Administration Policies and Operational Procedures

Title: **Proficiency Testing Policy**

Department: Laboratory Medicine Administration

Subject: Proficiency testing

Policy Number: 100-04-05

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 program (such as the College of American Pathologists, CAP) whenever such testing is available. Whenever such testing is not available, 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.

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.

- The laboratory coordinator in consultation with the clinical divisions performs annual re-assessment 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.
- 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.
- 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.
- 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.
- 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 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" since the review does not normally occur within the referring lab.

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

- 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 of evaluation and results are to be kept for not less than two years in each division responsible for the testing.

Alternative Performance Assessment System

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.

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

- 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

- 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 proficiency testing should be referred to another laboratory for testing. Testing results submitted to CAP must be the work of the laboratory that is enrolled in that survey.

Revision History:

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

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.

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.

5/9/11 – 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

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