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Laboratory Proficiency Testing

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

A. The purpose of proficiency testing (PT) is to promote optimal patient care by identifying significant differences between test results obtained by an individual laboratory and the true analytical value or identification based on expert referee analysis. Participation in College of American Pathologists (CAP) surveys allows outside evaluation of testing and promotes continued proficiency of the technical staff. The laboratories endeavor to enroll in surveys with analytes matching those for which the laboratory performs patient testing. Any unacceptable evaluation must be followed up with documented corrective action.

II. GENERAL INFORMATION:

A. Proficiency testing specimens must not be referred to other laboratories and are not accepted from other laboratories for analysis.

B. The laboratory integrates all PT testing and alternative performance assessment specimens within the routine laboratory workload, where applicable, and those specimens are analyzed by personnel who routinely test patient/client specimens, using the same primary method systems as for patient/client/donor specimens.

C. Repetitive analysis of any proficiency specimen by one or more individuals is acceptable only if patient/client specimens are routinely analyzed in the same manner. With respect to morphologic examinations (identification of cell types and microorganisms; review of electrophoretic patterns, etc.), group review and consensus identifications are permitted only for unknown specimens that would ordinarily be reviewed by more than one person on an actual patient specimen.

D. Laboratories that are subject to regulation by the Centers for Medicare and Medicaid Services

(CMS) are not permitted to test the same analyte from the same PT product on more than one instrument or method unless that is how the laboratory tests patient specimens and laboratory procedures are written to reflect that process.

E. The laboratory may not refer a proficiency testing specimen to a laboratory with a different Clinical Laboratory Improvement Act (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. Rather, the laboratory must submit a PT result of "test not performed" since the review does not occur within the referring laboratory.

F. Interlaboratory communication about proficiency testing samples before the deadline for submission of data to the proficiency testing provider is prohibited. PT challenges will NOT be disseminated to all lab staff until after the deadline for submission of results to the provider.

    1. 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.

G. Based on Centers for Medicare and Medicaid Services (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 only one of these methods (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. 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.

H. The CAP surveys are approved by the Centers for Medicare and Medicaid services (CMS), 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.

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

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

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

    1. In the event proficiency testing is used for educational purposes student testing of proficiency testing specimens can only be run AFTER the final date of submission.

L. PT records must not be shared with and should be inaccessible to personnel of other laboratories, including an affiliated laboratory until after the deadline for submission of results.

Laboratories that share a common computer system or personnel must have strict policies and procedures to ensure that personnel do not access proficiency testing records from other laboratories. Departments utilizing the LIS for ordering/resulting must use unique names and identifiers to prevent accidental discovery.

M. **Neonatal Bilirubin Proficiency Testing**

1. Proficiency testing materials with assigned reference values are used for testing at least annually to meet the College of American Pathologists (CAP) CHM.13810 standard:
    a. Neonatal bilirubin results in the range of 5 to 25 mg/dL are accurate and suitable for use with standardized clinical practice interpretive guidelines, with accuracy verified at least annually.

III. PROCEDURE:

A. **Receiving the Proficiency Testing Kit:**

1. When the survey is received, it is given to laboratory management or designee. The date of receipt is recorded on the packing slip and/or kit instructions. The survey specimens are inspected for sample integrity. Store specimens according to requirements stated in the survey instructions.
2. Notify CAP if specimens are not acceptable. Schedules of the yearly arrival dates of CAP specimens are provided by CAP and distributed to section management. In the event that a shipment does not arrive as expected (within 3 days of scheduled arrival), laboratory management or designee will contact CAP.
3. The survey instructions may need to be used by more than one technologist. Photocopies are made. They are then given to the technologists working in the section pertaining to each assay.
4. Check the listed analytes to determine which areas of the laboratory needs to analyze the samples. Arrange to have specimens analyzed for the constituents tested in the area of responsibility.
5. Read all kit information and instructions included in the test survey kit carefully to avoid errors. The survey kit contains instructions and specimens for analysis. Check the contents of the kit against the instructions.
    a. If the kit is incomplete or contains broken 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.
6. Results must be submitted to CAP by the due date indicated on the CAP website.
7. A Blank Result Form may be printed from the CAP website to record the results before entering them on the website.

B. **Analysis of PT Specimens:**

1. Survey testing is rotated among employees that perform the testing. The employees assigned a proficiency testing sample carefully read and follow the directions given

in the instructions. Check that testing is performed on the correct specimen vials.

