Adventist HealthCare

TRAINING UPDATE

Lab Location:	All sites	**Date Distributed:**	9/30/24
Department:	Core Lab	**Due Date:**	10/15/24
		Implementation:	**Immediately**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:
AHC.QA 4002 Proficiency Test Handling and Result Submission
Description of change(s):
Added special handing for YBC survey when C tropicalis is positive in Addendum D.

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

AHC.QA 4002 Proficiency Test Handling and Result Submission

Copy of version 7.0 (in review)

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Printed By Demetra Collier (110199)

Organization Adventist HealthCare

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	Lab Director	9/16/2024	6.0	Nicolas Cacciabeve MD Nicolas Cacciabeve	
Approval	QA Leader approval	9/6/2024	6.0	Cynthia Bowman-Gholston MT(ASCP) (104987)	
Approval	Lab Director	6/22/2023	5.0	Nicolas Cacciabeve MD Nicolas Cacciabeve	
Approval	QA Leader approval	6/21/2023	5.0	Cynthia Bowman-Gholston MT(ASCP) (104987)	
Approval	Lab Director	5/18/2021	4.0	Nicolas Cacciabeve	
Approval	QA Leader approval	5/18/2021	4.0	Cynthia Bowman-Gholston	
Approval	QA review	5/17/2021	4.0	Leslie Barrett	
Approval	Lab Director	4/13/2021	3.0	Nicolas Cacciabeve	
Approval	QA Leader approval	4/13/2021	3.0	Cynthia Bowman-Gholston	
Approval	QA review	4/8/2021	3.0	Leslie Barrett	
Approval	Lab Director	7/8/2020	2.0	Nicolas Cacciabeve	
Approval	QA Leader approval	7/7/2020	2.0	Cynthia Bowman-Gholston	
Approval	QA review	7/7/2020	2.0	Leslie Barrett	
Approval	Lab Director	10/21/2019	1.0	Nicolas Cacciabeve	
Approval	QA Leader approval	10/18/2019	1.0	Cynthia Bowman-Gholston	
Approval	QA review	10/16/2019	1.0	Leslie Barrett	

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
6.0	Approved and Current	Major revision	9/5/2024	9/16/2024	Indefinite
5.0	Retired	Major revision	6/21/2023	6/22/2023	9/16/2024
4.0	Retired	Major revision	5/17/2021	6/2/2021	6/22/2023
3.0	Retired	Major revision	4/8/2021	4/27/2021	6/2/2021
2.0	Retired	Major revision	7/7/2020	7/21/2020	4/27/2021
1.0	Retired	Initial version	10/16/2019	11/13/2019	7/21/2020

Linked Documents

- AG.F48 Survey Companion Document
- AG.F344 Survey Companion Document, Blood Bank

Non-Technical SOP

Title	**Proficiency Test Handling and Result Submission**
Prepared by	Leslie Barrett Date: 10/15/2019
Owner	Cynthia Bowman Gholston, Robert SanLuis Date: 10/15/2019

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:	

TABLE OF CONTENTS

1. PURPOSE

This document describes 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, AABB, or other agency).
- This procedure applies to all laboratory personnel involved in handling any aspect of the pre-analytic, analytic, and post-analytic laboratory processes.
- 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

3. RESPONSIBILITY

Responsible Party	Task
Laboratory Director	• Approval and implementation of this policy and any revisions. • Ensuring laboratory enrollment in PT programs required by regulatory agencies • Ensuring compliance with this SOP.
Laboratory Director or Designee	• Recurring review of this policy. • Ensuring appropriate handling of PT materials. • Signing the attestation form (or copy of the completed form).
Department Manager/Supervisor	• Ensuring compliance with this SOP in the pre/post-analytical department for which they are responsible. • Ensuring documented training for all employees prior to handling PT
Technical Supervisor/Technical Consultant	• Implementing and ensuring compliance in the areas for which they are responsible. • Review of PT results, instrument/method information and test units for accuracy. • Ensuring results will be reviewed and reported by the deadline to the PT provider • Ensuring documented training for all employees within 30 days of hire and prior to handling PT.
Testing personnel	• Testing PT samples in the same manner as patient samples, except where the nature of the PT material requires special handling. (See addendum D) • Documenting performance of all steps in the PT process on the companion document. • Processing PT samples with normal workflow (if not, document why- Example: • Utilizing the same repeat/dilution protocols and same calibration and quality control frequency, as patient testing. • Recording results on CAP forms and verifying method and reagent codes • Inputting results into the CAP website • Signing the attestation form (or copy of the completed form) • Returning the completed packet to the supervisor for review
Quality Assurance (QA) **Note:** This must be delegated in writing **by**	• Coordinating PT, including oversight of the log-in process. • Ensuring reflex testing order codes that would normally trigger referral of the patient sample to another laboratory for further

