

A close-up, top-down view of a multi-well microplate. The wells are arranged in a grid and contain various colored liquids, primarily yellow and orange, with some containing a dark, granular substance. The lighting is bright, creating a warm, golden-yellow glow across the entire scene.

BIOTECH PRIMER'S  
**COURSE SNAPSHOT**

**Medical Device & Diagnostics**

# Medical Device & Diagnostics

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### For more information contact

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 Stacey@BiotechPrimer.com

# Medical Device Development Primer

ONE-DAY MASTER COURSE LIVE, ONLINE

## OVERVIEW

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**Medical Device Development Primer** is a fast-paced, one-day preparatory course designed for professionals seeking a basic understanding of the industry. This course examines all aspects of medical device development, including the five development phases—market opportunity, evaluation, design, verification, and manufacturing. The course delves into the changing regulatory environment and focuses on the different pathways that devices travel for agency approval. Take this course to develop an understanding of the entire process required to bring a new medical device to market.

### Five Takeaways

1. Fluency in essential terminology and acronyms of the medical device industry.
2. Knowledge of the various approval pathways for a medical device to be marketed to patients.
3. An understanding of how to mitigate risk in a medical device.
4. An improved ability to communicate with engineers, colleagues and clients.
5. The ability to construct a medical device by following the traditional five phases of development.

## AGENDA

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### **Medical Device Overview** 9:00-9:30

Medical device defined  
Medical device diversity

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### **Medical Device Regulations** 9:30-10:30

Quality system regulations (QSRs)  
Current good manufacturing practices  
Good laboratory practices  
Good clinical practices  
Risk management plan  
Exemptions

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### **Break** 10:30-10:45

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### **Medical Device Regulations *continued***

10:30–12:00  
Rest of world approval pathways  
Home brew and combination devices  
    Software development  
    Prototyping  
    Medical device reporting  
Phase IV: verification  
Phase V: manufacturing transfer  
    Documentation  
    Equipment IQ/OQ/PQ  
Regulatory challenges  
Diagnostics  
Predicates  
New technologies  
Clinical studies

### **Lunch** 12:00-12:45

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### **Medical Device Development** 12:45-2:15

Phase I: market opportunity evaluation  
    Market analysis  
    Risk management plan  
Phase II: concept evaluation  
    Formulation steps  
    Feasibility  
Phase III: engineering design process  
    Design and development

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### **Break** 2:15-2:30

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### **Medical Device Approval** 2:30-3:15

Clinical trials  
Need for a gold standard  
Regulatory submissions  
Coding and reimbursement

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### **Wrap-Up** 3:15-3:30



# Medical Device Development Primer

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## PRICING

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Customized training for organizations

**\$11,000/** for up to  
24 participants

Customization fee may apply

Prescheduled master course

**\$895/** per  
person

Delivered live, online

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## DELIVERABLES

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Medical Device  
Development Primer  
course workbook



Course  
certificate



Access to course  
recording for 2 weeks



# Medical Device Development Immersion

TWO-DAY MASTER COURSE LIVE, ONLINE

## OVERVIEW

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**Medical Device Development Immersion** is a two-day course that surveys all aspects of medical device development. Learn about the changing regulatory environment and compare the FDA's and European Union's approval processes. Discover in detail the five phases of medical device development: market opportunity, evaluation, design, verification, and manufacturing. Take this course to develop an understanding of the entire process required to bring a new medical device to market.

### Five Takeaways

1. An improved ability to communicate with engineers, colleagues and manufacturers.
2. Fluency in medical device terminology and processes.
3. A toolbox to help design a medical device prototype.
4. Knowledge of the various approval pathways for each medical device class.
5. Risk mitigation in medical device development and approval.

