Alternative Proficiency Assessment Policy
Each laboratory must provide a means to verify the accuracy and reliability of all testing performed. Laboratory analytes that are not evaluated or scored in a CLIA approved Proficiency Testing program must have a method to assess and verify the accuracy and reliability of test results.
At least twice annually, every six months, the laboratory must verify the accuracy of any test or procedure performed that is not included in a formal PT program. All evaluation and verification activities must be documented. The documentation and review of the assessments are to be retained in the laboratory for a minimum of two years as required by CLIA regulations.

A. Alternative Proficiency Testing Methods

1. The laboratory must review their test menu to verify that each analyte is included in some form of alternative assessment procedure if one is not available in a formal Proficiency Testing (PT) program.

2. Each laboratory must determine which method will be used to assess the analytes for which no Proficiency Test is available. Options are listed below:

   a. Duplicate / Split Sample testing-
      In which a single sample is divided into aliquots, where one aliquot is tested on a particular assay system or by a particular analyst, other aliquots are tested on other instruments or by other analysts and the results are compared.

   b. CLIA Certified Laboratory Comparison
      Every six months, the laboratory sends five specimens to a CLIA-certified reference laboratory to compare results with its own laboratory.
c. **Interlaboratory Quality Control comparison**
   Interlaboratory quality control results are used to verify the continuing reliability of the tests not included in the proficiency testing program (for example, peer comparisons).

d. **Microscopic Testing**
   The technical supervisor of the lab retests random samples throughout the year to cover all testing staff.

e. **Anatomical Pathology**
   1. Peer review of interpretation of slides
   2. Peer review at case level including diagnosis

3. The alternative assessments chosen should be documented in the procedure manual. Each laboratory must have procedures for evaluation of results and define the limits of acceptability for the performance.

4. The documentation of the assessments must be retained in the laboratory so that trends can be identified. Corrective action in response to unacceptable results must be documented.

**B. Alternative Proficiency Assessment Procedures**

One of the following methods may be used to assess each analyte not included in a formal PT program.

The laboratory should select a variety of test results and concentrations to assess if available. This variation will allow for a comparison of results over time.

1. **Duplicate / Split Sample testing**
   a. **Internal Split** - The procedure evaluates interlaboratory agreement and testing errors.
      i. Rerun patient sample by a different method or
      ii. For operator dependent testing, rerun testing using a different operator.

2. **CLIA Certified Laboratory Comparison**
   Every six months, the laboratory sends five specimens to a CLIA-certified reference laboratory for comparison of its own results. Aliquots of the samples may be sent to another laboratory for testing. For some analytes, in which limited samples are available, two samples/specimens per assessment are adequate.

3. **Interlaboratory Quality Control comparison**
   a. The assessment includes participation in peer comparison programs that evaluate quality control data submitted from multiple laboratories.
   b. Many manufacturers have such programs; which can be used as an additional quality assurance tool along with PT.
4. Microscopic Testing
   a. Reevaluation of morphologic analyses includes
      i. Review of glass slide by supervisory personnel
      ii. Or review of unknown glass slide sets with lab staff

5. Anatomical Pathology Peer Review process
   a. Each interpreter would have the same slide(s) and patient information available.
      The desired outcome is for each individual to arrive at the same or close to the
      same conclusion for each case.
   b. An alternative method can include the comparison of laboratory findings against
      the patient’s final diagnosis as determined by the attending physician.
   c. For Electron Microscopy the interpreter would focus upon comparing the
      interpretation of individual or groups electromicrographs.

6. Alternative PT provider from another country/region

7. Government or University Interlaboratory comparison program
   a. For some testing that is not widely offered but has an important public health
      function and only a small number of labs perform the test, a government or
      university reference lab may provide interlaboratory comparison programs. Ex.
      Genetic testing, inborn errors of metabolism, etc.

8. Analysis of Manufacturer’s Calibration material to confirm performance*
   a. The use of calibration material or other reference material which is provided by
      the method manufacturer is acceptable. The material must be traceable to a
      reference material or procedure. The material used for assessment should be of a
      different lot than that used for method calibration.
      *This method should only be used when no alternative is available.

C. Alternative Proficiency Assessment - Allowable Differences
   1. The director of each laboratory must determine the acceptable differences allowed when
      evaluating the results obtained using their alternate assessment method.

   2. The laboratories must agree upon the criteria for evaluation prior to the initiating of split
      sample testing. The agreement should include:
      a. test methods and number of tests to use
      b. criteria for determining agreement
      c. whether assessment will be at specific levels or across a range of levels
      d. how disagreements are to be resolved, which may include
         i. reruns by one or both labs
         ii. which lab will be considered the reference lab
         iii. whether to consult a third lab

D. Alternative Proficiency Assessment Documentation
   1. Each laboratory must maintain records of the test assessments for at least two years.

   2. The laboratory director must evaluate the test assessments and document the review with a
      signature and date.
3. A copy of the documented evaluation of the assessment and review shall be maintained in the laboratory and a copy forwarded to the Pathology CQI Office (Reed Hall 311) at its completion.

4. Any unacceptable findings in results must be investigated and documented and retained with the test results.

5. Records should be stored in chronological order for easy retrieval, recommend records be maintained along with other formal proficiency documents.

E. Example of Alternative Proficiency Documentation:

1. The laboratory can assess agreement across the range of results by plotting results on a two dimensional graph with the results from the reference lab on the X axis and the other lab on the Y axis. A line of perfect agreement is drawn in the body of the graph (Y=X).

2. Visual assessments of the graph should be used to identify trends or bias.

3. The assessment should be evaluated to detect any clinically significant changes.

4. Documentation of the review of analyte results indicating allowable range is acceptable or not acceptable.

5. Signed and dated by laboratory director

6. A copy of documentation is to be forwarded to the CQI Office fax #614-7475.

7. Retain all records of assessment for at least two years in an organized manner.

References:


JCAHO. Laboratory and Point of Care Testing Accreditation Standards, QC.1.60, 2004. pg.190.

NCCLS. Assessment of Laboratory Tests When Proficiency Testing is not AvailableGP29-A, NCCLS, 940 West Valley Road, Suite, 1400, Wayne PA 19078, 2002

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