

REVISED PROCEDURE

3/12/19

Chemistry Procedure:

QC Program - Pre-Analytical, Analytical and Post Analytical Considerations

Revision on page 19

Section: **New Reagent Lot Validation- Centaurs**

Procedure: Centaurs (3/8/19)

Two levels of QC material are run to confirm acceptability of the new reagent lot. The ideal acceptable QC values of the new lot should fall within the given 1SD range of the peer based mean of the assay.

- 1) Enter the new lot and/or calibrator in the Reagent Logbook of the instrument being used.
- 2) Calibrate the new lot of reagent, run two levels of QC material and accept the reagent as valid if the QC falls within the 1SD range established and posted.
- 3) If the QC is outside the 1SD range, then attempt to troubleshoot so as get the QC within the 1SD range, otherwise, repeat Calibration.
- 4) If after the second calibration, the QC is outside the 1SD range, but within the 2SD range:
 1. Accept the Calibration
 2. Notify or leave a note to alert Senior techs of the QC situation with the new lot of reagent.
 3. At this point, run 5 patients with the old QC lot and if the results agree within 2SD, it will be considered a QC matrix issue.
- 5) If the patient results are unacceptable, then, do not use this lot. Attempt to borrow or procure another lot of reagent. Follow the above procedure to alert users of the QC issue with the reagent on that instrument.

PT
3/12/19