POLICY
Corewell Health East - CAP Proficiency Testing - Farmington Hills, Troy, Grosse Pointe, Livonia, Lenox

This Policy is Applicable to the following Corewell Health sites:
Corewell Health Beaumont Grosse Pointe Hospital, Corewell Health Beaumont Troy Hospital, Corewell Health Farmington Hills Hospital

Applicability Limited to:	N/A
Reference #:	32855
Version #:	2
Effective Date:	11/12/2025
Functional Area:	Clinical Operations, Laboratory
Department Area:	Lab - General, Laboratory Policies

1. Purpose and Objective

A. College of American Pathologists (CAP) accredited laboratories must participate in proficiency testing (PT) when available through CAP or a CAP-approved alternate provider for all patient tests designated by CAP.

B. To provide guidance to the laboratory staff regarding the policy and procedure for College of American Pathologists (CAP) Proficiency testing. This includes:
   1. Proper handling, analysis, review and reporting of proficiency testing materials.
   2. Investigation and correction of problems that are identified by unacceptable proficiency testing results.
   3. Investigation of results that, although acceptable, show bias or trends suggesting a problem.

C. Proficiency Testing (PT) serves as an evaluation of the laboratory as a system and the test results that are the outcome of the system. By comparing test results (i.e. final critique) with other laboratories using the same methodologies or instrumentation, the quality of test methods, equipment, supplies, reagents, and the skill of testing personnel can be assessed.

2. Definitions/Abbreviations

A. Designee – Designees must be qualified through education and experience to meet the defined regulatory requirements associated with the complexity of the testing as defined in the Personnel section of the College of American Pathologists (CAP) Laboratory General Checklist. GEN.53400 and GEN.53625.

B. CAP – College of American Pathologists

C. CLIA – Clinical Laboratory Improvement Act

D. PT – Proficiency testing

E. CMS – Centers for Medicare and Medicaid Services

F. SDI – Standard Deviation Indexes

3. Responsibilities

It is the responsibility of the Medical Director, Laboratory Manager/Lead Technologist/Designee to ensure the proficiency testing program is carried out in accordance with this policy/procedure.

4. Policy

A. The laboratory may not refer to or accept a proficiency testing specimen to a laboratory with a different CLIA number (even if the second is in the same health care system). This prohibition takes precedence over the requirement that proficiency testing specimens be handled in the same manner as patient specimens. For example, a laboratory's routine procedure for review of abnormal blood smears might be referral of the smear to a pathologist located at another site (i.e., with a different CLIA number than the referring laboratory). For proficiency testing specimens, the referring laboratory must NOT follow its routine procedure in this situation. The laboratory will refer to the PT provider kit instructions on how to record a result for a test not performed in the laboratory.

B. In accordance with CLIA-88 regulations, inter-laboratory communication regarding proficiency testing samples is strictly prohibited prior to the submission deadline. PT challenges will be shared with laboratory staff only after results have been submitted to the provider.
Any inter-laboratory communication on proficiency testing data or referral of testing PT specimens at another laboratory will result in disciplinary action(s) by the Director of the Laboratory for employees that participated.

C. Based on CMS requirements, if an analyte/test is performed by more than one method or instrument, only one PT survey should be ordered and tested by primary method at the time of the PT event (as decided by the section medical director). To verify that other methods/instruments are producing equivalent results, the following should be considered:
   1. Perform internal method/instrument comparisons that satisfy CAP checklist criteria.
   2. Freeze the PT material as soon as all initial testing is completed, if applicable per kit instructions. Once the PT resulting period is closed and results are received, the sample can be retested by the alternate method(s) and compared to the appropriate group results.
   3. Enroll in a non-CAP PT program for a method/instrument not used for CAP PT.

D. The CAP surveys are approved by the Centers for Medicare and Medicaid services (CMS), Association for the Advancement of Blood and Biotherapies [formerly the American Association of Blood Banks] (AABB) and are accepted by the CAP laboratory accreditation program, The Joint Commission and state regulatory agencies. The laboratory's survey results are sent by the CAP to the appropriate agencies above as documented evidence of the quality control.

