

CERTIFICATE COURSE ON
“ADVANCE MOLECULAR DIAGNOSTICS
AND NABL PROTOCOL FOR GOOD
LABORATORY PRACTICES”

Syllabus
2022-23

INDUSTRY FOR OFFERING THE COURSE



***Microbiological Laboratory Research
and Services India Private Limited
(MLRS), Coimbatore***

Collaborated with



**BHARATHIAR UNIVERSITY: COIMBATORE
(Centre for University & Industry Collaboration)**

Program Educational Objectives (PEOs)	
This programme aims to address the growing need of highly skilled clinical laboratory technologists trained in molecular methods for diagnosis of diseases. The specific programme objectives are to develop professionals with the following competencies,	
PEO1	Ability to comprehend, analyze and perform the relevant molecular tests to identify and report the pathogen in clinical samples
PEO2	Strong foundation in Good Laboratory Practices and National Accreditation Board for Laboratory Protocol
PEO3	Management of a clinical laboratory relevant to the current needs of the healthcare industry

Program Outcomes (POs)	
On completion of the Certification Course on Advance Molecular Diagnostics programme, the students will be able to,	
PO1	Demonstrate a broad understanding of background theory and information on a variety of nucleic acid-based procedures
PO2	Handle and process different clinical samples for nucleic acid-based procedures
PO3	Independently perform and troubleshoot nucleic acid-based procedures to identify the pathogen and report them in acceptable clinical format
PO4	Demonstrate proper laboratory quality control and containment procedures for PCR
PO5	Plan, articulate, implement and manage the molecular department of the clinical laboratory independently

Final Evaluation

- At the end of the course, candidates will be evaluated for their theoretical and practical knowledge.
- A Report of the Post-Training Assessment jointly conducted by Bharathiar University and MLRS
- Grades and Certificate will be provided by Bharathiar University at the end of the Course.

Bharathiar University, Coimbatore–641046

Centre for University and Industry Collaboration (BU-CUIC)

Industry Collaborative Programme

Certificate Course on “ **Advance Molecular Diagnostics and NABL Protocol for Good Laboratory Practices**”

SCHEME OF EXAMINATIONS

(For the students admitted from the academic year **2022-23** onwards)

S. No.	SUBJECT	Credits	Hours per Week			Marks for		Total Marks
			Lecture	Tutorial	Practical	CIA	ESE	
Course Duration – 6 Months								
Lecture								
1	Molecular Diagnostics of Disease	4*	2	2	-	50	50	100
2	NABL Protocols for Operation of a Molecular Diagnostic Laboratory	4^	1	1	2	50	50	100
Practical								
3	Handling Clinical Samples and Nucleic acid Extraction	6^	1	2	3	50	50	100
4	PCR Amplification Techniques (focus on RT-qPCR)	8^	1	3	4	50	50	100
5	PCR Data Analysis & Troubleshooting	6^	1	2	3	50	50	100
6	Biostatistics	2^	-	1	1	50	50	100
Total		30	6	11	13			600
CIA	Continuous Internal Assessment							
ESE	End Semester Examination							
*	General Component: 4 Credits							
^	Skill Component: 26 Credits							

Certification Course on “**Advance Molecular Diagnostics and NABL Protocol for Good Laboratory Practices**”

