Finishing School

**Syllabus**

**Certification Course on Clinical Reporting**

**using Advance Molecular Diagnostics and**

**Training for Laboratory Accreditation**

**Microbiological Laboratory Research**

**and Services India (P) Ltd**

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Ph: **0422 2425312)**

with

**Bharathiar University**

(A State University, accredited with “A++” Grade by NAAC, Ranked 21st among Indian Universities by MHRD-NIRF - 2023)

**Coimbatore - 641 046, Tamil Nadu,**

**2025 - 2026**

**INDIA**

**MICROBIOLOGICAL LABORATORY RESEARCH AND SERVICES (I) PVT. LTD**

**& BHARATHIAR UNIVERSITY**

**Certification Course on Clinical Reporting using Advance Molecular Diagnostics**

**and Training for Laboratory Accreditation**

**Background:**

The emergence of novel respiratory viruses—such as SARS (2003), H1N1 influenza (2009), and SARS-CoV-2 (COVID-19)—has revealed critical gaps in global diagnostic capabilities. Traditional methods often lack the speed and sensitivity needed for timely pathogen detection, delaying outbreak response and patient care. Molecular diagnostics has since transformed this landscape through tools like real-time PCR and next-generation sequencing (NGS), proving essential during public health crises.

However, challenges remain, including technical complexity, contamination risk, and a shortage of trained personnel. To address these, agencies like the NIH and India’s ICMR are scaling up molecular diagnostic infrastructure for pandemic preparedness and public health threats.

This course provides hands-on training in molecular methods, from nucleic acid extraction to Real-time PCR, sequencing and its result interpretation. In addition, the program emphasizes the importance of ISO 15189 accreditation—an international standard for quality and competence in clinical laboratories. Participants will be trained in essential Standard Operating Procedures (SOPs) aligned with ISO 15189 requirements, ensuring they understand quality management systems, documentation, and audit readiness. This knowledge is vital for laboratories seeking accreditation and for professionals aiming to uphold global standards in diagnostic accuracy, reliability, and patient safety.

**About the course:**

This Certification Course of 6 months' duration combines **theory and hands-on training** in molecular diagnostics.

* **Theory:** Delivered at **Bharathiar University**, covering foundational principles of molecular diagnostics and Good Laboratory Practices (GLP).
* **Practical Training:** Conducted at NABL accredited **Microbiological Laboratory, Coimbatore**, where participants gain experience using **advanced laboratory equipment** to perform diagnostic assays and the necessary SOPs required for laboratory accreditation.
* **Industry Seminars:** Interactive sessions with industry experts to discuss real-world applications and emerging trends.

 **Eligibility:**

Sciences and Engineering Graduates and Post-Graduates in Biotechnology, Microbiology, Biochemistry, Molecular biology and allied life sciences subjects, MBBS., MD and Ph.D. Candidates seeking opportunities or working in a clinical laboratory, hospital, academic/ research institution, pharmaceutical, and food industry, with an interest in Molecular diagnosis of Diseases.

**Practical Schedule:**

Participants will gain hands-on expertise in the following areas:

**1. Pre-Analytical Techniques**

**a) Clinical Sample Collection:**

* Proper methods for collecting and handling **blood, swabs, CSF, and tissue samples** (aseptic techniques, biohazard safety).

**b) Nucleic Acid Extraction & Preservation:**

* Manual (phenol-chloroform) and automated extraction (e.g., QIASympony) for DNA/RNA.
* Storage protocols for short- and long-term preservation (-20°C/-80°C).

**2. Core Molecular Techniques**

**c) PCR Amplification:**

* Endpoint PCR vs. **real-time PCR (qPCR)** for qualitative/quantitative analysis.
* Designing and optimizing thermal cycling protocols.

**d) Primer/Reagent Validation:**

* Testing primer specificity (BLAST, gel electrophoresis) and reagent QC.

**e) Quality Control Systems:**

* Internal controls (e.g., housekeeping genes) and external QC panels.
* Interpreting QC metrics for assay reliability.

