Atrium Health Wake Forest Baptist	**DOCUMENT TYPE:** Policy	**ORIGIN DATE** 2/2019
CLIA Lab Director: Greg Pomper, MD	**LAB DEPARTMENT:** QUALITY, SAFETY & ACCREDITATION	**CONTACT:** QUALITY, SAFETY & ACCREDITATION

APPLICABLE LABORATORY(S)):
☒ North Carolina Baptist Hospital (NCBH)
☐ Lexington Medical Center (LMC)
☐ Davie Medical Center (DMC)
☐ Wilkes Medical Center (WMC)
☐ High Point Medical Center (HPMC)
☐ Westchester
☐ Clemmons

POLICY PURPOSE

The purpose of this policy is to provide guidelines for correctly labeling reagents, calibrators, controls, stains, chemicals, and solutions.

SCOPE

This policy applies to all faculty, residents and employees in the Department of Lab & Pathology.

DEFINITIONS

A. Policy: As defined in the Policy on Creating and Amending Policy, a statement of principle that is developed for the purpose of guiding decisions and activities related to governance, administration, or management of care, treatment, services or other activities of WFBH. A policy may help to ensure compliance with applicable laws and regulations, promote one or more of the missions of WFBH, contain guidelines for governance, and set parameters within which faculty, staff, students, visitors and others are expected to operate.
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.

POLICY GUIDELINES

A. Reagent Labeling (COM.30300)

    1. All reagents, calibrators, controls, stains, chemicals, and solutions must be properly labeled as applicable and appropriate with the following elements:

a. Primary Container:

i. Content and quantity
ii. Concentration or titer
iii. Storage requirements
iv. Date prepared, filtered, aliquoted, or reconstituted.
v. Expiration date
vi. Preparer's initials
vii. Safety/Hazard information (GHS) (GEN.76200)

b. Secondary Container:

i. Identity/description of contents
ii. Quantity/concentration or titer if applicable
iii. Storage requirements
iv. Date prepared, filtered, aliquoted, reconstituted, etc.
v. Expiration date
vi. Lot # if applicable
vii. Preparer's initials
viii. Safety/Hazard information (GHS)

2. Information on the label that a user would need to know to properly use a solution should be included.

   Examples:

   Silver Nitrate Stain: *Minimize light exposure* may be written on the label in addition to the other information.

   Glucose Control: You must **change** the *expiration date* once you open the bottle. The new expiration date should be written on the label.

3. All primary and secondary container labels are neat and legible at all times. Replace labels that are stained, faded or begin to peel. Labels that are not legible are safety issues that could lead to harm to employees and/or patients.

4. Each lab section will ensure that labels in incoming containers of hazardous chemicals are not removed or defaced. (OSHA CFR.1910.1200(b)(3)(i))

B. Expiration Dates (COM.30400)
   1. All reagents, chemicals, controls, media, antibodies and stains are only used if in-date (not expired). Unless an exception has been preapproved for the use of expired products.
   2. Each lab section has a section specific policy defining their process for utilizing in-date products only for clinical testing. Unless an exception has been preapproved for the use of expired products.

3. If an expiration date has not been assigned by the manufacture, the Department of Lab & Pathology assigns an expiration date based on known stability, frequency of use, storage conditions and risk of deterioration.

4. Unless it is indicated that the manufacturer issued expiration date changes when opened, the lab must use the manufacturer's expiration. If the expiration changes once opened, then the lab will assign a new expiration date based on either guidance from the manufacturer's instruction or laboratory policy.

C. Labeling of Expiration Dates on Container Types

1. Primary Container
   - Addition of the expiration date is required if opening the container changes the expiration date.
   - If opening the container does not change the expiration date, the expiration date remains the same as it was issued by the manufacturer.
   - If there is no expiration date given on the primary container, use 12 months from the date opened as the expiration date.

2. Aliquots and Secondary Container
   - If a manufacturer's expiration date is given on the primary container or solution, use this as the expiration date on the aliquot label.
   - If the expiration date on the primary container changed after opening, then the expiration date for the aliquot will follow suit and use the same expiration date that was used for the primary container.
   - If there is no manufacturer-provided expiration date, use 12 months from the date aliquoted as the expiration date.

3. Reconstituted Reagents, Calibrators, Controls, Stains, Chemicals, and Solutions
   - If there is a manufacturer-recommended expiration date for reconstituted and prepared reagents, calibrators, controls, stains and chemicals, use it as the expiration date on the label.
   - If there is no expiration date given, use 6 months from the date prepared or reconstituted as the expiration date.

4. Reagents that are prepared daily (10% bleach, KOH, saline, water, etc.)
   - Label the container "**Prepared Daily**."
   - Expiration date is not required if container is label as directed above.
   - All other labeling requirements as directed in 3(A) above will also apply.

5. Test Kits and components
   - Components of a test kit should never be separated.
   - Although the individual components of the kit do have individual expiration numbers, each of these are traceable back to the original, single expiration number of the entire kit found on the outer container/packaging.

- The single kit expiration number on the outside packaging should be used for expiration tracking purposes.

B. Disposal of Expired Reagents

1. It is the responsibility of every laboratory staff member and testing personnel working in a clinical laboratory area within the Department of Pathology to check expiration dates before using any reagent, calibrator, control, stain, test kit or chemicals of any kind.
2. Under normal circumstances, expired reagents should never be used for clinical patient testing.
3. Expired reagents will be properly disposed of. Reagent disposal will be conducted according to established laboratory chemical safety procedures. Contact EHS or the laboratory safety office for questions.

LITERATURE REFERENCES:

CAP All Common Checklist, College of American Pathologists, 325 Waukegan Road Northfield, IL 60093-2750, www.cap.org © 06.04.2020
https://www.osha.gov/Publications/OSHA3636.pdf
https://www.osha.gov/dsg/hazcom/

RELATED POLICIES/PROCEDURES IN NAVEX:

ATTACHMENTS/LINKED DOCUMENTS IN TITLE 21:

REVISION DATES: REVIEW CHANGE SUMMARY AS REPRESENTED IN TITLE 21.