Course code	1	Molecular Diagnostics of Diseases	L	T	P	C
			2	2	-	4
Pre-requisite	Basics in Epidemiology, Immunology, Molecular Biology and Genetic Engineering		Syllabus Version		2022-23	
Course Objectives:						
The main objectives of this course are to:						
<ol style="list-style-type: none"> 1. Make students understand epidemiology of diseases 2. Make students understand Molecular Diagnostics and its related terminology used in clinical laboratories 3. Provide a strong foundation on the principle's different molecular techniques 4. Inculcate the knowledge application of molecular techniques in different fields 						
Expected Course Outcomes:						
On the successful completion of the course, student will be able to:						
1	Understand the epidemiology of diseases		K1, K2			
2	Understand the basics of molecular diagnostics and its terminology		K1, K2			
3	Learn the fundamentals of molecular techniques		K1, K2			
4	Learn the application of molecular techniques in different fields		K1, K2			
K1 - Remember; K2 - Understand; K3 – Perform; K4 - Analyse						
Unit:1	Epidemiology of Diseases		10 Lectures			
Introduction to Diseases – Types – Characteristics – Classification of Diseases – Epidemiological aspects of diseases of national importance – Epidemiological aspects of Non-Communicable Diseases – Emerging and Re-Emerging Diseases						
Unit:2	Overview of Molecular Diagnostics		15 Lectures			
History of diagnostics - Age of molecular diagnostics: Significance, Scope - Rise of diagnostic industry in Indian and global scenario –Molecular Techniques in diagnosis of diseases – Biomarkers in disease diagnostics – Different Terminology used in Clinical Laboratories						
Unit:3	Advance Techniques in Molecular Diagnostics – Lecture		20 Lectures			
Introduction to advance techniques in molecular diagnostics – MALDI-TOF identification of different bacterial species – Digital Droplet PCR – Next-Gen Sequencing						
Unit:4	Contemporary Issues		7 Lecture			
Guest lectures by academic/industry experts, online seminars – webinars						
Total Lectures						52 Lectures

Textbook(s) and Reference					
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. K.N Brahamadathan&Dr. Rohit Radhakrishnan					
Mapping with Programme Outcomes					
COs	PO1	PO2	PO3	PO4	PO5
CO1	S	L	L	L	L
CO2	S	L	L	L	L
CO3	S	L	L	L	L
CO4	S	L	L	L	L
*S-Strong; M-Medium; L-Low					

Course code	2	NABL Protocols for Operation of a Molecular Diagnostic Laboratory	L	T	P	C
			1	1	2	2
Pre-requisite	Understanding in Molecular Diagnostics		Syllabus Version		2022-23	
Course Objectives:						
The main objectives of this course are to:						
1. Make students understand protocols followed in molecular diagnostic laboratory						
2. Inculcate the knowledge in record and book keeping in molecular diagnostic laboratory						
Expected Course Outcomes:						
On the successful completion of the course, student will be able to:						
1	Explain Standard Operating Protocols involved in molecular diagnostic laboratories			K1, K2, K3, K4		
2	Maintain daily log books for clinical samples processed at the laboratory			K1, K2, K3, K4		
K1 - Remember; K2 - Understand; K3 – Perform; K4 - Analyse						

Unit:1	Protocols for Molecular Diagnostic Laboratory - Lecture	20 Lectures			
Standard Operating Protocols (SOP) for molecular diagnostic laboratory – NABL standard Documentation and protocols – Log book keeping for sample processing at clinical laboratory					
Unit: 2	Training in ISO 15189:2012 – Lecture and Practical	20 Lecture			
Overview of ISO 15189:2012 - Requirements for Quality and Competence - Policies processes and records requirements for conformity assessment bodies - Requirements and Procedures for Record – Quality assurance and quality control: Requirements and Importance - Training in Quality Control Department					
Total Lecture		40 Lectures			
Textbook(s)					
1	Williams, Bethany Jill, Chloe Knowles, and Darren Treanor. "Maintaining quality diagnosis with digital pathology: a practical guide to ISO 15189 accreditation." Journal of clinical pathology 72.10 (2019): 663-668.				
2	Moumtzoglou, Anastasius, ed. Laboratory Management Information Systems: Current Requirements and Future Perspectives: Current Requirements and Future Perspectives. IGI Global, 2014.				
3	Blokdyk, Gerardus. ISO 15189 Third Edition. N.p., Emereo Pty Limited, 2018.				
4	Burnett, David. A Practical Guide to ISO 15189 in Laboratory Medicine. United Kingdom, ACB Venture Publications, 2013.				
5	Modern Approaches to Quality Control. Croatia, IntechOpen, 2011.				
Course Designed By: Dr. K.N Brahamadathan &Dr. Rohit Radhakrishnan					
Mapping with Programme Outcomes					
COs	PO1	PO2	PO3	PO4	PO5
CO1	S	S	S	S	S
CO2	S	S	S	S	S
*S-Strong; M-Medium; L-Low					

