Wake Forest Baptist Medical Center	Reagent Labeling Policy	Dept:	Lab Compliance
		Effective Date:	02/14/2019
		Revised Date:	
		Contact:	Lab Compliance
Name & Title: Gregory Pomper, MD		Date Approved	2/6/19
Director Signature: GP			

1) **General Procedure Statement:**
   a. **Purpose:** To provide instructions for reagent, calibrator, control, stain, chemical and solution labeling in the Laboratory.

   b. **Responsible Department/Scope:**
      i. Procedure owner/Implementer: Department of Pathology
      ii. Procedure prepared by: Lab Compliance, Quality and Safety
      iii. Who performs procedure: Staff of the Laboratory

2) **Definitions:**
   - **Container:** A receptacle for holding a reagent or other substance. Examples would include but are not limited to a test tube, a jug, box or bottle.
   - **Department or Section:** An area of specialized expertise where reagents, test kits, and/or other supplies are delivered for testing. An individual area of responsibility within a laboratory.
   - **Hazard Warning Label:** A label or tag that describes chemical handling precautions, such as health, fire, reactivity, and any other specific hazards.
   - **Primary Container:** The original storage receptacle for holding a substance as received from a manufacturer or prepared in-house.
   - **Reagent:** A common term used to describe a component used in testing. Examples would include but are not limited to solutions, test kits, culture media, slides, stains, controls, calibrators and reagent water.
   - **Reagent Label:** A tag inscribed and affixed to a container for identification or description. It provides additional information for handling and storage to ensure optimal use of the reagent.
   - **Secondary Container:** Any receptacle into which a substance from a primary container is transferred after receipt or preparation.
   - **Solution:** Any commercially prepared or in-house prepared liquid stored in a container that is used in the testing process. Examples would include but are not limited to, rinse agents, wash mixtures, saline, bleach and buffer.
   - **Test Kit:** A packaged set of materials, reagents, and supplies, each considered necessary components for performance of an individual analysis or examination. In general, test kits are commercially prepared and packaged.

3) **Procedure:**

A. Reagent

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

Primary Container:

1. Content and quantity
2. Concentration or titer
3. Storage requirements
4. Date filtered or aliquoted, reconstituted
5. Expiration date
6. Preparer's initials
7. Safety/Hazard information (GHS)

Secondary Container:

1. Identity/description of contents
2. Quantity/concentration or titer if applicable
3. Storage requirements
4. Date prepared, filtered, aliquoted, reconstituted, etc.
5. Expiration date
6. Lot # if applicable
7. Preparer's initials
8. Safety/Hazard information (GHS)

- You may also include information on the label that a user would need to know to properly use a solution.

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

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

- Sections are responsible for ensuring that all primary and secondary container labels are neat and legible at all times. Sections are responsible for replacing labels when they become stained, faded or begin to peel. Labels that are not legible are safety issues that could lead to harm to employees and/or patients.

B. Expiration Dates

It is good laboratory practice to label all reagents calibrators, controls, stains and chemicals in the lab with a received and opened date for inventory management purposes.

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 is required to 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.
   - Therefore it is the single kit expiration number on the outside packaging that should be used for expiration tracking purposes.

D. **Disposal of Expired Reagents**

- 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.

- Under normal circumstances, expired reagents should never be used for clinical patient testing.
- Expired reagents will be properly disposed of. Reagent disposal will be conducted according to established laboratory chemical safety procedures. Contact EHS or the laboratory compliance office for questions.

3) **Review/Revision/Implementation:**
   - All procedures must be reviewed at least every 2 years.
   - Office of Record: Department of Pathology in the Laboratory Compliance Section.

4) **Related Procedures:**
   N/A

5) **References:**
   CAP All Common Checklist, College of American Pathologists, 325 Waukegan Road Northfield, IL 60093-2750, www.cap.org ©08/21/2017
   https://www.osha.gov/Publications/OSHA3636.pdf
   https://www.osha.gov/dsg/hazcom/

6) **Attachments: None**

7) **Revised/Reviewed Dates and Signatures:**

Review Date	Revision(s)	Signature