**3. Advanced Technologies**

**f) Allinity™ M Automated Analyzer:**

* Hands-on training for fully integrated PCR workflows (sample-to-result).

**g) Next-Generation Sequencing (NGS):**

* Library preparation (Illumina platforms), sequencing runs, and basic data generation.

**4. Data Analysis & Troubleshooting**

**h) Data Interpretation:**

* Analyzing qPCR curves (Ct values, melt curves), NGS read alignment, and variant calling.
* Identifying contamination, inhibition, and false positives/negatives.

**5. Laboratory Management & Compliance**

**i) SOP Development:**

* Drafting SOPs for assays (e.g., COVID-19 RT-PCR), equipment maintenance, and safety.

**j) NABL Accreditation Protocols:**

* Documentation, audit preparedness, and compliance with ISO 15189 standards.

**k) Daily Logbook Maintenance:**

* Recording experimental workflows, results, and deviations for traceability.

**Program Educational Objectives: :(PEOs) :**

|  |
| --- |
| This certification programme addresses the critical need for highly skilled clinical laboratory professionals trained in molecular methods for diseases diagnosis. The specific programme objectives are to develop professionals with the following competencies  |
| **PEO1** | To equip students with comprehensive theoretical knowledge of molecular diagnostics principles and their clinical applications. |
| **PEO2** | To develop advanced technical skills in modern molecular techniques and instrumentation used in diagnostic laboratories. |
| **PEO3** | To cultivate professional competencies in quality management, laboratory accreditation standards, and bioinformatics analysis. |

**Program Outcomes (POs):**

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| --- |
| On completion of the Certification in Hands-On Training for Molecular Diagnostics and Good Laboratory Practices in Clinical Laboratory programme, the students will be able to |
| **PO1** | Execute standardized protocols for nucleic acid extraction, PCR amplification, and next-generation sequencing with precision. |
| **PO2** | Operate and maintain sophisticated diagnostic equipment including real-time PCR systems and automated platforms. |
| **PO3** | Implement robust quality control systems and troubleshoot technical issues in molecular testing workflows. |
| **PO4** | Interpret complex diagnostic data and generate clinically actionable laboratory reports. |
| **PO5** | Design and optimize molecular assays while adhering to accreditation requirements and ethical guidelines. |

**Final Evaluation:**

 At the end of the course, candidates will be evaluated for their theoretical and practical knowledge and grades will be provided.

 6 Months internship certificate from Microbiological Laboratory, NABL accredited Clinical Laboratory will be provided at the end of the Course.

**Certification Course on Clinical Reporting using Advance Molecular Diagnostics**

**and Training for Laboratory Accreditation**

# SCHEME OF EXAMINATIONS

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| SubCode | Title of the course | Credits | Hours | Maximum Marks |
| Theory | Practical | CIA | ESE | Total |
| 1 | Core-1 | Fundamentals of Molecular Diagnostics  | 4 | 4 | - | 25 | 75 | 100 |
| 2 | Core - 2 | Laboratory Compliance & SOPs | 4 | 4 | - | 25 | 75 | 100 |
| 3 | Practical - 1 | Nucleic Acid Isolation & Quality Control | 6 | - | 6 | 25 | 75 | 100 |
| 4 | Practical - 2 | Real-Time PCR Amplification Techniques  | 6 | - | 6 | 25 | 75 | 100 |
| 5 | Practical - 3 | PCR Data Analysis and Troubleshooting | 6 | - | 6 | 25 | 75 | 100 |
| 6 | Practical - 4 | Automated Molecular Diagnostics | 6 | - | 6 | 25 | 75 | 100 |
| 7 | Swayam | Professional Certification Course | 2 | 2 | - | - | - | - |
| 8 | Project | Mini Project | 4 | - | 4 | 25 | 75 | 100 |
| Grand Total  | 38 | 10 | 28 | 175 | 525 | 700 |

**CIA** Continuous Internal Assessment

**ESE** End Semester Examination

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Subject code** | **1** | **Fundamentals of Molecular Diagnostics** | **L** | **T** | **P** | **C** |
| **4** | **✓** | **-** | **4** |
| **Core Paper - 1** | **Pre-requisite** | **Basic knowledge in microbiology and molecular biology** | **Syllabus Version** | **2025 -26** |

**Course Objectives:**

The main objectives of this course are to:

1. Introduce epidemiological principles and disease classification relevant to molecular diagnostics.
2. Explain the historical evolution, significance, and scope of molecular diagnostics in healthcare.
3. Familiarize students with key terminology, biomarkers, and techniques used in clinical laboratories.

