QA.PT.1.0 PROFICIENCY TESTING HANDLING OF SPECIMENS, TESTING AND RESULT SUBMISSION

STATEMENT OF PURPOSE

The proficiency testing (PT) program is designed to ensure the quality of laboratory results and patient reports. The results of the proficiency testing programs are used as an opportunity to correct problems, educate associates and improve the quality of services provided. The laboratory will participate in proficiency survey programs approved by CMS and CAP.

This document sets forth the process for receipt, handling, and testing proficiency test samples and for submitting PT results to any external agencies for evaluation.

SCOPE

This document applies to personnel involved in any phase of the proficiency testing process—pre-analytical, analytical, and post-analytical—including sample log-in, handling, analysis, and reporting of results. This document applies to all MACL laboratory locations.

OWNERS

QA and Safety Officer

RELATED DOCUMENTS

QA.PT.1.1 *Proficiency Testing Survey Companion Document*
QA.PT.1.2 *Proficiency Testing Do's and Don'ts Poster*
QC.PT.1.5 *Uploading PT Results to API*
QA.PT.2.0 *Proficiency Testing—Report Review and Follow Up*
QA.PT.2.1 *Response to proficiency Nonconformance Form*
QA.PT.2.2 *Non-Graded/Educational Response to Proficiency Survey Form*
QA.PT.2.3 *Non-Graded/Educational Response Code Key*
QA.PT.2.4 *Investigation of Proficiency Testing Bias Form*
QA.PT.3.0 *Proficiency Testing Not Available—Verifying Accuracy and Reliability of Test Results (Alternate PT)*
QA.PT.4.0 *Proficiency Testing—Handling of Inappropriately Referred PT Material*
QA.PT.5.0 *Processing CAP Surveys*
DOCCTR.SOP.3.0 *Records/Specimen Retention Requirements*

RESPONSIBILITY

A. The **Laboratory Director** (CLIA license holder) has overall responsibility for
   1. Approval and implementation of this SPP, including all subsequent revisions.
   2. Ensuring laboratory enrollment in PT programs as required by regulatory agencies, including CAP e-LAB Solutions PT program (refer to www.cap.org for enrollment instructions) and API (www.api-pt.com)
   3. Ensuring the implementation of this process in all relevant departments.
   4. Ensuring compliance with this process.
   5. The annual review of this document.
   6. Ensuring appropriate handling of PT materials.

B. The **QA and Safety Officer** is responsible for
   1. Maintaining required enrollment in PT programs as required by regulatory agencies. Appropriate enrollment must be reviewed annually.
   2. Managing the handling of all PT materials.
   3. Providing oversight of the PT program for the Regional, HBL & LSC Laboratories.
   4. Administering the CAP e-LAB Solutions and API Paperless Proficiency Testing Programs.
   5. Ensuring Alternative Performance Assessment is performed on analytes not covered by external proficiency testing programs. The need for alternative performance assessment must be reviewed annually (Refer to QA.PT.3.0 *Proficiency Testing Not Available—Verifying Accuracy and Reliability of Test Results*).

C. The **Technical Supervisor** of each MACL laboratory (Regional, HBL & LSC) is responsible for
   1. Implementation of this process in the department(s) or laboratory for which he/she is responsible in a technical capacity.
   2. Ensuring compliance with this process in his/her department(s).
   3. Review of PT results, instrument/method information and test units for accuracy.
   4. Updating the PT information in the S drive: Test Menu folder when new tests are added.
   5. Coordinating Proficiency Testing.
   6. Ensuring results are reviewed and reported by the deadline to the PT provider

D. **Testing personnel** are responsible for:
   1. Testing PT samples in the same manner as patient samples, <u>except</u> where the nature of the PT material requires special handling based on the PT program's instructions.
   2. Documenting performance of all steps in the proficiency testing process.

