CORE CONCEPT

Molecular Diagnostics Laboratory Management Course: PCR, NGS and Assay Validation

9 – 13 May 2027
Jeddah - Corniche four-star

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Ref: 1963_29149 **Date:** 9 – 13 May 2027 **Location:** Jeddah - Corniche four-star **Fees:** 19500 SAR

Introduction:

Molecular diagnostics laboratory management for PCR, NGS and assay validation is a 1-week course for molecular section leads in clinical, public-health and reference laboratories that ends with a Molecular Section Operating Plan for a case laboratory. Sections face false positives from amplicon carryover, assays launched without performance evidence and sequencing runs that fail late, raising turnaround and cost per test. Nominees already supervise extraction, real-time PCR or sequencing benches, and the course is taught as a case study on layout, validation and run data. CoreConcept Training Center delivers this molecular diagnostics laboratory management course.

Course Objectives:

- Map the molecular test menu, specimen flows and platform mix against demand and turnaround targets
- Design a unidirectional molecular layout with zone rules, UNG use, controls and wipe testing that keeps amplicon carryover out of results
- Plan verification and validation studies for qPCR and dPCR assays covering limit of detection, inclusivity, exclusivity and precision
- Set NGS library, run and bioinformatics pipeline acceptance criteria with version-controlled change records
- Investigate external quality assessment and proficiency testing failures and calculate cost per test for molecular services
- Assemble a Molecular Section Operating Plan for a case laboratory

Target Audience:

- Molecular section management staff responsible for PCR and sequencing service delivery, staffing and turnaround
- Laboratory management staff responsible for introducing new molecular assays, kits and platforms
- Public-health and reference laboratory staff responsible for outbreak testing surges and pathogen sequencing
- Quality management staff responsible for molecular validation files, EQA schemes and nonconformity follow-up
- Senior scientific and bioinformatics staff responsible for maintaining clinical sequencing pipelines

Course Outline:

Day 1: Molecular Section Scope, Service Demand and Current-State Review

- Molecular Test Menu Mapping Across Infectious, Oncology and Genetic Panels
- Specimen Types, Transport Media and Nucleic Acid Stability Rules
- PCR, Real-Time PCR, Digital PCR and NGS Platform Comparison
- Workload, Batching Pattern and Turnaround Time Baseline Review
- Current-State Gap Assessment Checklist for a Molecular Section

Day 2: Unidirectional Layout, Amplicon Contamination Control and Extraction

- Unidirectional Workflow Design for Reagent, Set-Up and Amplification Rooms
- Airflow, Dedicated Equipment and Gowning Rules per Molecular Zone
- UNG Carryover Prevention, Filter Tips and Single-Use Aliquots
- No-Template Controls, Extraction Blanks and Surface Wipe Test Schedule
- Automated Nucleic Acid Extraction Selection, Yield and Purity Checks

Day 3: Assay Verification and Validation for qPCR and dPCR

- MIQE Guidelines Checklist for Real-Time PCR Assay Reporting
- Limit of Detection Study Design With Probit Analysis
- Inclusivity and Exclusivity Panels for Target and Cross-Reactivity
- Precision, Reproducibility and Ct Value Drift Monitoring Plan
- Laboratory-Developed Test Versus Commercial Kit Verification Protocol

Day 4: NGS Quality Control, Bioinformatics Pipelines and Proficiency Evidence

- NGS Library Preparation QC With Fragment Size and Quantification
- Sequencing Run Metrics Review for Cluster Density and Coverage Depth
- Bioinformatics Pipeline Validation, Version Control and Change Records
- External Quality Assessment and Proficiency Testing Failure Investigation
- Cost per Test Model With Reagent, Run Utilisation and Labour

Day 5: Case Study Build of the Molecular Section Operating Plan

- Case Laboratory Zoning Plan and Contamination Control Rules
- Case Assay Validation Summary With Acceptance Criteria Table
- Case NGS Run Acceptance and Pipeline Change Procedure
- Case Turnaround Time and Cost per Test Improvement Targets
- Molecular Section Operating Plan Completion and Peer Review

Skills You Will Gain:

- Molecular Workflow Zoning
- Amplicon Contamination Surveillance
- Limit of Detection Study Design
- Molecular Assay Verification
- NGS Run Quality Review
- Bioinformatics Change Control
- Proficiency Testing Investigation
- Molecular Cost per Test Analysis

Why Attend This Course:

- Deliver a Molecular Section Operating Plan for a case laboratory to the laboratory director and the quality lead
- Decide whether a new assay, kit or sequencing panel is ready for patient reporting from documented validation evidence rather than supplier claims
- Avoid false positive reports from carryover, sequencing runs that fail late and costly repeat testing
- Share zoning rules, validation templates and run acceptance checklists with bench and quality colleagues

Conclusion:

Back at work, the participant presents the Molecular Section Operating Plan to the laboratory director, the quality lead and the molecular bench supervisors. They use it to decide room zoning and workflow rules, which assays need further validation work before patient reporting, and which NGS run and pipeline acceptance limits apply. After the first validation study or proficiency round run under the plan, the section should compare contamination findings, turnaround and cost per test with the plan targets and revise controls, batching rules and acceptance criteria where the evidence shows gaps.

Frequently Asked Questions FAQ:

What should participants know before a molecular diagnostics laboratory management course?

Participants should already supervise or work on extraction, real-time PCR or sequencing benches and be able to read run reports. Bringing anonymised layouts, validation files, EQA reports or workload data from their own laboratory helps the case study reflect real conditions.

How does a molecular diagnostics laboratory management course differ from a general medical laboratory quality course?

It narrows the focus to nucleic acid testing. General laboratory quality courses cover the whole quality system and routine quality control, while this course covers amplification zoning, carryover control, molecular assay validation, sequencing run quality and pipeline change control.

Why does molecular diagnostics laboratory management depend on a unidirectional workflow?

PCR makes very large numbers of copies of its target, so traces of amplified product can reach new reactions and cause false positives. Moving people, samples and materials only from clean areas towards amplification areas, with decontamination before anything returns, keeps amplicons out.

What do participants take back from the molecular diagnostics laboratory management course?

Participants take back a Molecular Section Operating Plan for a case laboratory, with a zoning plan, contamination control rules, an assay validation summary, NGS run acceptance and pipeline change procedures, and turnaround and cost per test targets.