Wake Forest Baptist Medical Center	Reagent Receipt and Handling CCL - 010	Dept: 324318	Critical Care Labs
		Effective Date:	Sept 1991
		Revised Date:	Feb 2019
		Contact:	Ann Shoffner
Name & Title: Greg Pomper, MD CLIA Laboratory Director		Date:	2/25/19
Signature: GPom			

1) **General Procedure Statement:** Proper storage, labeling, handling, validation and documentation of laboratory reagents are necessary to ensure quality of laboratory results.

   a. **Purpose:** To provide lab staff with guidelines about the labeling, handling and use of reagents.

   b. **Responsible Department/Party/Parties:**
      i. Procedure owner: Ann Shoffner
      ii. Procedure: Critical Care Lab (CCL) Staff
      iii. Supervision: Ann Shoffner
      iv. Implementation: Ann Shoffner and Critical Care Lab (CCL) Staff

2) **Procedure:**

   A. **Reagent Labeling:** Reagents, calibrators, controls, stains, chemicals, and solutions are properly labeled, as applicable and appropriate, with the following elements. This includes secondary containers that hold prepared reagents such as the SysWash on the Cobas e411.

      1. Content and quantity, concentration or titer
      2. Receipt date: Reagents received in the Critical Care Laboratories should be labeled with a label indicating the date received.
      3. Preparation date: The date a reagent is prepared for use, when applicable, should be documented on the reagent label.
      4. Open date: The date a reagent is opened and the initials of the person that opened it should be recorded on the label when appropriate.
      5. Expiration dates (original and modified if applicable): Expiration dates of a reagent noted to require adjustment when opened should be modified as such on the label by the person opening and placing the reagent into use per manufacturer's guidelines.
      6. Storage Requirements: Storage requirements must be listed on the container.

   B. **Expiration Date:** All reagents should be used within their indicated expiration date. Reagents should be discarded once the reagent has exceeded its expiration date. Reagents without an assigned expiration date from a manufacturer are assigned an expiration date of one year or less based on known stability, frequency of use, storage conditions and risk of deterioration.

   C. **Reagent Storage:** All reagents should be stored and handled according to the manufacturer's instructions.

   D. **Package Insert Verification:** The package insert from newly a received reagent, QC, etc. should be compared to that product's existing package insert to verify that changes have not taken place. Refer to the Package Insert Log Book and *CCL-097 Package Insert Log*. This can be done by comparing the versions of the two inserts. If the package insert versions match, no special action is required. If the versions of the inserts are different, then the new insert should be given to the manager and reviewed for changes. Additional action such as a process/procedure change may be required depending on the nature of the change.

E. **New Reagent Lot Validation:** New reagent lots should be verified with appropriate calibration and quality control per test procedures prior to being placed into use.

F. **Reagent Kit Components:** If there are multiple components of a reagent kit, we use components of reagent kits only within the kit lot unless otherwise specified by the manufacturer.

3) **Related Procedures:**
Department of Pathology – Reagent Labelling Policy

4) **Attachments:** none

5) **Related Forms:**
CCL-097 Package Insert Log

6) **References:** none

7) **Related CAP Standard(s):** COM.30300, COM.30500, COM.30350, COM.30450

8) **Review/Revision/Implementation:**
   - Review Cycle: All procedures must be reviewed at least every 2 years.
   - Office of Record: Department of Pathology, Critical Care Laboratory

9) **Previous Revision Date(s):** 6/93, 4/97, 3/01, 4/03, 4/07, 3/11, 6/14,

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

Reviewed/Revision Date:_____ Signature:_____

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