



**Hindi Vidya Prachar Samiti's**

**Ramniranjan Jhunjhunwala College**

**of Arts, Science & Commerce**

***(Empowered Autonomous College)***

**Affiliated to**

**UNIVERSITY OF MUMBAI**

**Syllabus for the B.Sc.**

**Program: B.Sc. Medical Laboratory Technology**

**National Education Policy (NEP 2020)**

**Level 5.5**

SEMESTER	:	V
TITLE	:	<b>Discipline specific elective I</b>
TITLE OF THE SUBJECT/COURSE	:	<b>Quality Control and Accreditation in Laboratory</b>
COURSE CODE	:	RJDSEMLT351
CREDITS	:	04
DURATION	:	60 hrs

LEARNING OBJECTIVES	
1	Understand the principles of quality control (QC) and quality assurance (QA) in clinical laboratories.
2	Describe pre-analytical, analytical, and post-analytical sources of errors.
3	Explain internal and external quality control procedures.
4	Understand accreditation standards such as NABL, ISO 15189, and CLSI guidelines.

Course Outcome No.	On completing the course, the student will be able to:	PSO Addressed	Bloom's Levels
CO1	Demonstrate knowledge of QC, QA, and TQM concepts in laboratory practice.	1, 3	BT level 1 & 2
CO2	Identify common laboratory errors and implement corrective actions.	1, 3	BT level 1 & 2
CO3	Perform internal QC and understand external QA programs.	1, 3	BT level 1 & 2

<b>SEMESTER V</b>			
<b>Course Code : RJDSEMLT351</b>		<b>Title: Quality Control and Accreditation in Laboratory</b>	<b>Credits</b>
<b>Unit</b>	<b>Unit Name</b>	<b>Topics</b>	<b>4</b>
I	Quality system in laboratories	Introduction to quality control and quality assurance, Total Quality Management (TQM), Pre-analytical, analytical, post-analytical errors, Internal quality control (IQC), External quality assurance schemes (EQAS), Precision, accuracy, sensitivity, specificity, Levey–Jennings charts and Westgard rules, Laboratory safety and risk management	2
II	Accreditation standards	Accreditation bodies: NABL, ISO 15189, Laboratory management system requirements, Standard Operating Procedures (SOPs) and documentation, Calibration and validation of instruments, Proficiency testing and audits, Good Laboratory Practices (GLP), Regulatory guidelines (CLSI standards), Continuous quality improvement and corrective actions	2
<b>References:</b> <ul style="list-style-type: none"> <li>• <b>Quality Assurance in the Clinical Laboratory</b> – James O. Westgard</li> <li>• <b>NABL 15189 Handbook / ISO 15189 Standards Guide</b></li> </ul>			

SEMESTER	:	V
TITLE	:	<b>DISCIPLINE SPECIFIC ELECTIVE 2</b>
TITLE OF THE SUBJECT/COURSE	:	<b>MOLECULAR BIOLOGY 1</b>
COURSE CODE	:	<b>RJDSEMLT352</b>
CREDITS	:	04
DURATION	:	60 hrs

**LEARNING OBJECTIVES**

1	Understand the basic structure and function of nucleic acids (DNA and RNA).
2	Describe the organization of genes and genomes in prokaryotes and eukaryotes.
3	Explain DNA replication, transcription, and translation processes.
4	Understand regulation of gene expression in prokaryotes and eukaryotes.

Course Outcome No.	On completing the course, the student will be able to:	PSO Addressed	Bloom's Levels
CO1	Demonstrate understanding of nucleic acid structure and function.	1, 2	BT level 1 & 2
CO2	Explain DNA replication, transcription, and translation mechanisms.	1, 2	BT level 1, 2 & 3
CO3	Describe gene regulation in prokaryotic and eukaryotic systems.		
CO4	Understand mutations, DNA repair, and recombination processes.	1, 2	BT level 1, 2 & 3

<b>SEMESTER V</b>			
<b>Course Code :</b> RJDSEMLT352		<b>Title: TMOLECULAR BIOLOGY 1</b>	<b>Credits</b>
<b>Unit</b>	<b>Unit Name</b>	<b>Topics</b>	<b>4</b>
I	Nucleic acid and genetic information	Structure and types of nucleic acids (DNA, RNA), DNA double helix and RNA structure, Prokaryotic and eukaryotic genome organization, Chromatin and nucleosome structure, Gene structure and function, Central dogma of molecular biology, DNA replication: enzymes and mechanism, RNA transcription: types, process, and regulation, Translation: ribosomes, tRNA, codons, and protein synthesis	2
II	Gene regulation and mutation	Operon concept in prokaryotes (lac, trp operons), Gene regulation in eukaryotes: enhancers, silencers, transcription factors, Post-transcriptional and post-translational modifications, Mutations: types, causes, and consequences, DNA repair mechanisms, Recombinant DNA technology: basic concepts, Molecular techniques: restriction enzymes, gel electrophoresis, blotting techniques (conceptual), Applications of molecular biology in medicine and biotechnology	2
<b>References:</b>  <b>Molecular Biology of the Gene</b> – James D. Watson  <b>Molecular Biology</b> – David Freifelder			