Course code	3	Handling Clinical Samples and Nucleic acid Extraction	L	T	P	C
			1	2	3	6
Pre-requisite	Epidemiology of diseases, Principles of molecular techniques used in diagnostics		Syllabus Version		2022-23	
Course Objectives:						
The main objectives of this course are to:						
1. Make students understand different types of clinical samples relevant to infectious disease						
2. Make students understand the handling and processing clinical samples						
3. Provide a strong foundation on Nucleic acid extraction from samples						

4. Inculcate the knowledge in processing clinical samples for molecular diagnosis					
Expected Course Outcomes:					
On the successful completion of the course, student will be able to:					
1	Understand the types of clinical samples				K1, K2
2	Learn SOP for handling and processing clinical samples				K1, K2
3	Learn nucleic acid extraction methods				K1, K2, K3, K4
4	Learn quantification of extracted nucleic acid				K1, K2, K3, K4
K1 - Remember; K2 - Understand; K3 – Perform; K4 - Analyse					
Unit:1	Clinical Samples - Lecture				5 Lectures
Types of Clinical Samples -Overview of sample collection and handling methods – SOP and precautions for Sample collection, handling and storage					
Unit:2	Nucleic Acid Extraction - Tutorial				10 Lectures
Introduction to nucleic acids – Types of nucleic acid extraction method - Major factors for selection extraction method - Basic steps in nucleic acid extraction - Analyse nucleic acid quantity and purity – Troubleshooting for nucleic acid extraction					
Unit:3	Nucleic Acid Extraction – Experiments				78 Hours
Preparation of Work-bench – Manual and Automated methods of nucleic acid extraction – Quantification of nucleic acid by Gel electrophoresis – Analysis and practical precautions for optimizing extraction yield					
Unit:4	Contemporary Issues				3 Lectures
Guest lectures by academic/industry experts, online seminars - webinars					
Total Lectures					18 Lectures
Textbook(s) and Reference					
1	Rapley, R. (Ed.). (2000). The nucleic acid protocols handbook. Springer Science & Business Media.				
2	Buckingham, L. (2019). Molecular diagnostics: fundamentals, methods and clinical applications. FA Davis.				
3	Sambrook, J., & Russell, D. W. (2006). The condensed protocols from molecular cloning: a laboratory manual (No. Sirsi) i9780879697723).				
Course Designed By: Dr. K.N Brahamadathan&Dr. Rohit Radhakrishnan					
Mapping with Programme Outcomes					
COs	PO1	PO2	PO3	PO4	PO5
CO1	S	M	L	L	L
CO2	S	S	L	L	L
CO3	S	S	L	L	L
CO4	S	S	L	L	L
*S-Strong; M-Medium; L-Low					

