ADVOCATE HEALTH	
Title: IHC Proficiency Testing Procedure (NCBH)	**Published Date:** 05/02/2025 **Last Review / Revised Date:** 05/02/2025
Document Type: ☐ Policy ☒ Procedure ☐ Guideline ☐ Other	**Content Applies to Patient Care:** ☒ Adults ☒ Pediatrics (Under 18) ☐ N/A
Scope: ☐ Enterprise ☐ Division(s): ☐ Area Name: ☒ Entity Name: NCBH ☒ Department Name: AP-IHC	

I. PURPOSE

The purpose of this procedure is to define the proficiency testing program for the Molecular Diagnostics Laboratory to include the following areas: selection of approved proficiency testing (PT) materials for regulated analytes, appropriate handling of PT samples, PT sample analysis, results reporting, results review, and employee training/competency assessments.

It is the policy of the IHC Lab to adhere to all proficiency testing standards and regulations of CLIA and/or other accrediting laboratory agencies, such as the College of American Pathology (CAP) and The Joint Commission (TJC).

II. SCOPE

This procedure applies to:

i. Procedure owner/Implementer: The IHC Lab
ii. Who performs procedure: Technologists in the IHC Lab

III. DEFINITIONS/ABBREVIATIONS

A. Procedure: A process or method for accomplishing a specific task or objective.
B. WFBH Lab System: Wake Forest Baptist Lab System is a health system that includes Wake Forest Baptist Medical Center and all affiliated organizations including Wake Forest University Health Sciences (WFUHS), North Carolina Baptist Hospital (NCBH), Lexington Medical Center (LMC), Davie Medical Center (DMC), Wilkes Medical Center (WMC), High Point Medical Center (HPMC), Lab at Westchester and Lab at Clemmons.

IV. POLICY

Policy Guidelines

Selection of Material

Analytes for which purchased PT material are available:

- Annually (by December 1) all purchased PT materials for regulated analytes will be reviewed by the supervisor of the IHC Lab in conjunction with the Medical Director.
- All purchased PT orders will be placed by the IHC Supervisor.

CAP proficiency surveys subscribed to:

CD30 – IHC, TMA
PM3 – IHC, TMA
PM1-IHC, TMA
GHER2- Gastric Her2 IHC, TMA
HER2-Her2 Immunohistochemistry, TMA
ISH-in situ Hybridization
MMR-DNA Mismatch Repair –IHC
PM2- ER/PR Immunohistochemistry
MK- Immunohistochemistry
PD-L1
MYCB-MYC/BCL2 Immunohistochemistry, TMA
P16
PIP-Performance improvement program, Surg Path
PIP1-Performance improvement program, Surg Path additional

For analytes for which purchased PT material is not available, an alternative performance assessment for determining reliability of testing is performed at least semi-annually.

Currently in the IHC Lab we have no analytes that qualify for alternative proficiency testing. In the event that tests qualify as such in the future they will be handled according to CAP guidelines.

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Handling and Analysis

- When the testing materials arrive, they are dated for the received date and stored in the manner recommended on the package.

- Samples are integrated into the daily workload and processed in the same manner as patient samples. Samples may be repeated, diluted, etc, **only** in the same manner as a patient sample.

- Samples are prepared per the package instructions. Damaged samples or replacement samples are handled per CAP instructions included with each kit.

- **Inter-laboratory communication regarding PT samples is strictly prohibited.**

- **Referral or sharing of PT samples with another laboratory is prohibited until after the deadline for submission of data to the proficiency testing provider.**

- 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 the Wake Forest Baptist Health Internal Audit and Compliance Office before they act. (The employee must also notify their manager.)

- Every attempt will be made to have all testing employees participate in purchased PT surveys or alternative methods. A log of testing personnel for PT surveys is maintained
  - All samples contained in a single test event will be tested by a single person to whom the event will be assigned by the lab manager on the day the event is assigned.
  - Individual test events will be rotated among all employees.
  - PT samples will be written on the daily worksheet.

Reporting

- All purchased PT material results are recorded using the PT testing forms provided with the kit. The forms must be completed and filed prior to the deadline for submission stated

on the form. Completed report forms are filed with pertinent work sheet, QC documentation, instrument data, etc. and maintained for at least two years.

- The attestation form must be signed by the person (s) handling the PT sample and the laboratory medical director (or designee), in addition to the electronic submission.

- All recorded information is checked for accuracy and completeness by the manager prior to submission. The manager or designee will not alter, correct or influence the results recorded by the testing personnel.

- Results are submitted to CAP for evaluation via electronically.

- The laboratory documents the handling, preparation, processing, examination and each step in the testing and reporting of results for all PT samples.

- The laboratory maintains a copy of all records, including a copy of the PT program report forms used by the laboratory to report PT results including the attestation statement provided by the PT program for at least two years.

a. Results Review

- All results represented within the testing event are reviewed, evaluated and signed by the section medical director or designee and the reports are filed in the yearly PT manual. Acceptable participation is defined as a passing score of 80% or more on the testing event.

- The results of all PT are included in the department monthly MQR report.

- For any results that did not receive a passing score, the manager and laboratory director evaluate and document possible reasons for the failure and any corrective action that may be necessary. Investigation may include clerical check and re-testing if possible. The manager and laboratory director reviews any ungraded sample or sample that lacks consensus on a case by case basis. The lab's results are compared with the detailed summary of peer laboratory performance. The laboratory director and manager provide feedback to the testing staff or Proficiency testing provider as needed.

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) New employee at the end of the probation review
    2) Annually, as part of the yearly lab specific competency assessment

- See section specific procedures for the checklist

V. CROSS REFERENCES

Proficiency Testing Policy (NCBH)

VI. RESOURCES AND REFERENCES

Department of Pathology Proficiency Testing Procedure

VII. ATTACHMENTS

Not Applicable