

AUDIT® MicroControls<sup>™</sup> Calibration Verification/Linearity System Trouble Shooting Guide

AUDIT<sup>®</sup> MicroControls<sup>™</sup> recommends the following checklist if your initial calibration verification fails for any specific analyte or analytes:

- 1. Quality Control Material
- Are there patterns among controls (e.g. all are below the mean, all are above the mean)?
- Are there any noticeable trends or shift over time?
- How is the accuracy and precision?
- 2. Acceptable Range
- Re-examine your laboratory's determination of the acceptable range for calibration verification material.
- What is your laboratory's current range around the expected target value for that specific analyte in question?
- 3. Reagent Changes
- Have there been any changes to your reagent?
- New lot of reagent?
- Different manufacturer?
- New formulation of current reagent (check package insert)?
- 4. Instrument Maintenance Logs
- Review daily, weekly, monthly, quarterly, semi-annual and annual logs for any deviations or changes.
- 5. Environmental
- Has the instrument been moved recently?
- Any changes to the environment of the instrument and its surroundings?
- 6. Servicing
- Has the instrument been serviced recently?
- Any software or hardware upgrades or changes?
- 7. Operation
- Are there new instrument operators?
- Any recent modification to the technique in how the assay is run?
- 8. Comparative Method
- Is there another nearby laboratory that can also run the calibration verification material to compare results?
- If all the above has been performed, and there are still problems, re-calibrate the instrument.
- If the instrument still does not perform within laboratory control limits, call the instrument manufacturer for further troubleshooting.