TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	1/3/2017
Department:	All staff	**Due Date:**	1/24/2017
		Implementation:	**1/24/2017**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Policy for Reagent Labeling and Handling SGAH.QDNQA728 v4.2

Note: this has been converted to a system SOP

Description of change(s):

Section 5.D: in item 8, change SOP reference to Chemical Hygiene Plan

This revised SOP will be implemented on January 24, 2017

Document your compliance with this training update by taking the quiz in the MTS system.

Title	**Policy for Reagent Labeling and Handling**
Prepared by	Dixie L. Ribickas and Rob Willis **Date: 08/15/2014**

Laboratory Approval		**Effective Date:**
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		

Review		
Print Name and Title	**Signature**	**Date**

Corporate Approval		**Corporate Issue Date: 11/03/14**
Print Name and Title	**Signature**	**Date**
Dianne Zorka, Director, Corporate Quality Assessment **Owner**	*On File*	**9/5/14**
Lee Hilborne, M.D. **Corporate Medical Director, Clinical Pathology**	*On File*	**9/5/14**

Retirement Date:	*Refer to the SmartSolve EDCS.*
Reason for retirement/replacement:	

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1. PURPOSE

This document sets forth the policy for the labeling, storage, and handling of reagents used for testing.

2. SCOPE

- This policy applies to:
  - All Quest Diagnostics owned and managed Clinical Pathology Laboratories
  - All departments that receive, store, handle, or use reagents and other testing components
  - All analytic reagents and other testing materials. This includes, but is not limited to, calibrators, standards, controls, solutions, culture media, slides and stains
  - Commercially prepared and in-house prepared reagents
- This policy does not apply to Anatomical Pathology laboratories. For Anatomic Pathology, refer to the Reagent Lot Verification for Anatomic Pathology SOP (AP751).
- This policy does not apply to consumable materials and supplies, such as plastic pipettes, paper test cards, plastic trays and wooden sticks, which do not have expiration dates.

3. RESPONSIBILITY

- The **Laboratory Director** is responsible for the approval of the initial document and any subsequent revisions.
- The **Laboratory Director or Designee** is responsible for the recurring review of this document.
- The **Technical Supervisor** is responsible for:
  - Implementing this policy in the department for which he/she is responsible
  - Ensuring compliance with the policy in the department for which he/she is responsible.
- All **Employees (Personnel) who handle reagents** must follow this policy.

4. DEFINITIONS

- **Container**: A receptacle for holding a reagent or other substance. Examples would include, but not be limited to, a test tube, jug, box, or bottle**.**
- **Department**: An area of specialized expertise where reagents, test kits, and other supplies are delivered for testing. This may be a RRL or an individual area of responsibility within a laboratory.
- **Global Harmonized System of Classification and Labeling of Chemicals (GHS):** is a system for standardizing and harmonizing the classification and labeling of chemicals.
- **Hazard Warning Label**: A label or tag that describes chemical handling precautions, such as health, fire, reactivity and any other specific hazards.
- **NFPA Rating System:** A hazard rating system developed by the National Fire Prevention Association, which incorporates a four-part diamond diagram to signify the health, fire, reactivity, and other hazards associated with a chemical.
- **Primary Container:** The original storage receptacle for holding a substance as received from a manufacturer or prepared in-house.
- **Reagent:** A common term, used hereafter, to describe a component used in testing. Examples would include, but not be limited to, solutions, test kits, culture media, slides, stains, controls, calibrators and reagent water (either commercially prepared or prepared in-house).
- **Reagent Label**: A tag inscribed and affixed to container for identification or description. It provides additional information for handling and storage to ensure optimal use of the reagent.
- **Safety Data Sheet (SDS)**: Written or printed material containing information and instructions on a hazardous chemical present in the laboratory. It includes details about the hazards and risks relevant to the substance, requirements for safe handling, and actions to be taken in the event of fire, spill, or overexposure.
- **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 not be 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 kit(s) are commercially prepared and packaged; however, they may be assembled in-house.

