Task Analysis- Quality Control

Topic: Quality Control

1. Define
   a. Quality control (QC)
   b. Quality assurance (QA)
   c. Accuracy
   d. Precision
   e. Reliability
   f. Acceptable range / Confidence interval / Confidence limits
   g. Gaussian distribution
   h. Standard deviation (SD)
   i. Coefficient of variation (CV)
   j. Built-in (internal) control (BIT)
   k. Lot number
   l. Calibrators/Standards
   m. Parallel testing
   n. Target value
   o. Outlier
   p. Shift
   q. Trend
   r. 2_{2S}
   s. Random analytical error (RAE)
   t. Systematic analytical error (SAE)
2. Organizations that determine quality standards
3. Purpose of performing QC
   a. Analytic process
   b. Instrument performance
   c. Reagent/media performance/stability
   d. Calibration verification
4. Types of controls
   a. Qualitative
   b. Quantitative
   c. Internal
   d. External
   e. Instrument performance
   f. Prepared in-house
   g. Commercially prepped
   h. Selecting appropriate control for type of sample being analyzed
5. Differentiate calibrators/standards from controls
   a. Application of each
6. QC rules
   a. Westgard's rules
   b. Multirule

  c. Policies may vary between laboratories
7. Statistics
  a. Mean
  b. Median
  c. Mode
  d. Standard deviation
  e. Coefficient of variation
  f. Normal distribution (Gaussian curve)
  g. Confidence intervals
    i. +/- 1 SD = 68.2% of data
    ii. +/- 2 SD = 95.5% of data
    iii. +/- 3 SD = 99.7% of data
8. Documenting QC
  a. Levey-Jennings chart
  b. Establishing acceptable ranges
  c. Who documents QC
  d. What QC needs to be documented
  e. When does QC need to be documented
  f. Why is documentation important
9. Evaluating QC results
  a. Using Levey-Jennings chart
    i. Determine values that fall outside acceptable limits when applying Westgard's rules (e.g., shifts, trends, outliers, 2-2 SD)
    ii. Presence of random or systematic analytical error
    iii. Possible cause of error and the corrective action needed
  b. Control limits/acceptable values
    i. Within 2 SD
  c. Identify outliers or failures
10. Troubleshooting QC results
  a. Corrective action
  b. Standards, reagents, or controls
  c. Instrument maintenance or repairs
  d. Basic troubleshooting steps
    i. Test procedure, technique, calculations, or transcription
    ii. Instrument performance
    iii. Reagent(s)
    iv. Calibration
    v. Control(s)
    vi. Using flow charts for troubleshooting QC failures
  e. Manual vs. Automated tests
  f. Qualitative vs. Quantitative assays
  g. Batch vs. Random-access assays
  h. One level vs. Two levels vs. Three levels of controls
  i. Third party controls

11. Quality control policies may vary between different laboratory departments and institutions
12. Parallel testing
    a. Run new lot in parallel with old lot (acts as control) to verify/validate new control
13. Lot-to-lot reagent confirmation
14. Monitor the performance (e.g., speed, timing, temperature, cleanliness) of basic laboratory equipment and supplies