Beaumont

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Proficiency Testing Procedure

Document Type: Procedure .

I. PURPOSE AND OBJECTIVE:

A. Purpose: This procedure applies to all testing processes or procedures that require proficiency testing.

B. Objective: Proficiency testing (PT) serves as an evaluation of the laboratory as a system and the test results that are the final 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.

II. GENERAL INFORMATION:

A. Each section in the Department of Clinical Pathology participates in an approved external PT program, accepted by the College of American Pathologists (CAP), and appropriate for the extent and complexity of testing performed in that laboratory. An alternative mechanism for verifying the accuracy and reliability of test methods for which there are no surveys available has been established and is defined in the section policy manuals. This alternate performance assessment is exercised at least semi-annually.

B. Inter-laboratory communication about PT samples before the deadline for submission of lab results to the PT provider **is prohibited**. PT challenges will NOT be disseminated to all lab staff until after the deadline for submission of results to the provider.

C. **Proficiency testing 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 must take appropriate steps to ensure that records are not readily accessible by other laboratories.**

D. Based on the 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). In order to verify that other methods/instruments are producing equivalent results, the following should be considered:

1. Perform internal method/instrument comparisons that satisfy CAP inspection 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.

E. It is strictly **prohibited** to refer PT specimens to an outside laboratory for testing or to accept PT from another laboratory; this includes other Beaumont Laboratories with different CAP numbers

F. In order to ensure PT sample integrity, it is expected that each laboratory section will expedite testing turn-around time. However, it is understood that specific analyte testing may not be performed daily and that PT sample analysis would be performed on the next routine testing day after receipt of the sample(s). CAP considers proficiency sample analysis to be one of the elements that can be used for competency assessment. Therefore, where appropriate and after the result submission deadline, PT samples may be distributed across shifts to maximize rotation opportunity for technologist participation

III. DEFINITIONS:

A. **Designee:**

1. Medical technologist level: Manager, medical technologist lead, or assigned medical technologist
2. Physician: Medical director of section, assigned pathologist, and/or technical director (medical technical director).

B. **Section Group**: A minimum of two medical technologist-level designees and two physician-level designees selected by each section.

C. **Support Team:** Clerk and two designated secretaries.

IV. SURVEY RECEIPT AND PROCESSING:

A. Support Team

1. Stamp survey with date of receipt. Indicate designee's name on survey and Support Team's initials. Define and record return due date on survey and Survey Log.
2. Deliver survey to appropriate lab section and obtain signature of receipt on Survey Log.

B. **Manager/ Designee**

1. Review the entire survey instruction section for special handling, methods, unit of measure, and reporting issues.
2. Distribute the survey specimens to the appropriate areas of the laboratory. **NOTE**: It is the responsibility of this designee to notify the support team if any activity occurs that may change the due date of the survey.
3. Where appropriate use the Laboratory Information System (LIS) system to order PT sample testing and print labels. Each laboratory section should have a procedure describing the process for PT sample labeling. Appropriate steps should be taken to ensure that results are not readily accessible to other labs in the Beaumont system.

C. **Technologists**

Treat PT specimens as any other patient specimen. The laboratory integrates all PT samples into the section's workload. These samples are analyzed by personnel who routinely test patient samples using the same primary methods used for patient samples.

1. Prior to analyzing any specimens, including PT samples, it is expected that the technologist:
   a. Reviews assay calibration dates to verify validity and recalibrates the assay if indicated.

b. Runs all appropriate quality control (QC) material and reviews results across all operating instrument platforms to ensure consistency of QC data.

2. Verify specimen identification by both survey label name and LIS label number (if used).
3. Analyze survey samples, where appropriate, using the barcode labels/ numbers. If indicated by normal patient analysis procedures, dilute and/or repeat samples using a fresh aliquot. If repeating the test, re-verify sample ID using the survey label name and LIS barcode label/number (if used)
4. If ordered in LIS, verify / release results in LIS system.
5. For abnormal results or problem specimens, as with patient specimens, refer to manager as necessary.
6. Sign survey result form (attestation statement required).
7. Provide the following items to the designee or manager:
   a. All QC associated with results
   b. Copy of current or new calibration data.
   c. All instrument printouts of results.
   d. LIS report form.
   e. All manual work cards/sheets
   f. Signed survey result form (attestation statement).

