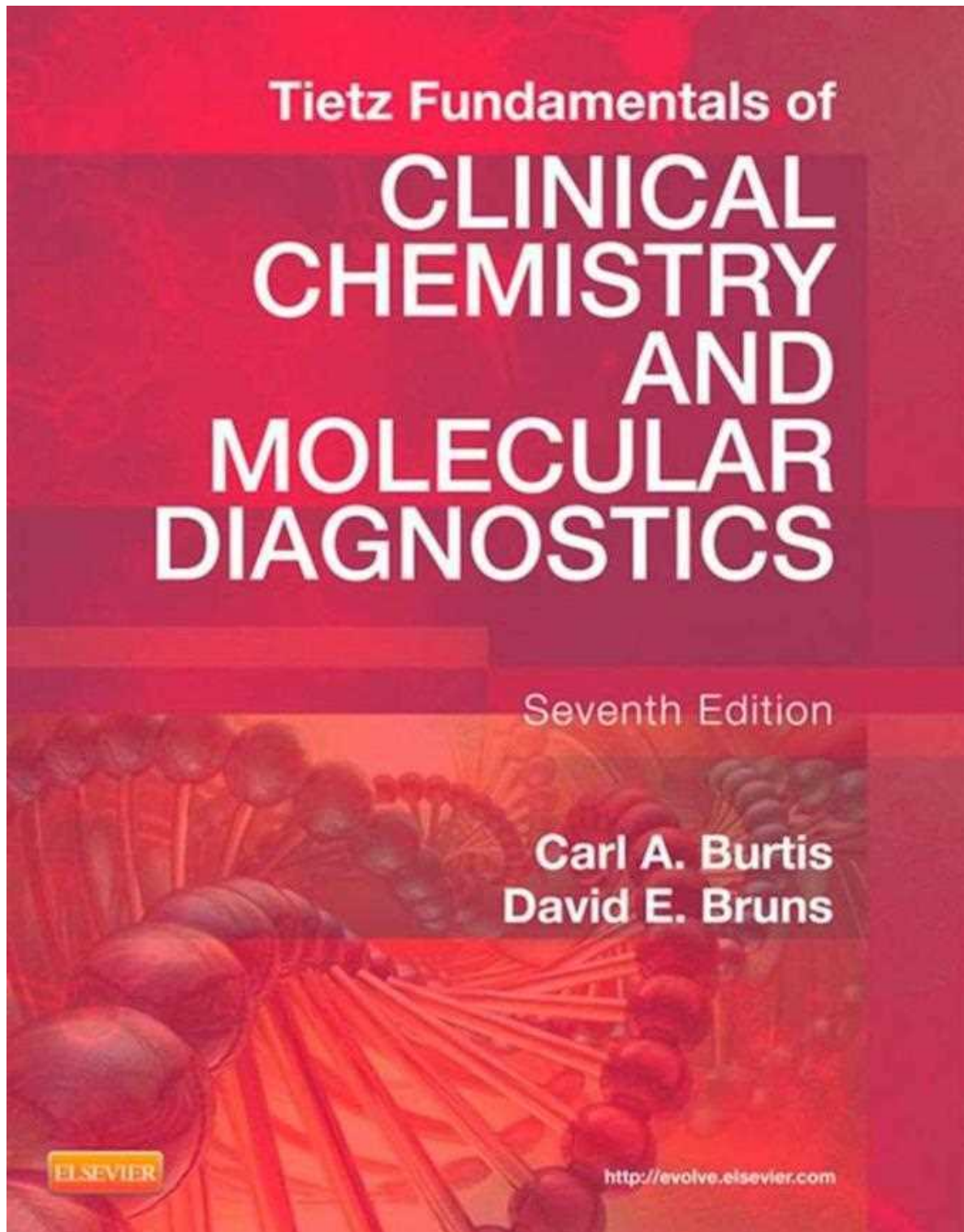# TEST BANK

Tietz Fundamentals of
Clinical Chemistry and Molecular Diagnostics

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7th Edition

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Chapter 01: Clinical Chemistry, Molecular Diagnostics, and Laboratory MedicineTest Bank

MULTIPLE CHOICE

1. An individual working in a clinical chemistry laboratory is married to a sales representative who works for a company that sells chemistry laboratory supplies. When the laboratory manager requests a list of needed supplies, cost of supplies, and vendors, this individual only recommends the spouse's company as the vendor. This is considered to be a(n):
    a. accounting issue.
    b. possible conflict of interest.
    c. maintenance of confidentiality issue.
    d. problem with resource allocation.