## AGENDA

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### DAY ONE

#### Medical Device Overview 9:00-10:30

Medical device defined  
Medical device diversity  
Industry sectors and top companies  
History of device regulation  
FDA approval pathways: 501(K), PMA

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#### Break 10:30-10:45

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#### Medical Device Regulations 10:45-12:00

Quality system regulations (QSRs)  
Current good manufacturing practices  
Good laboratory practices  
Good clinical practices  
Risk management plan  
Exemptions  
Rest of world approval pathways  
Special categories: home brew, combinations

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#### Lunch 12:00-12:45

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#### Medical Device Regulations *continued*

12:45-1:30

Regulatory challenges  
Diagnostics  
Predicates and new technologies  
Clinical trials  
Medical device reporting

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#### Medical Device Development 1:30-3:15

Phase I: market opportunity  
Market analysis  
Risk management plan  
Phase II: concept evaluation  
    Formulation steps  
    Feasibility  
Phase III: engineering design process  
    Design  
    Development  
    Prototyping

#### Wrap-Up 3:15-3:30

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### DAY TWO

#### Medical Device Development 9:30-11:00

Phase IV: verification  
Phase V: manufacturing transfer  
    Documentation  
    Equipment IQ/OQ/PQ  
    Biocompatibility  
    Sterilization  
    Shipping and storage

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#### Break 10:00-10:15

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#### Medical Device Approval 10:15-12:00

Clinical trials  
Need for a gold standard  
Regulatory submissions  
Business preparations  
Product launch preparations  
Coding and reimbursement

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#### Lunch 12:00-12:45

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#### Commercialization 12:45-2:00

Manufacturing scale-up  
Product launch  
Post-launch assessment

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#### Break 2:00-2:15

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#### Current Issues 2:15-3:15

The increasing role of the FDA  
Why are the newest devices in Europe?

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#### Wrap-Up 3:15-3:30



# Medical Device Development Immersion

## PRICING

Customized training for organizations

**\$18,000/** for up to 24 participants

Customization fee may apply

Prescheduled master course

**\$1,395/** per person

Delivered live, online

## DELIVERABLES



Medical Device Development Immersion course workbook



Course certificate



Access to course recording for 2 weeks

# Molecular Diagnostics Development

ONE-DAY MASTER COURSE LIVE, ONLINE

## OVERVIEW

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**Molecular Diagnostics Development** is a one-day exploration of diagnostics' journey from development to reimbursement geared for newcomers to the medical device industry. Understand concepts such as sensitivity, specificity, false positives, false negatives, and ROC curves. Learn how the FDA evaluates diagnostics and the various pathways to approval. The course ends with a look at how diagnostics are reimbursed on the market.

### Five Takeaways

1. An improved ability to communicate with scientists, regulators and clients.
2. Fluency in the essential terminology used in the diagnostics sector.
3. Statistics background needed to understand basic diagnostic measurements.
4. An understanding of how to interpret diagnostic measurements.
5. The ability to predict if a diagnostic would be approved by the FDA based on statistical analysis of sensitivity and specificity results.

## AGENDA

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### **Diagnostics' Role in Medicine Today**

9:00-9:30

What is a molecular diagnostic?  
Uses of diagnostic tests  
Types of diagnostic tests

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### **Statistical Features of Diagnostics**

9:30-10:15

Gold standards  
Measures  
Standard curve  
Measurement and distribution

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**Break** 10:15-10:30

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### **Statistical Measures of Tests** 10:30-11:30

False positive and false negative  
Sensitivity and specificity  
True positive  
*Activity: Sensitivity and Specificity*

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### **Measuring the Strength of a Test** 11:30-12:15

RADAR sensitivity and specificity  
Receiver operator curves (ROC curves)  
ROC curves reclassification analysis

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**Lunch** 12:15-1:00

### **Risk of Diagnostic Tests** 1:00-1:30

Low prevalence  
Mammography  
Invasive Procedures

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### **Development and Approval** 1:30-2:15

Testing against the gold standard  
Development of clinical tests  
Pathways to approval  
Class I  
Class II  
Class III

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**Break** 2:15-2:30

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### **How Diagnostic Tests Are Reimbursed**

2:30-3:15  
Center for Medicare and Medicaid Services  
Reimbursement in-hospital and outpatient  
Methods of economic evaluation

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**Wrap-Up** 3:15-3:30



# Molecular Diagnostics Development

## PRICING

Customized training for organizations

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Delivered live, online

## DELIVERABLES



Molecular Diagnostics  
Development course  
workbook



Course  
certificate



Access to course  
recording for 2 weeks

# The Science of Molecular Diagnostics

ONE-DAY MASTER COURSE LIVE, ONLINE

## OVERVIEW

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**The Science of Molecular Diagnostics** is a one-day course on the growing role of molecular diagnostics in health care. Learn how disease-causing mutations occur and about the diagnostics that identify how and where disease occurs. If your science background needs strengthening or you're new to the business, this course will have you up and running in no time.