DEFINITIONS

A. **Alternative Performance Assessment:** A laboratory administered program similar to proficiency testing that is used to evaluate performance of assays (i.e., are not covered by CAP's proficiency testing program or other commercial proficiency testing provider.
B. **API:** American Proficiency Institute
C. **Bias:** Bias results from a systematic error in the testing process. In proficiency testing results analysis, it most often appears as a laboratory's results for an analyte being mostly, if not all, on one side of the peer group mean.
D. **CAP:** College of American Pathologists.
E. **CLIA:** Clinical Laboratory Improvement Amendments.
F. **CMS:** Centers for Medicare and Medicaid Services. The Centers for Medicare and Medicaid Services (CMS) regulate all laboratory testing (except research, forensic and SAMHSA drug testing) performed on humans in the U.S. through the authority vested to them through the Clinical Laboratory Improvement Amendments (CLIA).
G. **Intra-laboratory** – Within the licensed laboratory (Example: Regional MACL).
H **Inter-laboratory** – Between laboratories (Example: MACL Regional and MACL CHN or MACL and Quest).

I. **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.

J. **Multi-department Surveys:** Surveys containing analytes for two or more different departments within the same CLIA licensed laboratory.

K. **Trend:** More often used in evaluating quality control results, a trend is essentially a pattern in proficiency testing results when compared to the peer group means and distribution statistics. An example of a trend could be a progressively more biased set of proficiency testing results from one event to the next.

OVERVIEW OF GENERAL REQUIREMENTS FOR PROFICIENCY TESTING

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

PROGRAM COMPLIANCE

A. The laboratory must participate in a CMS-approved proficiency program for all CLIA specialties and sub-specialties included in the laboratory's testing menu.

B. If a proficiency test program is not available, the analyte must be challenged by an Alternative Performance Assessment at least twice per year.

TESTING COMPLIANCE

A. Unless explicitly directed otherwise by the PT provider in the written instructions, PT samples must be treated and reported like a patient sample. **DO NOT refer any part of a proficiency test sample, or data for review, to another laboratory (including a MACL laboratory), even if you would normally refer a patient sample or data.**

B. 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.)

C. When multiple persons and/or instruments are routinely used for patient testing, PT materials must be rotated among testing personnel, shifts, and instruments.

D. 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".

E. If reflex testing would normally trigger referral of the sample to another laboratory for further testing, the **PT sample must not be referred to another laboratory**. Only the initial screening result generated by the enrolled laboratory can be reported. Note: Any reflex tests automatically generated by the LIS must be cancelled in the system.

F. 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.

G. Normal calibration protocols and schedules must be followed.

H. All survey documents, including copies of PT forms, attestation forms, instrument printouts, and a printed copy of the electronic results submitted to the PT provider and the associated confirmation, must be retained on site at the performing laboratory for at least two years and be readily available for review. Offsite storage (beyond the two most current years) must comply with RECMGT.1.0 *Records/Specimen Retention Requirements*.

PT REFERRAL PROHIBITION

A. CLIA prohibits the referral of any PT material to another laboratory for testing. *See Procedure for the Handling of Inappropriately Referred Proficiency Material.*

1. 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 published results).
2. If a laboratory receives PT material from other laboratories, sites, or locations, sequester the material and do not test.
3. Immediately notify the Supervisor, Manager, Vice President of Operations, QA and Safety Officer, or the Medical Laboratory Director to facilitate immediate investigation of the suspect PT.
4. If the laboratory determines that it has received PT samples from another laboratory for testing the Medical Laboratory Director will provide appropriate notification to CMS.
5. PT samples should be suspected if:
    a. “AAB”, “AAFP”, “ACCU”, “ACCUTEST”, “ACP”, “API”, “ASCP”, “ASIM”, “CAP”, “CTS”, “EXC”, “EXCEL”, “MLE”, “NY”, “PROFICIENCY”, “SURVEY”, or “WSLH” is included in the patient identification.
    b. The specimen appears to be a commercially prepared product or has the physical characteristics compatible with the consistency of an active PT survey sample.
    c. The words “Proficiency” or “Survey” appear on the label.

