

Procedure	Quality Management – Proficiency Testing
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Prepared by	Date Adopted	Supersedes Procedure #
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Review Date	Revision Date	Signature
7/8/07		<i>Brooks Jackson</i>

OBJECTIVE:

The goal of the Quality Management Program is to establish a structure that helps provide high quality laboratory services. This includes development of a system that provides for the continuous monitoring and evaluation of patient care activities within the Department of Pathology. Laboratory performance is evaluated in pursuit of these goals.

The department monitors pre-analytical, analytical and post analytical processes. A quality control system maximizes the quality of laboratory testing to produce the accurate and timely results needed in support of quality patient care. Functions periodically reviewed include policies, procedures, staffing, and personnel qualifications. Each is evaluated to include hospital and departmental goals. Because of the rapidly changing environment, goals and standards must be continuously reassessed.

POLICY:

Quality management is the continuing process whereby the laboratory ensures quality, maintains compliance with applicable laws, regulations and institutional policies, and pursues quality improvement activities.

The Department of Pathology focuses on quality defined in each of the following sections: Lab Structure and Function, Quality Assessment programs, and **Proficiency Testing**.

I. Proficiency Testing (PT)

The laboratory is enrolled and participates in a CMS-approved proficiency testing program for each test performed.

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- A. The Department of Pathology is enrolled in the College of American Pathology (CAP) proficiency program for most analytes. If a CAP survey is not available, an equivalent approved external survey provider will be used.
1. Appropriate CAP surveys are selected by each section of the department and ordered annually by the Pathology CQI Office.
 2. All PT surveys are delivered to the Pathology CQI Office, which assures that surveys are directed to the performing section of the department immediately.
 3. Performing area will note the due date for the survey and plan work accordingly.
 4. On the day the survey is processed, the proficiency samples will be treated as a routine specimen. Tests will be run by the technologist/technician assigned to the workstation. Survey specimens must be tested the same number of times that patient samples are routinely tested. Survey samples are not run in duplicate unless a routine specimen would be run in duplicate. Referral of PT samples for testing to a reference lab is prohibited, including confirmatory testing. Interlaboratory communication about PT samples before submission of data is prohibited.
 5. Test results of PT samples will be reviewed by the Supervisor, Quality Assurance Specialist or Technical Specialist of the areas or their designee and sent to the proficiency provider.
 6. Survey forms will be coded and returned on line or faxed in the required time frames. The attestation form provided by the PT program must be signed by the analyst and the Laboratory Director
 7. Supervisors, Quality Assurance Technologists, Technical Specialists or Lead Technologists will review PT result reports. Any reported deficiencies will be investigated and the corrective action resulting from identified problems will be documented.
 8. Survey results requiring comments, investigation, and corrective action will be reviewed, signed and dated by the appropriate Laboratory Director. Review and corrective action documentation is required for incorrect responses, failure to submit timely survey results, omissions, ungraded/educational results and transcription errors. When requested, investigation summaries will be sent to the Maryland Department of Health and Mental Hygiene Laboratory Licensing Program. Communication with the State is coordinated through the Pathology CQI Office.
 9. Complete PT records shall be kept in the performing laboratory department for two (2) years. Complete records include:

- a. Test handling, preparation, processing, instrument print outs, worksheets, results reported
 - b. Signed attestation statement provided by the proficiency provider
 - c. Problem or potential problem documentation and corrective action when indicated
 - d. Documented review of each proficiency report by the laboratory director
10. All survey results that are in compliance and do not require comments and investigation shall be reviewed and signed by the appropriate Laboratory Director.
11. The review shall also include investigation of any acceptable result showing trends suggestive of procedural problems. Ungraded challenges due to lack of peer consensus or educational challenges shall be reviewed for laboratory performance and the reported circumstances resulting in the lack of consensus.
- B. Alternative Proficiency testing for assays which are not found in CAP or equivalent external survey providers:
1. Each area will set up and document an alternative mechanism to assure the quality of the assay.
 2. This system will be used at least twice a year.
 3. Results of this alternative system will be documented, signed and dated by the Supervisor, Quality Assurance Specialist or Technical Specialist. Any deficiencies will be investigated and the corrective action resulting from identified problems will be documented.
 4. The Faculty Laboratory Director or designee will review and sign all documentation.

REFERENCES: GP26-A2 Application of a Quality System Model for Laboratory Services; Approved Guideline (2003), 2nd Edition. NCCLS

Valenstein, P. (Editor) *Quality Management in Clinical Laboratories: Promoting Patient Safety Through Risk Reduction and Continuous Improvement*. Northfield, Illinois: College of American Pathologists; 2005.