HACKETTSTOWN REGIONAL MEDICAL CENTER
LABORATORY POLICY MANUAL

CLINICAL LABORATORY TECHNICAL PROCEDURES MANUALS

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Effective Date: September 23, 1996	**Policy No: GENLAB 4.11**
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Reviewed Date: 02/19/12	**Authority: Laboratory Director**
Revised Date: 01/12	**Page: 1 of 3**

PURPOSE

To provide a guide for the preparation of all written procedures in the laboratory in order to provide consistency and to ensure that all technologists have precise instructions for performing each laboratory procedure.

POLICY

Procedure title should be concise and descriptive and should include the test name, type of specimen and method or instrument where applicable. The procedure title should be followed by a brief summary.

The procedure must be documented with the name and title of the author, and the dates when placed into use, reviewed, and removed from use. The procedure must be initially reviewed by the Laboratory Director. New Procedures will be inserviced, discussed at a lab meeting, and placed in the appropriate departmental Procedure Book. A copy of the procedure will be placed on the bulletin board in the lab or in Blood Bank with a cover sheet entitled “New or Modified Procedure Training Record.” This document highlights the key point and provides documentation that the staff is knowledgeable about the new procedure or policy. Staff members are required to read and sign off on the new procedure. The procedure must be reviewed at least biennially by the Laboratory Director or his designee. See attached schedule for Procedure Manual Review. The designee can be the Laboratory Manager and the Laboratory Supervisor. Minor changes can be noted on the original, signed, dated, and documented on the review page. All staff members are required to review policies and procedures annually as part of their yearly competency review.

A technical procedure should be explicit and complete and include a principle, specimen requirements, reagents and materials needed, instrumentation, calibration protocol, procedure step-by-step directions, quality control protocol, reference ranges, calibrations, procedure notes, and references. Discontinued Procedures are kept for two years.

PRINCIPLE

The principle should be written in paragraph form and include the test methodology and the clinical reasons for performing the test.

SPECIMEN REQUIREMENTS

Specimen requirements should include:

1. Patient preparation
2. Specimen collection instructions
3. Type of specimen and container, and alternate specimen types
4. Optimum and minimum specimen volume requirements
5. Specimen storage and stability

REAGENTS AND EQUIPMENT

Reagents and equipment requirements should be listed and include:

1. The name and manufacturer and supply company
2. A bold type statement of any health or safety information
3. Directions for reagent preparation
4. Storage and stability

CALIBRATION

Calibration instructions should include:

1. The name and manufacturer and supply company
2. Preparation, storage, and stability
3. Step-by-step procedure for calibration
4. Frequency which calibration should be performed
5. Specify acceptable tolerances and what to do when tolerances are not met

QUALITY CONTROL

Quality control instructions should include:

1. The name and manufacturer and supply company
2. Preparation and storage requirements
3. The frequency that controls need to be run
4. QC limits and corrective actions

PROCEDURE

The procedure should be written using step-by-step directions. Verbiage for "**NOTES**:" should include explanations for special precautions, possible sources of error, helpful hints, and health or safety hazards.

CALCULATIONS

Calculations should include:

1. Stepwise instructions
2. The equation including units
3. A precise example

REPORTING RESULTS

The results section should include:

1. Reference ranges specifying sample type, age, and sex if applicable
2. Identify abnormal and critical results and procedure to report these results
3. Guidelines on acceptable reporting format: rounding off, units, assay reportable range, dilution protocol, interpretive phrases
4. Limitations including interfering substances and invalid results

REFERENCES

The following items should be included in the reference section when used as a source of information:

1. Literature sources, manufacturer product insert, textbooks, etc.