Course code	4	PCR Amplification Techniques (Focus on RT-qPCR)	L	T	P	C
			1	2	6	9
Pre-requisite	Nucleic acid extraction, Basics in PCR amplification and gel electrophoresis		Syllabus Version		2022-23	
Course Objectives:						
The main objectives of this course are to:						
1. Make students understand the principles of PCR techniques						
2. Provide a strong foundation on different types of PCR with emphasis on Real-Time PCR						
3. Inculcate the knowledge in performing Real-Time PCR with clinical sample						
4. Make students understand about Primers and Probes used in PCR experiments						
5. Inculcate the knowledge in Primer and Probe designing						
Expected Course Outcomes:						
On the successful completion of the course, student will be able to:						
1	Explain the basic steps involved in PCR			K1, K2, K3, K4		
2	Identify the components of PCR and reverse transcription PCR			K1, K2, K3, K4		
3	Recognize the characteristics of real-time PCR			K1, K2, K3, K4		
4	Identify the techniques used to detect products in real-time PCR			K1, K2, K3, K4		
5	Explain the roles of PCR controls			K1, K2, K3, K4		
6	Perform Primer designing for the detecting clinical samples			K1, K2, K3, K4		
7	Troubleshoot issues in Primer designing			K1, K2, K3, K4		
K1 - Remember; K2 - Understand; K3 – Perform; K4 - Analyse						
Unit:1	PCR Techniques - Lecture			5 Lectures		
Introduction to PCR – Types of detection chemistries – PCR product analysis – Application of PCR techniques						
Unit:2	Real-Time PCR – Tutorial			10 Lectures		
Introduction to Real-time PCR – Protocol for Real-Time PCR – Understanding Real-time PCR software – Real-time PCR product Analysis						
Unit:3	Reverse Transcription - Tutorial			10 Lectures		
Introduction to Reverse Transcription – Priming Strategies – Efficiency and Reproducibility – Protocol for Reverse Transcription-Real-Time PCR – RT Real-Time PCR product analysis						
Unit:4	PCR / Reverse Transcription Real-Time PCR - Practical			78 Hours		
Performing PCR with known samples – Performing Reverse Transcription Real-Time PCR with known samples – Reverse Transcription Real-Time PCR on different up-market instruments – PCR product Analysis						
Unit: 5	Primer and Probe Design – Tutorial			10 Lectures		
Introduction to Primer design – Primer dimer formation – Important consideration for						

primer design – Designing tools available for primer design – Design of hydrolysis Probes
– Evaluation of Primer (*in-silico&in-vivo*)

Unit:6	Contemporary Issues					2 Lectures
Guest lectures by academic/industry experts, online seminars - webinars						
					Total Lectures	37 Lectures
Textbook(s)						
1	Biassoni, R., &Raso, A. (2016). Quantitative real-time PCR. Humana.					
2	Molecular Biology LabFax, T.A. Brown (Ed.), Bios Scientific Publishers Ltd., Oxford, 1991					
3	Apte, A., & Daniel, S. (2009). PCR primer design. Cold Spring Harbor Protocols, 2009(3), pdb-ip65.					
4	Park, M., Won, J., Choi, B. Y., & Lee, C. J. (2020). Optimization of primer sets and detection protocols for SARS-CoV-2 of coronavirus disease 2019 (COVID-19) using PCR and real-time PCR. Experimental & molecular medicine, 52(6), 963-977.					
5	Basu, C. (Ed.). (2015). PCR primer design. New york: Humana Press.					
Course Designed By: Dr. K.N Brahamadathan &Dr. Rohit Radhakrishnan						
Mapping with Programme Outcomes						
COs	PO1	PO2	PO3	PO4	PO5	
CO1	S	S	S	S	M	
CO2	S	S	S	S	M	
CO3	S	S	S	S	M	
CO4	S	S	S	S	M	
CO5	S	S	S	S	M	
CO6	M	M	S	M	M	
CO7	M	M	S	M	M	
*S-Strong; M-Medium; L-Low						

Course code	5	PCR Data Analysis & Troubleshooting	L	T	P	C
			1	2	3	6
Pre-requisite	Advance knowledge in PCR and Real-time PCR		Syllabus Version		2022-23	
Course Objectives:						
The main objectives of this course are to:						
1. Make students understand the analysis of PCR products						
2. Make students understand quantification of nucleic acid using Real-Time PCR						
3. Provide a strong foundation on optimizing and troubleshooting PCR experiments						
4. Inculcate the knowledge in clinical reporting						