E. CAP provides multiple surveys for laboratory testing. These surveys are selected by each department based on the instrumentation and the scope of testing offered.

F. All survey samples should be treated as potentially infectious and should be handled with universal precautions.

G. Survey results may be used to assess the competency of the individuals performing the testing.

H. PT results must not be shared with and should be inaccessible to personnel of other laboratories, including an affiliated laboratory until after the deadline for submission. Laboratories that share a common laboratory information system (LIS) or testing personnel must have strict policies and procedures to ensure that personnel do not access proficiency testing records from other laboratories.

5. Procedure

A. Survey Receipt and Processing

Includes sample preparation, sample storage requirements, handling warnings and guidelines.

1. Upon receiving the CAP survey package in the laboratory, determine which department the enclosed survey belongs to.
2. Inform the department manager, supervisor or designee of the arrival of the survey whether verbally or by written note.
3. Place survey in the designated storage area.

4. Read all kit information and instructions included in the test survey kit carefully to avoid errors. Check the contents of the kit against the instructions. If the kit is incomplete or contains broken, leaking, or unlabeled specimens, contact the CAP within 10 calendar days following the actual shipping date for a free replacement NOTE: If kit does not contain a result form or instructions, they may be printed from the CAP website.
5. Follow directions on the CAP Survey form.
6. Results will be documented through the LIS or worksheets (as specified by your department).

B. Analysis of PT Specimens

1. Employees will be assigned a CAP sample to perform testing.
2. Prepare specimen(s) according to instructions for Proficiency Testing as stated in the kit instructions.
3. Perform all necessary Quality Control (QC), calibration, and maintenance prior to testing as for patient runs.
4. Integrate Survey samples into the routine laboratory workload.
5. Survey samples must be analyzed by personnel who routinely test patient samples. The educational purposes of proficiency testing are best served by a rotation that allows all technologists to be involved in the PT program.
6. Use the same primary method (or multiple methods) systems as for patient samples.
7. Replicate analysis acceptable only if patient samples are routinely analyzed in the same manner.
8. Use normal laboratory protocol for repeats, dilutions, and reporting limits. Use of “less than or greater than” for resulting will be listed in the instructions for the proficiency test samples.
9. Perform calculations as routinely required for each test and according to CAP instructions.
10. Attach the instrument printouts, quality control results and Survey Result Form together and return them to the department manager, supervisor or designee. The department manager, supervisor or designee will review for clerical errors, correct methodology, and completeness.
11. Place the remaining samples of the proficiency kit in the appropriate storage area in case it is needed for retesting.
12. Do not pour aliquots back into original vial in case troubleshooting is required after evaluation of survey has been completed and returned
13. Attestation Form
    a. All employee(s) performing the testing must sign the Testing Personnel portion of the Attestation Form.
    b. The proficiency testing attestation statement must be reviewed and signed by the laboratory director or qualified designee as per CAP.
        1) For High Complexity testing, the employee must have the CAP qualifications of a Technical Supervisor.
        2) For Moderate complexity testing, the designee must have the CAP qualifications of a Technical Consultant.
    c. The attestation statement may be signed after submission of results and deadline.

C. Reporting PT Results

1. Record the results according to the instructions.
    a. If new instrumentation or new methodology has been introduced, enter the corresponding codes on the report form.
    b. Check that all tests reported have the proper codes.
2. Laboratories must report PT results to the same extent as patient testing.
    a. Use of PT samples between the Primary and Secondary analyzer should be tested so that the same PT sample is not repeated on both analyzers, unless patient samples are similarly tested.
    b. If the laboratory is performing qualitative testing only, then report only the qualitative results.
    c. If the laboratory is reporting quantitative testing only, then report only the quantitative PT results.

d. If the laboratory is reporting both qualitative and quantitative testing, then report both PT results.
e. For purposes of CAP accreditation, semi-quantitative testing is considered qualitative.
f. **All survey results will be verified by two technologists for clerical errors in each department, before results are submitted to CAP, thus a verification system will be in place for all manual entries**.