2. Prepare specimen according to instructions for Proficiency Testing as recommended by CAP.
3. Perform all necessary Quality Control (QC) and maintenance prior to testing as for patient runs.
4. The specimens are then tested in the same manner as patient specimens within the routine workload using the same primary method systems as for patient/client samples. The defined laboratory rechecks are followed where specified for patient samples.
    a. 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.
5. Transcribe the results to the result form. For those specimens that have direct instrument readout have the readout accompany the form.
    a. In the event proficiency testing is used for educational purposes student testing of proficiency testing specimens can only be run AFTER the final date of submission.
6. Attach the instrument printouts, quality control results and result form together and return them to the department supervisor. The supervisor or designee will review for clerical errors, correct methodology, and completeness.
7. Perform calculations as routinely required for each test and according to CAP instructions.
8. Place the remaining samples of the proficiency kit in the appropriate storage area in case it is needed for retesting. (Most samples can be frozen).
9. **Records of the proficiency testing - instrument printouts, raw data must be kept for eight years.**
10. The proficiency testing attestation statement must be signed (physical or electronic signature) by the laboratory director or qualified designee as per the attached Laboratory Designee Table for Proficiency Testing, and all individuals involved in the testing process.

C. **Reporting of Results:**

1. A copy of the completed report form is made and retained in the department.
2. The result form is entered electronically by management or designee.
3. 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.
4. Laboratories should 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.

5. 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.

   f. Under the "Data" Column, Click on the "Enter Data" field. This will open the PDF document form to enter your results.

   g. Verify that the method codes, instrument codes and units of measure are correct for each analyte you are resulting. Using patient reports or manual worksheets, enter the results for each analyte you are resulting.

   h. Save each page as you complete them.

   i. Once all pages are entered print a copy of the CAP result form.

   j. Verify all results entered on the CAP result form exactly match the results from the patient reports

   k. Data can be edited any time prior to the due date.

   l. Manual entries of results will be verified by at least 2 staff members and signed/initialed whenever possible.

   m. **Approve and Submit by Manager or designee:**

      i. 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.

      ii. The Blank Result Form (if applicable), and signed Attestation Form will be kept in the appropriate CAP Survey binder.

      iii. The survey kit instructions, 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.

iv. **Maintain documents for a minimum of 8 years.**

D. **Survey Result Evaluations:**

1. When the survey evaluation is returned, it is reviewed by the Medical Director, section Medical Director, or designee with appropriate corrective action taken for each unacceptable result..
2. Review evaluation, including educational challenges and challenges that were not graded due to lack of consensus.
3. Results should be investigated that, although acceptable, show bias or trends.
4. Each unacceptable PT or alternative performance assessment result (any result or specimen not meeting defined acceptability criteria) must be evaluated in a timely manner to determine the impact on patient test results and correct problems identified.
5. For results that were not graded due to lack of consensus, results submitted after the cut-off date, results not submitted, or result form not correctly completed such as submitting the wrong method code or recording the result in the wrong place, performance must be accessed by performing a self-evaluation.
6. Using the CAP evaluation booklet, compare results to those of similar methods/ instruments. The Medical Director or designee will determine if the submitted results are acceptable when compared to the peer group. Any analyte, graded or ungraded falling outside acceptable limits must be investigated:
    a. Review for clerical errors.
    b. Review reporting units.
    c. Repeat analysis if specimen is available.
    d. Review of control, calibration, and instrument function records.
    e. Review of previous survey results.
    f. Review of methodology.
    g. Review if patient results were affected.
7. Document investigation and corrective action on Survey Corrective Action Report. Attach survey corrective action report to survey report.
8. Complete evaluations **WITHIN 60 DAYS OF RECEIPT**. Exceptions may be necessary if the section is waiting for feedback from a manufacturer.
9. If you do not receive a copy of an evaluation report within sixty days after submitting your response, contact a Surveys Coordinator to prevent the generation of a Surveys Exception Report (SER).
10. Report any transcription errors to CAP immediately.
11. Review the evaluation report and follow up corrective action, if any, with the Medical Director or section pathologist. The corrective action report must be signed by the:

a. Testing personnel if applicable
b. Manager/Supervisor/Designee
c. Medical Director
d. Administrative Director

12. File the evaluation report in the CAP Survey book.
13. **Keep evaluation reports for 8 years.**
14. An exception report will be generated for and analytes falling below the 80% acceptable limits. Fill out the report including:
    a. How you investigated the problem.
    b. Your conclusion as to the cause of the unacceptable result.
    c. Specific corrective action taken to prevent recurrence.
    d. Evidence that the problem was successfully corrected.
    e. The signature of the Medical Director.
    f. Attach supporting documentation such as quality control data from the day of the analysis or calibration and instrument service records when appropriate.
    g. A copy of this documentation may be requested during the next on-site inspection.

