Wake Forest Baptist Medical Center	**Proficiency Testing Procedure**	**Dept:**	**Pathology**
		Effective Date:	**June 2004**
		Revised Date:	**2/14/2020**
		Contact:	**Laboratory Compliance and QA**
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Signature: Electronically Signed			

General Procedure Statement: Scope: Defines the proficiency testing (PT) program to include the following areas: selection of approved PT materials for regulated analytes, appropriate handling of samples, sample analysis, results reporting, event results review and employee training/competency assessments. For purposes of photograph/image identification in CAP PT Programs, it is strongly recommended that current educational resources be available to the bench technologist. Examples include bench top resource guides, color atlases and glossaries provided as part of the survey.

It is the policy of the Department of Pathology and any other laboratory area performing lab testing subject to proficiency testing requirements under CLIA (Clinical Laboratory Improvement Amendments), to adhere to all proficiency testing standards or regulations of CLIA and/or other accrediting laboratory agencies such as: College of American Pathology (CAP), American Association of Blood Banks (AABB), American Society of Histocompatibility and Immunogenetics (ASHI), Commission on Office Laboratory Accreditation (COLA) and The Joint Commission (TJC).

a. **Responsible Department/Party/Parties:**
   i. Procedure owner: WFBH Department of Pathology
   ii. Procedure: WFBH Department of Pathology and Satellite laboratories.
   iii. Supervision: WFBH Department of Pathology, Pathology and Lab Medicine Directors and Section Managers.
   iv. Implementation:
   WFBH Department of Pathology Chair, named CLIA Laboratory Medical Director,Department of Pathology Administrative Director ,Pathology Lab Medicine Directors and Laboratory Compliance.

2) Definitions:

- **Regulated Analyte** – analytes that according to CLIA federal regulations require a laboratory to enroll in and successfully participate in a CMS approved proficiency testing program.

- **Unregulated Analyte** – analytes performed by a laboratory that are not included in the regulated listing found in the Federal Regulations Subpart I

3) Procedure:

a. Selection of Material

Regulated Analytes for which purchased PT materials are available*:*
If PT materials are available to be purchased for regulated analytes, then purchase is required vs. an alternative assessment.

- Annually (by December 1) all purchased PT materials for regulated analytes will be reviewed by Section Managers and Section Medical Directorsto ensure ALL tests performed are accounted for.
- PT providers may offer purchased materials for some unregulated analytes as well. If any areas choose to purchase these materials for unregulated tests they may do so at the same time. All purchased PT orders will be prepared by the Section Manager. After order forms are completed, they should be forwarded to Vickie Smith in Lab Administration. She will be responsible for processing the requests for payment and ensuring that each order is applied to the appropriate lab department for budget purposes. To be reviewed for accuracy and completeness once the orders are complete.

- ***Unregulated Analytes:***
  - All tests for which there is no PT materials available for purchase must still be evaluated at least biannually with an acceptable PT alternative.

    **For Predictive Marker proficiency testing and alternative performance requirements please refer to CAP Standard - COM.01520 for direction.

  - Acceptable alternative methods include:

    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 other instruments or by other analysts and the results are compared.

    CLIA Certified Lab to Lab Comparison
    Every six months, the laboratory sends five specimens to a CLIA-certified reference laboratory to compare results with its own laboratory.

    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).

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

Anatomical Pathology
- Peer review of interpretation of slides
- Peer review at case level including diagnosis

IHC and ISH Predictive Marker Assessment
The term predictive marker is used to refer to immunohistochemical (IHC) and in situ hybridization (ISH) tests used to predict responsiveness to a specific treatment independent of other histopathologic findings. Rather than confirming a specific diagnosis, these tests differentiate predicted responsiveness to a target therapy.

The following requirements for participation in proficiency testing or alternative performance assessment must be followed:

● HER2, ER, and/or PgR breast predictive marker IHC interpretation
Participation in CAP Surveys or CAP-accepted PT programs is required. IHC slides may be sent to another facility for staining only and be interpreted at the originating laboratory.

● HER2 breast predictive marker ISH interpretation
Participation in CAP Surveys or CAP-accepted PT programs is required, unless hybridization (ISH) is performed at a different laboratory (different CAP/CLIA number). If hybridization and interpretation are performed at different laboratories, the interpreting laboratory must perform alternative performance assessment at least semi-annually and must not participate in formal (external) PT.