**Expected Course Outcomes:**

On the successful completion of the course, student will be able to:

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| --- | --- | --- |
| 1. | Classify diseases based on epidemiological and molecular characteristics. | K2 |
| 2. | Explain the historical milestones in diagnostics and the rise of the molecular diagnostics industry. | K1 |
| 3. | Identify biomarkers and their role in disease diagnosis. | K2 |
| 4. | Compare molecular techniques used for different disease categories. | K4 |
| 5. | Use standard terminology in clinical laboratory reports. | K3 |
| **K1 -** Remember**; K2 -** Understand**; K3 - Apply; K4 - Analyze; K5 - Evaluate; K6 - Create** |
|  |
| **Unit: 1** | **Epidemiology of Diseases** | **12 Hours** |
| Disease Types & Characteristics - Communicable vs. non-communicable; acute vs. chronic, Endemic, epidemic, pandemic (e.g., COVID-19 vs. diabetes). Classification Systems - By etiology (infectious, genetic, environmental), By body system (respiratory, cardiovascular, neurological). Diseases of National Importance - India: TB, malaria, dengue, hypertension, Global: HIV, hepatitis, antimicrobial resistance. Emerging/Re-emerging Threats - Zoonotic diseases (Nipah, Zika), Climate-linked diseases (vector-borne infections) |
| **Unit: 2** | **Evolution of Molecular Diagnostics** | 1. **Hours**
 |
| Historical Milestones - Microscopy → ELISA → PCR → NGS → CRISPR, Key breakthroughs (Human Genome Project, RT-PCR for COVID-19). Diagnostic Industry Growth - Global leaders (Roche, Abbott, Thermo Fisher), India’s Diagnostic market. Regulatory Landscape - FDA/CE-IVD/CDSCO approvals, ICMR/NABL guidelines in India |
| **Unit: 3** | **Core Techniques & Biomarkers** | 1. **Hours**
 |
| Nucleic Acid-Based Methods - PCR variants (Real-Time, multiplex, nested, digital), Sequencing (Sanger for validation, NGS for panels). Protein & Cellular Biomarkers - ELISA for proteins, FISH for chromosomal abnormalities. Point-of-Care Technologies - LAMP, CRISPR-Cas for rapid testing, Microfluidics and lab-on-a-chip devices |
| **Unit: 4** | **Laboratory Standards & Terminology** | **12 Hours** |
| Quality Metrics - Sensitivity, specificity, PPV/NPV, LoD (Limit of Detection) and LoQ (Limit of Quantification). Accreditation Protocols - NABL/ISO 15189 documentation requirements, SOPs for equipment calibration. Clinical Reporting - Standard terminology, Ethical considerations. |
| **Unit: 5** | **Contemporary Issues** | **5 Hours** |
| Expert lectures by academic/industry experts, online seminars - webinars |
| Total Lecture hours | **53 Hours** |

**Recommended Textbooks and References**

1. Last JM. Dictionary of Epidemiology. 4th ed. New York: Oxford University Press; 2001
2. Sintchenko, V. (2010). Infectious disease informatics. Springer Science+ Business Media, LLC.
3. Straif-Bourgeois, S., Ratard, R., & Kretzschmar, M. (2014). Infectious Disease Epidemiology. Handbook of Epidemiology, 2041–2119. https://doi.org/10.1007/978-0-387-09834-0\_34
4. Hanson, K. E., Caliendo, A. M., Arias, C. A., Englund, J. A., Lee, M. J., Loeb., & Mustafa, R. A. (2020). Infectious Diseases Society of America guidelines on the diagnosis of COVID-19. Clinical infectious diseases.
5. Persing, D. H., Tenover, F. C., Hayden, R. T., Ieven, M., Miller, M. B., Nolte, F. S., ... & van Belkum, A. (Eds.). (2020). Molecular microbiology: diagnostic principles and practice. John Wiley & Sons.

