40. **When should calibration verification be performed?**

- When QC fails to meet established criteria
- When lot numbers of reagents change
- After major maintenance or service
- When recommended by the manufacturer
- At least every 6 months

41. **What is matrix effect?**

The matrix is all of the components of a sample other than the analyte. The preparation of calibrators, quality control materials, and proficiency-testing samples may involve processes such as freezing or lyophilization or the addition of substances such as preservatives that cause them to react differently than fresh patient specimens. This is known as matrix effect.

42. **What is linear range?**

The range of analyte values that a method can directly measure on the specimen without any dilution, concentration, or other pretreatment not part of the usual assay process. It is also known as analytical range, analytical measurement range (AMR), or reportable range. The range must be revalidated at least every six months and following changes in lot numbers of reagents or major system components.

43. **What must be done when the patient value exceeds the linearity of the analyzer?**

The specimen must be diluted and retested. The value obtained must be multiplied by the reciprocal of the dilution used. For example, a 1:2 dilution would be multiplied by 2. Many analyzers are capable of doing this automatically.

44. **What is autoverification?**

A process by which the computer performs the initial verification of test results. Any data that fall outside of set parameters should be reviewed by the operator. The autoverification process should be tested at least annually and whenever there is a change to the system.

45. **What is a delta check?**

A comparison of a patient's test results with his/her previous results. When the change exceeds a predetermined limit, the cause must be investigated to rule out laboratory error.

46. **How are reference ranges established?**

100-150 data points are gathered from a representative healthy client population and arranged in sequential order. The reference range is the values between the 2.5% position at the low end and the 97.5% position at the high end. Since this represents the 95% confidence limit, one normal person in 20 will fall outside the reference range. Each laboratory should establish its own reference ranges or verify the use of published data. Reference ranges were previously called normal values.

47. **When should reference ranges be reevaluated?**

When there is a change in methodology or patient population.

48. **What must be done when a critical value is obtained on a specimen?**

The physician or other responsible healthcare professional must be notified immediately. If the results are delivered verbally or by phone, the receiver should read back the values to ensure accuracy. Critical value notification may be by computer or fax but delivery must be confirmed by telephone call. Critical value notification must be documented. This documentation should include the date, time, responsible laboratory