### Five Takeaways

1. Scientific background to understand how mutations occur and cause disease.
2. An overview of the most innovative diagnostics within the biopharma industry.
3. Importance of biomarkers in disease and diagnostics.
4. An understanding of how DNA- and protein-based diagnostics work.
5. How to interpret diagnostic results.

## AGENDA

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### **Diagnostics Overview** 9:00-9:30

Diagnostic defined  
Uses of diagnostics  
Types of diagnostics  
Biomarkers

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### **Science Driving Molecular Diagnostics: DNA and Proteins** 9:30-10:30

DNA structure and function  
Chromosomes and genes  
How DNA codes for proteins  
Protein structure and function  
Proteome  
*Lab: DNA Isolation and Extraction*

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### **Break** 10:30-10:45

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### **Genetic Variation: Basis of Disease**

10:45-12:00  
Alleles  
Mutations: genetic variation  
Genetic basis of disease  
Personalized medicine  
Companion diagnostics  
*Activity: Genetic Variation Taste Test*

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### **Lunch** 12:00-12:45

### **How Molecular Diagnostics Work: DNA-Based Diagnostics** 12:45-1:45

Polymerase chain reaction  
Reverse-transcriptase PCR  
DNA microarrays and SNP chips  
Next-generation sequencing  
Big data and rare disease  
Third-generation sequencing  
*Activity: Microarray to Determine Drug Metabolism*

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### **Break** 1:45-2:00

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### **How Molecular Diagnostics Work: Protein-Based Diagnostics** 2:00-2:45

Antibodies  
ELISA assays  
Multiplexed ELISA  
Bead immunoassay  
Lateral flow immunochromatographic assay  
Protein chromatography

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### **Liquid Biopsies** 2:45-3:15

Cell-free DNA  
Exosomes  
Circulating tumor cells

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### **Wrap-Up** 3:15-3:30



# The Science of Molecular Diagnostics

## PRICING

Customize training for organizations

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Customization fee may apply

Prescheduled master course

**\$895/** per person

Delivered live, online

## DELIVERABLES



The Science of Molecular Diagnostics course workbook



Course certificate



Access to course recording for 2 weeks

# Medical Device & Diagnostics

## Online Classes

Learn anywhere, at your own pace. Designed for individuals, customized for organizations.

### LEVELS

Each online class is given a level to help individuals choose the appropriate course based on their background and needs. For all level 2 and 3 courses a suggested prerequisite will be given but is not mandatory to take.

**Level 1: Foundational** For non-scientists new to biopharma and for those who need a refresher on the fundamental science driving the health care industry

**Level 2: General** For individuals who possess a general understanding of science fundamentals

**Level 3: Advanced** For individuals who have a good grasp of the science and biopharma industry

### PRICING

Each individual online course: **\$150** BIO member price: **\$120**

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*\*For BIO member companies only*

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- **Contact:** Stacey Hawkins at [stacey@biotechprimer.com](mailto:stacey@biotechprimer.com) to learn more.

# Diagnostics' Role In Medicine Today

41-MINUTE ONLINE COURSE | LEVEL 1

## OVERVIEW

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**Diagnostics' Role In Medicine Today** introduces the ever-expanding molecular diagnostics industry. Diagnostics save lives by helping to pinpoint the exact cause and location of disease. Learn the purpose of each type of diagnostic, the science behind personalized medicine, and how companion diagnostics help doctors prescribe medication and dosage correctly the first time. If you are new to this area of health care, **Diagnostics' Role in Medicine Today** will provide a solid foundation on which to build your diagnostic acumen.

### Five Takeaways:

1. Cite how biomarkers are used in molecular diagnostics.
2. Describe the types of measurements employed by diagnostics.
3. Identify the main purposes of each diagnostic category.
4. Explain how companion diagnostics take advantage of a patient's genetic variation.
5. Connect diagnostics to improved disease treatment through personalized medicine.