E. **Escalation Process for Proficiency Testing (PT) Failures of CLIA-Regulated Analytes/ Subspecialties/Specialties:**

1. **Unsatisfactory PT performance -** Failure to attain at least 80% for a regulated analyte/ subspecialty/ specialty (ABO, Rh, and Compatibility Testing requires 100%). Clerical errors or data omissions are considered unsatisfactory PT performance.
    a. These must be investigated, and documentation of corrective action must be maintained by the laboratory for inspection purposes.
2. **Unsuccessful PT performance -** Unsatisfactory PT performance in 2 consecutive or 2 out of 3 testing events. Unsuccessful PT performance and unsuccessful PT participation are interchangeable/equivalent.
    a. Requires the laboratory to complete and return a Proficiency Testing Compliance Notice (PTCN) response form to the CAP, documenting corrective action taken to prevent further PT failures.
3. **Repeat unsuccessful PT performance (Cease Testing)-** Unsatisfactory PT performance in 2 sets of 2 out of 3 testing events over the most recent 12 PT events (4 years) for a CLIA regulated analyte, subspecialty, or specialty.
    a. Requires that the laboratory cease patient/client testing for the regulated analyte/ subspecialty/ specialty for a period of 6 months.
4. **Cease Patient Testing for Repeat PT Failures:**
    a. If the laboratory is instructed by CAP to cease patient testing, for an

analyte or test due to repeat unsuccessful PT testing, the laboratory will do so.

b. Patient testing will not resume until after the laboratory has received approval from CAP to resume testing.

5. **Cease Testing Reinstatement Requirements:**
    a. Laboratories with repeat unsuccessful PT performance for a regulated analyte/ subspecialty/ specialty will be required to cease patient/client testing for that test. Per CLIA, cease testing will be enforced for 6 months.
        i. **Before the laboratory can resume testing, it must:**
            a. Determine the reason for the PT failures.
            b. Determine whether patient results were impacted by the PT failures and take appropriate action if patient results were affected.
            c. Develop and implement a corrective action plan to prevent future PT failures.
            d. Perform 2 events of successful reinstatement PT.
            e. Submit to the CAP appropriate documentation such as:
                i. Investigation report
                ii. Corrective action plan
                iii. Patient impact analysis
                iv. Retraining documentation
                v. Evidence on how the laboratory will ensure patient/client results are not reported during the cease testing period
                vi. Observe the CLIA-mandated 6 month cease testing period Performing patient/client testing during a cease testing period may result in an adverse action against the laboratory's accreditation status.
    b. Note: If the regulated test is performed in more than one area or by more than one method in a single CLIA/CAP number, the cease testing directive applies to all areas and methods performing the regulated test.

6. **Proficiency Testing Compliance Notice (PTCN)**
    a. The Laboratory 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 non-participation in PT are all considered PT failures.

b. An email will be sent to your laboratory to the laboratory director, quality contact, and PT monitoring contact. The email will include links to the PTCN Dashboard page where you will be able to see the newly cited PTCNs.

c. PTCNs requiring a formal response will be denoted with a status of **Ready for Response** on the PTCN Dashboard

    i. Responses to PTCNs can be completed in CAP's e-Lab Solutions Suite. This online process enables Labs to enter responses and upload supporting documents as well as:

        a. View all performance and non-participation PTCNs online

        b. Assign designated staff in your laboratory to review and respond to a non-participation or performance PTCN

        c. Allow the Laboratory Director to review and approve responses prior to submission

        d. Request an extension online for the return of your response to the CAP if more time is needed.

d. The completed response and all supporting documentation must be filed in the appropriate CAP Binder. This documentation will be reviewed during the next onsite inspection.

Attachments

Dearborn Laboratory Designee Table for Proficiency Testing

Laboratory Designee Table Proficiency Testing - Wayne & Canton

Laboratory Designee Table Proficiency Testing- Taylor Trenton

Proficiency Testing Corrective Action Documentation

Approval Signatures

Step Description	Approver	Date
Medical Directors	Muhammad Arshad: Chief, Pathology	4/11/2024
Medical Directors	Jeremy Powers: Chief, Pathology	4/9/2024

Policy and Forms Steering Committee Approval (if needed)	Kimberly Cole: Spec, Operations	3/25/2024
Site Laboratory Leaders	Christopher Ferguson: Mgr, Laboratory	3/19/2024
	Kimberly Cole: Spec, Operations	3/18/2024

Applicability

Dearborn, Taylor, Trenton, Wayne

Beaumont HEALTH

Beaumont Laboratory
Dearborn

Dearborn Laboratory Designee Table for Proficiency Testing

Laboratory Section	Designee
Chemistry	Stephanie Mullins, Supervisor Michelle Alexander, Medical Technologist Lead
Serology/Immunology	Stephanie Mullins, Supervisor Michelle Alexander, Medical Technologist Lead
Hematology/Coagulation/Urinalysis	Helga Groat, Supervisor Lillian Reid, Medical Technologist Lead
Microbiology	Vacant, Manager Julie Backus, Medical Technologist Lead Migena Haldeda, Medical Technologist Lead
Transfusion Services	Kelly Sartor, Supervisor Dr. Jeremy Powers Melissa Bajcz, Medical Technologist Lead
Point of Care Testing	Stephanie Mullins, Supervisor Rina Patel, Medical Technologist Lead Avani Shah, Medical Technologist Lead Sara Hermiz, Medical Technologist Lead Aliaa Alnasiry, Medical Technologist Lead Jessica Czinder, System Manager