B. Intra-laboratory or inter-laboratory communication regarding PT materials or results is prohibited until the PT provider has formally published the results. Questions regarding the administration of the PT program or material integrity may be directed to the Supervisor, Manager, Director, COO, Medical Laboratory Director, QA and Safety Officer, or the PT provider, but communications or discussions concerning PT results are prohibited.

EMPLOYEE RESPONSIBILITIES AND CORRECTIVE ACTION FOR NON-COMPLIANCE WITH THIS POLICY

A. Knowingly referring a PT sample to another laboratory prior to publication of results by the PT provider may result in corrective action up to and including termination.

B. Knowingly communicating with another laboratory about PT results prior to publication of results by the PT provider may result in corrective action up to and including termination.

C. Knowingly accepting a PT sample from another laboratory prior to publication of results by the PT provider may result in corrective action up to and including termination.

D. Failure to notify the Supervisor, Manager, COO, QA and Safety Officer, or Medical Laboratory Director of receipt of suspected PT samples may result in corrective action up to and including termination.

E. Failure to fully cooperate and be truthful in any investigation regarding suspected non-compliance with this policy may result in corrective action up to and including termination.

RESULT COMMUNICATION PROHIBITION

A. If another laboratory initiates communication regarding PT results before the survey results have been published by the PT provider, the laboratory must not discuss the results with the other laboratory. The laboratory staff that received the communication must immediately notify the Supervisor, Manager, Director, COO, QA and Safety Officer, or Medical Laboratory Director.

ENROLLMENT IN PROFICIENCY TEST PROGRAMS

A. The site manager or supervisor must notify the Quality Specialist when new testing is added and ensure that an approved PT program covers all analytes. If PT is not available, the analyte must be covered by an Alternative Performance Assessment.

B. The QA and Safety Officer must ensure that an approved PT program covers all analytes, or where PT is not available, is covered by an Alternative Performance Assessment.

C. Enrollment in a PT program or the need for Alternative Performance Assessment must be reviewed:
   1. Whenever new analytes are added to the test menu.
   2. On an annual basis, as proficiency testing needs are reassessed and documented.

TYPES OF PROGRAMS

A. The College of American Pathologists (CAP) Proficiency Testing Program and American Proficiency Institute (API) are the primary providers of proficiency test surveys for all MACL laboratories.
   1. The laboratory must enroll in and use the CAP e-LAB Solutions program and API Paperless Proficiency testing program(s) as required by test menu and PT provider(s).

B. Other PT providers may be used to meet proficiency testing requirements for specific analytes that are not covered by CAP programs or at the discretion of the Medical Laboratory Director.

   NOTE: 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).

ALTERNATIVE PERFORMANCE ASSESSMENT

A. For tests not covered by CAP, API or other commercial PT programs, the laboratory must develop alternative performance assessment systems to determine the reliability of analytic testing. Alternative Performance Assessments must:
   1. Mimic proficiency testing program to the degree possible.
   2. Be performed at least twice yearly.
   3. Contain at least 2 challenges (two levels, positive and negative, etc.).
   4. Be evaluated against established (documented) grading expectations.
   5. Be reviewed by the same individual(s) who review(s) PT performance.
   6. Have documented corrective action when grading expectations are not met.

B. Refer to QA.PT.3.0 *Proficiency Testing Not Available—Verifying Accuracy and Reliability of Test Results* for details.

PT SPECIMEN REQUIREMENTS

A. Proficiency testing materials must be specific for the specimen type tested.

B. Different sample types with different reference ranges and physiological concentrations require separate proficiency test programs (Examples: serum sodium and urine sodium, serum glucose and CSF glucose, molecular assays such as SDA, and PCR methods requiring different transport media).

