HACKETTSTOWN REGIONAL MEDICAL CENTER LABORATORY POLICY MANUAL SIX MONTH CORRELATION STUDIES

Effective Date: April 2009 Policy No: GENLAB 9.33 Cross Referenced: Origin: General Lab

Reviewed Date: 3/29/12 Authority: Laboratory Director

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PURPOSE: Under the current CLIA regulations, any laboratories performing a moderately complex method are required to perform and document a correlation with back up instrumentation every six months.

PROCEDURE: The following instruments are used for backup and require six months correlation:

Stago Satellite Parameters
PT
PTT

EXL200 Parameters

Sodium Albumin Troponin Potassium **Total Protein** Creatine Kinase Alkaline Phosphastase Chloride **CKMB** Glucose Calcium Amylase **BUN ALT** Lipase Creatinine **AST Total Bilirubin** $C0_2$

- 1. Pick twenty patient samples from routine run that have already been resulted on primary instrumentation.
- 2. Repeat these twenty patient samples on corresponding backup instrument.
- 3. Enter data into Confirm software, as a comparison study.
- 4. Submit printout to Laboratory Manager for review.
- 5. Keep instrument data in labeled envelope.
- 6. Completed correlations are located in the Correlation Study binder.

EXPECTED RESULTS

The correlation coefficient "r" should be greater than or equal to 0.9.

REFERENCE

ASCP Workshop, Complying with Regulations and Passing Inspections: Successful Strategies and Practical GamePlans, Sharon Ehimeyere, Ph.D. MT (ASCP) and Ronald H. Laessig, Ph.D.

Evaluation, Verification, and Maintenance Manual, CAP, Reprinted September 1999