TRAINING

Lab Location:	GEC, SGAH & WAH	**Date Distributed:**	3/19/2014
Department:	Technical staff	**Due Date:**	4/19/2014

DESCRIPTION

Purpose of training:

Attached is an excerpt from the SOP Proficiency Test Handling and Result Submission, QDNQA711.v5 that contains the requirements for PT Program Compliance and PT Testing Compliance.

Review the requirements and take the quiz.

The quiz questions are focused on your understanding of the principles for handling proficiency test material. Please read the questions carefully, and refer to the procedure as needed.
You **must score 100%** on the quiz.

Excerpt from SOP Proficiency Test Handling and Result Submission, QDNQA711.v5

PROGRAM COMPLIANCE:

- The laboratory must participate in a CMS-approved proficiency program for all CLIA specialties and sub-specialties included in the laboratory's testing menu.
- If a proficiency test program is not available, the analyte must be challenged by an Alternative Performance Assessment at least twice per year.
- Where required, the laboratory must also enroll in state mandated PT programs.
- Quest Diagnostics **MUST NOT ACCEPT*** proficiency sample(s) from another laboratory (including another Quest Diagnostics laboratory).
- Quest Diagnostics **MUST NOT TEST*** any proficiency sample(s) received from another laboratory (including another Quest Diagnostics laboratory).
- Quest Diagnostics **MUST NOT REFER*** any portion of a proficiency test sample to another laboratory (including another Quest Diagnostics laboratory).
- Quest Diagnostics **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 there are concerns about the assay, reagents or run containing a PT sample, contact the Technical Supervisor.

  ***** See *Procedure for Handling Inappropriate Referral of Proficiency Material or Inter/Intra-laboratory Communication of Proficiency Test Information* (QDNQA712)**.**

TESTING COMPLIANCE:

- **Unless explicitly directed otherwise by the PT provider in the written instructions**, PT samples must be treated and reported like a patient sample. ***Exception:*** *Do Not Refer any PT sample as you might for a patient (e.g., Reflex / Confirmatory testing)*
- Whenever possible, survey samples must be accessioned into the Laboratory Information System (LIS).
- The main BU and each affiliated site (RRL, hospital) must use unique accounts in the LIS. Access to such accounts should be restricted to prevent simultaneous review of results from the same survey across multiple sites.
- **PT samples must be examined, handled, and tested along with the laboratory's regular workload by testing personnel using the laboratory's routine methods.** (Some special handling may be required due to the nature of the PT materials, but the PT samples must be treated in the same manner as patient samples to the extent possible.)
- If a PT sample exceeds the analytical measurement range (AMR) of the assay, it must be tested and reported like a patient sample. For example, if patient samples are diluted and retested, the PT sample is diluted and retested. If patient samples are reported as "greater than", the PT sample is reported as "greater than".
- 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. (Note: Any reflex tests automatically generated by the LIS must have a unique order code built specific for proficiency testing without reflex / confirm.)
- There is to be no discussion of any aspect of an active PT event with others outside of the testing lab, such communications cannot occur until after the results have been formally evaluated by the PT provider.
- If the laboratory is unable to perform PT because an instrument or method is down:
  - Notify the QA department.
  - Alert the PT provider OR follow instructions on the PT forms.
  - Ensure the order codes for the affected PT tests are canceled.
  - DO NOT allow PT material to be sent to a referral laboratory for testing.

- Perform PT only for the primary method when multiple methodologies exist for a single test.
- Do not perform PT using the “Second Instrument” material option from CAP.
- PT samples must not be tested more than once unless a repeat protocol for patient testing is specifically defined by the test SOP and the PT sample meets the repeat criteria.
- When multiple persons and/or instruments are routinely used for patient testing, PT materials must be rotated among testing personnel, shifts, and instruments.
- Normal calibration protocols and schedules must be followed.
- Limit access of PT results to employees as a requirement of their job function – do not access other sites PT results.
- All survey documents, including copies of forms returned to the PT provider, must be retained on site at the performing laboratory for at least two years and be readily available for review. Off site storage (beyond the two most current years) must comply with the Quest Diagnostics Records Management Program requirements.