Laboratory Test Selection and Interpretation
Learning Objectives*

The graduating medical student should be able to:

**General**
1. Demonstrate an understanding and ability to apply the concepts of diagnostic sensitivity and specificity of a laboratory test to a specific clinical situation.

2. Define negative and positive predictive value and explain how these values are influenced by the prevalence (prior probability) of disease in defined populations (Bayes theorem).

3. Apply concepts of predictive value in clinical situations in which predictive values provide critical information for developing patient care screening, diagnostic, prognostic, and therapeutic pathways/algorithms.

4. Describe how reference intervals are derived and used and the different types of reference intervals, including those derived from population distributions, from expert consensus recommendation, or from evidence-based determination of “threshold” values based on a test’s predictive value in a clinical algorithm.

5. Explain how reference intervals may be partitioned or stratified by age, sex, race, clinical state, e.g. pregnancy, or other factors.

6. Explain why 5% of laboratory test results from healthy individuals might fall outside a reference interval.

7. Explain the concept of variability in repeated measurements, as well as variability within and between individuals.
8. Describe the contributors to analytical uncertainty – imprecision and inaccuracy, and their respective measures - coefficient of variation and bias; how the sources of variability relate to clinical interpretation of changes in test results and in the diagnosis of clinical conditions.

9. Discuss the long-reaching consequences of ordering unnecessary testing with consideration as to whether routine daily monitoring tests constitute unnecessary testing.

10. Using an understanding of reference intervals, explain why unnecessary testing may lead to higher health care costs and increased risk for the patient.

11. Discuss the consequences of failing to utilize noninvasive or minimally invasive diagnostic procedures before proceeding to invasive approaches.

12. Explain the roles of preanalytical and postanalytical variables in affecting test results and thereby impacting patient care.

13. Identify common sources of preanalytical errors.

14. Describe the effects of blood-drawing technique on test results.

15. Compare and contrast the use of specimen tubes with various colored tops, as well as other specimen containers, and why they cannot be used interchangeably.

16. Explain the importance of proper and unique identifiers for patient specimens and specimen containers.

17. Define “critical value” and “turnaround time,” and explain why critical values are directly reported to the health care provider for immediate action.
18. Compare and contrast uses of “stat” and “routine” test priorities.

19. Describe the broad categories of situations that may result in test interference, e.g. incomplete tube fill, hemolysis, lipemia, bilirubinemia, cross-reacting and interfering substances.

20. Explain why one should expect differences in results between laboratories using different methodologies when evaluating tests.

21. Demonstrate the ability to properly draw blood via venipuncture.

22. Describe what “point-of-care” (POC) testing is, and discuss why values generated using POC methods may be less precise and also differ, on average, from values generated in the clinical laboratory.

23. List the basic components of quality control that must be integrated into POC procedures.

24. Compare and contrast “universally” recognized test panels as defined by the American Medical Association Current Procedural Terminology and test “panels” defined by individual practitioners.

25. List the advantages and disadvantages of using test panels and “reflex” testing when placing patient orders.

**Molecular Diagnostics**

26. Explain the general principles of molecular diagnostics testing in the screening, diagnosis, and/or monitoring of infectious, genetic, and oncologic diseases.

27. Describe the place of pharmacogenetic testing in clinical care.

28. Describe the legal, ethical, and social implications of genetic testing.
29. Compare and contrast genetic testing techniques, including amplification, sequencing-based tests, cytogenetics, fluorescence in situ hybridization, comparative genomic hybridization, and other common methodologies and the limitations of each, as well as sources of false-positive and false-negative genetic tests; understand quantitative polymerase chain reaction testing.

- Educating Medical Students in Laboratory Medicine, B. Smith, et al., Am J Clin Pathol 2010;133:533-542
  http://ajcp.ascpjournals.org.proxy.its.virginia.edu/content/133/4/533.full

**Resources:**

Clinical Laboratory Tests: Which, Why, and What Do The Results Mean?, F. Wians, American Society for Clinical Pathology
http://labmed.ascpjournals.org/content/40/2/105.full

http://qualitysafety.bmj.com/content/22/Suppl_2/ii6.full.html#ref-list-1

Genetics and Social Science Testing Methods, National Coalition for Health Profession Education in Genetics

Testing in the Clinical Lab: Which Types of Testing are Performed in the Various Areas of the Clinical Laboratory? University of Indiana, Department of Pathology & Laboratory Medicine
http://pathology.iupui.edu/education/undergraduate/clinical-lab-science/testing-in-the-clinical-lab/

Laboratory Tests Interpretation, Nurses Research Publication

Laboratory Medicine: The Diagnosis of Disease in the Clinical Laboratory, M. Laposata, 2010, pages 1-10, Claude Moore Health Sciences Library
Molecular Diagnostics, Department of Pathology, Yale School of Medicine
http://medicine.yale.edu/pathology/diagnosticprograms/moleculardiagnosics

Modified November 2014