5. POLICY

A. Overview

1. All purchased reagents must be labeled as defined in Section B1, and stored and handled as specified by the manufacturer.
2. All in-house prepared reagents, solutions, culture media, stains and similar testing materials must be appropriately labeled as defined in Section B1. Storage and handling requirements must be defined by the laboratory.
3. These requirements apply to both primary and secondary containers.
4. Specific state or local regulations may specify additional or more strict labeling or handling requirements than state in this policy. Laboratories are required to verify the applicable regulations and update this policy accordingly.

B. Labeling :

1. All **primary or secondary container** labels (purchased or in-house prepared) must include the following elements:
    - Identity/description of contents
    - Quantity and concentration or titer, if applicable
    - Lot number
    - Storage requirements
    - Date prepared or reconstituted by the laboratory
        - For **New York State** licensed laboratories, all containers must also be labeled with the date opened.
    - Expiration date and/or time, as applicable.
    - New expiration date and/or time must be recorded when opening or preparing testing reagent changes the expiration date and/or time (Refer to Section D3).
    - For **New York State** licensed laboratories, all containers must be labeled with the identity of the preparer.
    - Safety hazard information. If the manufacturer does not include safety hazard information on the container or the reagent is prepared in-house, refer to the following for specifications or guidance:
        - Reagent specific SDS information
        - GHS or NFPA label or label elements
        - Quest Diagnostics Chemical Hygiene Plan (CHP) (QDEHS706)
        - CHP Secondary Container policy and label examples (Addendum A)

2. Secondary containers must be labeled with identity of the preparer. This is a requirement of the Quest Diagnostics Chemical Hygiene Policy.

3. Label multiple components of Test Kits as follows:

IF….	Then
A test kit contains multiple vials of the same or different reagents and meets the following criteria: • The outer package/container of the kit itself is clearly labeled with all information specified in this policy • Component reagents are clearly traceable to the original kit at all times • Components are never separated from the kit	The individual vials do not need to be marked.
Any of the individual components change expiration date upon opening,	Each container must be marked with the new expiration date.

4. If it is not possible to label a container with all the required information, the labeling requirements may be recorded on a log (paper or electronic).
    - Laboratories that choose to employ a log must have a documented process to trace the reagent back to the log to ensure that the reagent is used within the expiration date.
5. While useful for inventory management, labeling reagents with the "date received" is **not** required.
6. For a reagent that is prepared each day of use (e.g., 10% bleach, rinse, deionized water):
    - Label the container **"PREPARED DAILY"**.
    - Expiration date is not required. However, the preparation date must be written on the container.
    - All other labeling requirements apply (refer to Section 5B1 or 5B2 above).
7. For any reagent **without** a manufacturer's assigned expiration date, complete the following steps (listed in the order of priority):
    - Contact product manufacturer to obtain written documentation of the expiration dating. Implement applicable expiration dates according to the manufacturer's instructions.
    - Contact the Best Practice Team for guidance on Corporate Standard SOPs as applicable.
    - If the manufacturer or the Best Practice Team does not provide guidance for expiration dating, each facility must assign an expiration date in accordance with their local policy.
        - The assigned expiration date should be based on known stability, frequency of use, storage conditions and risk of contamination.
        - Material stability can be established with literature or reference from a reliable source (SDS).
        - All supporting documentation of the expiration date assignment must be kept with the validation record.

