



SATHYABAMA

INSTITUTE OF SCIENCE AND TECHNOLOGY

(DEEMED TO BE UNIVERSITY)

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School of Allied Health Sciences

Department of Medical Laboratory Technology

1.2.2 - Number of Programmes in which Choice Based Credit System (CBCS)/elective course system has been implemented during the year 2023 -2024

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SAMB3001	GOOD LABORATORY PRACTICE				L	T	P	EL	CREDITS	TOTAL
					3	0	0	0	3	100

COURSE OBJECTIVES

- ☐ The course of study enhances student's knowledge on essential practices that need to be followed inside a laboratory / industry.
- ☐ The course of study enhances student's awareness on safety measures and Industry standards.
- ☐ Student will get familiar to good lab practices including awareness/ safety in a clinical lab.

UNIT 1 INTRODUCTION TO GOOD LABORATORY PRACTICE

9 Hrs.

Overview of GLP principles and objectives, Historical development and regulatory framework of GLP, Roles and responsibilities of different stakeholders, Understanding the importance of GLP in research and development, Clinical laboratory professional duty to the patient, duty to colleagues and other professionals, Good Laboratory Practice (GLP), Introduction to Basics of GLP and Accreditation, Aims of GLP and Accreditation, Advantages of Accreditation, Brief knowledge about National and International Agencies for clinical laboratory accreditation.

UNIT 2 ETHICS IN MEDICAL LABORATORY PRACTICE

9 Hrs.

Ethics in relation to Pre-Examination procedures, Examination procedures, reporting of results, preserving medical records Procurement of equipment and Inventory Control

UNIT 3 DOCUMENTATION AND RECORD KEEPING

9 Hrs.

Importance of accurate and complete documentation, Types of laboratory records and their purpose, Standard operating procedures (SOPs) and protocols, Data recording, organization, and archiving, good documentation practices and electronic data management systems.

UNIT 4 QUALITY CONTROL IN THE LABORATORY

9 Hrs.

Understanding quality assurance (QA) and quality control (QC), Equipment calibration and maintenance, Method validation and verification, Analytical quality control (AQC) and proficiency testing, Handling and disposal of laboratory reagents and samples.

UNIT 5 SAFETY AND REGULATORY COMPLIANCE

9 Hrs.

Laboratory safety guidelines and regulations, Hazard identification and risk assessment, Personal protective equipment (PPE) and safety protocols, Chemical handling, storage, and waste management, Compliance with relevant regulatory bodies (e.g., FDA, EPA).

Max. 45 Hrs.

COURSE OUTCOMES

On completion of the course, students will be able to know

- CO1- Student will have knowledge of Ethical Principles and standards for a clinical laboratory
- CO2 - Acquire knowledge about laboratory practice, to know about Ethics in Medical laboratory Practice.
- CO3 - Knowledge of instrument calibration and importance.
- CO4 - Awareness on safety measures and Industry standards.
- CO5 - Understand the Good Laboratory guidelines.
- CO6 - Apply the knowledge of Health care & Awareness in laboratory practice.

TEXT / REFERENCE BOOKS

1. Milton A. Anderson GLP Essentials: A Concise Guide to Good Laboratory Practice, 2nd Edition, Published by CRC press.
2. Teitz, (2007), Fundamentals of Clinical Chemistry, 6th edition, Elsevier Publications.
3. Henry's Clinical Diagnosis and Management by Laboratory Methods, (2011), 22nd edition, Elsevier.

SAMB4001	ENDOCRINOLOGY AND TOXICOLOGY	L	T	P	EL	CREDITS	TOTAL
		3	0	0	0	3	100

Course Objectives

- To develop an understanding of the role of the endocrine system in maintaining homeostasis and health.
- To understand the integrative workings of the human body by studying this signaling system

Unit I Introduction

9 Hrs.

Difference between hormones and enzymes - Classification of hormones - Regulation and general mechanism of action of hormones

Unit II Pituitary gland & hypothalamus

9 Hrs.

Hormones of the Anterior Pituitary - Growth hormone, Prolactin, Gonadotropin, Follicle Stimulating hormone, Luteinizing Hormone, Thyroid stimulating hormone (TSH), Adrenocorticotrophic hormone (ACTH), Hormones of neurohypophysis- Oxytocin, Antidiuretic hormone (ADH)

Unit III Hormones of the Thyroid gland

9 Hrs.

Chemistry and normal physiology, Thyroid disorders-goiter, myxedema, autoimmune thyroiditis, tumors of the thyroid gland, hyperthyroidism, Graves' disease, Calcitonin, Parathyroid Hormone (PTH), Hormone of pancreas - Insulin- its metabolic effects on carbohydrates, fats & protein, control of insulin secretion, Glucagon- functions, metabolic effects, blood glucose regulation, Diabetes mellitus, Somatostatin

