Chapter 01: Clinical Chemistry, Molecular Diagnostics, and Laboratory Medicine Test 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.

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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.

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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.

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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.

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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.

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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.

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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.

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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.

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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.

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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.

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