TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	1/5/2016
Department:	Technical staff	**Due Date:**	1/15/2016
		Implementation:	**1/15/2016**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Proficiency Test Handling and Result Submission GEC / SGAH / WAH. QDNQA711v6.2

Survey Companion Document, Blood Bank AG.F344.0

Description of change(s):

Section 12: specify review & submission on-site

Section 14: add BB form number

Addendum B: remove ‘site-specific’ qualifier for QA

This SOP and FORM will be implemented on January 15, 2016

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

Approved draft for training

Non-Technical SOP

Title	**Proficiency Test Handling and Result Submission**	
Prepared by	Patricia Maloney, Virginia Sturmfels, Christine Vernusky, Dianne Zorka	**Date: 2/12/2015**

Laboratory Approval	**Effective Date:**	
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates		

Review		
Print Name and Title	**Signature**	**Date**

Corporate Approval	**Corporate Issue Date:** 2/16/15	
Print Name and Title	**Signature**	**Date**
Lee Hilborne, MD, MPH **CQA Medical Director**	***Signature on file***	**2/12/2015**
Ronald Kennedy, MD **Acting Chief Laboratory Officer**	***Signature on file***	**2/12/2015**

Retirement Date:	*Refer to the SmartSolve EDCS.*
Reason for retirement/replacement:	

Form revised 2/2/07

TABLE OF CONTENTS

1. PURPOSE

This document sets forth the procedure for receipt, handling, and testing of proficiency test (PT) samples and for submitting PT results to any external agency (federal, state, or other) for evaluation.

2. SCOPE

- This procedure applies to proficiency testing irrespective of regulated status of the analyte designated by CMS (i.e., regulated and non-regulated analytes).
- This procedure applies to all proficiency material irrespective of the provider (e.g., CAP, AAB, WSLH, Pennsylvania, New York or other State agency).
- This procedure applies to all appropriate personnel[1] (pre-analytical, analytical, and post-analytical) in all Quest Diagnostics laboratories, including main and esoteric laboratories (e.g., Quest Diagnostics Nichols Institutes, Focus, Athena,), RRLs, all remote accessioning locations (including off-site Quest Diagnostics employees that accession specimens), Quest Diagnostics managed sites or hospital labs with licenses in the Quest Diagnostics name except as detailed below.
- All staff (as appropriate for their job description) will be trained on this process at:
  - Time of hire
  - Whenever changes are made to the process

[1] Appropriate personnel include any staff involved in handling any aspect of the pre-analytic, analytic, and post-analytic 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 (e.g., Specimen Processing, Technical Operations, Referral Testing and Client Services & Solutions personnel).

EXCEPTIONS TO THIS PROCEDURE:

- Stand alone Point of Care Testing Sites (POCT). These sites must follow the standard POCT policy specific for this type of testing (*Proficiency Test Handling and Results Submission for Point of Care Testing Sites*, QDPS82).

