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|  | **REAGENT POLICY**  **CL-CH150** | **Dept:** | Clinical Core Lab-  Chemistry Section |
| **Effective Date:** | April 25, 2008 |
| **Revised Date:** | June 11, 2019 |
| **Contact:** | Clinical Core Lab-  Chemistry Management |
| **Name & Title:** Gregory J. Pomper, MD  Medical Director of Pathology Laboratories | | **Date:** |  |
| **Signature:** | | | |

1. **General Procedure Statement:** 
   1. **Scope:** To provide laboratory testing personnel with instructions on reagent

storage, and handling as deemed appropriate by industry practices and

regulatory agencies to assist in quality patient care.

* 1. **Responsible Department/Party/Parties:** 
     1. Procedure owner: Clinical Core Laboratory Management-Chemistry
     2. Procedure: Clinical Core Laboratory Personnel
     3. Procedure prepared by: Elma Wilson / Emily Dockery
     4. Supervision: Clinical Core Laboratory Management-Chemistry

Clinical Core Laboratory Specialist and Designees

Medical Director Clinical Chemistry

1. Implementation: Clinical Core Laboratory Management-Chemistry

Clinical Core Laboratory Specialist and Designees

Medical Director Clinical Chemistry

1. **Definitions: NA**
2. **Procedure:** To be performed by all Chemistry personnel.

**LABELING:**

1. Content and quantity, also concentration
2. Storage requirements
3. Date prepared or reconstituted and initial
4. Expiration date
5. Any precautions necessary
6. Any reagent with no definite expiration per manufacturer such as diluted acid or buffer use for maintenance expiration is 6 months after preparation.

**STORAGE:**

All reagents are stored and handled according to the manufacturer recommendations**.**

Reagents are stored in a manner that will prevent environmentally-induced alterations that could affect reagent stability and test performance. Prepared reagents are also stored accordingly.

The temperature of the storage areas such as freezers, refrigerators and room Temperatures are monitored daily. Reagents that are subjected to unacceptable storage conditions must be evaluated for potential impact on patients and maintain records and document actions taken.

**REAGENT EXPIRATION DATES:**

All reagents and chemicals are used within their indicated expiration dates. Discard all expired reagents and chemicals. The lab assigns expiration dates on reagents and chemicals that do not have manufacturer-provided expiration date. The Laboratory assigned expiration date is based on known stability, frequency of use, storage conditions, and risk of deterioration**.** Water used for dilution should be changed daily with date and initial. A new expiration date must be recorded if opening the container changes the expiration date or storage requirement. Prepared reagents, diluents, maintenance wash or buffer and others, follows the requirement of manufacturers suggested expiration dates or the Lab assigned expiration dates. All reagents are stored per manufacturer’s instructions. Temperature requirements can be found on reagent packaging and in individual assay procedures.

**NEW REAGENT LOT CONFIRMATION:**

New reagent lots are checked against old reagent lot to confirm that the matrix of the new reagent lot does not affect patient results before or concurrently with being placed in service. If the matrix of the new reagent is different from the old lot, it may impact the calibration status of the instrument and the consistency of patient results. Improper storage during shipping may impact the ability of the reagent to perform properly.

**Qualitative Comparison:**

Retest at least one positive and one negative sample. If available retest weakly positive sample also.

Document results on the lot to lot log.

Examples of suitable reference materials for qualitative tests include:

* Positive and negative patient samples tested on a previous lot
* Previously tested proficiency testing materails
* External QC materials tested on a previous lot
* If none of the above options is available, control material provided by the assay manufacturer with the new test kit

**Quantitative Comparison:**

Use 3 previously run patient samples and if possible choose samples that are low, midpoint and high. The use of patient samples confirms the absence of matrix interference. Use of current QC materials to test the new lot if patient sample is not available, reference materials provided by the method manufacturer with method specific and reagent lot specific, Proficiency Testing materials with peer group established means can all be used to test reagent lot to lot correlations. Comparison results should be within 25%. Results are documented on the reagent lot to lot log sheet. Example of a log sheet for Chemistry is found in the back of this procedure.

**Notes:**

* All reagents are stored according to the manufacturer or procedure recommendations.
* No expired reagents are to be used. It is technologist’s responsibility to monitor the expiration dates.
* It is not acceptable laboratory practice to mix reagent components of different lots. If there are components of a reagent kit, it must be used together within the same lot. If a new lot of reagent is used, all components must be replaced at that time. Follow manufacturer suggestions.

**New Reagent Lot (Lot to Lot)**

New reagent lots are validated before any patient testing can be performed. All reagents placed in the instrument should be logged in and run QC. The manufacturer recommendations are followed when a new lot of reagent is placed into service. This may include calibration, QC or other means of testing to verify the matrix of the new lot of reagent is performing as specified. We also perform quality control check and run 3 patients that were assayed with the previous lot to validate the assay. The result of the lot to lot patient correlations should not exceed 25% difference from the old lot number. This information is used to determine if QC material is acceptable for this validation. No patient can be sent out if QC is not acceptable using the QC rules. If QC is not acceptable, call the manufacturer for options or recommendation. Ask Medical Director for guidance.

**Research and Validation Materials**

Any research or validation materials stored in fridges or freezers along with in use materials must be labeled as “FOR RESEARCH USE ONLY”. They cannot be used for patient testing until all proper validation documentation has been signed and approved.

1. **Review/Revision/Implementation:**
   1. Review Cycle: 2 years
   2. Office of Record: Department of Clinical Core Laboratory-Chemistry
   3. All new procedures and procedures that have major revisions must be signed by the Laboratory Director.
   4. All reviewed procedures and procedures with minor revisions can be signed by the designated section medical director.
2. **Related Procedures:**
3. **References, National Professional Organizations, etc.:**
4. **Attachments:**
   1. Lot to Lot Log Sheet
5. **Revision Dates:**

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| **Review Date** | **Revision Date** | **Signature** |
|  | Research and Validation Materials section added 6/11/2019 |  |
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