● HER2 PT for breast predictive marker testing is method specific. Laboratories interpreting HER2 results performed by multiple methods must participate in the required PT or perform alternative performance assessment as described above for each method.

● Semi-annual alternative performance assessment is required for other predictive marker tests for which CAP does not require proficiency testing.

Examples of alternative performance assessment include but are not limited to:

i. Participation in a PT or external assessment program if available (e.g., PD-L1);

ii. Split sample analysis with another method or another laboratory;
iii. Use of assayed materials, or clinical validation by chart review.

- For predictive markers performed by methods other than ISH And IHC, refer to COM.01300 and COM.0150.

- Documentation of the unregulated test, method of alternative PT being utilized must clearly documented in writing and held in each section.

  *** Alternative Performance Assessment (APA) Test List developed by CAP may be used to help laboratories keep track of this information. This form can be found located on the CAP.org website under e-LAB Solutions Suite and will serve as appropriate documentation.

- Documentation of alternative assessments chosen should be documented in the procedure manual along with a method of evaluation of results and defined limits of acceptability for the performance. Corrective actions in response to unacceptable performance to alternative assessments must also be documented and maintained in the same manner as purchased PT surveys.

- The CLIA Lab Director in conjunction with the Section Medical Director will be responsible for determining the acceptable differences allowed when evaluating the results obtained using alternative assessment methods.

  Assessment of the results can take place by utilizing various methods but a commonly suggested method paired with split sample testing would include: agreement across the range of results by plotting results on a two dimensional graph. The lab referenced to would represent the X axis and your lab the Y axis. A line of agreement is drawn in the body of the graph (Y=X). Upon visual assessments of the graph any trends or bias should be easily identified. Documentation of the acceptability of the results should be performed by the section and reviewed, signed and dated by the Medical Director and/or the CLIA Lab Director. If the results are not acceptable, corrective actions and documentation (CAPA) will be necessary.

  For in situ hybridization testing other than predictive marker testing, and other complex molecular and sequencing-based tests (including but not limited to microarray-based tests, multiplex PCR-based tests, and next generation sequencing-based tests), alternative performance assessment may be performed by method or specimen type rather than for each analyte or tested abnormality.

For tests such as allergen testing, alternative performance assessment may be performed in batches of analogous tests.

b. Handling and Analyzing

- The laboratory integrates all proficiency testing samples within the routine laboratory workload, and those samples are analyzed by personnel who routinely test patient/client samples, using the same primary method systems as for patient/client/donor samples. Samples may be repeated, diluted, etc. in the same manner as a patient sample.

  This policy strictly prohibits referral or acceptance of proficiency testing specimens for analysis from other laboratories. This prohibition takes precedence over the requirement that proficiency testing specimens be handled in the same manner as patient specimens.

  For example, a laboratory's routine procedure for review of patient abnormal CBC blood smears might be referral of the smear to a pathologist located at another site. (Different CAP/CLIA number). For proficiency testing specimens, the laboratory must NOT follow its routine procedure to refer the specimen. If the PT sample meets laboratory-defined criteria for referral to a pathologist prior to reporting and the pathologist is at another site, the pathologist must review the PT sample at the physical location of the laboratory performing the PT. Alternatively, the laboratory must refer to the PT provider kit instructions on how to record a result for a test not performed the laboratory.

  Laboratories that perform testing using a distributive testing model where portions of the process are performed at another laboratory with a different CAP/CLIA number must not participate in formal PT, as this is considered PT referral by CMS and is strictly prohibited. An alternative performance assessment must be performed at least semiannually in lieu of formal PT in these situations. Common examples of distributive testing include:
  - ● In situ hybridization and slide interpretation performed at separate laboratories
  - ● Next generation sequencing wet bench process, bioinformatics processes, and/or interpretation performed at different laboratories
  - ● Leukemia/lymphoma flow cytometry panels and pathologist interpretation of the data at different laboratories

Immunohistochemistry (IHC) slides are permitted to be sent to another facility **for staining only**.

- The laboratory (which is subject to regulation by the Centers for Medicare and Medicaid Services (CMS) do not test the same analytes from the same PT product on more than one instrument or method unless that is how the laboratory tests patient specimens. 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.
- Laboratories subject to CMS regulation are 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.

  Samples are to be run on a single analyzer, yielding a single result, which is reported. (To prevent duplicate testing and comparison of results).