**Course Designed by Dr. Rohit Radhakrishnan, Director (Operations & Research), MICROSERV**

**Mapping with Programme Outcomes**

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| --- | --- | --- | --- | --- | --- |
| **Cos** | **PO1** | **PO2** | **PO3** | **PO4** | **PO5** |
| **CO1** | L | L | M | L | L |
| **CO2** | L | L | L | L | M |
| **CO3** | S | M | L | L | L |
| **CO4** | M | S | L | S | L |
| **CO5** | L | S | M | M | L |
| \* S - Strong; M - Medium; L – Low |

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| **Subject code** | **2** | **Laboratory Compliance & SOPs** | **L** | **T** | **P** | **C** |
| **4** | **✓** | **-** | **4** |
| **Core Paper - 2** | **Pre-requisite** | **Basic understanding of molecular biology techniques and clinical laboratory workflows.** | **Syllabus Version** | **2025 -26** |

**Course Objectives:**

The main objectives of this course are to:

1. Understand regulatory frameworks (NABL/ISO/CAP) for molecular diagnostics labs
2. Develop skills to create, implement, and audit Standard Operating Procedures (SOPs)
3. Master documentation practices for quality assurance and accreditation

**Expected Course Outcomes:**

On the successful completion of the course, student will be able to:

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| 1. | Explain NABL/ISO 15189 requirements | K2 |
| 2. | Develop compliant SOPs | K6 |
| 3. | Perform internal quality audits | K4 |
| 4. | Maintain accreditation documentation  | K3 |
| 5. | Troubleshoot compliance gaps. | K5 |
| **K1 -** Remember**; K2 -** Understand**; K3 - Apply; K4 - Analyze; K5 - Evaluate; K6 - Create** |
|  |
| **Unit: 1** | **Regulatory Frameworks** | **12 Hours** |
| Overview of NABL, ISO 15189, CLIA, CAP. Differences between research vs clinical lab standards. Case studies of accreditation failures |
| **Unit: 2** | **SOP Development & Validation** | **12 Hours** |
| Components of effective SOPs (title, purpose, scope). Version control and change management. Hands-on: Draft SOP for PCR assay |
| **Unit: 3** | **Quality Audits & Documentation** | 1. **Hours**
 |
| Internal vs external audit processes. Corrective/Preventive Action (CAPA) systems. Electronic vs paper record-keeping |
| **Unit: 4** | **Risk Management & Ethics** | **12 Hours** |
| Identifying lab hazards (biological, chemical). Data integrity and patient confidentiality (HIPAA/GDPR). Ethical dilemmas in molecular testing |
| **Unit: 5** | **Contemporary Issues** | **5 Hours** |
| Expert lectures by academic/industry experts, online seminars - webinars |
| Total Lecture hours | **53 Hours** |

**Recommended Textbooks and References**

1. Quality Management in the Laboratory (Westgard)
2. \*ISO 15189:2022 Medical Laboratories - Requirements\*
3. NABL 112 Guidelines for Molecular Testing
4. Clinical Laboratory Compliance (Diana Voorhees)

**Course Designed by Dr. Rohit Radhakrishnan, Director (Operations & Research), MICROSERV**

**Mapping with Programme Outcomes**

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| --- | --- | --- | --- | --- | --- |
| **Cos** | **PO1** | **PO2** | **PO3** | **PO4** | **PO5** |
| **CO1** | L | M | S | M | L |
| **CO2** | L | S | L | S | L |
| **CO3** | L | S | M | M | L |
| **CO4** | L | M | L | S | L |
| **CO5** | L | M | L | M | M |
| \* S - Strong; M - Medium; L – Low |

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| --- | --- | --- | --- | --- | --- | --- |
| **Subject code** | **3** | **Nucleic Acid Isolation & Quality Control** | **L** | **T** | **P** | **C** |
| **6** | **-** | **✓** | **6** |
| **Practical -1** | **Pre-requisite** | **Basic pipetting skills and biosafety awareness.** | **Syllabus Version** | **2025 -26** |

