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| Policy or Procedure Subject:  Chemistry Calibration Policy | | | No. 01 |
| Department or Section:  Chemistry | | Prior Issue Date: | Issue Date:  07/27/2020 |
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Objective or Purpose:

1. Calibration standard procedures must be implemented to monitor and to ensure the optimal performance of instrumentation and assays.

Calibration:

1. Calibrations are performed according to the manufacturer’s instructions for each test system.
   1. Assay calibration intervals and requirements vary. It is best practice to check the individual assay package insert or procedure manual to verify calibration intervals and requirements.
2. Included in the manufacturer’s instructions for calibration are:
   1. Frequency
   2. Concentration of materials
   3. Criteria for acceptability
3. Calibrations are reviewed for acceptability on the instrumentation software. Assays with an invalid calibration will not be available for patient testing.

Calibration Materials:

1. Calibration materials provided by the manufacturer for the specific test system or assay should be used for calibrations.
   1. Using manufacturer calibration materials ensures that system-specific target values are being produced.
   2. All other calibration materials that are not provided by the manufacturer must be approved by the Laboratory Director or designee.

Recalibration Criteria:

1. Assays must be recalibrated under the following circumstances:
   1. New lot of reagent or change of lots.
   2. Quality control is deviating from standard mean or shifts outside of the acceptable limits.
   3. After major preventive maintenance.
   4. As recommended by the manufacturer.

Qualitative Assay Calibration:

1. Assays that utilize a quantitative cutoff value to distinguish a qualitative negative or positive value must follow the appropriate protocol for establishing a cutoff range.
   1. Cutoff values are established with the initial calibration and set-up of the assay and with every calibration thereafter.
   2. Calibrations of qualitative assays follow the standard frequency that is set by the manufacturer.
   3. Qualitative assay calibrations utilize materials that are provided by the manufacturer to ensure a system-specific target value is produced.
   4. Qualitative assay calibrations and recalibrations follow the same protocol as quantitative assays:
      1. New lot of reagent or change of lots
      2. Quality control is deviating from standard mean or shifts outside of acceptable limits.
      3. After major preventative maintenance.
      4. As recommended by the manufacturer.