## AGENDA

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- **Defining Diagnostics** explains how biomarkers are used in molecular diagnostics to measure patient body chemistry and function that may or may not lead to disease.
- **Uses of Diagnostics** explains how diagnostics are used in health care today. Purposes include screening, diagnosis, prognosis, drug selection, drug treatment, monitoring, and disease management.
- **Types of Diagnostics** states the purpose for the different types of diagnostics including chemistry, immunochemistry, hematology, cytology, microbiology, infectious disease, imaging, and molecular testing.
- **The Science Behind Molecular Diagnostics** links DNA mutations and disease to the development and workings of companion diagnostics.
- **Selecting a Treatment** illustrates how companion diagnostics inform physicians on the best course of treatment for patients, including medication and dosage choice. This medication specificity is called personalized medicine.

# Medical Device Development

57-MINUTE ONLINE COURSE | LEVEL 2

SUGGESTED PREREQUISITES: DIAGNOSTICS' ROLE IN MEDICINE TODAY,  
MEDICAL DEVICE OVERVIEW AND REGULATION

## OVERVIEW

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**Medical Device Development** provides a detailed look at the five stages of medical device development including market opportunity evaluation, concept evaluation, engineering design, verification/validation and manufacturing transfer. If you are an engineer, manufacturer, information technologist, investor or someone who finds themselves in development, Medical Device Development will broaden your knowledge of the entire development process.

### Five Takeaways:

1. Understand the importance of the five phases of medical device development.
2. How to evaluate market opportunity.
3. Determine the manufacturing feasibility based on a medical device's design.
4. Learn the required prototype specifications needed in device design, documentation and testing.
5. Appreciate the process of device scale-up production.

## AGENDA

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- **Market Opportunity Evaluation** explains how to evaluate the value and opportunity of the product, the user and the market.
- **Concept Evaluation** determines the feasibility of the medical device's conceptual design and how that blueprint is used to map out the key steps in product design.
- **Engineering Design** discusses how required medical device prototype specifications are designed, documented and tested.
- **Verification and Validation** advocates for a process of verification and validation in engineering builds, packaging, labeling, human factors testing and manufacturing.
- **Manufacturing Transfer** shows the arduous process of how to move from small scale to large scale production.

# Medical Device Overview and Regulation

57-MINUTE ONLINE COURSE | LEVEL 2

SUGGESTED PREREQUISITES: DIAGNOSTICS' ROLE IN MEDICINE TODAY

## OVERVIEW

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**Medical Device Overview and Regulation** explores the diversity of the medical device industry by highlighting its various sectors, top companies and major regulatory bodies worldwide. Device classification and each classification's differing approval pathways are outlined in detail. The course concludes with a look at the quality system regulations and risk management plans you must follow. If you are new to medical device, Medical Device Overview and Regulation will provide an understanding of the industry's regulatory breadth.

### Five Takeaways:

1. Identify the major sectors, worldwide regulatory organizations and top companies of the medical device industry.
2. Classify medical devices based on potential risk.
3. Explain the major medical device approval pathways.
4. Discuss how the Code of Federal Regulations and Good Practices enforce regulatory compliance.
5. Develop a risk management plan for a medical device.

## AGENDA

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- **Overview of Medical Device Types** identifies the major medical device sectors and describes the history of medical device regulation.
- **FDA Medical Device Classification** explains how to classify medical devices into Class I, Class II, or Class III based on risk assessment.
- **FDA Approval Pathways for Medical Device** maps the medical device approval pathways, including how approval of a product can be obtained if a new device is being compared to a predicated device.
- **FDA Regulatory Compliance for Medical Device** surveys various compliance laws including the Code of Federal Regulations, Good Lab Practices, Good Clinical Practices, and current Good Manufacturing Practices as they relate to medical devices.
- **Medical Device Risk Management Plans** demonstrates how to develop a risk management plan for a medical device.
- **Medical Device Regulatory Bodies Worldwide** lists the worldwide regulatory bodies for medical devices.

