HACKETTSTOWN REGIONAL MEDICAL CENTER
LABORATORY POLICY MANUAL
IMPLEMENTATION OF NEW DIAGNOSTIC EQUIPMENT OR METHODOLOGY

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Effective Date: June, 2002	**Policy No: GENLAB 9.27**
Cross Referenced:	**Origin: General Lab**
Reviewed Date:	**Authority: Laboratory Director**
Revised Date: 01/12	**Page: 1 of 1**

PURPOSE: To establish the policy for the implementation of new equipment or a new testing methodology.

POLICY: When new diagnostic equipment is introduced into the Laboratory or methodology is changed, the performance of the equipment must be evaluated. It is the responsibility of the Department of Pathology to ensure that these changes will not affect patient care. The methods used to ensure testing quality include, but are not limited to: precision, accuracy, analytical sensitivity, quality control, proficiency testing, and recovery (data validation). The effect of interfering substances on sample analysis must be documented when reporting results. Such information is available from reagent manufacturers. The reportable range must be verified/established and validated for each analytic procedure before implementation. This includes both the analytical measurement range (AMR) and the clinically reportable range(CRR).

Data validation is the process during which data is checked and accepted or rejected based on an established set of criteria. This requires the critical review of a body of data to locate and identify spurious results. A correlation study is performed using a minimum of 20 specimens covering the AMR and reference ranges of the method. A linear regression of method correlation must be between 0.85 and 1.15 using Confirm software. Normal results and abnormal results must correlate even if linear regression is not applicable.

Samples used for correlation studies must be stored according to the manufacturer's recommendations until testing of the new method/instrument is performed. Each sample should be run on the current and new methods and comparsions made using the Confirm software. Results out of the established criteria should be carefully reevaluated.

Sensitivity, Precision, and Accuracy studies must be performed using the manufacturer’s guidelines. Evaluation must be made to determine acceptability of the results. Quality control ranges must be established according to the Quality Control Department of Pathology Acceptability Guidelines.

Original correlation data must be reviewed by the Medical Director or designee (Laboratory Manager or Supervisor) and submitted to the State (Clinical Laboratory Improvement Service) and a fee paid. Testing may begin after approval notification is received from the state.

REFERENCES:

CAP Checklist, June 2009
CLSI. Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline – Third Edition. C28-A3 Vol. 28 No. 30
The Laboratory Quality Assurance System, Thomas A.Ratliff Jr.
Laboratory Quality Management, George S. Cembrowski & R Neill Carey
Fundamentals of Clinical Chemistry, 3rd edition, Norbert W. Tietz