**Course Objectives:**

The main objectives of this course are to:

1. Master manual and automated nucleic acid extraction techniques.
2. Evaluate extraction quality using spectrophotometry, fluorometry and electrophoresis.
3. Troubleshoot common isolation issues (degradation, contamination). regulatory frameworks (NABL/ISO/CAP) for molecular diagnostics labs

**Expected Course Outcomes:**

On the successful completion of the course, student will be able to:

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| 1. | Perform extractions from diverse samples | K3 |
| 2. | Assess nucleic acid purity/yield | K4 |
| 3. | Compare manual vs. kit-based methods  | K4 |
| 4. | Document QC results for accreditation | K3 |
| 5. | Optimize protocols for difficult samples  | K5 |
| **K1 -** Remember**; K2 -** Understand**; K3 - Apply; K4 - Analyze; K5 - Evaluate; K6 - Create** |
|  |
| **Types of Clinical Samples & Pre-Analytics** | **9 Hours** |
| 1. **Overview of Sample Collection Methods**
	* *Content:*
		+ Blood (EDTA/streak tubes), swabs (nasopharyngeal/oropharyngeal), tissue (FFPE/fresh frozen), CSF, urine
		+ Blood bank standards
	* *Practical:*
		+ Demonstration: Proper Swab Collection Technique
2. **SOPs for Sample Handling & Storage**
	* *Content:*
		+ Temperature requirements (RT, 4°C, -80°C)
		+ Transport regulations (IATA, triple packaging)
	* *Practical:*
		+ **Exercise: Labelling & Aliquoting Serum Samples**
3. **Precautions for Infectious Samples**
	* *Content:*
		+ Biosafety levels (BSL-2+ protocols)
		+ Inactivation methods (heat, AVL buffer)
 |
| **DNA Isolation Techniques** | **9 Hours** |
| 1. **DNA Isolation from Clinical Blood Samples Using Manual Magnetic Bead-Based Extraction**
	* *Skills:* Bead mixing, magnetic separation, elution buffer optimization
	* *QC:* Nanodrop purity (A260/A280 >1.8), yield calculation
2. **DNA Isolation from Clinical Tissue Samples (FFPE) Using Manual Magnetic Bead-Based Extraction**
	* *Skills:* Deparaffinization, proteinase K digestion, bead binding efficiency
	* *QC:* Gel electrophoresis (intact high-molecular-weight DNA)
3. **DNA Isolation from Buccal Swabs Using Silica Column Kits**
	* *Skills:* Cell lysis, column washing, low-elution-volume recovery
 |
| **RNA Isolation Techniques** | **9 Hours** |
| 1. **RNA Isolation from Whole Blood Using TRIzol® LS Method**
	* *Skills:* Phase separation, RNA precipitation, DNase I treatment
2. **Viral RNA Extraction from Nasopharyngeal Swabs Using QiaSymphony Automation**
	* *Skills:* Cassette loading, pathogen protocol selection, error handling
3. **miRNA Isolation from Plasma Using Magnetic Bead-Based Kits**

*Skills:* Small RNA enrichment, bead-to-sample ratio optimization |
| **Automated High-Throughput Systems** | **9 Hours** |
| 1. **High-Throughput DNA Extraction from 96 Blood Samples Using QiaSymphony**
	* *Skills:* Batch processing, barcode tracking, reagent replenishment
2. **RNA Extraction from 24 Tissue Samples Using Elite Automation System**
	* *Skills:* Cartridge loading, tip clog troubleshooting
3. **Yield Comparison: Manual vs. Automated Extraction (Paired Samples)**
	* *Skills:* Data analysis (coefficient of variation), cost-effectiveness assessment
 |
| **Quality Control & Troubleshooting** | **9 Hours** |
| 1. **Spectrophotometric QC of Extracted Nucleic Acids (Nanodrop)**
	* *Skills:* A260/A230 salt contamination check, dilution factor calculations
2. **Cross-Contamination Testing in Automated Systems (Negative Controls)**
	* *Skills:* PCR amplification of control genes, result interpretation
3. **Automated System Alarms (QiaSymphony/Elite)**
* Skills: Error code interpretation, recovery protocols
 |
| **Contemporary Issues** | **5 Hours** |
| Expert lectures by academic/industry experts, online seminars - webinars |
| Total Lecture hours | **50 Hours** |