Unit IV Adrenal cortex and medulla

9 Hrs.

Adrenocortical hormones-synthesis and secretion, Aldosterone & its function, Addison's disease, Glucocorticoids & functions, Mineralocorticoids & functions, Cortisol & functions, Cushing's syndrome, Conn's syndrome, Adrenal medulla-metabolism of catecholamines, Hormones of the gonads, Testosterone, Estrogens, Progesterone, their synthesis and functions, Human Chorionic Gonadotropin (HCG), hormone, menstrual cycle, Menopause

Unit V Toxicology

9 Hrs.

Introduction of Toxicology, Alcohol poisoning, Lead poisoning, Zinc poisoning, Mercury poisoning drugs abuse, screening procedure for drug screening, Spot tests, hair and urine test, Immunoassay for drugs.

Max. 45 Hrs.

COURSE OUTCOMES:

On completion of the course, student will be able to

CO1: Explain the roles of the endocrine system in maintaining homeostasis, integrating growth and development, responding to environmental insults and promoting successful reproduction

CO2: Investigate how the secretion of hormones is regulated, including the principles of negative and positive feedback mechanisms

CO3: Apply endocrinological principles to determine the pathophysiological basis

CO4: To learn about consequences of specific endocrine disorders

CO5: Understand the role of Toxicology for diagnosis, Correlate the presence of a Toxicology with its associated affected organ system

CO6: Differentiate between carbohydrate-rich Toxicology, protein-rich Toxicology, enzymatic Toxicology, and oncofetal antigens

TEXT / REFERENCE BOOKS

1. Basic Medical Endocrinology, H. Maurice Goodman, Academic Press, Elsevier, 2003
2. Endocrinology – An Integrated Approach, S.S. Nussey& S.A. Whitehead, 2001
3. Textbook of Endocrinology – S Dharmalingam, Jaypee Publishers, 2010
4. Endocrinology: Hormones and Human Health” Prakash S Lohar, MJP Publishers, 2005

SAMB3002	ADVANCED DIAGNOSTIC TECHNIQUES	L	T	P	EL	CREDITS	TOTAL
		3	0	0	0	3	100

COURSE OBJECTIVES

□ To provide an advance foundation in Laboratory Techniques where which is an emerging discipline with a broad conceptual approach that transcends all sections of advance molecular techniques.

UNIT 1 INTRODUCTION TO MOLECULAR DIAGNOSIS OF GENETIC DISEASES 9 Hrs.

Laboratory application of nucleic acid technologies to elucidate, diagnose, monitor disease state and to evaluate non-disease status techniques for the detection of DNA, and RNA structures at the molecular level

UNIT 2 MOLECULAR DIAGNOSTICS 9 Hrs.

Basic principles and techniques-nucleic acid biochemistry-Relation to laboratory evaluation of disease and establishing a molecular diagnostic laboratory facility, equipment, personnel. Clinical testing process, quality assurance, clinical validation and accreditation.

UNIT 3 MOLECULAR GENETICS 9 Hrs.

Molecular diagnosis of genetic diseases. Choice of techniques, choice of applications, special concept unique to molecular genetic disorders, specific disease examples. Application of molecular methods in clinical microbiology.

UNIT 4 MOLECULAR TECHNIQUES 9 Hrs.

PCR techniques and their applications. Blotting techniques (Southern, Northern and western).

UNIT 5 MODERN ADVANCED TECHNIQUES 9 Hrs.

Biochips, Lab on a chip (LoC), Microarray technology: basic methodology and application.

Max. 45 Hrs.

COURSE OUTCOMES

On completion of the course, students will be able to know

CO1- Apply knowledge of molecular structure and genetic function, especially DNA and RNA.

CO2 - Understand the molecular diagnostic procedures relates to DNA replication.

CO3 - To know about Molecular genetics and function of different types of nucleic acid.

CO4 - Apply the knowledge of molecular testing in the clinical laboratory.

CO5 - To know about molecular testing in the clinical laboratory.

CO6 - To learn most commonly performed applications in the clinical laboratory.

TEXT / REFERENCE BOOKS

1. Blackburn, G.M. and Gait, M.J. (1996). Nucleic acids in chemistry and biology. Oxford University Press.
2. Bruce Alberts, Dennis Brag, Julian Lewis, Martin Raff, Keith Roberts, James D. Watson. (1994). Molecular Biology of cell. Garland Publishing Inc.
3. Hames, B.D. and Rickwood, D. (1990). Gel Electrophoresis – A Practical Approach, Oxford University Press, New York.
4. Sambrook, J and Russell, D.W. (2001). Molecular Cloning – A Laboratory Manual, 3rd Edition, Vol I, II, III, Cold Spring Harbour Laboratory Press, New York.
5. Westermeier, R. (1993). Electrophoresis in Practice, VCH, Federal Republic of Germany.

