

Statistical Features of Diagnostics

47-MINUTE ONLINE CLASS | LEVEL 3

SUGGESTED PREREQUISITES: DIAGNOSTIC DEVELOPMENT AND APPROVAL,
DNA-BASED DIAGNOSTICS, PROTEIN-BASED DIAGNOSTICS

OVERVIEW

Statistical Features of Diagnostics surveys the measurements used to assess a diagnostic's accuracy. Diagnostics must achieve a certain level of accuracy before receiving regulatory approval. Learn the meaning of variability, sensitivity and specificity and how each is calculated. Learn how these measurements are used to determine false negative and false positive percentages. If you are new to diagnostic development and need a primer on the measurements needed to achieve regulatory approval this class is for you.

Five Takeaways:

1. Produce and interpret a standard curve to analyze a diagnostic's test results.
2. Recognize types of data distributions and how each is used to determine if a patient falls in the normal or abnormal range for a disease.
3. Choose the correct measurement to determine the disease state of a patient.
4. Explain how precision, bias, specificity and sensitivity measurements determine the accuracy of a diagnostic.
5. Discuss how false positive and false negative percentages and their comparison to the "Gold Standard" determine if one receives regulatory approval for a novel diagnostic.

AGENDA

- **Introduction to Measurements and Determining Unknowns** introduces the concept of measurements and discusses the process of producing, using and interpreting a standard curve when attempting to determine the results of a diagnostic test.
- **Measures: Variability and Distributions** explains how a diagnostic's variability measurements determine if a patient falls into a normal or abnormal distribution for a disease.

Continued



- **Examples of Test Distributions** shows how the analysis of various bi-modal distributions determine if patients fall within the normal or abnormal range for a disease and how to identify an ideal distribution for a specific diagnostic.