# Medical Device Approval and Commercialization

55-MINUTE ONLINE COURSE | LEVEL 3 | SUGGESTED PREREQUISITES: MEDICAL DEVICE OVERVIEW AND REGULATION, MEDICAL DEVICE DEVELOPMENT

## OVERVIEW

**Medical Device Approval and Commercialization** explains the medical device approval process from initial regulatory submission through commercialization. Learn the diverse best practices accompanying a successful regulatory outcome, including manufacture scale-up, reimbursement strategy, product launch and post-launch assessment. If you are working in the diagnostics industry, this course gives you a game plan to undertake a successful launch.

### Five Takeaways:

1. Choose the appropriate level of clinical trial based on risk assessment to the patient.
2. Explain the process of obtaining approval to initiate human clinical trials to test a new medical device.
3. List the challenges of launching a new medical device in terms of marketing, sales, reimbursement and manufacturing scale-up.
4. Outline a reimbursement strategy for coverage, coding and payment of a medical device.
5. Write a post-launch assessment and surveillance protocol.

## AGENDA

- **Clinical Trials for Medical Device** discusses how to choose the appropriate level of clinical trial for a medical device based on that device's risk assessment to the patient.
- **Investigative Device Exemption** explains the process of obtaining approval to initiate human clinical trials, including how to identify a reference device and the importance of testing a new device against the reference device when seeking FDA approval.
- **Regulatory Submission for Medical Device** reviews the time cycle for submission approvals.
- **Business Decisions for Medical Device Launch** helps you think through the challenges of a product launch in terms of marketing, sales, reimbursement, and manufacturing.
- **Manufacturing Scale-Up for Medical Device** highlights the challenges involved in scaling up manufacturing in preparation for product launch and lists the time cycle for manufacturing scale-up.
- **Reimbursement for Medical Device** demonstrates how to outline a reimbursement strategy for coverage, coding and payment.
- **Medical Device Product Launch** lists the various pre-launch preparations and shows how to write a post-launch assessment and surveillance protocol. It concludes with a look at the mandatory medical device reports required by the FDA.

# Diagnostic Development and Approval

50-MINUTE ONLINE COURSE | LEVEL 1

SUGGESTED PREREQUISITE: DIAGNOSTICS' ROLE IN MEDICINE TODAY

## OVERVIEW

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**Diagnostic Development and Approval** describes the regulatory pathways for different categories of diagnostics, emphasizing the differences between in vitro diagnostics and laboratory-developed tests. Quality system regulations are extensively reviewed. The course ends with a discussion on the economic evaluation of novel diagnostics. Diagnostic Development and Approval helps anyone in the diagnostics industry expand their diagnostics development acumen.

### Five Takeaways:

1. Discuss the differences in diagnostic oversight by the FDA and the CMS.
2. Explain the US regulatory process for in vitro diagnostics with laboratory developed tests.
3. Recognize FDA's Class I, Class II, and Class III diagnostics.
4. Summarize the EU diagnostics approval process.
5. Discuss the challenges in receiving diagnostic reimbursement in the US.

## AGENDA

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- **Diagnostics: Regulation of New Clinical Tests** summarizes the regulatory pathways for different categories of diagnostics and explains the differences in oversight from the Center of Medicare and Medical Services with the FDA.
- **Approval Process for Laboratory Developed Tests** compares the regulatory differences between in vitro diagnostics and laboratory developed tests.
- **Diagnostic Regulatory Pathways** describes the regulatory burden of Class I, II, and III diagnostics and how to assess a diagnostic's class based on its risk profile. The FDA's 501(k), de novo 510(k), and premarket approval regulatory pathways are explained.
- **Quality Control of Diagnostics** highlights the application of quality system regulations for diagnostics.
- **European Union Approval Pathways for Diagnostics** provides a synopsis of the EU's diagnostic approval process.
- **Reimbursement for Diagnostics** describes the methodology for economic evaluation and reimbursement of novel diagnostics. Lastly, the US standard reimbursement codes for diagnostics are reviewed.

# How Diagnostics Work: DNA-Based Diagnostics

44-MINUTE ONLINE COURSE | LEVEL 2

SUGGESTED PREREQUISITES: THE BIOLOGY OF BIOTECH, DIAGNOSTICS' ROLE IN MEDICINE TODAY, STATISTICAL FEATURES OF DIAGNOSTICS

## OVERVIEW

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**How Diagnostics Work: DNA-Based Diagnostics** explains the molecular science and technology used in a common set of diagnostic tools, including the various types of PCR, SNP chips, next-generation sequencing and microRNA techniques. Gain entry to the fast-paced field of molecular diagnostics by taking this course.