3. RESPONSIBILITY

- The **Laboratory Director** (CLIA license holder) has overall responsibility for:
  - Local approval and implementation of this standard operating procedure (SOP), including all subsequent revisions.
  - Ensuring laboratory enrollment in PT programs as required by Quest Diagnostics and regulatory agencies, including CAP e-LAB Solutions PT program (refer to www.cap.org for enrollment instructions).
  - Ensuring the implementation of this SOP in all relevant departments.
  - Ensuring compliance with this SOP.
- The **Laboratory Director or designee** is responsible for:
  - The recurring review of this procedure.
  - Ensuring appropriate handling of PT materials.
  - Signing the attestation form (or copy of the completed form).
- The **Technical Supervisor** is responsible for:
  - Implementing and ensuring compliance with this procedure in the analytical department(s) or laboratory(ies) for which he/she is responsible.
  - Review of PT results, instrument/method information and test units for accuracy.
  - Ensuring documented training in his/her department(s) for all employees including new hires and those returning from FMLA (within 30 days of hire / return AND prior to handling PT samples).
  - Approving and submitting PT results on the CAP website, after review.
- The **Testing personnel** are responsible for:
  - Testing PT samples in the same manner as patient samples, except where the nature of the PT material requires special handling.
  - Documenting performance of all steps in the proficiency testing process.
  - Processing PT samples with normal workflow (if not, document why).
  - Utilizing the same repeat/dilution protocols and same calibration and quality control frequency.
  - Signing the attestation form (or copy of the completed form).
- **Quality Assurance,** as delegated by the **Laboratory Director (in writing,** see Addendum A**)** is responsible for:
  - Coordinating Proficiency Testing including oversight of the log-in process.
  - Ensuring that reflex testing order codes that would normally trigger referral of the patient sample to another laboratory for further testing is not used for any PT. For these tests a unique order code for the initial test without reflex, must be built for PT. Refer to section 10 Post Analytical Requirements, local step 1.
  - Ensuring results are reviewed and reported by the deadline to the PT provider.
  - Maintaining required enrollment in PT programs as required by Quest Diagnostics and regulatory agencies. Appropriate enrollment must be reviewed annually.
  - Managing the handling of all PT materials.

- Providing oversight of the PT program for affiliated Rapid Response Laboratories (or in the case of hospitals, providing oversight of the PT program for all departments in the laboratory).
- Administering the CAP e-LAB Solutions program.
- Ensuring Alternative Performance Assessment is performed on analytes that are not covered by external proficiency testing programs. The need for alternative performance assessment must be reviewed annually.

4. DEFINITIONS

- **Alternative Performance Assessment (APA):** A laboratory administered program similar to proficiency testing that is used to evaluate performance of assays (e.g., analytes that are not covered by CAP PT, other Commercial/State PT or CQA.NQA PT).
- **CLIA:** Clinical Laboratory Improvement Amendments.
- **CMS:** Centers for Medicare and Medicaid Services Agency that regulates 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).
- **CQA:** Corporate Quality Assessment. The quality oversight organization within Quest Diagnostics responsible for Clinical Pathology services
- **NQA:** National Quality Assessment. The quality oversight organization within Quest Diagnostics responsible for Anatomic Pathology services
- **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.
- **User Class Identifier (UCI):** A code that separates logical areas for global and routine program storage.

5. OVERVIEW OF GENERAL REQUIREMENTS FOR PROFICIENCY TESTING

Laboratory Director delegation of proficiency testing responsibilities must be in writing (see Addendum A) and list the specific individual(s) to whom the responsibilities have been assigned.

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, temporary or permanent referral/ redirect to another laboratory*
- Survey samples must be accessioned into the Laboratory Information System (LIS).
  - Reflex Testing: Do not use reflex test codes when the "reflexed to" test is referred to and performed at another laboratory. Create a separate stand alone test code for the initial test to prevent accidental referral. **Note**: Approved site-specific modified process mandates the creation of LIS rules to flag on the computer screen, when any attempt is made to refer the specimen to another laboratory for testing. Refer to section 10 Post Analytical Requirements, local step 1.
  - Panels / Profiles: 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. **Note**: Site-specific modified process includes CAP-only test ordering profiles for large chemistry surveys. To limit the possibility of ordering a reflex lab test, the QA team maintains the ordering codes, by event, on a spreadsheet. Refer to procedure Proficiency Test Order Entry.
- The main BU and each affiliated site (RRL, hospital) must use a unique QA client account number in the LIS. Access to such accounts should be restricted to prevent simultaneous review of results from the same survey across multiple sites (e.g. laboratories on the same UCI).
- **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. Refer to section 10 Post Analytical Requirements, local step 1.)

- 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.
  - Ensure the order codes for the affected PT tests are canceled. Alert the PT provider OR follow instructions on the PT forms.
- 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 where access is 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.

