### KAISER MEDICAL CARE PROGRAM ORANGE COUNTY AREA POLICIES AND PROCEDURES

TITLE:	CLINICAL LABORATORY P&P MANUAL	INDEX NO:	02-215-01
<b>SECTION:</b>	GENERAL	ORGIN DATE:	5-26-17
<b>SUBJECT:</b>	REAGENT LABELING, STORAGE, AND	REVIEW DATE	
	HANDLING		
		REVISION DATE	

### REAGENT LABELING, STORAGE, AND HANDLING

#### **POLICY**

Reagents, stains, and solutions must be properly labeled, stored, and handled appropriately according to manufacturer's instructions.

# Reagent Labeling

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

- 1. Content and quantity, concentration or titer
- 2. Storage requirements
- 3. If prepared in-house, date prepared, filtered or reconstituted
- 4. If prepared commercially, date of receipt and opening (or reconstitution)
- 4. Expiration date. If opening or reconstitution changes the expiration date, the new expiration date must be indicated.

Mark the reagents as follows:

- When received R, Date
- When opened O, Date, Initials

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. Labeling with "date received" and "date opened" is not routinely required; however if opening the container changes the expiration date, storage requirement, etc., a new expiration date must be recorded.

This policy also applies to the labeling of chemicals used in the laboratory to prepare reagents or during the preanalytic and analytic phases of the testing process.

## Reagent Storage and Handling

Reagents and media must be stored and handled as recommended by the manufacturer to prevent environmentally-induced alterations that could affect reagent stability and test performance. Prepared reagents must be properly stored, mixed, when appropriate, and discarded when stability parameters are exceeded.

If a problem is identified with a reagent that was used for patient testing (e.g. expired vial or reagent subjected to unacceptable storage conditions, etc.), the potential impact must be evaluated on patient test results and records of the evaluation and actions taken must be maintained.

Appropriate storage temperature must be maintained and recorded daily. Document corrective action taken when tolerance limits are exceeded.

### Reagent Expiration Date

All reagents, chemicals, and media must be used within their indicated expiration date.

Expiration date must be assigned to any reagents and media that do not have a manufacturer-provided expiration date.

This policy also applies to the labeling of chemicals used in the laboratory.

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SUBJECT	TIMECARD MAINTENANCE	INDEX NO:	02-215-03
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## Document History Page

Change type: New, Major, Minor etc.	Changes Made to SOP – describe	Signature responsible person/date	Med. Dir. Reviewed/ Date	Lab Manager reviewed/ date	Date change Imp.
New		Judith Remolar 5/26/17			

Imp. =Implemented