### Five Takeaways:

1. Summarize the uses of DNA probes in diagnostics.
2. Describe the use of polymerase chain reaction in diagnostic applications.
3. Explain how microarray technology is exploited in diagnostic applications.
4. Cite the importance of next-generation sequencing technologies in the diagnostics industry.
5. Discuss how microRNA technology could lead to advancements in diagnostic technology.

## AGENDA

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- **Polymerase Chain Reaction (PCR) Technology** summarizes the use of DNA probes and how PCR technology works as a diagnostic. PCR is the tool that enabled the biotech revolution.
- **Microarray Technology** explains SNP chip technology and discusses the use of SNP chips in diagnostic applications.
- **Next Generation Sequencing Technology** looks at various next-generation sequencing tools and discusses the omnipotent diagnostic applications these machines offer.
- **microDiagnostics Technology** summarizes how microRNA works and its application in diagnostics development.

## WHAT PEOPLE ARE SAYING

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*"The Biotech Primer webinars on diagnostics are an outstanding educational resource for professionals in the med device industry."* – Training Specialist

# How Diagnostics Work: Protein-Based Diagnostics

40-MINUTE ONLINE COURSE | LEVEL 2

SUGGESTED PREREQUISITES: THE BIOLOGY OF BIOTECH, DIAGNOSTICS' ROLE IN MEDICINE TODAY, STATISTICAL FEATURES OF DIAGNOSTICS, AND ANTIBODIES

## OVERVIEW

**How Diagnostics Work: Protein-Based Diagnostics** focuses on antibodies: what they are, where they come from and how they work. Various antibody-based diagnostics, such as sandwich and bead immunoassays, multiplexed assays, lateral flow assays and chromatography are explained in detail. Develop an understanding of these diverse tools and how to interpret results, knowledge that can be applied in research, drug development, and patient care.

### Five Takeaways:

1. Define the various types of protein-based diagnostics.
2. An improved ability to explain how biomarkers are used in diagnostics.
3. Explain how antibodies are used in diagnostics.
4. Understand the fundamental science of protein-based diagnostics.
5. Interpret the information gained from the following assays: antibody diagnostics, ELISA, bead immunoassays, lateral flow assays, and chromatography diagnostics.

## AGENDA

- **Defining Protein-Based Diagnostics** introduces protein-based diagnostics by explaining the importance of biomarkers in diagnostics. A biomarker is a measurable molecule indicative of disease.
- **Antibody Technology** explains the importance of antibody structure and how that structure contributes to its function. Antibody structure and function are exploited by the medical device industry for diagnostic use.
- **Enzyme-Linked Immunosorbent Assays (ELISA) Technology** demonstrates the technology and how to interpret results of the widely-used screening test known as an ELISA.
- **Bead Immunoassay Technology** extends your ELISA knowledge by showing how ELISA technology can be adapted into more high throughput techniques, such as multiplexed bead assays.
- **Lateral Flow Assay Technology** explains how lateral flow immunochromatographic assay works, its applications and how to interpret its results.
- **Chromatography Technology** describes the applications of column chromatography in diagnostics and how to interpret its results.

# Statistical Features of Diagnostics

47-MINUTE ONLINE COURSE | LEVEL 3

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

## OVERVIEW

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**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 course 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

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- **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.
- **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.

*Continued*

- **Measurement Considerations** reviews the concept of sample and instrument variability and best practices in reducing variability. It also describes how to choose the correct measurement to determine the disease state of a patient.
- **Accuracy of a Measurement** explains how precision and bias measurements determine the accuracy of a diagnostic.
- **Specificity and Sensitivity** contrasts sensitivity and specificity and explains how to calculate and interpret these measurements.
- **Positives and Negatives** describes how to calculate and interpret false positive and false negative percentages.
- **Risks of Diagnostics** defines positive predictive value and discusses how to calculate and interpret it. Additionally, it explains how to use a receiver operating characteristic (ROC) curve to interpret the strength of a diagnostic.
- **Examples of Diagnostics: Mammogram and PSA Testing** highlights the risks associated with screening for low prevalence diseases.