6. ENROLLMENT IN PROFICIENCY TEST PROGRAMS

- Quality Assurance staff or their designee must ensure that an approved PT program covers all analytes, or where PT is not available, is covered by an alternative performance assessment.
- Enrollment in a PT program or the need for Alternative Performance Assessment must be reviewed:
  - Whenever new analytes are added to the test menu.
  - Whenever current analytes are deleted from the test menu, referred to another laboratory or the methodology is changed.
  - On an annual basis, as proficiency testing needs are reassessed and documented.

TYPES OF PROGRAMS:

- The College of American Pathologists' (CAP) Proficiency Test Program is the primary provider of proficiency test surveys for all Quest Diagnostics' laboratories.
- The laboratory must enroll in the CAP e-LAB Solutions program.
- The laboratory must ensure enrollment in a state program if required by state law.
- Other PT providers may be used to meet proficiency testing requirements for specific analytes that are not covered by CAP programs or at the direction of CQA/NQA.

PROGRAM REQUIREMENTS:

- Proficiency testing is required only for the primary method used to test an analyte. Secondary methods are evaluated internally by performing method comparison studies with the primary method (twice each year).

- If multiple instruments are used for the same test, testing of additional instruments may only be performed after the survey evaluation report has been generated from the survey provider.
- Proficiency testing materials must be specific for the specimen type tested.
- Different sample types with different reference ranges and physiological concentrations require separate proficiency test programs (e.g., serum sodium and urine sodium, plasma glucose and CSF glucose, molecular assays such as Aptima, SDA, and PCA methods requiring different transports).
- Samples types that are documented to be equivalent (same physiological concentration and reference range) do not require separate proficiency test programs (e.g., plasma and serum glucose).
- For miscellaneous "fluids", a sample type with a representative fluid matrix and similar physiological concentration is sufficient (e.g., the lab must enroll in all applicable, specific fluid surveys when available). Enrollment in the CAP Body Fluid (FLD) survey is appropriate for synovial, thoracic, etc. However, where fluid specific material is available (e.g., CSF) the laboratory must enroll as appropriate.
- In special cases, substitute specimen types such as lyophilized culture organisms or photomicrographs may be appropriate.

7. PROGRAM REQUIREMENTS POINT OF CARE TESTING (POCT) WITHIN A MODERATE OR HIGH COMPLEXITY LABORATORY:

- Only one survey may be ordered for each type of POCT performed. Any testing of additional instruments may only be performed after the survey evaluation report has been generated from the survey provider.
- If additional proficiency testing is needed, extra surveys may be ordered from a different CLIA approved proficiency testing provider. (e.g., blood gases are tested on i-Stats at 5 different locations within the hospital. The laboratory may order only one CAP-AQ survey for the hospital.)
    - The exception to this is the survey for waived whole blood glucose testing. The survey has been designed to accept multiple testing sites.
- Proficiency testing must be performed by the personnel that routinely perform the testing (e.g., nursing, respiratory therapy). Ideally the results should be faxed or sent electronically directly to CAP (or other survey provider) from the unit that performs the testing.
- The POCT manager may perform the secondary review providing the person performing the review does not review the same survey for any other testing sites.

8. ALTERNATIVE PERFORMANCE ASSESSMENT (APA)

For tests not covered by CAP PT, other Commercial/State PT or CQA/NQA PT, the laboratory must develop alternative performance assessment systems to determine the reliability of analytic testing. The Alternative Performance Assessment system must:

- Mimic a proficiency testing program to the degree possible.
- Be performed at least twice yearly.
- Contain at least 2 challenges (e.g., two levels, positive and negative).
- Be evaluated against established (documented) grading expectations.

- Be reviewed by the same individual(s) who review(s) PT performance.
- Have documented corrective action when grading expectations are not met.

