HACKETTSTOWN REGIONAL MEDICAL CENTER LABORATORY POLICY MANUAL LABORATORY REAGENT MANAGEMENT

Effective Date: July, 2010 Policy No: GENLAB 9.35 Cross Referenced: Origin: General Lab

Reviewed Date: 01/12 Authority: Laboratory Director

Revised Date: 05/11 Page: 1 of 1

PURPOSE:

To monitor the receipt, labeling and use of all reagents used in testing so that lot numbers and reagent viability can be tracked.

POLICY:

Upon receipt of a reagent into the laboratory, it will be labeled with the receive date on the reagent container. When the reagent is placed in use, the date opened and the open expiration date should be placed on the reagent container. The reagent will also be documented on the 'Diluent/Reagent Log' in each department. The log contains the reagent name, lot#, date placed in use (date opened) and expiration date (after placed in use). All reagents will be discarded when it has expired. Any reagents that are substandard or have deteriorated will be removed from use and documented on 'Diluent or Reagent Log'. All log sheets will be stored for 2 years. See departmental specific procedures under Procedures section.

PROCEDURE:

All Quality Control and Calibration material will have the date opened and open expiration date written on the bottle.

Chemistry:

- Reagent/diluent log for all diluents and reagents placed on instruments
- Siemen's Dimension EXL w/LM and EXL 200 maintain a history of reagent used and calibrator lot #s in the instrument.
- The reagent flex lot #s and calibrator lot #s are also printed on each calibration and stored for 2 years.
- The reagent lot #s used for each test is stored in the instrument and can be extracted to a flash drive if a reagent recall or problem occurred.

Hematology:

- The "reagent Data Entry" screen is printed daily and placed in notebook
- "Diluent or Reagent Log" for all others

Coagulation:

- Reagent lot #s are sequestered on a yearly basis.
- Any new lot #s of reagent (ie. D Dimer) are documented in the QC/Reagent change notebook
- above the lab Supervisor's desk.
- "Diluent or Reagent log" for all other reagents not sequestered.

Urinalysis and Microbiology:

• Enter Lot # information on QC Daily Log

Blood Bank:

• see separate departmental procedure(s)

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