    ANS: B
    Concern has been raised over the interrelationships between practitioners in the medical field and commercial suppliers of drugs, devices, equipment, etc., to the medical profession. Similarly, relationships have been scrutinized between clinical laboratorians and manufacturers and providers of diagnostic equipment and supplies. These concerns led the National Institutes of Health (NIH) in 1995 to require official institutional review of financial disclosure by researchers and management of situations in which disclosure indicates potential conflicts of interest.

    DIF: 1   REF: Page 4-5   OBJ: 6 | 7

2. A patient visits her physician stating that her prescribed painkiller is not working to reduce the pain following her recent surgery. A friend of the patient claims that the same painkiller "worked wonders" to reduce her pain after the same surgery. The physician states that the difference in the effect of the drug might be caused by____, which is studied in pharmacogenetics.
    a. epidemiology
    b. an inherited disease
    c. a conflict of interest
    d. a genetic variation in drug-metabolizing enzymes

    ANS: D
    Pharmacogenetics is the study of the genetic variation of drug metabolism between individuals.

    DIF: 1   REF: Page 3   OBJ: 1

3. John works in a molecular diagnostics laboratory and receives a blood sample that has the name of a close friend printed on the bar-coded label. The genetic test that is ordered on the friend's sample would provide diagnostic information about a disorder that has a poor prognosis, and the test is usually performed by John. He asks a fellow employee to analyze the sample for him and not divulge the results. This ethical issue concerns:
    a. confidentiality of patient genetic and medical information.
    b. a conflict of interest.
    c. resource allocation.
    d. diagnostic accuracy.

ANS: A
Clinical laboratorians have long been responsible for maintaining the confidentiality of all laboratory results, a situation made even more critical with the advent of increasingly powerful genetic testing.

DIF: 1   REF: Page 4   OBJ: 6 | 7

4. Molecular diagnostic testing methods and results can be:
    a.   qualitative only.
    b.   quantitative only.
    c.   either qualitative or quantitative.

ANS: C
Molecular diagnostic methods can be either qualitative or quantitative in nature, depending on the clinical need.

DIF: 1   REF: Page 3   OBJ: 5

5. Clinical epidemiology, which is the study of the patterns, causes, and effects of health and disease in certain populations, has provided the clinical laboratory with methods that evaluate the effects and outcomes of laboratory testing. This allows for a more effective:
    a.   process of determining the cost of the testing methods.
    b.   selection and interpretation of laboratory tests.
    c.   determination of the boundaries between the components of the clinical lab.
    d.   conduct assessment.

ANS: A
Clinical epidemiologists have introduced methods to evaluate the effects and value of laboratory testing in healthcare. These developments are expected to play an increasing role in the selection and interpretation of laboratory tests.

DIF: 1   REF: Page 3   OBJ: 4

6. Analysis of which one of the following by molecular diagnostic methods provides a measure of processes that are *ongoing* at the time of blood sampling?
    a.   Genetic variation in an individual's response to a drug
    b.   Circulating plasma nucleic acids
    c.   Malignant lymphomas
    d.   Histocompatibility

ANS: B
Molecular diagnostics, given its very high sensitivity, has been applied to the study of plasma nucleic acids (or circulating nucleic acids). Plasma nucleic acids analysis has been made possible by the discovery that dying cells in the body release their DNA and RNA into the extracellular compartment and ultimately into the bloodstream, where they can be detected and analyzed. Given their short half-life in circulation (less than 24 hours), plasma nucleic acids provide a measure of processes that are ongoing at the time of blood sampling.

DIF: 1   REF: Page 3   OBJ: 5

7. A healthy individual with no clinical signs or symptoms of disease visits his physician for a routine physical examination. Blood samples are collected and sent to the laboratory. The tests requested on the sample are for general laboratory analyses, including a complete blood count, a panel of general chemistry tests (including glucose, protein, cholesterol, and others), and an analysis of urine. This type of testing in laboratory medicine is directed at:
   a. confirming a clinical suspicion of disease.
   b. selecting a treatment for disease.
   c. ruling in a diagnosis.
   d. screening for disease in the absence of clinical signs or symptoms.