D. **Manager/Designee:** Follow these steps as appropriate for your section:

1. Where appropriate, review calibration date and data for acceptability.
2. Review QC records associated with survey results.
3. Review instrument printouts for result verification and LIS report (if used).
4. Review results for appropriateness of offset factors, dilutions, and repeat correlation.
5. Review method sheet to ensure proper method is being reported.
6. Review units of measure to ensure appropriate units are reported.
7. Record results into the CAP database online. Do not verify results at this point.
8. Print the results from the CAP database and use a two-person read-back method to check transcribed results between run data and CAP database printout. The read-back method can be performed with a technologist, manager, section medical director or biomedical staff member.
9. If the two-person read-back was not done with the section medical director or technical director member, the completed result form and support documents should still be reviewed by one of those individuals.
10. **NOTE:** Each department will determine if the medical director prefers to receive all results at once or to review as they are completed due to procedure schedule issues.

E. **Section Medical Director or Technical Director**

This review may have been completed as part of the two-person read-back method as described above. If not, the section medical director/technical director should:

1. Review instrument printouts for result verification and LIS report.
2. Review results for appropriateness of offset factors, dilutions, and repeat correlation

3. Review method sheet to verify proper method is being reported.
4. Review units of measure to verify appropriate units are reported.
5. Review transcribed results, method codes, and units of measure.
6. Sign reviewed/completed result form. (The Clinical Pathology Medical Director or qualified designee and all individuals involved in the testing process must sign the PT Testing Attestation statement.)
7. Return report form and all paperwork to the section manager/designee.

F. **Manager/ Designee**

1. Verify and release all results in the CAP database for submission.
2. Print the CAP's "Received Notification." Attach to paperwork.
3. File all paperwork for future reference.
4. Maintain document for a minimum of 2 years.

V. INCOMING CAP SURVEY EVALUATIONS / RESULTS:

A. **Support Team**

1. Stamp the survey with the date of receipt. Indicate designee's name on front cover.
2. Deliver original evaluation to section manager/designee on the day received.

B. **Manager/Designee/Section Medical Director/Technical Director**
There must be ongoing evaluation of PT and alternative assessment results. Appropriate corrective actions must be taken for each unacceptable result.

1. Review evaluation, including educational challenges and challenges that were not graded due to lack of consensus. It is recommended that the laboratory investigate acceptable results that show significant bias or trends. Document this investigation on the evaluation report, and document review on the form, next to these results. If a more comprehensive investigation is necessary, instead of writing information on the evaluation report, a separate report may be written and signed.
2. If results are acceptable, the report should be signed by the appropriate manager, designee and the technical director and/or the medical director.
3. If any results need an explanation (e.g. lack of consensus), add hand-written comments to the report.
4. If any result(s) is/are considered unacceptable by the PT provider, complete a detailed investigation. Document the following and prepare a written report. The written report should be signed by the section manager, designee (if appropriate), and section head. It should then be submitted to the Medical Director, Clinical Pathology for final review and signature, and be filed by the Quality Assurance Coordinator.
    a. Detailed investigation of the problem.
    b. Conclusion as to the cause of the incident.
    c. Specific corrective action taken to prevent recurrence of incident.
    d. Evidence that the corrective action resolved the problem.
    e. Supporting documentation.

5. NOTES

   a. *Each laboratory section should have criteria for proactively reviewing suspicious results which may be indicative of potential issues, even though they are not considered "unacceptable" by the PT provider. Examples may be results >3 SDI, trending to 1 side of mean, etc. Such investigations should be documented and reviewed/signed by the medical director. If a significant problem is identified, the report should also be referred to the Medical Director, Clinical Pathology.*

   b. **Complete evaluations WITHIN 60 DAYS OF RECEIPT.** Exceptions may be necessary if the section is waiting for feedback from a manufacturer.

VI. CEASE PATIENT TESTING FOR REPEAT PT FAILURES:

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

A. **Clinical Pathology Medical Director**

   1. Review the evaluation form and corresponding responses for appropriateness.
   2. When the evaluation/documented responses are approved (i.e. signed), forward all survey documents to the Support Team.

B. Support Team

   1. Make a complete copy of all survey documents and distribute to the section manager within three days of receipt.
   2. Send all original survey documents (when signed/final) to the Quality Assurance Coordinator for filing.

VII. REFERENCES:

A. College of American Pathologists *Laboratory General Checklist*, current version.

B. Accreditation Requirements when a PT Result is Linked to a Non-Graded Exception Code, Laboratory Accreditation Manual, current version, College of American Pathologists, Northfield, IL.

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
	Peter Millward: Chief, Clinical Pathology	3/10/2020
Policy and Forms Steering Committee Approval (if	Jennie Green: Mgr Laboratory	3/10/2020

Step Description	Approver	Date
needed)		
	Brittnie Berger: Dir, Lab Operations C	3/10/2020
	Jennie Green: Mgr Laboratory	3/4/2020

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