Status **Active** PolicyStat ID **12213457**

Origination	9/11/2019	Document Contact	Kimberly Cole
Last Approved	8/17/2022	Area	Laboratory-Quality
Effective	8/17/2022	Applicability	Dearborn, Taylor, Trenton, Wayne
Last Revised	8/17/2022		
Next Review	8/16/2024		

Laboratory Proficiency Testing

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

A. The purpose of proficiency testing 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. Beaumont Health Laboratories endeavors 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.

B. When the survey is received it is given to laboratory management or designee. It is then dated upon arrival on the specimen container and on the data input form. The survey specimens are inspected for sample integrity. Store specimens according to requirements stated in the instruction sheet. 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.

C. The survey report form and 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.

D. The completed form must be returned to CAP by the due date indicated on the report form.

II. PROCEDURE:

A. 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.

B. Survey testing is rotated among employees that perform the testing. The employee receiving the survey carefully reads and follows the directions given on the survey form. Check that testing is performed on the correct specimen vials.

C. 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. Transcribe the results to the working survey form. For those specimens that have direct instrument readout have the readout accompany the working survey report.

    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.

D. Results are to be transcribed to the final survey report and/or entered online. After completing the form, proofread for clerical errors. Surveys entered online, should be printed, and proofed before the results are approved and released. The individual/s proofreading should sign and date.

E. Records of the proficiency testing - instrument printouts, raw data must be kept for two years.

F. The proficiency testing attestation statement must be signed 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.

G. Inter-laboratory communication about proficiency testing before the deadline for submission of data is prohibited. Accepting proficiency testing specimens from another laboratory for testing in our laboratory is prohibited. Sending proficiency specimens to a reference laboratory is also prohibited.

H. A copy of the completed survey report form is made and retained in the department.

I. The report form is entered electronically or faxed by laboratory management or designee.

J. When the survey evaluation is returned, it is reviewed by the Medical Director, section Medical Director, and section management. Review evaluation, including educational challenges and challenges that were not graded due to lack of consensus. Results should be investigated that, although acceptable, show bias or trends. 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 completed correctly such as submitting the wrong method code or recording the result in the wrong place, performance must be accessed by performing a self evaluation. 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:

    1. Review for clerical errors.
    2. Review reporting units.
    3. Repeat analysis if specimen is available.
    4. Review of control, calibration, and instrument function records.
    5. Review of previous survey results.
    6. Review of methodology.

7. Review if patient results were affected.

K. Document investigation and corrective action on Survey Corrective Action Report. Attach survey corrective action report to survey report.

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

M. 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).

N. Report any transcription errors to CAP immediately.

O. 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:

1. Testing personnel if applicable
2. Manager/Supervisor/Designee.
3. Medical Director
4. Administrative Medical Director

P. File the evaluation report in the CAP Survey book.

Q. Keep evaluation reports for 3 years. Transfusion Services reports, keep for 5 years.

R. An exception report will be generated for and analytes falling below the 80% acceptable limits. Fill out the report including:

1. How you investigated the problem.
2. Your conclusion as to the cause of the unacceptable result.
3. Specific corrective action taken to prevent recurrence.
4. Evidence that the problem was successfully corrected.
5. The signature of the Medical Director.
6. Attach supporting documentation such as quality control data from the day of the analysis or calibration and instrument service records when appropriate.
7. A copy of this documentation may be requested during the next on-site inspection.

Attachments

Dearborn Laboratory Designee Table for Proficiency Testing

Proficiency Testing Corrective Action Documentation

Taylor, Trenton, Wayne Laboratory Designee Table for Proficiency Testing

Approval Signatures

Step Description	Approver	Date
Medical Directors	Muhammad Arshad: Physician	8/17/2022
Medical Directors	Jeremy Powers: Chief, Pathology	8/17/2022
Policy and Forms Steering Committee Approval (if needed)	Kimberly Cole: Lab Quality Coord	8/16/2022
Policy and Forms Steering Committee Approval (if needed)	Gail Juleff: Project Mgr Policy	8/16/2022
Site Laboratory Leaders	Jennie Green: Mgr, Division Laboratory	8/16/2022
Site Laboratory Leaders	Amy Conners: Dir, Lab Operations A	8/16/2022
Site Laboratory Leaders	Kimberly Geck: Dir, Lab Operations B	8/16/2022
	Kimberly Cole: Lab Quality Coord	8/16/2022