Responsible Party	Task
the Laboratory Director	testing are blocked by the LIS when ordered for any PT. Refer to section 10.3 Post Analytical Requirements, step 1. • Maintaining enrollment in PT programs as required by regulatory agencies. Appropriate enrollment must be reviewed annually. • Managing the handling of all PT materials. • Providing oversight of the PT program for all departments in the laboratory. • Administering the CAP e-LAB Solutions program. • Ensuring Alternative Performance Assessment will be performed on analytes not covered by external PT 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, or other Commercial/State PT).
- **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.

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.
- The laboratories **MUST NOT ACCEPT*** proficiency sample(s) from another laboratory (including another Quest Diagnostics laboratory).
- The laboratories **MUST NOT TEST*** any proficiency sample(s) received from another laboratory (including another Quest Diagnostics laboratory).
- The laboratories **MUST NOT REFER*** any portion of a proficiency test sample to another laboratory (including another Quest Diagnostics laboratory).
- The laboratories **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 any laboratory). If there are concerns about the assay, reagents or run containing a PT sample, contact the Technical Supervisor.

***** See procedure *Handling Inappropriate Referral of Proficiency Material or Inter/Intra-laboratory Communication of Proficiency Test Information.*

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. LIS rules are created to flag on the computer screen to block referral of the specimen to another laboratory for testing. Refer to section 10.3 Post Analytical Requirements, step 1.
  - Panels / Profiles: **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.
- Each affiliated lab site 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.
- **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 (see addendum D), 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.
- There is to be <u>no</u> 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 personnel.
  - 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 records management program requirements.

6. ENROLLMENT IN PROFICIENCY TEST PROGRAMS

- QA 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 PT needs are reassessed and documented.

6.1 TYPES OF PROGRAMS:

- The College of American Pathologists' (CAP) Proficiency Test Program is the primary provider of proficiency test surveys for all Adventist System 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 CAP-Approved PT providers may be used to meet proficiency testing requirements for specific analytes that are not covered by CAP programs.

6.2 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).
- 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 PT is needed, extra surveys may be ordered from a different CLIA approved PT 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.)
- 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/supervisor may perform the secondary review, provided the review is performed at the testing location.

8. ALTERNATIVE PERFORMANCE ASSESSMENT (APA)

For tests not covered by CAP PT or other Commercial/State 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

- QA 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 is used to assist in tracking PT specimens throughout the entire process.
- 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 LIS. Unusual sample types that do not resemble patient specimens (such as photomicrographs) are exempt from this requirement.

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

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 lab. • **Caution:** since delays have been experienced, close monitoring should be made of anticipated receipt date.
2	Survey materials will be addressed to the Senior QA 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. **Note**: see Addendum C for HER2 and/or PM2 surveys kits
4	The QA specialist (or group 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. CAP should be notified by phone as soon as possible if survey materials are damaged, stored improperly or otherwise unacceptable for testing. In these circumstances CAP will provide replacement survey material. Any specimen mishandling generated by the testing laboratory, will require payment for replacement samples, if available. • **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	On the shipping day, the QA specialist, Group Lead, or designee will: • Print a blank test result form from the CAP web site. • Order tests to be performed in the LIS. Refer to procedure Proficiency Test Order Entry for details. (Note: some testing will not qualify for LIS orders due to special CAP handling instructions, i.e. Sysmex Hematology and Sysmex RT, these materials will still be part of the mailbox notification. The Group Lead will take special care with these surveys to ensure timely completion and return of results to CAP.) • Print accession labels. • Place all accession labels, reprinted CAP result form, and Survey Companion document into a clear plastic sheet protector. • Use a sharpie pen to record the year, shipment, and testing department along the spine of the page protector, and deliver to the supervisor, group lead, or designee to await the kit arrival. • Send a mailbox message to the appropriate staff, alerting them to expect the shipment, and that the testing has been ordered as received. Upon kit arrival, the QA specialist, Group Lead, or designee will:

Step	Action
	• Open the CAP box. • Inspect the materials. • Carefully read CAP testing instructions and highlight any changes. • Alert the testing staff to any photomicrographs from fluid specimens that we do not test. • Deliver CAP proficiency material to the CAP refrigerator or other appropriate storage. • Calculate internal due date for results (i.e. 48 to 72 hours from time of laboratory arrival); document this date on the Survey Companion Document. • Send LIS mailbox to the section supervisor, manager and Group Lead(s) announcing the receipt and result due date (48 to 72 hours) of the survey arrival.
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, if not already noted in step 5 above. • 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

10.1 PRE-ANALYTICAL REQUIREMENTS:

- All PT 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.
- Survey samples must be accessioned into the Laboratory Information System (LIS) whenever possible. Employees are responsible for treating PT samples ethically and confidentially.
- 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 rule **must** be created the LIS to prevent the automatic accidental referral. Refer to section 10.3 Post Analytical Requirements, step 1.

Step	Action
1	The **testing technologist** matches the specimen numbers against the LIS labels, verifying that the kit number (LIS label first name) corresponds with the kit number on the survey result form, and applies the accession labels to the specimens.

Step	Action
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 companion 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 is responsible to communicate with CAP and request replacement samples.

10.2 ANALYTICAL REQUIREMENTS:

- PT samples must be tested according to the laboratory assay procedure 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, PT 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.
- **Note**: During assay downtime or when assay failures occur and patient samples are referred to another laboratory:
  - **DO NOT** refer the PT samples
  - The laboratory must ensure that no PT samples are unintentionally sent out, referred, or redirected to another laboratory during instrument or assay downtimes.

Step	Action
1	• The Group Lead must ensure that the survey is completed within 48 ton72 hours of receipt in the laboratory. • 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.

Step	Action
3	For photomicrograph: • The performing technologist must record their tech code beside each result on the manual CAP reporting form. • If internet reference sources are used in photomicrograph identification, print and submit with the CAP raw data for supervisory review. • If a photomicrograph meets criteria for pathology review, submit sample, *the CAP instructions and the list of result options*, along with the pathology review form to pathologist, along with your estimated identification. **Provide the pathologist with a cell identifcation atlas along with the challenge photos.** **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).

10.3 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 along with the PT survey results.
- 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 individuals who performed the PT, as well as the instrument(s) used.
- The attestation form (or copy of the completed form) must be signed by the individuals performing the testing and the laboratory director or qualified designee.
- Testing personnel or other designated individuals 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/Consultant, 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. This review must include data from the original instrument printout to the final PT reporting form, or on-line result entry field.

- 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 have been 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.
9	The manager/supervisor or designee must sign the CAP Attestation Statement. **The laboratory director is the only authorized signature for the BB Attestation Statement.**

12. REVIEW AND SUBMISSION OF PT RESULTS

- The Technical Supervisor/Consultant (or designee) must perform a final review of the paperwork to detect clerical errors, errors in methods, units, etc. This final review may also involve transcription of information from a copy to the original survey form, or into the on-line result entry site.
- 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, the method must ensure receipt will occur before the submission deadline and 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, use the result printout to verify that submitted results were correct, before the final submission date. Results can be revised up until 2359 on the submission date.
    - For CAP surveys, the 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.
- QA staff or their designee performs a final review of the paperwork to verify the director or designee signature is present, prior to filing the raw data. They place the signed attestation pages in the CAP surveys binder, arranged by the survey name.

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.
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 B) • 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.
6	The QA specialist files the Attestation Statements, in the CAP survey notebook or appropriate, and all other raw data and printouts in the raw data file..

13. RELATED DOCUMENTS

- Handling Inappropriate Referral of Proficiency Material or Inter/Intra-laboratory Communication of Proficiency Test Information**,** QA procedure
- Proficiency Test Results Evaluation, QA procedure
- Proficiency Test Order Entry, QA procedure
- CAP Online Proficiency Testing, QA procedure
- Survey Companion Document (AG.F48, AG.F344)

14. REFERENCES

- CLIA Public Health 42 CFR Part 493 of CLIA Inspector Interpretive Guidelines.
- CAP Laboratory Requirements (www.cap.org).
- Quest Diagnostics *Policy for Proficiency Test (PT) Handling and Result Submission* (QDMOQ711v11.1)

15. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SGAHQDNQA711v6.3		
1	7/7/20	Section 10.2: Added note for instrument downtime Section 14: Updated QD policy title and number	L Barrett	C Bowman-Gholston
2	4/7/21	Section 9: Added reference to Add. C Section 16: Added Add. C for HER2 & PM2 Handling	C Bowman-Gholston	C Bowman-Gholston
3	5/17/21	Header: Added FWMC Section 10.2.3: Highlighted 'record tech code beside results that they identified'. Added process for internet reference sources.	C Bowman-Gholston	C Bowman-Gholston
4	6/21/23	Section 6.1:inserted CAP approved Section 9.5: bullet 2, removed ELU Bullets 12 & 13, added 72 hours Section 10.2: action #1, added 72 hours Section 10.2: #3 Added Provide a cell identification atlas along with the photomicrograph for pathologist review. Section 11.9: added details on who should sign the BB survey attestation statement. Section 12: Changed time from 2300 to 2359 Addendum B: added e-LAB Solutions Suite, interface result transmission Header: Changed site to All Laboratories Footer: Changed SOP prefix to AHC	C Bowman-Gholston	C Bowman-Gholston
5	9/3/24	Added Addendum D: list of exceptions for handling PT like patient samples.	D Collier	C Bowman-Gholston
6	9/27/24	Added exception instructions for YBC survey to addendum D	D Collier	C Bowman-Gholston

16. ADDENDA

A: QA Manager – PT Delegation
B: CAP Website Submission Process
C: Receiving and Distributing HER2 and PM2 Survey Kits
D: **Exceptions to Handling PT Samples the Same as Patient Samples**

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.	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.)
12.	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.
13.	Ensures annual PT compliance training is conducted and documented in all appropriate departments as required.
14.	**Procedure Review:** *Ensure that approved procedures are available, complete, and reflect current practice. Submit SOPs to the Laboratory Director for approval.* ***Recurring review*** *SOPs according to the laboratory's document control policy.* Ensure that an approved procedure manual is available to all personnel for Quality Assurance processes. [Quest Diagnostics policy requires the Laboratory Director to sign QA procedures when 1) initially placed in use, 2) a change is made to a procedure, or 3) there is a change in Laboratory Director. The review of procedures may be reapportioned to the department manager.]

Laboratory Name and Location: _____

Name of Individual	Activity

Laboratory Director Signature **Date**

Addendum B

CAP Website Submission Process

Core Laboratory

- Data entry by performing technologist or via enters results online via e-LAB Solutions Suite, interface result transmission
- Result review performed by Group Lead or second technologist
- Result release performed by Supervisor or designee
- QA review by 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 QA specialist

Addendum C

Receiving and Distributing HER2 and PM2 Survey Kits

A. HER2 and PM2 Surveys (General Information):
   - These surveys ship twice a year to SGMC and WOMC.
   - These surveys are tested in the Pathology Department.
   - The surveys will arrive in the laboratory on either Tuesday or Wednesday.
   - The shipping label on the outside of the box will indicate either **HER2** or **PM2.**

B. Upon arrival:
   - Staff will obtain a bright orange pre-printed label, instructing the delivery of the kit to Michael L. @ CCPL**.**
   - Place the orange label onto the plastic wrap covering the original CAP shipping box.
   - **DO NOT OPEN THE BOX!**
   - Deliver the labeled box to the Pathology Department for processing and reporting.

Addendum D

Exceptions to Handling PT Samples the Same as Patient Samples

Some PT samples require special handing unlike that required for patient testing. It is imperative that the kit instructions be read and followed very carefully. There may be special instructions for sample preparation, analysis, or reporting. Some of the exceptions are listed below.

PT Name	Tests	Special Handling (not required for patient testing)
FH9	CBC	The PT CAP samples are not accessioned into the LIS as are patients and most other PT samples for analysis. The sample number provided by CAP on the sample tube is used and the sample is run in QC mode per kit instructions.
LS	Parathyroid Hormone	The LS samples for PTH are reconstituted according to the directions in the kit instructions. Be careful to use the correct reconstitution directions for the specific sample name being run. (There may be two different reconstitution directions depending on CAP sample name)
Retic	Reticulocytes	The PT CAP samples are not accessioned into the LIS as are patients and most other PT samples for analysis. The sample number provided by CAP on the sample tube is used and the sample is run in QC mode per kit instructions.
UAA1	**Automated** microscopic	**This survey is for automated microscopic urinalysis results only.** Do not spin down, view and report a manual microscopic as directed in the Auwi SOP, when the results are held in DI for manual microscopic verification. **Report the automated microscopic only.**
YBC	Yeast Blood Culture, Molecular	There is an exception to reporting process for this test when *C tropicalis* is identified. We do not report this organism for patients and the result is automatically hidden in our system. When this organism is identified on a CAP survey, we do not report it, and instead enter a code 11. When a code 11 is used, an explanation for using the code is documented on the result form in the comments section.