3. Report results on CAP website in the following manner:
   a. Log onto the CAP web site.
   b. Select e-Lab Solutions.
   c. Under the tab, Proficiency Testing/Quality Improvement, select Result Form Data Entry.
   d. Choose a kit from the list or use the filter options to change what kits are listed.
   e. Click on the arrow next to the survey to open the details for the survey you want to result.
      1) Under the "Data" Column, click on the "Enter Data" field. This will open the PDF document form to enter your results.
         a) Verify that the method codes, instrument codes and units of measure are correct for each analyte you are resulting. Using patient reports, instrument printout, manual worksheets, or other, enter the results for each analyte you are resulting.
         b) Save each page as you complete them.
         c) Once all pages are entered print a copy of the CAP result form.
         d) Verify all results entered on the CAP PT result form exactly match the results from the patient reports.
         e) Note: Data can be edited any time prior to the due date.
         f) **NOTE: All manual entries of results will be verified by at least 2 lab members and signed/initialed whenever possible**.

4. Manager, Supervisor or designee
   a. Once all results on the CAP result form have been verified, Click Approve and Submit to CAP icon. Review the CAP form for completeness one last time. Then select the Approve icon.
   b. The Survey Result Form (if applicable) and signed Attestation Form will be kept in the appropriate CAP Survey binder.
   c. Instrument printouts, Laboratory Information System (LIS) result printouts (if applicable), and other testing data will be maintained within the department files for review if necessary.
   d. Maintain documents for a minimum of 2 years.

D. Receipt of PT Evaluation Survey Report

1. When the Survey Evaluation results are received, they will be sent to the Laboratory Manager/Supervisor/designee.
2. The Laboratory Manager/Supervisor/designee will complete all necessary reviews/investigations.
3. The completed signed evaluation will then be returned to the Laboratory Manager/Supervisor/designee for filing within the department.

E. Review of PT Evaluation Survey Report

1. There must be ongoing evaluation of PT and alternative assessment results. All results will be reviewed by the Laboratory Manager/Supervisor/designee and appropriate documentation and follow-up conducted. The completed evaluation will be reviewed/signed by the Medical Director/designee.
   a. Review should include but not limited to: Educational challenges, results that show bias or trends, results that were not graded due to lack of consensus, results submitted after the cut-off date, results not submitted, unacceptable results, or result form not completed correctly such as submitting the wrong method code or recording the result in the wrong place. The performance must be assessed by performing a self- evaluation. Document investigation on the evaluation report next to the result.

b. For Unacceptable Results/Unsatisfactory Performance/Critical performance, a detailed investigation must occur.
c. Neonatal bilirubin results must be assessed for accuracy of its instrument/test system over the range of bilirubin values appropriate for the clinical guidelines (5-25 mg/dL) and documented annually on one of the NB CAP survey evaluations.
d. Investigate impact to patient results to determine if results were affected and if a patient lookback is needed.

2. Trends and Biases Review

It is recommended that each laboratory section review results which may be indicative of potential issues, even though they are not considered unacceptable by the PT provider. Evaluation criteria to be determined by each laboratory section and laboratory Medical Directors.

a. Some examples may include:
   1) Results exceeding >2 SDI or 3 SDI
   2) Average of SDI is > 1.5
   3) Difference between the largest and smallest SDI is >4
   4) Persistent results on one side of the target value.
b. Document troubleshooting as necessary.
c. See CAP Troubleshooting Guide for PT testing for more examples which can be found on the CAP website

3. Ungraded/Not Graded

CAP uses exception reason codes that signify the PT for an analyte has not been graded. The exception reason code is located on the evaluation report in brackets to the right of the result. The laboratory must identify all the analytes with an exception reason code and investigate the acceptability of its performance with the same rigor as if it were an unacceptable performance. When an exception reason code is present on the laboratory's evaluation, the laboratory must review the all- participant statistics for any explanatory information. The actions required for the following codes include but are not limited to:

a. Review all data concerning the Not Graded result to ensure the correct result was submitted.
b. Check that the correct method and instrument codes were submitted.
c. Compare the result to the peer group as provided in the CAP Survey report.
d. All findings will be evaluated by the department Manager/designee for remedial action, if necessary, and documented.
e. Documentation of review/investigation can be completed on evaluation report or other form if needed.
f. The above report will be filed along with the original evaluation in the appropriate CAP survey binder.

