HACKETTSTOWN REGIONAL MEDICAL CENTER LABORATORY POLICY MANUAL VERIFICATION OF REFERENCE INTERVALS

Effective Date: July, 2009 Policy No: GENLAB 9.29 Cross Referenced: Origin: General Lab

Reviewed Date: Authority: Laboratory Director

Revised Date: 01/12 Page: 1 of 1

PURPOSE: To establish reference intervals which will be included in patient's reports.

PRINCIPLE: Reference intervals may be different for different instruments or population groups. The laboratory verifies reference intervals established by the instrument manufacturer or published source. Reference intervals illustrate expected values. They are useful to the physician in the assessment of the patient's clinical condition.

PROCEDURE: As follows.

- Run 25 samples from healthy individuals if verifying a sourced reference range.
- Run 120 samples if establishing new reference range
- Enter results into Confirm software
- Compare calculated values with manufacturer's reference ranges. Agreement should be within 10%.

EXPECTED RESULTS: Values should agree within 10%. If there is a significant difference, it may be necessary to run more samples and/or adjust the references range to the new values.

Reference: CLSI. Defining, Establishing, and Verifying Reference Intervals in the Clincial Laboratory: Approved Guideline – Third Edition. CLSI document C28-A3. Wayne, PA.