C. Samples types that are documented to be equivalent (same physiological concentration and reference range) do not require separate proficiency test programs (Example: plasma glucose and serum glucose).

D. 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.).

E. In special cases, substitute specimen types such as lyophilized culture organisms or photomicrographs may be appropriate.

RECEIPT OF PROFICIENCY TEST SAMPLES

A. **CLIA regulations prohibit testing of PT specimens received from clients or other laboratories.** See QA.PT.4.0 *Proficiency Material—Handling Inappropriate Referral.*

B. The Quality Specialist (Regional lab) or supervisor/designee (HBL and LSC) must track the scheduled mailing dates for PT materials and follow-up with the appropriate PT provider when materials are not received as expected.

C. Personnel in departments that initially receive PT materials must be trained to recognize these shipments and to immediately deliver them to the designated contact.

D. Survey materials must always be personally delivered to the responsible individual (i.e., not left in a mailbox or on a desk).
   1. 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.

E. The survey kit must be visually checked to ensure it is complete and that components are received in good condition.

F. Required paperwork must be initiated to track the survey through the pre-analytic and analytic processes and result reporting.

   NOTE: A *Survey Companion Document* (QA.PT.1.1) is furnished to assist laboratories in tracking PT specimens throughout the entire process.

G. Survey samples and paperwork must be delivered to designated individuals in the testing area who are responsible for coordinating or performing PT testing.

H. All affected personnel must be notified of the survey receipt and result due date.

I. When possible, PT samples for Chemistry and Hematology surveys need to be accessioned into Sunquest Information System. Unusual sample types that do not resemble patient specimens (such as photomicrographs) are exempt.
   1. For proper accessioning format see step #4 in the Pre-Analytical Requirements

TESTING PROFICIENCY SAMPLES

A. Pre-Analytical Requirements
   1. All proficiency samples must be prepared according to survey instructions and properly labeled.
   2. Unusual conditions (e.g., leakage, hemolysis, particulate matter, turbidity, failure of samples that require repeating to give consistent results, etc.) must be reported to a supervisor immediately and documented.
   3. If sample integrity problems are observed, another specimen may be requested from the PT provider.
   4. Accessioning of samples
      a. Use function REH in the Sunquest information system
      b. Use assigned last name for each site as assigned by the QA department
      c. Use the survey sample name as the first name for the sample

      Example: Apple, CH01 where apple is the site's assigned last name and CH01 is the sample name.

   5. If PT samples cannot be bar-coded, or there is no access to Sunquest, the identity of the sample must be visually verified each time it is used.

B. Analytical Requirements

1. PT samples must be tested according to the test SOP and in the same manner as patient samples. **DO NOT refer any part of a proficiency test sample, or data for review, to another laboratory (including a MACL laboratory), even if you would normally refer a patient sample or data.**
2. 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.
3. If, for some reason, the PT samples cannot be tested with an actual patient load (e.g., rarely ordered tests, short stability PT materials, etc.), the reason for the special run containing only PT samples should be documented.
4. PT samples must be assigned to associates who routinely perform testing. For example: it is not appropriate to assign PT samples exclusively to the most experienced technologists. Additionally, responsibility for testing PT samples should be rotated among those associates who perform that testing so that the same individuals do not perform the same testing on PT samples for several consecutive PT events.

CAUTION	When an associate works at more than one laboratory facility, it is the associate's responsibility to ensure they are not assigned the same PT specimen testing at more than one laboratory. This applies whether working at another MACL lab or a non-MACL facility. Managers with rotating testing personnel should be cognizant of this possibility and plan accordingly when assigning PT testing.

5. Multi-department surveys: 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. Upon completion of the survey, the department designated as last to perform testing will return the completed forms to the primary testing department. The primary testing department will be responsible for submitting results to the PT provider and maintaining documentation for the PT event.
6. If a test is performed on multiple shifts, proficiency testing must be rotated among all shifts during the course of the year.
7. An instrument must not be specially calibrated immediately prior to running PT samples.
8. Repeat testing can only be performed when required by the test SOP and must meet the same repeat requirements used for patient testing.
9. 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.

