Chapter 02: Selection and Analytical Evaluation of Methods—With Statistical Techniques
Test Bank

MULTIPLE CHOICE

1. A *statistic* is a:
   a. constant that describes some particular characteristic of a population.
   b. value calculated from the observations in a sample to describe a particular characteristic of that sample.
   c. complete set of all observations that might occur as a result of performing a particular procedure according to specified conditions.
   d. graphic device for displaying a large set of data.

   ANS: B
   A statistic is a descriptive measure of a sample; it is a value calculated from the observations in a sample to describe a particular characteristic of that sample.

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2. A population mean (μ) is calculated by which one of the following formulae?
   a. $\Sigma x_i/N$
   b. $(b - 1)/SE(b)$
   c. $(x2_i - x1_i)$
   d. $\Sigma(x_1 - \mu)^2/N$

   ANS: A
   The parameter most commonly used to describe the central location of a population of N values is the *population mean* (μ):

   $$\mu = \frac{\Sigma x_i}{N}$$

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3. Which one of the following is the correct formula for calculating the percent coefficient of variation of a set of measurements?
   a. CV = standard deviation × 100%
   b. CV = standard deviation ÷ 100%
   c. CV = (standard deviation ÷ mean) × 100%
   d. CV = (mean + standard deviation) ÷ 100%

   ANS: C
   The coefficient of variation is the measure of relative imprecision. The value of CV% is determined by calculating the ratio of the SD to the mean multiplied by 100%.

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4. The type of method comparison that compares the average results between two analyses with the differences between varying concentration values of the two analyses is referred to as a(n):
   a. Deming analysis.

b. linear regression plot.
c. ordinary least-squares plot.
d. Bland-Altman difference plot.

ANS: D
When comparing values obtained with two different methodologies, the average values of the results are plotted against the differences between the values obtained from the two methods. This examines the differences at varying analyte concentrations to determine whether a problem exists at a certain concentration.

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5. How is the formula for population standard deviation (σ) stated?
   a. The positive square root of the mean ÷ sum of squared differences between mean and individual values
   b. Square root of the mean ÷ (N – 1)
   c. The positive square root of the [(sum of squared differences between mean and individual values) ÷ N]
   d. The sum of squared differences ÷ the positive square root of the mean

   ANS: C
   Standard deviation describes the dispersion (or variance) of values around a central point (typically the mean). Variance is calculated by summing the squared differences between the population mean and each individual sample value and dividing this sum by the population size. This results in a large number, thus SD is the positive square root of this variance.

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6. Two types of error may be encountered during analysis of a substance. The type of error that occurs with a constant or predictable difference or trend, either positive or negative, and thus is related to bias, is a(n) _____ error.
   a. systematic
   b. random
   c. analytical
   d. All of the above are correct.

   ANS: A
   Systematic error is a component of error, which in the course of a number of analyses of the same measure and/or analyte remains constant or varies in a predictable (proportional) way. This type of error will directly influence the mean value and affects bias.

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7. A research project examining cholesterol values using a new Cholestcheck assay produces the following cholesterol values from a random sample of 14, 25-year-old women:
   Mean = 137 mg/dL
   2 standard deviations = 6 mg/dL
   N = 14
   The coefficient of variation percent for this assay is:
   a. 1.14%.
   b. 2.19%.

c. 4.38%.
d. 9.49%.

ANS: B
CV% is calculated by dividing a standard deviation by the mean and then multiplying that value by 100%. In this case, one standard deviation is equal to 3 mg/dL (6 mg/dL ÷ 2), which is divided by 137 and equals 0.02189. This value multiplied by 100% equals 2.189 or 2.19.

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8. You are performing a precision study on a new chemistry analyzer in your hospital lab by analyzing a single sample many times. The study involves performing the analysis on different shifts using different calibrators and analysis by different laboratorians. This aspect of precision is referred to as:
a. repeatability.
b. reproducibility
c. validity.
d. reliability.

ANS: B
One aspect of precision is reproducibility, the closeness of agreement between results of measurements performed under changed conditions of measurements (e.g., time, operators, calibrators, and reagent lots).

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9. Following a precision study in which repeatability and reproducibility of 20 samples are assessed, which one of the following formulae would be used to determine the *total* standard deviation (σ^2_T)?
a. $\sigma^2_{\text{within-run}}/2 + \sigma^2_{\text{between-run}}$
b. $(x2_i - x1_i)$
c. $\Sigma(x_1 - \mu)^2/N$
d. $\sigma^2_{\text{within-run}} + \sigma^2_{\text{between-run}}$

ANS: D
The degree of precision is usually expressed on the basis of statistical measures of imprecision, such as the standard deviation. The total standard deviation (σ^2_T) may be split into within-run and between-run components using the principle of analysis of variance components (variance is the squared standard deviation):
$\sigma^2_T = \sigma^2_{\text{within-run}} + \sigma^2_{\text{between-run}}$

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10. The ability of an analytical method to assess small variations of the concentration of an analyte, and that is often expressed as the slope of the calibration curve, is referred to as:
a. analytical specificity.
b. analytical sensitivity.
c. limit of detection.
d. analytical range.