C. Storage

1. Store all reagents as specified by the manufacturer's instructions.
2. If storage requirements change after a reagent container is opened or prepared, the laboratory must ensure the new storage requirement is implemented.
3. When specified, reagents must be stored in an area that has an acceptable temperature range that is equivalent to, or within, the manufacturer's requirements.
4. A frost-free freezer may be used to store reagents and controls provided that the function of these materials is not compromised and the storage conditions are maintained within the specifications of the manufacturer.
    - Patient samples used as reagents may be stored in a frost-free freezer only if protected from thawing.
5. Temperature must be monitored and recorded for appropriate temperature maintenance in all storage areas. Refer to ***Temperature and Humidity Quality Control*** procedure.
    - If ambient storage temperature is indicated, there must be documentation that the defined ambient temperature is maintained and corrective action taken when tolerance limits are exceeded.
    - Temperatures may be recorded using a continuous monitoring system or a maximum/minimum thermometer.
6. Hazardous materials must be secured and stored as specified by the manufacturer (e.g., stock supplies of flammable reagents must be stored in fire resistant cabinets, stock supplies of concentrated acids must be stored in acid cabinets). Refer to the product SDS or container labeling for guidance.

D. Handling

1. The reagent label must be inspected by the testing personnel prior to being placed into use for patient testing to ensure the product has not exceeded the specified expiration date.
2. Prepared reagents must be properly stored, mixed when appropriate, and discarded when stability parameters are exceeded.
3. When opening or preparing a reagent changes the original expiration date:
    - Refer to the product insert, container or technical SOP to determine the appropriate time interval for the new expiration date.
    - Record the expiration date as an exact date (e.g. month/year, number of hours, days, or weeks after preparation).
    - When a reagent expires in intervals of days, weeks, or months following preparation, reconstitution, or opening, the new expiration is based on a 12:00 am to 11:59 pm "day."

IF…	**THEN**
Opening or reconstituting a reagent requires a new expiration date	Calculate the new expiration date based on the time interval specified in the product insert.
The vendor assigns expiration as a specific date	The reagent may be used up to 11:59 pm on the expiration date.
The vendor assigns expiration as a month/year	The reagent may be used up to 11:59 pm on the last day of the expiration month.

IF…	THEN
The vendor assigns expiration in days or weeks after preparation	The reagent may be used up to 11:59 pm of the expiration day (regardless of time of preparation).
The vendor assigns expiration in hours	Personnel must document the expiration date and time on the reagent label. • Reagents may be used up to the number of hours specified from date/time of opening/preparation/reconstitution.

Example 1: A reagent is opened or reconstituted on 10/07 with a three day expiration date. The reagent will expire at 11:59 pm on 10/10.

Example 2: The vendor specifies that a reagent expires 72 hours after preparation. The reagent is prepared at 1:00 pm on 11/15/14. This reagent expires at 12:59 pm on 11/18/14.

4. Reagents must not be used for patient testing beyond the manufacturer's specified expiration date. Reagent stability may only be extended by the manufacturer via written documentation, which must be retained.
5. For Immunohematology only, rare antisera may be used beyond their expiration date if appropriate positive and negative controls are run each day of use and react as expected. (NOTE: This exception is not permitted in **New York State** licensed laboratories). Expired antisera may be used only under the following circumstances:
   - Reagents must be unique, rare, or difficult to obtain, or
   - Delivery of new shipments of reagents is delayed through causes not under the control of the laboratory.
   - The laboratory must document the validation of the performance of expired reagents in accordance with the written laboratory policy.
6. Do not interchange reagents and/or critical components of test kits (unless written permission is provided by the kit manufacturer).
7. Discard contaminated, deteriorated, or compromised reagents regardless of expiration date. Contact the vendor for replacement and/or credit.
8. Dispose of all expired reagents in accordance with the current package insert. For questions regarding reagent disposal, refer to the Chemical Hygiene Plan SOP**,** local Environmental Health and Safety (EHS) Officer, and/or product manufacturer.
9. Expired reagents may be retained for non-patient testing purposes only if they are:
   - Segregated from in-date reagents in a manner that prevents inadvertent use
   - Clearly marked "Do not use for patient testing"

6. RECORDS MAINTENANCE

Records are maintained according to the requirements published in the Quest Diagnostics *Records Management Program Reference Guide*.