9. RECEIPT OF PROFICIENCY TEST SAMPLES

- Quality Assurance staff or their designee must track the scheduled mailing dates for PT materials and follow-up with the appropriate PT provider when materials are not received as expected.
- Personnel in departments that initially receive PT materials must be trained to recognize these shipments and to immediately deliver them to the designated contact.
- Survey materials must always be personally delivered to the responsible individual (e.g., not left in a mailbox or on a desk).
  - **Note**: If survey materials must be stored overnight or over a weekend, the designated recipient must ensure that the materials are stored at the proper temperature (as indicated on the shipping package) and issue a written communication to the individual(s) who will be responsible for initial processing of the survey kit.
- The survey kit must be visually checked to ensure it is complete and that components are received in good condition.
- Required paperwork must be initiated to track the survey through the analytical process and result reporting.
  - **Note**: A Survey Companion Document (Addendum A) is furnished to assist laboratories in tracking PT specimens throughout the entire process and may be modified for local use.
- Survey samples and paperwork must be delivered to designated individuals in the testing area who are responsible for coordinating or performing PT testing.
- All affected personnel must be notified of the survey receipt and result due date.
- Whenever possible, PT samples must be accessioned into the Laboratory Information System (LIS). Unusual sample types that do not resemble patient specimens (such as photomicrographs) are exempt from this requirement.
  - Reflex Testing: Remember to create a separate stand alone test code for the initial test when the “reflexed to” test is referred to and performed at another laboratory. Refer to section 10 Post Analytical Requirements, local step 1.
  - Panels / Profiles: 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.

One individual may NEVER

- handle or test PT samples from the same survey at more than one site
- review PT results from the same survey at more than one site before formal evaluation is received
- approve PT results for CAP submission from the same survey at more than one site

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Step	Action
1	PT materials may arrive by mail or express carrier (FedEx, UPS). • Mail is delivered Monday through Friday • Express carrier items are received in purchasing and then delivered to the Laboratory. • **Caution:** since delays have been experienced, close monitoring should be made of anticipated receipt date.
2	Survey materials will be addressed to the Senior Quality Assurance Specialist or section designee, i.e. POC surveys may be addressed to the POC Coordinator.
3	The person receiving the survey should immediately deliver CAP proficiency materials to the QA specialist or Group Lead in absence of QA staff.
4	The QA specialist (or lead) initials and dates the survey instruction booklet, and initiates the Survey Companion Document. • Inspect/review CAP materials and complete the Receipt of Shipment section of the Survey Companion form. The College of American Pathologists (CAP) should be notified by phone as soon as possible if survey materials are damaged, stored improperly or otherwise unacceptable for testing. CAP is able to provide replacement survey material in some cases. • Note: if the sample(s) cannot be judged for particulate matter, hemolysis or turbidity without opening the containers, mark that item 'N/A' and it will be evaluated by the testing tech. • If received by Group Lead, send an email to QA team
5	The QA specialist will • Document receipt date in the CAP PT database (MS Excel file) • Carefully read CAP materials and highlight any changes. • Alert the testing staff to any photomicrographs from fluid specimens that we do not test • Order tests to be performed in the LIS. Refer to procedure Proficiency Test Order Entry for details. • Print Accession labels • Place all specimens, Accession labels, CAP booklet, Survey Companion form and reporting forms into a biohazard bag. • Deliver CAP proficiency material to the CAP refrigerator or other appropriate storage. • Calculate internal due date for results (48 hours from time of LIS order) • Send LIS mailbox to the section supervisor, manager and Group Lead(s) announcing the receipt and result due date (48 hour) of the survey.
6	The Group Lead will • Be alerted by the pending log and LIS mailbox that survey material has been received. • Review and note any highlighted changes on the CAP materials. • Assign to shift based on rotational schedule (A = day, B = evening, C = night) • Place survey material and instructions in the designated area. For specimens shared between clinical laboratory sections, additional copies of instructions are distributed appropriately.

10. TESTING PROFICIENCY SAMPLES

PRE-ANALYTICAL REQUIREMENTS:

- All proficiency samples must be prepared according to survey instructions and properly labeled.
- Unusual conditions (e.g., leakage, hemolysis, particulate matter, turbidity, failure of samples that require repeating to give consistent results) must be reported to a supervisor immediately and documented.
- If sample integrity problems are observed, another specimen may be requested from the PT provider.
- If PT samples cannot be bar-coded, the identity of the sample must be visually verified each time it is used.
- If the PT survey includes an analyte that is a reflex to test (e.g. confirmatory testing) and the reflexed to test is referred to and performed at another laboratory, a separate stand alone test code for the initial test **must** be created to prevent the automatic accidental referral. Refer to section 10 Post Analytical Requirements, local step 1.
- If the PT survey is accessioned using a Panel / Profile and 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.

Step	Action
1	The testing technologist matches and applies Accession labels to specimens.
2	When additional preparation steps of the PT materials are required in order to perform testing, ***the technologist carrying out these steps initials/signs and dates the survey document***.
3	The technologist completes the Integrity, Preparation and Handling section of the Survey Companion form. If the survey materials are deemed unacceptable for testing, notify the section supervisor and QA team immediately. QA staff are responsible to communicate with CAP and request replacement samples.

ANALYTICAL REQUIREMENTS:

- PT samples must be tested according to the test SOP and in the same manner as patient samples.
- PT samples must be built onto a patient load (when applicable) and must be analyzed by the same individuals who perform testing on patient samples.
- If, for some reason, the PT samples cannot be tested with an actual patient load (e.g., rarely ordered tests, short stability PT materials), the reason for the special run containing only PT samples must be documented.
- If multiple departments use the same PT samples, the department supervisor of the primary testing department must coordinate the testing process with other areas to ensure that sample stability is not exceeded.
- If a test is performed on multiple shifts, proficiency testing must be rotated among all shifts during the course of the year.
- An instrument must not be specially calibrated immediately prior to running PT samples.

- Repeat testing can only be performed when required by the test SOP and must meet the same repeat requirements used for patient testing.
- Photomicrographs or other prepared reference materials must be given to a single technologist. Consensus identification by a group of technologists is not appropriate. (Note: Consultation regarding unusual findings may be done according to the existing written protocol used for actual patient specimens.)
- QC release requirements must be the same as those used for patient result release.
- Predictive Markers (HER2 and Other Immunohistochemical Stains[2])
  - If you ordinarily send specimens to an outside laboratory for immunohistochemical staining (but do your own interpretation), the CAP samples must be also be sent to the same reference lab for staining.
  - The laboratory that interprets HER2 or predictive marker slides stained by another facility must enroll in an accepted PT program and report the results of their interpretation following their usual methods.
  - If the laboratory routinely accepts unstained slides on patient samples for immunohistochemical staining only, it MAY accept unstained PT survey slides for staining.

Step	Action
1	• The Group Lead must ensure that the survey is completed within 48 hours. • Use the LIS pending log to monitor.
2	• Proficiency samples are to be tested immediately after aliquot is prepared. They are kept covered when not 'on the instrument'. • All calculations are performed as for patient testing, unless otherwise directed by CAP.
3	• For photomicrograph: o The performing technologist must record their tech code beside each result on the manual CAP reporting form. o If a photomicrograph meets criteria for pathology review, submit sample and the pathology review form to pathologist, along with your estimated identification. **Note**: If this would require submitting sample to another site or facility, **STOP**. Select the response 'would refer' on the CAP answer form.
4	The performing technologist completes the Analytic Process section of the Survey companion form, including documentation of unusual occurrences (see form for examples).

POST-ANALYTICAL REQUIREMENTS:

- When PT samples are logged into the LIS, results must be entered and released at the same time as patients on the same run.
- When PT results are released, LIS reports must be printed (as applicable) and retained with the PT survey results.

[2] CMS has ruled that IHC staining is a *process,* not an *analysis* and so the process of staining can be sent out but the **interpretation,** which is the analysis, must be done where the patient interpretations are routinely done. The same rule **does not** apply to FISH probes. CMS has ruled that FISH probe application **is analysis** and therefore cannot be referred.

- After testing, any remaining PT material may be retained under appropriate storage conditions until after the survey results are received from the PT provider for possible use in survey failure investigations (e.g., review of sample labeling or retesting of sample, when possible).
- PT material, slides, photomicrographs, etc. may be used for educational and/or competency, after results have been formally evaluated by the PT provider.

Step	Action
1	Results are entered and released in the LIS in the same manner as patient testing. **Note**: Reflex reference lab tests that are normally triggered by certain test results are blocked by the LIS. The following message will display: **CAP Survey no reflex testing required**

11. DOCUMENTATION OF PROFICIENCY TEST RESULTS

- Test records must clearly identify the individual(s) who performed the proficiency test, as well as the instrument(s) used.
- The attestation form (or copy of the completed form) must be signed by the individual(s) performing the testing.
- Testing personnel or other designated individual(s) in the department must transfer all required information to the PT result form (or copy of the form). All required information regarding instrumentation, method, results obtained, units of measure, attestation statements, etc. must be recorded and reviewed.
- The Technical Supervisor, Department Supervisor, Manager, or other designated individual must perform a secondary review of the PT documentation to ensure that all information has been correctly entered.
- The laboratory must maintain a distinctive file that includes copies of all associated test records (worksheet, instrument printout, printed reports etc.) and other documentation directly associated with the PT testing event.

Step	Action
1	All testing worksheets, printouts and forms must be documented with technologist identification and date.
2	The performing technologist completes the manual CAP reporting forms*, enters results onto CAP website and prints the submitted results. Refer to the procedure CAP Online Proficiency Testing for specific details. Return reporting forms and all worksheets/instrument printouts to Group Lead or designee upon completion. * For photomicrographs, the performing technologist must record tech code beside each result on the manual CAP reporting form.
3	Each technologist performing reconstitution or any phase of testing for the proficiency material must sign the attestation statement.

4	Group Lead or designee: • Receives results back from technologists. • Prints LIS reports and collates with instrument printouts. • Verifies that the method codes are correct. • Compares result format, reporting units, etc. from previous survey with current survey, verify test results are reported correctly.
5	If an analytical error or omission is detected, document on CAP reporting forms and initiate corrective action. If clerical errors are detected, document on CAP reporting forms and indicate correct data.
6	Group Lead or designee enters corrected results onto CAP website and reprints the report. Initial each page of the report. Refer to the procedure CAP Online Proficiency Testing for specific details.
7	Group Lead or designee reviews online entry before accepting and completes the Post Analysis section of the Survey Companion form.
8	When review is completed, all paperwork is submitted to the manager / supervisor.

12. REVIEW AND SUBMISSION OF PT RESULTS

- The attestation form (or copy of the completed form) must be signed by the Laboratory Director or designee. (Note: This signature does not have to be obtained prior to reporting results to the PT provider.)
- Results must be submitted to the PT agency on or before the due date, according to the PT provider's instructions. See section 3, Technical Supervisor responsibilities.
- If results are mailed, use a mailing method that ensures receipt will occur before the submission deadline and that can be tracked or verified.
- If results are faxed, confirm that the fax was successful, all pages were faxed, and that the fax was directed to the correct telephone number. Maintain a record of receipt confirmation.
- If results are submitted electronically, verify that results are correct before final submission.
- For CAP surveys, the QA Manager or other designated individual(s) should review receipt and accuracy of survey results on their website (www.cap.org). Incomplete transmissions or incorrect data entry by CAP can be corrected prior to the survey evaluation.
- Quality Assurance staff or their designee performs a final review of the paperwork to detect clerical errors, errors in methods, units, factors, etc. This final review may also involve transcription of information from a copy to the original survey form.

Step	Action
1	The manager/supervisor or designee reviews the response form on the CAP website, including method codes and reporting units. The review must be performed at the corresponding laboratory site.