ANS: B

Analytical sensitivity is the ability of an analytical method to assess small variations of the concentration of analyte. This is often expressed as the slope of the calibration curve.

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11. Method selection involves consideration of several different criteria. Assessment of a candidate method's precision, accuracy, and analytical specificity are components of which one of the following categories?
    a. Analytical performance criteria
    b. Medical criteria
    c. Instrument parameters
    d. Descriptive measures criteria

    ANS: A
    In evaluation of the performance characteristics of a candidate method, precision, accuracy (trueness), analytical range, detection limit, and analytical specificity are of prime importance. These are aspects of analytical performance criteria.

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12. The statistical analysis used to compare values obtained by a new method with those obtained by an established method is:
    a. a Student *t* test.
    b. standard deviation.
    c. regression analysis.
    d. limit of detection.

    ANS: C
    Regression analysis is commonly applied when comparing the results of analytical method comparisons. Typically an experiment is carried out in which a series of paired values is collected when comparing a new method with an established method.

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13. The Student *t* distribution:
    a. compares a sample mean to a population mean using the population.
    b. compares the means of two samples using sample statistics.
    c. assesses the means of samples prior to and following some intervention.
    d. assesses the significance of difference between more than two variables.

    ANS: B
    A Student *t* distribution analysis is commonly used in significance tests, such as the comparison of sample means. Therefore, if a random sample can be taken from a Gaussian population, then the sample SD can be calculated from the sample means.

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14. A list of intervals followed by a list of frequencies is referred to as a:
    a. frequency histogram.
    b. range.
    c. cumulative frequency distribution.
    d. frequency distribution.

ANS: D
A frequency distribution is constructed by dividing the measurement scale into cells of equal width; counting the number, n_i, of values that fall within each cell; and either drawing a histogram or listing the number of values in each cell.

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15. The type of regression analysis that is considered to reliably estimate the relationship between modified target values and that takes into account errors in both methods 1 and 2 is _____ regression analysis.
    a. Deming
    b. ordinary least-squares
    c. nonparametric
    d. random error

ANS: A
To reliably estimate the relationship between modified target values, a regression procedure taking into account errors in both $x1$ and $x2$ is preferable (a situation termed the *Deming approach*). Although the OLR procedure is commonly used in method comparison studies, it does not take errors in $x1$ into account but is based on the assumption that only the $x2$ measurements are subject to random errors.

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16. Comparisons of measurement values between clinical laboratories require a hierarchical approach that obliges routine clinical chemistry measurements to be referred back to a reference measurement procedure. This concept is known as:
    a. uncertainty.
    b. error.
    c. traceability.
    d. reliability.

ANS: C
To ensure reasonable agreement between measurements of routine methods, the concept of traceability comes into focus. Traceability is based on an unbroken chain of comparisons of measurements leading to a known reference value. A hierarchy of methods exists with *a reference measurement procedure* at the top, *selected measurement procedures* at an intermediate level, and finally *routine measurement procedures* at the bottom.

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17. To systematically assess errors associated with laboratory results, a parameter associated with the result of a measurement that characterizes the dispersion of the values reasonably attributed to the substance being measured is considered. This parameter is expressed by a formula that includes preanalytical, analytical, and traceability components and is referred to as:
    a. uncertainty.
    b. error.
    c. traceability.
    d. reliability.

ANS: A
To assess in a systematic way errors associated with laboratory results, the *uncertainty* concept has been introduced into laboratory medicine. The formal definition of uncertainty is "a parameter associated with the result of a measurement that characterizes the dispersion of the values that could reasonably be attributed to the measurand."

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18. In a chemistry methods analysis, linearity refers to the:
    a. closeness of agreement between independent results of measurements obtained under stipulated conditions.
    b. closeness of agreement between the average value obtained from a large series of results of measurements and a true value.
    c. analyte concentration range over which measurements are within the declared tolerances for imprecision and bias of the method.
    d. relationship between measured and expected values over the range of analytical measurements.

    ANS: D
    Definition: linearity refers to the relationship between measured and expected values over the range of analytical measurements.

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19. In the calibration hierarchy, a reference measurement procedure, which is a fully understood procedure of highest analytical quality, is at the top. This procedure is associated with which one of the following types of error?
    a. Calibration error
    b. Specificity error
    c. Pure random error
    d. Systematic error

    ANS: C
    A reference measurement procedure is associated only with pure, random error, whereas a routine method typically has some additional bias related to errors in calibration and limitations with regard to specificity.

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20. In a qualitative point-of-care test, *clinical sensitivity* is considered as the:
    a. probability of classifying a result as positive.
    b. probability of classifying a result as negative.
    c. ability of an analytical method to assess small variations of the concentration of an analyte.
    d. ability of an assay procedure to determine specifically the concentration of the target analyte in the presence of potentially interfering substances.

    ANS: A

Qualitative point-of-care tests are primarily assessed on the basis of their ability to correctly classify results in relation to the cutoff value. The probability of classifying a result as positive is called the *clinical sensitivity*, while classifying a result as negative (below the cutoff) is termed the *clinical specificity*.

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