4. Proficiency Testing Performance for Investigation of the Unacceptable PT

Unacceptable proficiency testing results are investigated thoroughly by the department and findings reviewed with the Manager/Designee.

Note: Attached Forms:

a. Laboratory Proficiency Testing Failure Report shall be utilized for documentation.
b. Proficiency Testing/External Quality Assessment Exception Investigation Worksheet optional worksheet
c. Investigation:

A written summary of the steps the laboratory took to determine the nature of the problem and supporting documentation of the investigation. The following list is provided for example and not comprehensive:

1) Examining QC performance, instrument calibration validity and reagent performance prior to, during, and after the original analysis of the PT specimen(s).
2) Reanalyzing PT specimens, if possible.

3) Contacting the instrument/reagent manufacturer for assistance.
4) Changing reagent lot numbers.
5) Changing instrument settings.
6) Verifying instrument functionality.
7) Verifying that the PT material was processed in the correct instrument mode.

d. Conclusion
Document the conclusion of the investigation. Evaluate the effect (if any) on patient results.

e. Corrective Action
Document corrective action that has been taken to prevent recurrence of the problem. Examples are (not comprehensive):
1) Creating a process to verify clerical entries prior to PT result submission.
2) Changing the frequency of calibration.
3) Retraining testing personnel of the current procedure.
4) Revising the testing procedure and retraining the testing personnel.
5) Replacement of a critical operating component of the instrument.

f. Evidence That Problem Was Successfully Corrected.
Examples are (not comprehensive):
1) Verification that quality control is within acceptable limits.
2) Requesting additional material for repeat testing, if available.
3) Monitor results of subsequent surveys.
4) Supporting documentation

g. Review and Signature
The final complete response will be reviewed and signed by the Laboratory Manager/Supervisor/designee and Medical Director/designee

5. **Proficiency Testing Compliance Notice (PTCN)**
Lab may receive a PTCN for failure to enroll in PT, participate in PT or for unsatisfactory performance from CAP. The PTCN contains instructions regarding the actions that must be taken. Please note that clerical errors, failure to return results by the due date, and nonparticipation in PT are all considered PT failures.
   a. The laboratory manager/designee will receive in a separate mailing/email the Proficiency Testing Exception Summary (PTES) packet that includes the following:
      1) Instructions on how to respond to a PT exception.
      2) A Proficiency Testing Exception Summary Response Form.
      3) A summary of the scores for the current and the previous three events.
   b. A complete investigation should be conducted with supporting documentation as described under the Unacceptable PT section.
   c. Document the actions taken to resolve the issue so the failure does not occur again.
   d. The completed PTES form and supporting documentation will be reviewed and signed by the Manager and Medical Director/designee.
   e. A formal response to the CAP may not be required, however, subsequent failures for the analyte/subspecialty could result in more serious actions including a mandate to cease testing.
   f. The completed PTES form and all supporting documentation must be filed in the appropriate CAP Binder. This documentation will be reviewed during the next onsite inspection.

6. **Analytes where No External Proficiency Testing Program is Available**
For patient tests in which PT through CAP or a CAP-approved alternate provider is not available, an appropriate alternative performance assessment (APA) must be performed. This may include split sample analysis with reference or other laboratories, split samples with an established in-house method, assayed material, regional pools, and clinical validation by chart review, or other suitable and documented means.
   a. The assessment can be accomplished through:
      1) Correlation studies.