10. Quality control release requirements must be the same as those used for patient result release.

C. Post-Analytical Requirements

1. When PT samples are logged into the LIS, results must be entered and released using the same process as patient testing.
2. When PT results are released, LIS reports must be printed (as applicable) and retained with the PT survey results.
3. 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).
4. PT material, slides, photomicrographs, etc. may be used for educational and/or competency, after results have been published by the PT provider.

PT DO'S AND DON'TS POSTER

A. A poster is provided (QA.PT.1.2 *Proficiency Testing Do's and Don'ts Poster*) that covers important points in this SPP relating to acceptable and unacceptable actions related to PT testing and PT samples. This poster is to be placed on the laboratory's bulletin board and in any workstations where the laboratory associates feel such a reminder could be useful.

DOCUMENTATION OF PROFICIENCY TEST RESULTS

A. Intra-laboratory or inter-laboratory communications regarding PT results prior to the evaluation of the survey is prohibited. Laboratory personnel cannot discuss or divulge PT results to associates in other laboratories or departments, even if this is routinely done for patient samples.

B. Test records must clearly identify the individual(s) who performed the proficiency test, as well as the instrument(s) used.

C. Results Reporting
   1. Manual recording: Testing associate 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 (eg, method code, reagent information or software version), results obtained, units of measure, attestation statements, etc. must be recorded and reviewed.
   2. File upload: See Attachment QC.PT.1.5 *Uploading PT Results to API*.

D. A Manager, Supervisor, or other designated individual must perform a secondary review of the PT documentation to ensure that all information has been correctly entered into the electronic reporting system or on the paper submission forms if no electronic reporting available.

   Note: Survey data must remain within the four walls of the CLIA laboratory until results are evaluated by the PT provider.

E. 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.

F. The Manager, Supervisor or designee performs a final review of the paperwork to detect clerical errors, errors in methods, units, factors, etc. If not already performed, this final review may also involve transcription of information from a paper copy to the electronic filing system or, if not available from the PT provider, the original survey form. A proofreading step after manual input into the electronic reporting system is required to minimize clerical errors.

G. Review must be performed within the four walls of the CLIA licensed facility. A rotational schedule is utilized to assign Technical Supervisor review of PT results at Lab Service Centers. If the designated Technical Supervisor is not available, the LSC testing personnel are to contact the Laboratory Manager or COO.

H. The attestation form (or copy of the completed form) must be signed by the Laboratory Medical Director (required for Transfusion Services or Cytology) or designee (all other areas).

I. Results must be submitted to the PT agency on or before the due date, according to the PT provider's instructions.

REVIEW AND SUBMISSION OF PT RESULTS

A. Regardless of submission method, verify that results are correct before final submission.

B. For CAP surveys, the Manager, Supervisor, Quality Specialist or other designated individual(s) should review receipt and accuracy of survey results on their website (www.cap.org or www.api-pt.com). Incomplete transmissions or incorrect data entry can be corrected prior to the survey evaluation deadline.

C. Save a paper copy of the electronic submission's confirmation. If results must be mailed, use a mailing method that ensures receipt will occur before the submission deadline and that can be tracked or verified. If results must be 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.

RECORDS MAINTENANCE

A. Proficiency Testing records are maintained per DOCCTR.SOP.3.0 *Record and Specimen Retention Requirements*.

REFERENCES

A CAP Laboratory General Checklist (www.cap.org).
B. CLIA Public Health 42 CFR Part 493, January 24, 2003.
C. Klee G.G. and Westgard JO. Quality Management. In: *Fundamentals of Clinical Chemistry 6th Ed.,* Burtis CA, Aswood ER, and Bruns DE, eds. Saunders Elsevier, St. Louis, MO. 2008: pp.249-262.