Administration Policies and Operational Procedures

Title: **Proficiency Testing Policy**

Department: Laboratory Medicine Administration

Subject: Proficiency testing

Policy Number: 100.004.008

Effective Date: August 12, 2003

Policy:
All clinical testing performed in the UW Medicine Department of Laboratory Medicine must be enrolled in an accredited proficiency testing, PT, program (such as the College of American Pathologists, CAP) whenever such testing is available. The list of analytes for which CAP requires proficiency testing is available on the CAP website [http://www.cap.org/]. Alternative providers of materials for these regulated analytes must be approved by CAP. For regulated analytes, if the CAP and CAP-accepted PT programs are oversubscribed, it is required that the laboratory to attempt to enroll in another CMS-approved PT program.

Whenever such testing is not available, alternative performance assessments (biannual verification) must be performed. The division responsible for that area of testing will determine the most effective procedure to ensure that this quality assurance activity is performed using CAP PT requirements as the basis for each determination.

All clinical testing performed in the Department of Laboratory Medicine is appropriately described in each laboratory's College of American Pathologist (CAP) Activity Menu according to the policy established in CAP requirements. It is the responsibility of each site coordinator to assure that this menu is updated and current at all times. A review of the CAP site activity menu must occur at least annually. This review must be documented. A laboratory's participation in proficiency testing or alternative performance assessments must include all analytes on this list for which it performs patient testing.

Documentation for all steps should be maintained by the division responsible for that testing.

External proficiency testing program:
Specimens are to be handled and assays are to be performed as closely as is practical and in the same manner as regular, routine patient samples. It is acknowledged that some elements in this quality assurance process may require special handling due to the nature of some proficiency materials.

- No laboratory may refer any external proficiency testing to any other laboratory with a different CLIA number regardless of any existing policy for referring patient samples. This prohibition applies even if the second laboratory is part of the department of Laboratory Medicine or any affiliates. The proficiency testing result should be submitted as "test not performed" for any review or confirmation that does not normally occur within the performing lab.

- Proficiency testing specimens are not accepted from other laboratories for analysis. This prohibition applies even if the second laboratory is part of the department of Laboratory Medicine or any affiliates.

- Any and all communication, written, oral or electronic, concerning proficiency testing results is strictly prohibited between laboratories prior to the deadline for the submission of data to the proficiency-testing provider.

- No laboratory may run proficient testing materials on multiple instruments or shifts either within one division or between divisions within one CLIA license prior to submitting PT results unless patient samples with similar results would have been treated that way.

- The laboratory coordinator in consultation with the clinical divisions performs annual re-assessment and purchase of appropriate proficiency testing material.

- The most suitable materials containing appropriate proficiency testing will be chosen. Consideration is given to sample material, intent of evaluation material, and frequency of testing when the choice is made.

- If the laboratory (under one CLIA license) uses multiple methods for an analyte, proficiency samples must be analyzed by the primary method at the time of the PT event, or rotated among primary methods each PT shipment. Clinical laboratories are subject to CMS regulation and not allowed to order multiple PT kits for the purpose of testing the same sample/analyte on multiple instruments or methods prior to the due date for submitting results to the provider.

- Frequency of proficiency testing should be at least biannual.

- Samples for proficiency testing are received into individual divisions. The receiving division is responsible for the distribution of sample material and for the timely return/evaluation of results to proficiency testing provider for consensus assessment.

- Each reporting division must assure that any proficiency testing attestation statement are appropriately signed by the laboratory director or qualified designee and all individuals involved in the testing process.

- Specimens received in the laboratory are to be reconstituted, if necessary, strictly by the protocol in the accompanying survey kit instructions observing carefully any and all time and/or handling restrictions present.

- Testing that is entered into the LIS system for incorporation into normal patient workflow should use the flowing lab locations that are specific to each CLIA license.

MNE	Decription	CLIA #
HCAP	HMC CAP PT samples	50D0631627
UCAP	UWMC CAP PT samples	50D0631935
EVCAP	Eastlake CAP PT samples	50D0921396
HHCAP	Hall Health CAP PT samples	50D1020929
RCAP	Roosevelt Clinic CAP PT samples	50D0896226
HPCAP	Hematopathology CAP PT samples	50D1064286

- The required assay should be performed as outlined in normal division clinical procedures and evaluated according to the established policies for evaluation of patient testing.

- Proficiency testing should be performed with routine patient samples by a technologist normally scheduled for that assay using the same primary method systems as for patient samples.

- No special considerations should be accorded the samples through the assay process.

- It is acceptable to rotate PT samples across shifts and by different technologists as long as those shifts and staff are also responsible for resulting patient testing. It is recognized that proficiency testing can be an important part of competency assessment.

- All proficiency testing results are reviewed for acceptability according to established acceptance parameters. Documentation of this review is to be kept in the records of the division responsible for that area of testing.

- Proficiency testing performance is assessed on all external proficiency testing challenges that were not formally graded. Reasons for a proficiency challenge not being graded may include, but not be limited to, lack of consensus, late submission, or incorrect or unreadable form submissions.

- Results that are found to be unacceptable should be evaluated further. A written record is to be made of any additional evaluation and any corrective actions that have been or will be taken.

- Any corrective actions that have been taken in response to proficiency testing challenges should be documented in the division responsible for testing and review of all results.

- Records for testing should include all instrument tapes, work cards, computer printouts, if applicable as well as evaluation reports, evidence of review, and documentation of follow-up/corrective action

- Records of evaluation and results are to be kept for not less than two years in each division responsible for the testing. Specific requirements may be established for different periods of retention for some testing. It is the responsibility of each division to assure that all PT records, external or alternate methods, are kept for the required amount of time.

- Documentation for non-CAP proficiency testing material purchase must be kept in each division. Records can consist of items such as purchase orders or sample exchange agreements.

Alternative Performance Assessment System (biannual verification)

An alternative performance assessment system to determine the accuracy and reliability of analytic results of patient samples will be developed by the divisions responsible for the clinical testing in those areas when no external proficiency testing is available, such as CAP. A variety of alternative performance assessment methods may be used including, but not limited to, split sample analysis with reference or other laboratories, split samples with an established in-house method, assayed material, regional pools, clinical validation by chart review, or other suitable and documented means.

It is the responsibility of the laboratory director to define such alternative performance assessment procedures, as applicable, in accordance with good clinical and scientific laboratory practice.

- Participation in ungraded/educational proficiency testing programs also satisfies this requirement.

- Alternative performance assessment testing should be performed at least biannually.

- Standards for acceptability and assessment should be established prior to using any material for this purpose.

- The required assay should be performed as outlined in normal division clinical procedures and evaluated according to the established policies for evaluation of patient testing.

- Alternative performance assessment should be performed with routine patient samples by a technologist normally scheduled for that assay

- It is acceptable to rotate alternative performance assessment samples across shifts and by different technologists as long as those shifts and staff are also responsible for resulting patient testing. It is recognized that proficiency testing can be an important part of competency assessment.

- No special considerations should be accorded the samples through the assay process.
- Any and all communication, written, oral or electronic, concerning any proficiency testing results is strictly prohibited between laboratories prior to the evaluation of data by the division director or designee.
- The laboratory director, or designee, will review alternative performance assessment results for acceptability according to developed acceptance parameters. Documentation of this review is to be kept in the records of the division responsible for that area of testing.
- Any corrective actions that have been taken in response to this alternative performance assessment system should be documented.
- Records of evaluation and results are to be kept for not less than two years.
- No samples for alternate performance assessment should be referred to another laboratory for testing except as part of a potential evaluation after assessment of performance has been documented.
- Testing evaluation of results in all alternative performance assessments must be based on the work of the laboratory performing patient testing.

Division procedures can be in addition to any procedure, policy, or process described in this document but cannot countermand any conditions or prohibitions.

Each laboratory division is required to have written procedure(s) for the

1. Proper handling, analysis review, and reporting of proficiency or alternative assessment program 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
4. Assessing performance on PT challenges that were intended to be graded but were not for any reason.

Related documents:

1. List of analytes for which CAP requires PT testing: CAP website at http://www.cap.org
2. Proficiency Testing Tool box: CAP Accreditation Resources at CAP website (http://www.cap.org) through e-LAB Solutions Suite.

Revision History:

Version 2 - 8/9/05 – Revised to include specific sections for review of submissions not formally reviewed by external accredited programs.

Version 3 - 8/30/06 - Revised to include the words "the deadline for the submission" to bullet nine. Added "using the same primary method systems as would be used for patient testing" to bullet 6. Added last bullet to indicate the prohibition of the referral of proficiency testing to any other laboratory for testing.

Version 4 - 3/25/07 - V4 - Revised to include specific language regarding referral of PT testing to a lab with a different CLIA number. Bullet #10 under External proficiency testing program.

Version 5 - 5/8/11 – V5 Added bullet #11 to include specific language regarding a prohibition for intra-divisional running on multiple instruments, shifts or technologists unless normal patient procedures indicate such actions.

Version 6 - 5/30/13 – V6 – Added policy and responsibility for CAP test Activity Menu in the policy section. Added bullet # 6 regarding attestation. Added provision for use of PT materials for competency purposes. Added specific language to require divisions to have written procedures. Added related document section. Rearranged bullet order and clarified language to emphasize the existing prohibitions regarding communication or exchange of materials between labs.

Version 7 – 5/31/15 – Removed Children's Virology from list of Cap sites. Replaced Phyllis Daum with Tammy Tam as the process owner

Version 8 – 7/12/2017 – Revised frequency of CAP site activity menu review. Added bullet #2 prohibiting PT acceptance from other labs. Updated PT requirements for multiple methods on same analyte. Updated attestation statement requirement. Removed ", or designee," from the responsibility to define alternative performance assessment procedures. Updated "related documents" with the latest CAP PT resources. Corrected some random typos. Updated the "authorized by" to Dr. Geoffrey Baird.

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Process Owner: Wing Yan (Tammy) Tam Laboratory Coordinator Date: 7/17/17

Authorized by: Dr. Geoffrey Baird, M.D., Ph.D., Chairman, Laboratory Medicine Date: 7/14/17