ON-DEMAND, SHORT CLASS | LEVEL THREE | 47-MINUTES

SUGGESTED PREREQUISITE:

DIAGNOSTIC DEVELOPMENT AND APPROVAL, DNA-BASED DIAGNOSTICS, PROTEIN-BASED DIAGNOSTICS

biotechPrimer
Life Science Training From Industry Experts

Understanding Diagnostic Measurements

OVERVIEW

Understanding Diagnostic Measurements surveys the measurements used to assess a diagnostic's accuracy because a test must achieve a certain level of accuracy before receiving regulatory approval. Understand how these measurements determine false negative and false positive percentages. Learn the meaning of variability, sensitivity, and specificity and calculate each. This course is for those new to diagnostic development who need a primer on the necessary measures to achieve regulatory approval.

Five Takeaways:

1. Produce and interpret a standard curve to analyze a diagnostic's results.
2. Recognize types of data distributions and how each is used to determine if a patient's condition falls in the normal or abnormal range.
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 determines regulatory approval for a novel diagnostic.

AGENDA

Introduction to Measurements
The gold standard
Requirements for regulatory approval
Types of diagnostic measurements
Direct and indirect measurements
Determining unknown analyte concentrations
Standard curve estimations
Constructing a standard curve
Reading a standard curve
Science of colorimetric assays

Variability of Measurements
Variability defined
Distribution of values
Graphic display of distributions
Bi-modal distribution
Variability factors

Examples of Test Distributions
Blood pressure and cholesterol
Cholesterol predicts atherosclerotic disease
Bi-model distribution
Ideal distribution

Testing Accuracy

Measurement considerations
Accuracy defined
False positive and false negative defined
Specificity and sensitivity defined
Reading specificity and sensitivity distributions
Reading true positive and true negative distributions
Reading false negatives and false positive distributions
Reading positive and negative predictive value distributions
Reading low prevalence distributions
Example: mammograph for breast cancer
Example: PSA diagnostic for prostate cancer