**Recommended Textbooks and References**

1. QIAGEN QiaSymphony Handbook
2. Automation in the Clinical Lab (Hawker & Schlank)
3. Molecular Cloning: A Laboratory Manual (Sambrook)

**Course Designed by Dr. Rohit Radhakrishnan, Director (Operations & Research), MICROSERV**

**Mapping with Programme Outcomes**

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| --- | --- | --- | --- | --- | --- |
| **Cos** | **PO1** | **PO2** | **PO3** | **PO4** | **PO5** |
| **CO1** | S | M | L | L | L |
| **CO2** | S | M | L | M | S |
| **CO3** | M | S | L | M | L |
| **CO4** | M | S | L | S | L |
| **CO5** | S | M | M | M | L |
| \* S - Strong; M - Medium; L – Low |

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| **Subject code** | **4** | **Real-Time PCR Amplification Techniques** | **L** | **T** | **P** | **C** |
| **6** | **-** | **✓** | **6** |
| **Practical -2** | **Pre-requisite** | **Basic PCR principles and pipetting skills.** | **Syllabus Version** | **2025 -26** |

**Course Objectives:**

The main objectives of this course are to:

1. Master real-time PCR setup, optimization, and data analysis on diverse platforms.
2. Compare detection chemistries (SYBR Green, TaqMan, hydrolysis probes).
3. Apply qPCR for clinical diagnosis (pathogen detection, gene expression)..

**Expected Course Outcomes:**

On the successful completion of the course, student will be able to:

|  |  |  |
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| 1. | Set up qPCR runs on 4 instrument types | K3 |
| 2. | Analyze amplification curves and other parameters | K4 |
| 3. | Select appropriate detection chemistry  | K4 |
| 4. | Troubleshoot failed runs (inhibition, primer-dimers) | K5 |
| 5. | Validate qPCR assays for clinical use | K6 |
| **K1 -** Remember**; K2 -** Understand**; K3 - Apply; K4 - Analyze; K5 - Evaluate; K6 - Create** |
|  |
| **Instrument-Specific Workflows** | **9 Hours** |
| 1. **Rotor-Gene Q: SYBR Green Assay Setup**
	* *Skills:* Tube loading, melt curve analysis, high-resolution optics
2. **Bio-Rad CFX96: Multiplex TaqMan Probe Assay**
	* *Skills:* FAM/HEX channel setup, baseline threshold adjustment
 |
| **Detection Chemistries** | **9 Hours** |
| 1. **SYBR Green vs. TaqMan: Sensitivity Comparison** (Quant Studio)
	* *Skills:* Limit of detection (LoD) calculations
2. **Probes for Respiratory Pathogen Detection (MIC PCR)**
* Skills: Discrimination Plots
 |
| **Clinical Applications** | **9 Hours** |
| 1. **Bacterial Detection**
	1. Klebsiella pneumoniae Detection (TaqMan Probe, Bio-Rad CFX96)
	* *Skills:* DNA extraction from sputum/urine, Interpretation of amplification curves (Ct ≤ 30 for positivity)
	1. *Pseudomonas aeruginosa Strain Typing (HRM, Rotor-Gene Q)*
	* *Skills:* SYBR Green amplification, HRM to differentiate *wild-type* vs. *mucoid strains,* Melt peak analysis (Tm shift ±0.5°C = variant)
2. **Fungal Detection**
	1. *Candida auris Detection (TaqMan Probe, Quant Studio)*
* *Skills:* Cross-validation with *internal control* (human DNA)
	1. *Aspergillus spp. Identification (HRM, MIC PCR)*
* *Skills:*Pan-fungal *ITS region* amplification, HRM-based species differentiation (*A. fumigatus* vs. *A. flavus*)
1. **Viral Detection**
	1. *HPV Genotyping (TaqMan Probe, Rotor-Gene Q)*
	* *Skills:* 5-plex probe setup (HPV 16/18/31/33/45), *Ct cutoff validation* for clinical reporting
	1. Influenza Variant Screening (HRM, Bio-Rad CFX96
* *Skills:* HRM to flag *variants of concern* (Delta: T19R melt shift)
1. **Digital Droplet PCR (Advanced Quantification)**