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2	If errors or omissions are detected, identify problem and initiate corrective action. If clerical errors are detected, document on CAP web printout and make online correction. Supervisor notifies employee via the appropriate mechanism.
3	The manager/supervisor or designee • reviews and approves submitted results on CAP website (see addendum C) • prints the Kit Transaction History as documentation • completes the Post Analysis section of the Survey Companion form, including signature at the bottom **Note**: Result review and submission may only be done at the laboratory site where the testing was performed.
4	The supervisor delivers the response form and **ALL** supporting documentation to the QA specialist before the survey due date.
5	The QA specialist reviews all documentation and signs the Survey Companion form. If any errors, omission or discrepancies are detected, consult with the manager/supervisor or designee and initiate corrective action. The QA specialist records testing personnel and submission date in the CAP database.
6	The QA specialist files all information in the CAP survey notebook(s) or appropriate files.

13. RECORDS MAINTENANCE

Records are maintained according to the requirements for Proficiency Testing records published in the Quest Diagnostics *Records Management Program*.

14. RELATED DOCUMENTS

- Quest Diagnostics *Procedure for Handling Inappropriate Referral of Proficiency Material or Inter/Intra-laboratory Communication of Proficiency Test Information* (QDNQA712)
- Quest Diagnostics *Process for Evaluation of Proficiency Test Results* (QDNQA716)
- Quest Diagnostics *Proficiency Test Handling and Results Submission for Point of Care Testing Sites* (QDPS82)
- Quest Diagnostics *Records Management Program*
- Proficiency Test Order Entry, QA procedure
- CAP Online Proficiency Testing, QA procedure
- Survey Companion Document (AG.F48, AG.F344)

15. REFERENCES

- CLIA Public Health 42 CFR Part 493 of CLIA Inspector Interpretive Guidelines.
- CAP Laboratory Requirements (www.cap.org).

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16. REVISION HISTORY

Version	Date	Revision Purpose	Name
1.0	3/2007	New	
1.1	4/2007	See Revision History in Version 1.1	Ruthi Breazeale Virginia Sturmfels
2.0	7/2008	See Revision History in Version 2.0	Patricia Maloney Karen Rupke Ruthi Breazeale
3.0	11/2009	See Revision History in Version 3.0	Patricia Maloney Ruthi Breazeale Karen Rupke
4.0	8/2010	See Revision History in Version 4.0	Patricia Maloney Karen Rupke
5.0	12/2011	o Added clarification and simplification to Scope, Exceptions and Responsibility sections o Added requirements for signing of attestation and reflex testing unique order codes o Changed labeling of Appendices / Addendum	Patricia Maloney Karen Rupke Christine Vernusky
6.0	2/2015	o Clarification and additional guidance for reflex testing and panels / profiles	Patricia Maloney Virginia Sturmfels Dianne Zorka Christine Vernusky
6.0	4/9/2015	Adopting corporate issued version 6. Cover page: Add Local Effective Date message Sections 3,5,9,10: Add reference to local step 1 in section 10 Post Analytical Requirements. Section 3: Add PT submission to Technical Supervisor Section 5: Add site-specific LIS process Section 14: Move Companion Document from addenda, add local SOPs Section 17: Re-number addenda, add B	L Barrett C Bowman-Gholston
6.1	11/19/15	Section 12: specify review & submission on-site Section 14: add BB form number Addendum B: remove ‘site-specific’ qualifier for QA	L Barrett C Bowman-Gholston

17. ADDENDA

Addendum	File Name	Title
A	N/A (at end of this file)	QA Manager – PT Delegation
B	N/A (at end of this file)	CAP Website Submission Process

Form revised 2/2/07

Addendum A

QUALITY ASSURANCE MANAGER
Proficiency Testing Delegation

I authorize the qualified individual(s) listed below to manage proficiency testing activities within this laboratory. I also reapportion the laboratory director responsibilities listed under 493.1445(e)(4) to this (these) individual(s). Specific duties include:

Activity	Description
1.	Coordinate proficiency testing (PT) activities within the laboratory.
2.	Ensure that the laboratory is enrolled in an HHS approved PT program for all testing performed and is reviewed on an annual basis.
3.	Ensure that alternative assessment is performed for tests that do not have an external PT program.
4.	Ensure that PT samples are tested as required under Subpart H of 42 CFR Part 493.
5.	Ensure that PT results are reviewed and returned within the timeframes established by the proficiency testing program.
6.	Provide oversight of Rapid Response Laboratory (RRL) proficiency testing programs.
7.	Administer the CAP e-LAB program within the laboratory.
8.	Ensure that all PT results received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.
9.	Ensure that an approved corrective action plan is followed when any PT result is found to be unacceptable or unsatisfactory.
10.	Ensure that the laboratory director is aware of the laboratory's PT performance statistics, PT failures, and corrective actions.
11.	Ensure that monthly summary statistics regarding PT performance and non-conformances are furnished to National Quality Assurance staff according to NQA established guidelines.
12.	Assist the Laboratory Director with his/her formal response to Proficiency Test Exception Summaries (PTES) or other notifications of unsuccessful PT performance. (Note: the actual written response must come from the Laboratory Director.)
13.	Ensure that the Laboratory Director notifies NQA, Medical Regulatory Affairs and Legal Operations whenever 2 of 3 consecutive proficiency testing events are unsuccessful or to report identification of any PT violation.
14.	Ensures annual PT compliance training is conducted and documented in all appropriate departments as required.

Laboratory Name and Location: _____

Name of Individual	Activity

Laboratory Director Signature **Date**

Form revised 2/2/07

Addendum B

CAP Website Submission Process

Core Laboratory

- Data entry by performing technologist
- Result review performed by Group Lead or second technologist
- Result release performed by Supervisor or designee
- QA review by ~~site-specific~~ QA specialist

Blood Bank

- Data entry by any technologist
- Result review performed by Group Lead or second technologist
- Result release performed by Group Lead or designee
- QA review by ~~site-specific~~ QA specialist

Testing Department: Blood Bank

SURVEY COMPANION DOCUMENT

Survey Agency: CAP	Date Kit Received:
Survey Name and Shipment:	Received By:

Receipt of Shipment/Integrity of Sample: (*performed by the receiving technologist or QA*)

Perform a visual inspection of specimens to ensure:

1. Samples were received in good condition without spills, breakage, or missing components.
2. There is no evidence of extreme temperature problems.
3. There is no evidence of particulate matter, hemolysis, or turbidity.

If visual inspection reveals potential issues that may affect testing results:

1. Notify CAP and attempt to obtain replacement sample(s).
2. Document all anomalies in the comments section located on the back page of the CAP result form

Integrity, Preparation and Handling of Specimens: (*performed by the testing technologist(s)*)

Prior to testing:

1. Read the survey instructions and make note of any special testing requirements.
2. Verify the sample identification to ensure the correct sample is being tested.
3. Perform a visual inspection of the specimen to ensure there is no particulate matter, hemolysis, or turbidity that will affect testing.
4. Properly mix red cell suspensions.

If issues that may potentially affect testing results are noted,

1. Notify CAP and attempt to obtain replacement sample(s).
2. Document all anomalies in the comments section located on the back page of the CAP result form.

After testing:

1. Enter results into the LIS as required.
2. Print a copy of LIS results using function “Blood Bank Inquiry” and “Show Reaction Results.”
3. Bubble results on the result form.
4. Sign the attestation statement.
5. Return samples to the designated storage location of the refrigerator.

Data Entry: (performed by the technologist who enters results into the CAP website)

1. Verify all testing was performed and all testing techs signed the attestation statement.
2. Enter the results on the CAP website.
3. Print and save results.

Result Review: (performed by the group lead or designee)

1. Verify method codes for correctness.
2. Verify results were correctly transcribed to the CAP website.
3. Verify all testing was performed.
4. Verify antibody codes for correctness.
5. Initial the top page of the survey results form to indicate a secondary review has been performed.

Result submission: (performed by the supervisor/manager or designee)

1. Ensure a secondary review was performed.
2. Electronically submit results to CAP.
3. Retain a printed copy of the online result submission.
4. Route the survey to the medical director for review and signature.

Reviewed by: _____ **Date:** _____

Comments (continue on back if necessary):