7. RELATED DOCUMENTS

- Quest Diagnostics Chemical Hygiene Plan (QDEHS706)
- Quest Diagnostics Records Management Program (QDCOM738)
- Temperature and Humidity Quality Control, local QA procedure

8. REFERENCES

1. Clinical Laboratory Improvement Amendments of 1988; final rule. Fed Register. 2003(Jan 24):7164 [42CFR493.1252(c)], Department of Health and Human Services, Centers for Medicare and Medicaid Services.
2. Laboratory Accreditation, Checklists, College of American Pathologists, Laboratory Accreditation Program, Northfield, IL. 60093

9. DOCUMENT HISTORY

Version	Date	Section	Revision	Revised By	Approved By
1.0	8/2010		Released as an approved draft		
2.0	10/2010	5.1 Labeling B	Added "solutions" to list of items to be correctly labeled. Incorporated NY State labeling requirements into required elements.	P. Sundara	
2.0	10/2010	5.1 Labeling C	Labeling C - *Clarified the language.*	P. Sundara	
2.0	10/2010	5.2 Storage	Added the following: *Note: Some manufacturers may require that the reagents and/or controls be stored in non-frost free (manual defrost) freezers.*	P. Sundara	
3	08/15/14	All	Updated to current SOP format and rearranged the sequence of information.	D. Ribickas	D. Zorka
3	08/15/14	All	Updated verbiage to current regulatory requirements.	D. Ribickas	D. Zorka
3	08/15/14	5D Handling	Added guidelines for calculating and documenting reagent expiration dates.	R. Willis	D. Zorka
3	08/15/14	Addenda	Removed ROXI and exchanged with CHP container policy	D. Ribickas	D. Zorka
4	10/27/14	5.A	• Combined primary and secondary containers. • Added laboratory responsibility to update this document locally with additional state and local requirements, if applicable.	K. Grimes	D.Zorka

4	10/27/14	5.B.1	• Combined primary and secondary labeling requirements. • Added New York state labeling requirement to include date opened and preparer's identity. • Moved requirement for preparer's identity on secondary containers to step 2. • Additional verbiage for safety hazard labeling.	K. Grimes	D.Zorka
4	10/27/14	5.B.6	Deleted redundant information about new expiration dating.		
4	10/27/14	5.D	• Reversed step 4 and 5. • Clarified exception for using expired reagents to apply to Immunohematology reagents and exclusion for New York licensed laboratories.	K. Grimes	D.Zorka
4	11/10/14	 Cover page 5.C, item 5 7	Adopting corporate issued version 4. Add local Effective Date message Add local SOP Add local SOP	L. Barrett	C. Bowman
4.1	12/6/16	Header 5.D, item 8	Add other sites Change SOP reference to CHP	L. Barrett	C. Bowman

10. ADDENDA

Addendum	Title
A	CHP Labeling on Secondary (Workplace) Containers

Addendum A: CHP Labeling on Secondary (Workplace) Containers

1. Secondary workplace containers commonly used in the lab may incorporate the GHS label or label elements; or may remain an alternate labeling system (e.g. the NFPA rating system) which provides the user with specific information regarding the physical and health hazards of the hazardous chemical.
2. Workplace labels or other forms of warning must be legible, in English, and prominently displayed on the container, or readily available in the work area throughout the work shift. Employers with employees who speak other languages may add the information in their language to the material presented, as long as the information is presented in English as well.
3. If needed, the label information can be placed in the work area (e.g. on the instrument or device used to hold the container) if the label does not fit on the actual container.
4. Workplace container labels should also contain the preparation date, expiration date, technician's initials or other pertinent information for the material in question.
5. Hazardous chemical waste must be labeled in accordance to the requirements outlined in the Chemical Hazardous Management and Disposal Waste SOP.

Sample workplace container labels: