Proficiency Testing Policy

Purpose: This policy has been developed to meet the Clinical Laboratory Improvement Amendments (CLIA) Conditions 493.801 (Condition Requirement for Enrollment and Testing of Samples) and 493.803 (Condition Requirement for Successful Participation) and Standard 493.1236 (Standard Requirement for Evaluation of Proficiency Testing Performance).

Principle: CLIA requires that a laboratory enroll in a Centers for Medicare and Medicaid Services (CMS)-approved proficiency testing (PT) program for the specialties and subspecialties for which it is certified. In addition, the laboratory must show successful participation in a PT program as defined by obtaining a score of at least 80%.

1. Enrollment and Testing of Samples

1.1. The Ohio Department of Health Laboratory (ODHL) will enroll in a CMS-approved PT program for each specialty and subspecialty under the CLIA certificate.

1.2. The ODHL will notify Health and Human Services (HHS) of the approved program or programs in which it chooses to participate to meet this requirement.
  1.2.1. This requirement is met when the CMS-approved PT program transmits the laboratory enrollment to the CMS PT monitoring system.

1.3. Should an assay not be available from a CMS-approved PT program, the ODHL will establish and maintain the accuracy of its testing procedure. This may be accomplished by alternative approaches such as:
  1.3.1. Saving known positive and negative samples and preparing in-house PT samples;
  1.3.2. Splitting patient samples and sending a portion to a reference laboratory and comparing the results; or
  1.3.3. Sharing known specimens with regional laboratories.
  1.3.4. The PT must take place twice annually.

1.4. See the "Procedure for Receipt of Proficiency Testing Specimens" for guidance on the receipt of proficiency testing samples.

1.5. All PT samples are tested in the same manner as patient samples.

1.5.1. The samples must be examined or tested with the regular patient workload by personnel who routinely perform the testing in the laboratory, using routine methods.

1.5.2. The individuals testing or examining the samples and the laboratory director must sign an attestation form that the samples were integrated into the patient workload using routine methods.

1.5.2.1. The signed attestation form must be provided to the section supervisor (along with the PT results) for review and approval before final submission of results to the PT agency/laboratory.

1.5.3. The PT samples are tested the same number of times as routine samples.

1.6. The ODHL will not engage in any inter-laboratory communications pertaining to the results of the PT samples until after the date by which the PT results must be reported to the PT agency /laboratory.

1.7. No PT samples or portions of samples will be sent to another laboratory for analysis.

1.7.1. If another laboratory sends a PT sample to the ODHL, notification must be made to CMS.

1.8. Residual PT samples will be saved to assist with troubleshooting any failed PT challenges, as applicable.

1.8.1. Upon successful PT performance or completion of troubleshooting, residual samples may be utilized for training, competency assessment, or verification/validation studies.

2. Evaluation of Proficiency Testing Performance

2.1. The laboratory director or a designee will assess the performance of the PT challenges (including ungraded challenges because of lack of consensus) upon receipt from the PT agency/laboratory.

2.2. Once the laboratory director or designee has reviewed and signed the PT results, copies are provided to the appropriate supervisor for review.

2.2.1. All staff trained in the assay will review the PT results and acknowledge review.

2.2.2. Original signed documents are placed in that year's survey binder and maintained by the laboratory director or designee.

2.3. Failure of a PT challenge will result in an investigation and corrective action, as applicable.

2.3.1. The section supervisor is responsible for the corrective action (using the "Proficiency Test Corrective Action form").

2.3.2. All corrective actions will be documented within one (1) month after the results have been received and reviewed unless an exemption has been provided by the laboratory director.

2.3.3. Original copies of corrective actions are placed in that year's survey binder along with the signed PT result(s).

3. Record Retention

3.1. All documents related to PT challenges will be retained for a minimum of two (2) years.

4. References

4.1. CLIA Standard 493.801; Condition requirements for Enrollment and Testing of Samples
4.2. CLIA Standard 493.803; Condition requirements for Successful Participation
4.3. CLIA Standard 493.1236; Standard requirements for Evaluation of Proficiency Testing Performance

5. Related Documents

5.1. CLIA Procedure: Procedure for Receipt of Proficiency Testing Specimens
5.2. CLIA Form: Proficiency Test Corrective Action Form

Signature Approvals

QA Officer _____ Date 2/2/2015

Laboratory Director _____ Date 2/2/2015