4.1. Absolute Quantification of Klebsiella pneumoniae Carbapenemase (blaKPC) Genes* *Skills:* Droplet generation and partitioning, Threshold setting (copies/µL), Comparison with qPCR (limit of detection)
 |
| **Contemporary Issues** | **5 Hours** |
| Expert lectures by academic/industry experts, online seminars - webinars |
| Total Lecture hours | **50 Hours** |

**Recommended Textbooks and References**

1. QIAGEN QiaSymphony Handbook
2. Automation in the Clinical Lab (Hawker & Schlank)
3. Molecular Cloning: A Laboratory Manual (Sambrook)

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**Mapping with Programme Outcomes**

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| --- | --- | --- | --- | --- | --- |
| **Cos** | **PO1** | **PO2** | **PO3** | **PO4** | **PO5** |
| **CO1** | S | M | L | L | L |
| **CO2** | S | M | L | M | S |
| **CO3** | M | S | L | M | L |
| **CO4** | M | S | L | S | L |
| **CO5** | S | M | M | M | L |
| \* S - Strong; M - Medium; L – Low |

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| --- | --- | --- | --- | --- | --- | --- |
| **Subject code** | **5** | **PCR Data Analysis and Troubleshooting**  | **L** | **T** | **P** | **C** |
| **6** | **-** | **✓** | **6** |
| **Practical -3** | **Pre-requisite** | **Advance PCR principles**  | **Syllabus Version** | **2025 -26** |

**Course Objectives:**

The main objectives of this course are to:

1. Master **data analysis** for probe-based qPCR, HRM, and ddPCR across platforms.
2. Develop **troubleshooting protocols** for common PCR failures.
3. Validate clinical results using **industry-standard software**.

**Expected Course Outcomes:**

On the successful completion of the course, student will be able to:

|  |  |  |
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| 1. | Analyze probe-based qPCR data (Ct, ΔΔCt) | K4 |
| 2. | Interpret HRM melt curves for genotyping | K4 |
| 3. | Quantify targets using ddPCR (copies/µL) | K4 |
| 4. | Troubleshoot amplification failures | K5 |
| 5. | Generate clinical reports with SOPs | K6 |
| **K1 -** Remember**; K2 -** Understand**; K3 - Apply; K4 - Analyze; K5 - Evaluate; K6 - Create** |
|  |
| **Probe-Based qPCR Data Analysis** | **9 Hours** |
| 1. **MIC Platform: Absolute Quantification of Pathogens**
	* *Skills:* Threshold setting, standard curve generation (R² >0.98).
	* *Dataset:* SARS-CoV-2 ORF1ab/N gene multiplex.
2. **Rotor-Gene Q: Multiplex Probe Analysis (FAM/HEX)**
	* *Skills:* Channel crosstalk correction, efficiency calculations.
 |
| **HRM Data Interpretation** | **9 Hours** |
| 1. **Rotor-Gene Q: Bacterial Strain Typing**
	* *Skills:* Limit of detection (LoD) calculations
 |
| **ddPCR Data Analysis** | **9 Hours** |
| 1. **QX100: Low-Abundance AMR Gene Detection**
	* *Skills:* Droplet count thresholding, Poisson statistics.
	* *Dataset:* blaNDM-1 in Klebsiella (LOD: 1 copy/µL).
2. **QX100: Rare Variant Quantification**
	* *Skills:* Fractional abundance calculations (<1% sensitivity).
 |
| **Troubleshooting & Reporting** | **9 Hours** |
| 1. **Failed Amplification Root-Cause Analysis**
	* *Skills:* Inhibition checks (SPUD assay), primer-dimer identification.
2. **Clinical Report Generation**
	* *Skills:* LIMS entry, critical value reporting (e.g., Ct >35 = indeterminate).
 |
| **Contemporary Issues** | **5 Hours** |
| Expert lectures by academic/industry experts, online seminars - webinars |
| Total Lecture hours | **50 Hours** |