2) Blind testing of specimens with known results.
3) Exchange of specimens with other hospitals.
4) Other equivalent systems.
5) The results must be reviewed by the Department Medical Director and/or Manager.

b. The review should include their findings, any direction given and documentation.
c. After review, results will be retained in the CAP survey binder with the other proficiency test results.
d. Reports will be reviewed by the Medical Director/designee.
e. There will be no communication regarding results of the external specimens until all results have been received and reviewed by the Medical Director/designee.
f. This applies to both waived and nonwaived tests.
g. Semiannual (twice a year) APA must be performed.
h. A list of tests defined by the laboratory as requiring APAs must be completed yearly. See attached form. “Alternative Performance Assessment (APA) Test List”
i. **Testing Process**:
   1) Appropriate number of samples will be collected. A variety of values is desirable, if available.
   2) These samples should be free of substances that interfere with the analyte being tested.
   3) Samples should be analyzed at the initiating laboratory and then split and analyzed at the other laboratories on the same day, if possible, to eliminate any variable of deterioration.
   4) Samples can be sent by the laboratory courier system, at an appropriate transport temperature for the analyte being tested, to Royal Oak, Grosse Pointe, Troy or Farmington Hills.
   5) Samples going to a reference laboratory for testing, should be sent at the appropriate temperature to ensure that testing will be performed by the reference laboratory. Improperly shipped samples may be rejected.
   6) Downtime labels may be used to identify alternate proficiency testing samples, if needed.
   7) Each laboratory performing testing will complete the included testing form and return the results to the initiating laboratory.

7. **Cease Patient Testing**
   a. If the laboratory was instructed by the CAP to cease patient testing for an analyte or subspecialty due to repeat unsuccessful proficiency testing, lab records will demonstrate that no patient results were released until after the lab received approval from the CAP to resume patient testing.
   b. To resume patient testing, the lab must meet the conditions that are outlined in the cease patient testing notification.
   c. There must be evidence of compliance of the following:
      1) There must be records of communication notifying staff and physicians that testing is suspended for a required period OR
      2) LIS report verifying that no patient results were reported for the affected analyte or subspecialty during the cease testing frame OR
      3) Patient reports indicating name and address of lab where testing was performed during the affected period OR
      4) Send out log to referral lab.

6. Revisions

Corewell Health reserves the right to alter, amend, modify or eliminate this document at any time without prior written notice.

7. Procedures Superseded and Replaced: This procedure supersedes and replaces the following procedures as of the effective date of this procedure: [33337 Corewell Health East - Laboratory Proficiency Testing Procedure - Grosse Pointe & Troy]

8. References

A. College of American Pathologists (CAP) All Common Checklist, current edition
B. College of American Pathologists (CAP), Laboratory General Checklist, current edition.

9. Policy Development and Approval

Document Owner:
Laura Judd (Operations Specialist)

Writer:
Tracie Rusicka (Operations Specialist)

Reviewer(s):
Deanna Long (Medical Technologist Lead), Edgar Chawan-Martinez (Medical Technologist Lead), Ghada Hawasli (Medical Technologist Lead), Joseph Zatkoff (Medical Technologist Lead), Karrie Torgerson (Medical Technologist Lead), Michelle Moy (Medical Technologist Lead), Nicole Owens (Medical Technologist Lead), Paul DeRonne (Medical Technologist Lead), Rachel Eikenberry (Medical Technologist Lead), Susan Pelley (Medical Technologist Lead), Udayasree Bartley (Medical Technologist Lead)

Approver(s):
Elzbieta Wystepek (Dir, Laboratory Services), Hassan Kanaan (OUWB Clinical Faculty), Jennifer Yaker (Mgr, Laboratory), John Pui (Chief, Pathology), Kelly Walewski (Mgr, Laboratory), Kristin Russell (Mgr, Laboratory), Laura Judd (Operations Specialist), Masood Siddiqui (Staff Pathologist), Ryan Johnson (OUWB Clinical Faculty), Sarah Britton (VP, Laboratory Svcs), Steven Mladenovic (Mgr, Lab Support Svcs), Subhashree Mallika Krishnan (Staff Physician), Teresa Lovins (Supv, Laboratory), Theresa Ross (Supv, Laboratory)

10. Keywords:

Not Set