u>MOST LIKELY</u> a proficiency test sample, QA must:	
	a.	Immediately contact: • Local Laboratory Director (CLIA license holder) AND • Corporate Medical Regulatory Affairs
	b.	Review LIS for ALL accessions submitted by this client (on day of event) and determine if other suspicious samples were submitted.
	c.	Determine if ANY of the suspect PT tests were performed or reported. Delete all suspect PT tests (if any have been ordered) with a generic "Test Not Performed" message and document action in the LIS problem tracking).
	d.	Sequester all samples, requisitions and reports (as applicable). Take pictures of samples/material received by the laboratory. NOTE: Any samples sequestered during this process may be disposed of when the event is closed by the regulatory agency or the laboratory.

Step	Action….	
	e.	Complete documentation as required on Addendum A.
	f.	Retain all associated documents in the QA department in a designated file labeled "Suspect PT Investigations".
	g.	Report to originating department the outcome of the investigation.
4.	If it is determined that the order is MOST LIKELY a proficiency test sample, the Laboratory Director must:	
	a.	In collaboration with Corporate Medical Regulatory Affairs, provide appropriate and timely notification as appropriate to regional CMS, CAP or the state agency to report the suspected event.
	b.	Contact the client (Laboratory Director) and notify them that CMS, CAP or the State Agency has been/will be contacted.
5.	If a State, Federal or other regulatory agency requests additional information, as per the *Federal and State Agency Laboratory Performance Investigations* SOP, contact Corporate Medical Regulatory Affairs.	

11. RELATED DOCUMENTS

- Quest Diagnostics *Proficiency Test Handling and Results Submission* (QDNQA711)
- Quest Diagnostics *Proficiency Test Handling and Results Submission for Point of Care Testing Sites* (QDPS82)
- Quest Diagnostics *Suspect Proficiency Samples Poster* (QDNQA319)
- *Federal and State Agency Laboratory Performance Investigations* SOP and Program Directive

12. REFERENCES

- CLIA Public Health 42 CFR Part 493.801(b)(3)&(4)
- CAP Laboratory Requirements (www.cap.org)

13. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SGAHQDNQA712v6.2		

14. ADDENDA

	Title
A	Suspect Proficiency Sample Form
B	Reflex Testing Process
C	Downtime Process

ADDENDUM A

SUSPECT PROFICIENCY SAMPLE FORM

Date Received/Identified: _____

Department: _____

Identified By: _____ Time: _____

Patient Identification on requisition: _____

Client # and/or Name: _____

Accession # (if available) _____

Reason for suspecting PT referral: _____

_____

Location of sequestered sample(s): _____

QA notified via: E-mail _____ Voice mail _____ Memo _____ LIS _____ other _____

Date and time: _____

By Whom: _____

QA Investigation: Performed by: _____

Date: _____

Was result reported? □ Yes □ No Did LIS search finds related samples? □ Yes □ No

Other relevant information:

_____

_____

_____

_____

Resolution:

_____

_____

_____

Notification:

❑ Corporate Medical Regulatory Affairs Date: _____

Name: _____

❑ Legal Operations Attorney Date: _____

Name: _____

❑ Laboratory Director Date: _____

Name: _____

❑ Client Date: _____

Name: _____

❑ Originating Dept Date: _____

Name: _____

Most likely determined to be PT: □ Yes □ No (If Yes, CMS Notification Required)
Is this material from New York State? □ Yes □ No (If Yes, NYS Notification Required)

❑ CMS Date: _____

Name (CMS Contact): _____

❑ NYS Date: _____

Name (NYS Contact): _____

Name: _____

Title: _____

Signature: _____ Date: _____
(Laboratory Director or designee)

Attachment(s) specify below: (e.g. requisitions, reports, LIS audit trail documents)

❑ _____

❑ _____

ADDENDUM B

Reflex Testing Process

Test Code	Test Name	Corrective Actions for Test Codes Reflexed automatically to another Laboratory
HIVRS2	HIV 1 2 Screen	LIS (Sunquest) is programmed with a special rule for results that automatically order a reflex test. If the location is 'CAP' , the following message displays: *CAP Survey no reflex testing required* **Staff are trained to cancel the reflex test**
QSTRP	Strep Group A Antigen	
RSV	Respiratory Syncytial Virus	
INFAB	Influenza A/B Virus Antigen	

ADDENDUM C

Downtime Process

A. Instrument or Test Down
- If an instrument or test system is down, Proficiency Test (PT) samples will NOT be performed.
- PT samples will be sequestered by QA or the supervisor
- If in-house testing is resumed before the survey due date, the PT samples will be processed and tested following the routine SOP.
- If unable to test (testing is not available in-house prior to survey due date or PT sample has exceeded stability), QA will report to the PT Provider that the laboratory is unable to analyze the survey samples (e.g., submit Code 11 for CAP surveys).

B. Incoming Specimens from Another Lab Site
- Prior to testing samples sent from another lab, the person who unpacks the specimens will review the Tracking list that is sent with the samples.
- The list is reviewed for suspect PT samples. If a suspect sample is identified, refer to section 6 of this SOP for necessary action and notification.

No Proficiency Test (PT) samples are sent out, referred, or redirected