**Recommended Textbooks and References**

1. *Real-Time PCR Data Analysis* (Bio-Rad Laboratories)
2. *Digital PCR: Principles and Applications* (Springer)
3. *Clinical PCR Troubleshooting Guide* (QIAGEN)

**Course Designed by Dr. Rohit Radhakrishnan, Director (Operations & Research), MICROSERV**

**Mapping with Programme Outcomes**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Cos** | **PO1** | **PO2** | **PO3** | **PO4** | **PO5** |
| **CO1** | M | M | L | S | L |
| **CO2** | L | L | L | M | S |
| **CO3** | S | M | L | M | L |
| **CO4** | M | S | M | M | L |
| **CO5** | L | M | S | M | L |
| \* S - Strong; M - Medium; L – Low |

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| --- | --- | --- | --- | --- | --- | --- |
| **Subject code** | **6** | **Automated Molecular Diagnostics**  | **L** | **T** | **P** | **C** |
| **6** | **-** | **✓** | **6** |
| **Practical -4** | **Pre-requisite** | **Advance PCR Principles and experimental knowledge**  | **Syllabus Version** | **2025 -26** |

**Course Objectives:**

The main objectives of this course are to:

1. Operate and maintain the **Alinity m** system for clinical testing.
2. Validate automated assay performance (sensitivity, specificity).
3. Troubleshoot common instrument alerts and result discrepancies.

**Expected Course Outcomes:**

On the successful completion of the course, student will be able to:

|  |  |  |
| --- | --- | --- |
| 1. | Perform sample-to-result workflows on Alinity m | K3 |
| 2. | Interpret Alinity m assay outputs (e.g., Ct, target calls) | K4 |
| 3. | Validate assay performance per CLIA/NABL standards | K5 |
| 4. | Resolve common errors (e.g., clot detection, low volume) | K5 |
| 5. | Document maintenance and QC logs for audits | K3 |
| **K1 -** Remember**; K2 -** Understand**; K3 - Apply; K4 - Analyze; K5 - Evaluate; K6 - Create** |
|  |
| **System Orientation & Workflow** | **9 Hours** |
| 1. **Alinity m Startup and Shutdown Procedures**
	* *Skills:* Cartridge loading, waste management, daily startup checks.
2. **Sample Loading and Barcode Scanning**
	* *Skills:* Primary tube vs. secondary aliquot handling
 |
| **Assay Validation** | **9 Hours** |
| 1. **SARS-CoV-2 Assay Verification**
	* *Skills:* LoD determination, precision testing (20-run CV <5%).
2. **Multiplex Respiratory Panel (RP2) Testing**
	* *Skills:* Target call interpretation (e.g., Flu A vs. RSV).
 |
| **Troubleshooting** | **9 Hours** |
| 1. **Error Code Resolution**
	* *Skills:* Clot detection in primary tubes, low sample volume alerts.
2. **Cross-Contamination Prevention**
	* *Skills:* Cleaner cartridge handling, workspace decontamination.
 |
| **Quality & Compliance** | **9 Hours** |
| 1. **Monthly Maintenance and Calibration**
	* *Skills:* Photocalibration, fluidics checks.
2. **Audit Preparation**
	* *Skills:* Electronic record review (e.g., QC trends over 30 days).
 |
| **Contemporary Issues** | **5 Hours** |
| Expert lectures by academic/industry experts, online seminars - webinars |
| Total Lecture hours | **50 Hours** |

**Recommended Textbooks and References**

1. *Alinity m System Operator’s Manual* (Abbott)
2. *Molecular Diagnostics: Automation and Quality Control* (Springer)
3. *CLIA/NABL Accreditation Guidelines*

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