Expected Course Outcomes:					
On the successful completion of the course, student will be able to:					
1	Analyse the results of PCR products	K1, K2, K4			
2	Quantify nucleic acid using Real-Time PCR	K1, K2, K4			
3	Standardize PCR experiments for optimum product yield	K1, K2, K3, K4			
4	Identify and troubleshoot inconsistent results in PCR	K1, K2, K3, K4			
5	Understand clinical reporting of PCR data	K1, K2, K3, K4			
K1 - Remember; K2 - Understand; K3 – Perform; K4 - Analyse					
Unit:1	PCR Data analysis& Reporting–Practical	78 Hours			
Analysis of PCR product – Evaluate and set threshold cycle (Ct) in Real-time PCR – Quantification of nucleic acid using Real-time PCR data–Clinical reporting of PCR data					
Unit:2	PCR Troubleshooting –Lecture & Tutorial	25 Lectures			
Factors affecting performance of PCR /Real-time PCR – Quality control guidelines for PCR /Real-time PCR – Optimizing PCR /Real-time PCR experiments					
Total Lecture					25 Lectures
Textbook(s)					
1	Vijgen, L., Moës, E., Keyaerts, E., Li, S., & Van Ranst, M. (2008). A pancoronavirus RT-PCR assay for detection of all known coronaviruses. In SARS-and Other Coronaviruses (pp. 3-12). Humana Press, Totowa, NJ.				
2	Molecular Biology LabFax, T.A. Brown (Ed.), Bios Scientific Publishers Ltd., Oxford, 1991				
Course Designed By: Dr. K.N Brahamadathan&Dr. Rohit Radhakrishnan					
Mapping with Programme Outcomes					
COs	PO1	PO2	PO3	PO4	PO5
CO1	S	S	S	S	M
CO2	S	S	S	S	M
CO3	S	S	S	S	M
CO4	S	S	S	S	M
*S-Strong; M-Medium; L-Low					

Course code	6	Biostatistics	L	T	P	C
			-	1	1	2
Pre-requisite	Basics in quantification, PCR / Real-time PCR techniques, Epidemiology of diseases		Syllabus Version		2022-23	
Course Objectives:						
The main objectives of this course are to:						

1. Make students understand the basics of biostatistics					
2. Provide a strong foundation on different types of statistical tools					
Expected Course Outcomes:					
On the successful completion of the course, student will be able to:					
1	Perform statistical analysis of clinical data				K1, K2, K3, K4
K1 - Remember; K2 - Understand; K3 – Perform; K4 - Analyse					
Unit:1 Biostatistics– Tutorial 10 Lectures					
Types of variables - Probability distributions, Central Limit Theorem and confidence intervals - Statistical analysis of numerical data - Statistical analysis of categorical data - Effect Size, Sample Size and statistical Power - Correlation and Regression - ROC analysis					
Unit:2 Biostatistics – Practical 10 Lectures					
Descriptive statistics - Inferential statistics - Multiple case simulation					
Total Practical					20 Lectures
Textbook(s)					
1	Rosner, B. (2016). Fundamentals of Biostatistics, Eighth Edition, Cengage Learning, Boston, MA, US.				
2	Daniel, W. W., and Cross, C. L. (2013). Biostatistics: A Foundation for Analysis in the Health Sciences, Tenth Edition, John Wiley & Sons, Inc., NY, US				
3	Zar, A. H. (2010). Biostatistical Analysis, Fifth Edition, Pearson, London, UJ.				
4	Pagano, M., and Gauvreau, K. (2018). Principles of Biostatistics, Second Edition, Chapman and Hall/CRC Press, NY.				
5	Purohit, S. G., Gore, S. D., and Deshmukh, S. R. (2008). Statistics Using R, Narosa Publishing House, New Delhi, India				
Course Designed By: Dr. K.N Brahamadathan &Dr. Rohit Radhakrishnan					
Mapping with Programme Outcomes					
COs	PO1	PO2	PO3	PO4	PO5
CO1	S	S	S	S	M
*S-Strong; M-Medium; L-Low					