- Samples are prepared per the package instructions.
- Proficiency testing records must not be shared with and should be inaccessible to personnel of other laboratories, including an affiliated laboratory until after the deadline for submission of results. Laboratories that share a common computer system must take appropriate steps to ensure that records are not readily accessible by other laboratories.
- It is the responsibility of every laboratory employee to understand that the referral (receiving or sending) of any proficiency samples while the testing event is still in progress (before the due date) is prohibited. In the event any employee should be asked to engage in such practice, they are required to immediately notify the CLIA Laboratory Director in charge of their lab and/or the WFBH Laboratory Compliance Officer. Every attempt will be made to have all testing employees participate in purchased PT surveys or an alternative method.
    - Except in limited circumstances where patient testing occurs over more than one work shift and thus multiple employees conduct the testing (e.g., in the microbiology lab where cultures and testing can take longer that one shift), all samples contained in a single test event will be tested by a single person to whom the event will be assigned by laboratory management and will be completed as soon as practicable following assignment. All proficiency tests will use the same procedures used for patient samples requiring the same test. In those instances where multiple employees conduct a proficiency test, each

employee conducting the test must sign the attestation statement for the event.
    - Individual test events will be rotated, where applicable, throughout the lab as follows – Event 1 will be tested by 1st shift employees, Event 2 will be tested by 2nd shift employees and Event 3 will be tested by 3rd shift employees.
    - If patient samples are written on a daily log, PT samples should be logged.

c. Reporting

- For purchased PT materials, results are recorded as directed per kit instructions, using the PT testing forms provided, within the allotted time frame indicated for that event. Completed report forms are filed with pertinent work sheets, QC documentation, instrument data, etc. and are maintained for at least 2 years within each lab section.
- The attestation sheet must be signed by the analyst(s) and the laboratory director (or designee), in addition to electronic submission.
- All recorded information is checked for accuracy and completeness by the manager prior to submission.
- Results are submitted to the appropriate agency for evaluation via fax, mail or electronically.
- The laboratory must document the handling, preparation, processing, examination and each step in the testing and reporting of results for all PT samples.

The laboratory must maintain a copy of all records, including a copy of the PT program report forms used by the laboratory to record PT results including the attestation statement provided by the PT program for two years. These are maintained in each section lab.

d. Results Review

- As delegated by the CLIA lab director, the section medical director or section manager or laboratory specialist will review all results (graded, ungraded, educational, etc.) represented within the testing event. During the event review process ungraded analytes and educational responses must be assessed for acceptable performance in addition to graded responses. In the event the ungraded or educational result is found to be unacceptable based on peer data review, corrective action process will be required.

  If a PT challenge was intended to be graded, but was not, for reasons such as:

1) The laboratory submitted its results after the cut-off date,
2) The laboratory did not submit results,
3) The laboratory did not complete the result form correctly (for example, submitting the wrong method code or recording the result in the wrong place). Then the laboratory should perform their own assessment of the PT challenge. The PT assessment for ungraded challenges must include an assessment/conclusion from the medical director (or designee) as to whether the laboratories response was acceptable or not.

- Acceptable participation in the event means you received a passing score of 80% or more on the testing event.
- For any results that did not receive a passing score in the event, the manager must evaluate and document possible reasons for failure and any corrective action that may be necessary.
- An internal CAPA form must also be completed of the score on the entire event is below 80%.
- Depending on the PT provider utilized, additional documentation submission back to the PT provider may be necessary. Consult the PT provider instructions and follow their guidance as necessary in addition to section specific documentation.

e. Training/Competency Assessment

- Employees within the laboratory will receive specific training on the handling and testing of PT samples and events at the following intervals:
  1) Initial new employee laboratory orientation (new employee checklist)
  2) New employee end of probation review (at 90 days)
  3) Annually as part of every employees yearly lab specific competency assessment thereafter.

- Orientation/Competency Assessment procedures may vary between sections. See Section specific procedures for checklists and procedure.

4) Review/Revision/Implementation:

a. Review Cycle: 2 years
b. Office of Record: Department of Pathology

5) Related Policies: N/A

6) References, National Professional Organizations, etc.:

CLIA Regulations Section 493.1236 Standard: Evaluation of proficiency testing performance 2004.

CLIA Regulation and Guidance Brochures, Brochure #8 Proficiency Testing

College of American Pathology Standards for Proficiency Testing

7) Attachments: N/A

8) Revision Dates: January 23, 2017, May 15, 2017, March 16, 2018, November 13, 2019, February 14, 2020

9)