   ANS: D
   Testing in laboratory medicine may be directed at (1) *confirming* a clinical suspicion; (2) *making,* or *ruling in,* a diagnosis; (3) *excluding,* or *ruling out,* a diagnosis;, (4) assisting in the *selection, optimization, and monitoring* of treatment; (5) providing a *prognosis*; (6) *screening* for disease in the absence of clinical signs or symptoms; or (7) establishing and monitoring the severity of a physiologic disturbance. The field of laboratory medicine includes clinical chemistry and areas such as microbiology and hematology. The general tests ordered on this healthy individual are done to screen the physiologic systems despite the absence of any symptoms.

   DIF: 2   REF: Page 2   OBJ: 2

8. The discipline involved in the selection, provision, and interpretation of diagnostic testing that uses primarily samples from patients is:
   a. clinical chemistry.
   b. hematology.
   c. laboratory medicine.
   d. molecular diagnostics.

   ANS: C
   The term "laboratory medicine" refers to the discipline involved in the (1) selection, (2) provision, and (3) interpretation of diagnostic testing that uses primarily samples from patients.

   DIF: 1   REF: Page 1   OBJ: 1 | 3

9. A male laboratorian works in the clinical chemistry laboratory of a large hospital. He is approached by his friend, who is a representative of a drug company, and asked to analyze some patient samples for drug levels of a specific drug that the representative's company sells and that these patients use. The representative wants to publish a report on the rate of drug absorption and distribution of this drug and tells his laboratorian friend that he will personally reimburse him for his time. What ethical issues come into play here?
   a. Resource allocation and conflict of interest
   b. Maintenance of confidentiality and publishing issues
   c. Maintenance of confidentiality, conflict of interest, and publishing issues.
   d. Resource allocation, maintenance of confidentiality, conflict of interest, and publishing issues.

   ANS: D

Resource allocation, maintenance of confidentiality, conflict of interest, and publishing issues are being compromised by the representative and the laboratorian if the laboratorian follows through with the request. Using laboratory resources for a study that has not been approved by the institutional review board is a resource allocation issue, revealing results of laboratory tests is a confidentiality issue, receiving money to run laboratory tests from an individual with a direct interest in the laboratory results is a conflict of interest, and publishing the results of the testing would possibly be considered fraudulent and inappropriate.

DIF: 2   REF: Page 4-5   OBJ: 3 | 6 | 7

TRUE/FALSE

1. Molecular diagnostics testing is only used by the clinical chemistry laboratory.

 ANS: F
The discipline of molecular diagnostics, which entered the realm of laboratory medicine in multiple forms and in multiple fields, includes but is not limited to the study of hematopoietic malignancies, such as malignant lymphomas and leukemias; the existence of nonhost nucleic acids (microorganisms, graft-donor, fetal nucleic acids during pregnancy); and assessment of solid tumors.

DIF: 1   REF: Page 3   OBJ: 1 | 5

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

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.

   DIF: 1   REF: Page 10   OBJ: 3

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):

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

   DIF: 1   REF: Page 10   OBJ: 3 | 11

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%.

   DIF: 1   REF: Page 10   OBJ: 11

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.

DIF: 2   REF: Page 19   OBJ: 1 | 6

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.

DIF: 1   REF: Page 10   OBJ: 1 | 11

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.

DIF: 2   REF: Page 7   OBJ: 1 | 7

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.

  DIF: 2   REF: Page 20 OBJ: 11

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).

  DIF: 2   REF: Page 13 OBJ: 1 | 4

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. $\sigma^2_{within-run}/2 + \sigma^2_{between-run}$
  b. $(x2_i - x1_i)$
  c. $\Sigma(x_1 - \mu)^2/N$
  d. $\sigma^2_{within-run} + \sigma^2_{between-run}$

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):
$\sigma^2_T = \sigma^2_{within-run} + \sigma^2_{between-run}$

  DIF: 2   REF: Page 13 OBJ: 4 | 11

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.

DIF: 1   REF: Page 6   OBJ: 1 | 4

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.

    DIF: 1   REF: Page 7-8   OBJ: 2

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.

    DIF: 1   REF: Page 20   OBJ: 1 | 5

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.

    DIF: 2   REF: Page 11   OBJ: 1 | 3

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.

DIF: 1   REF: Page 9   OBJ: 1

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.

     DIF: 2   REF: Page 21   OBJ: 8

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.

     DIF: 2   REF: Page 28   OBJ: 1 | 9

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.