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Laboratory Reagent Labeling

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

This procedure provides guidance for the process of the receipt, labeling and handling of laboratory reagents and solutions. Appropriate receipt, labeling and storage of supplies, controls, reagents, and other materials facilitates the proper usage of the product and inventory control. Maintaining an appropriate inventory level establishes adequate materials are available. Refer to the department specific procedures for any special instructions for reagents and solutions used in the specific laboratory.

II. PROCEDURE:

Standing purchase orders are set up for many reagents and controls in the laboratory. These are renewed annually or as needed and are adjusted based upon usage history or anticipated future needs. Standing orders are shipped automatically. Other reagents are ordered as needed. It is the responsibility of the staff to follow the labeling requirements so that reagent and solution identities are clear.

A. Receiving Reagents

1. When reagents, controls, and supplies are received into the laboratory, they are unpacked by a laboratory employee that works in the area in which the reagent, standard or control is used.
2. Check the shipment for accuracy of the item and volume ordered. If there is a discrepancy regarding the products received, notify a Lead Medical Technologist, Supervisor or Manager.
3. Inspect the product for evidence of deterioration or damage. If the supplies are not in acceptable condition or have had prolonged improper temperature exposure, report to a Lead Medical Technologist, Supervisor or Manager.
4. Upon receipt in the laboratory, use of department specific labeling to indicate a **"NEW LOT"** or **"NEW SHIPMENT"**, when applicable.
5. Use department specific labeling for **"LOT IN USE "** for items which have the appropriate calibration and/or quality control (QC) complete and are currently being used.

B. Storing of supplies, reagents, and controls

1. Store all supplies, controls, and reagents according to manufacturer's recommendations; designated refrigerator, freezer or storage shelf, which will be maintained at the appropriate temperature. For

example, if refrigeration is required the reagents are stored in an appropriate refrigerator with temperatures recorded daily. Out of range temperatures must be addressed appropriately and corrective action noted.

2. Always rotate stock by putting the newest items (with the longest expiration dates) in the back and the oldest items (with the shortest expiration dates) to the front of the refrigerator, freezer or storage shelf.
3. Check the expiration dates on all items each time they are used to verify their stability according to the manufacturer's specifications. Notify a Lead Medical Technologist, Supervisor or Manager if supplies, controls, calibrators and reagents are found past the manufacturer's stated expiration date.

C. Reagent and solution labeling

1. The identity of all reagents must be clearly indicated on the outside of the container.
2. If a label is no longer legible, a replacement label must be placed on the outside of the container.
3. Lot number must be unobstructed.
4. The expiration date of reagents, if not tracked by the analyzer, must be on the reagent label.
5. A new expiration date, if different from manufacturer's expiration date, must be on the label.
6. If the open reagent stability differs from the preprinted expiration date on the manufacturer's label, note the new expiration date on the label or container.
7. For reagents, standards, calibrators or controls that either require transferring the material to another container or preparation/reconstituion by a lab employee, include the following on the label:
    a. Name of contents
    b. Quantity, concentration or titer (as appropriate)
    c. Lot number, if applicable
    d. Date of preparation
    e. Expiration date
    f. Initials of person preparing the material
    g. Chemical hazard label, as appropriate. Refer to the Laboratory Chemical Hygiene Plan.
    h. NOTE: The above elements may be recorded in a log (paper or electronic), rather than on the containers themselves, providing that all containers are identified so they are traceable to the appropriate data in the log.
8. Secondary containers filled with cleaning supplies may be labeled with only the common name of the contents (e.g., "10% bleach") as long as the full name of the chemical(s) in the container and the information about any potential hazards can be found in the Safety Data Sheets (SDS).

D. Reagents Without Expiration Date

1. If a reagent or solution has no expiration date indicated by the manufacturer, the laboratory department will assign an expiration date based on known stability, frequency of use, storage conditions and risk of deterioration. Inability to obtain expected quality controls results will result in discontinuation of use regardless of assigned expiration dates.
2. Consult the manufacturer's website/catalog for assistance in determining the expiration date, as needed.

E. Unlabeled Solutions and Reagents

1. Any and all unlabeled or illegibly labeled chemicals must be disposed of immediately.

F. Preparation and Storage of Frozen Aliquots

1. Reconstitute controls and standards according to procedure or manufacturer's insert directions.
2. Label each aliquot with:
    a. Name of the constituent
    b. Date of preparation
    c. Lot number
    d. Expiration date
3. Store at the appropriate freezer temperature.

G. Expired Reagents, Standards and Controls

1. A reagent, standard or control with an expiration date containing the day, the month and the year will be considered to be expired at midnight of the expiration date.
2. The use of expired reagents and controls is prohibited. Expired reagents, standards and controls are removed from service and replaced.
3. Discard the expired reagents and notify the Lead Medical Technologist, Supervisor, Manager or ordering personnel, if necessary.
4. Transfusion service laboratories may use rare reagents (ie, rare antisera and selected panel red cells to determine the specificity of red cell antigens and antibodies) beyond their expiration date if appropriate positive and negative controls are run each day of use and react as expected. The laboratory must have in-date reagents for routine antigen typing and antibody panel testing.

III. REFERENCES:

A. College of American Pathologists Laboratory General and All Common Checklists, Current Version

B. Proper Handling of Reagents, Standards and Controls - Farmington Hills

C. Proper Handling of Reagents, Standards and Controls-Troy

D. Coagulation General Directives-RO

E. Reagent Tracking-Grosse Pointe and Lenox

F. Dearborn, Taylor, Trenton, Wayne Coagulation Reagent Reconstitution And Stability

G. Dearborn Laboratory Auto Technical Reagent/Supply Labeling

H. Performance Guidelines for Analytical Methods - Royal Oak

I. Laboratory Chemical Hygiene Plan

J. Dearborn, Taylor, Trenton, Wayne Reagent Labeling

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
CLIA Site Licensed Medical Directors	Muhammad Arshad: Physician	10/7/2022
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CLIA Site Licensed Medical Directors	John Pui: Chief, Pathology	9/20/2022
CLIA Site Licensed Medical Directors	Ryan Johnson: OUWB Clinical Faculty	9/20/2022
Policy and Forms Steering Committee Approval (if needed)	Jennie Green: Mgr, Division Laboratory	9/20/2022
Policy and Forms Steering Committee Approval (if needed)	Gail Juleff: Project Mgr Policy	9/20/2022
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Operations Directors	Kimberly Geck: Dir, Lab Operations B	8/25/2022
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Operations Directors	Joan Wehby: Dir, Lab Operations C	8/24/2022
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	Jennie Green: Mgr, Division Laboratory	8/23/2022

Applicability

Dearborn, Farmington Hills, Grosse Pointe, Royal Oak, Taylor, Trenton, Troy, Wayne