



# GUJARAT TECHNOLOGICAL UNIVERSITY

Program Name: Bachelor of Science

Level: Under Graduate

Branch Name: Honors/ Honors With Research (Biotechnology)

Course / Subject Code: BS03001061

Course / Subject Name: Laboratory Testing and Quality Assurance

W.e.f. Academic Year:	2025-26
Semester:	3
Category of the Course:	Skill Enhancement Courses

**Prerequisite:** Students must have a basic understanding of biology, chemistry, and analytical techniques. Familiarity with laboratory procedures, data interpretation, and regulatory guidelines is beneficial.

**Rationale:** This course provides a comprehensive understanding of laboratory testing methodologies and quality assurance principles in scientific and industrial settings. It covers analytical techniques, validation procedures, regulatory compliance, and quality control measures to ensure accuracy, reliability, and reproducibility of test results. Students will gain practical knowledge of standard operating procedures (SOPs), accreditation standards, and best practices in maintaining laboratory quality and integrity.

## Course Scheme:

Teaching Scheme			Total Credits	Assessment Pattern and Marks				Total Marks
L	T	PR		Theory		Practical		
			ESE (E)	PA(M)	ESE (V)	PA (I)		
1	0	2	2	0	50	50	0	100

## Course Content:

Sr. No.	Course Content	No. of Hours	% of Weightage
1	<b>Fundamentals of Laboratory Testing and Quality Assurance</b> Definition and significance of laboratory testing, role of quality assurance in clinical, industrial, and research laboratories. Types of laboratory tests: biochemical, microbiological, molecular, and analytical tests. Importance of laboratory accreditation and regulatory bodies (NABL, ISO, CLSI) in maintaining testing standards. Concepts of accuracy, precision, specificity, and sensitivity in laboratory testing. Factors affecting laboratory test results and their standardization.	5	33



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2	<b>Laboratory Quality Control and Good Laboratory Practices (GLP)</b> Concept of quality control in laboratory testing: internal and external quality control measures. Good Laboratory Practices (GLP): principles, documentation, and compliance. Standardization of reagents, sample handling, and importance of proper calibration. Statistical methods for evaluating test performance: mean, standard deviation, coefficient of variation. Use of quality control charts (Levey-Jennings charts) and application of Westgard rules. Identification and troubleshooting of laboratory errors, impact of pre-analytical, analytical, and post-analytical variables on quality.	5	33
3	<b>Quality Assurance in Laboratory Diagnosis and Research</b> Role of quality assurance in diagnostic and research laboratories, importance of Standard Operating Procedures (SOPs) in laboratory practices. Quality management systems (QMS) and their role in ensuring reliability and reproducibility of test results. Validation and verification of laboratory methods, performance evaluation of diagnostic tests. Role of external quality assessment schemes (EQAS) in maintaining quality standards. Application of artificial intelligence and automation in laboratory diagnostics, emerging trends in quality assurance and lab management.	5	34

## Reference Books:

1. **The Laboratory Quality Assurance Systems:** A Manual of Quality Procedures And forms, 3<sup>rd</sup> Edition - Authored by Thomas A. Ratliff.
2. **Quality Assurance and Quality Control in The Analytical Chemical Laboratory:** A Practical Approach, 2<sup>nd</sup> Edition – Authored by Piotr Konieczka.
3. **Quality Management in Clinical Laboratories:** Optimizing Patient Care, 2<sup>nd</sup> Edition – Authored by Richard W. Brown.
4. **Textbook of Medical Laboratory Technology:** Editors Praful B. Godkar, Darshan P. Godkar.

## Course Outcome:

After Completion of the Course, Student will able to:

Sr. No	Course Outcomes	RBT Level
1	Explain the principle of laboratory testing, quality control, and regulatory compliance.	UN,RM,AP
2	Apply statistical methods, including standard deviation and Levey-Jennings charts, for quality assessment.	UN,RM,AP, AN



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4	Interpret regulatory guidelines for Good Laboratory Practices (GLP) and accreditation requirements.	UN, RM, AP AN
5	Implement biosafety, laboratory waste management, and ethical guidelines in laboratory testing.	UN, AP, AN, CR

\*RM: Remember, UN: Understand, AP: Apply, AN: Analyze, EL: Evaluate, CR: Create

## List of Experiments:

1. **Quality Control of Biochemical Tests** - Analysis of quality control samples and interpretation of Levey-Jennings charts.
2. **Calculation and Interpretation of Standard Deviation and Coefficient of Variation** - Statistical analysis for evaluating test performance.
3. **Validation of Analytical Methods** - Assessing precision, accuracy, specificity, and sensitivity of an analytical method.
4. **Proficiency Testing and Error Rectification** - Conducting blind sample testing, detecting errors, and troubleshooting quality control failures.
5. **Biosafety, Laboratory Waste Management, and Compliance Check** - Implementing biosafety protocols, proper disposal of hazardous waste, and audit of laboratory compliance according to NABL/ISO guidelines.

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