SAMB4002	DIAGNOSTIC MOLECULAR BIOLOGY	L	T	P	EL	CREDITS	TOTAL
		4	0	0	0	4	100

Course Objectives

- To provide a good foundation in molecular biology where importance is laid on the master molecule
- Subject is an emerging discipline with a broad conceptual approach that transcends all sections of anatomic and clinical pathology.

Unit I Basic principles in molecular diagnostics

12Hrs.

Organizations of molecular diagnostic laboratory-Bio-membranes and the sub-cellular organization of eukaryotic cells.

Unit II Molecular structure of genes and chromosomes

12Hrs.

Organization of cellular DNA into chromosomes –morphology and functional elements of eukaryotic chromosomes –chromosomal organization of genes and non-coding DNA.

Unit III Structure of Deoxy nucleic Acids (DNA)

12Hrs.

ABZs of DNA Secondary Structure, Denaturation and Renaturation of DNA, Supercoils and Cruci forms: Tertiary Structure in DNA. DNA replication –repair-recombination –mutation – Regulation of the eukaryotic cell cycle-gene control in development-Cellular energetics

Unit VI Ribonucleic Acid

12Hrs.

Types and function of RNA. Primary, Secondary and Tertiary Structure of RNA. The role of RNA in protein synthesis-stepwise formation of proteins on ribosome.

Unit V The synthesis of macromolecules and the genetic code

12Hrs.

synthesis of biopolymers- nucleic acid synthesiss. Molecular oncology including DNA assay for T and B-cell rearrangement- analysis for translocation, oncogene analysis -translocation gene mutation in various cancer, Molecular histocompatibility testing, forensic identity testing by DNA analysis.

Max. 60 Hrs.

COURSE OUTCOMES:

On completion of the course, student will be able to

CO1: Apply knowledge of cellular structure and function, especially DNA and RNA

CO2: Understand the DNA replication, repair and recombination in prokaryotes with that of eukaryotes.

CO3: To know about RNA synthesis and processing and function of different types of RNA.

CO4: To know about protein synthesis and inhibition factors of protein synthesis.

CO5: Apply the knowledge of molecular testing to the most commonly performed applications in the clinical laboratory

CO6: To learn about molecular diagnostic procedures and their clinical uses

TEXT / REFERENCE BOOKS

1. Albert B. Bray D and Lewis J Molecular biology of the cells, 2nd edition New York Garland Publications 1989.Brown, T.A. (1999). Gene Cloning. 3rd edition. Chapman and Hall Publications, U.S.A.
2. Burrell, M.M. (1993). Enzymes of Molecular Biology, Humana Press.
3. Chirikjian, J.G. (1995). Biotechnology – Theory and Techniques, Vol. II, Jones and Burtlett Publishers.
4. Lewin, B. (2000). Genes VII. Oxford University Press, Oxford.
5. Antony, J.F., Griffiths, Gilbert, W.M., Lewontin, R.C. and Miller, J.H. (2002). Modern genetic analysis, Integrating Genes and Genomes, 2nd edition, WH Freeman and Company, New York.

SAMB3003	LABORATORY AUTOMATION & QUALITY CONTROL	L	T	P	EL	CREDITS	TOTAL
		3	0	0	0	3	100

COURSE OBJECTIVES

- ☐ To introduce the concept of quality management, to apply the significances of analyzers in automation.
- ☐ To apply the significances of analyzers in automation and to introduce the concept of quality management.

UNIT 1 AUTOMATION

9 Hrs.

Introduction to automation, study on the instrumental concepts and definition of batch analysis, sequential analysis, discrete analysis etc. Detailed study on the steps in automated analysis, reagent handling, chemical reaction phase, reaction vessels, cuvettes in discrete analyzers and measurement using absorbance, electrochemical measurements and transmittance photometry.

UNIT 2 AUTO ANALYZERS

9 Hrs.

Continuous flow analyzers, discrete and Centrifugal analyzers auto analyzers-advantages, Dry chemistry analyzers, Random access analyzers (RAA), Micro particle enzyme immunoassay, Immulite automated immunoassay analyzers.

UNIT 3 CELL COUNTERS

9 Hrs.

Study on the different type of cell counters, available and their principle of operation, basic principle in estimating each parameter. Brief study on the operation and quality control of automated laboratory analyzers.

UNIT 4 INTRODUCTION TO QUALITY CONTROL

9 Hrs.

Demonstration of various methods of quality control, Preparation of Quality control charts, a) Levy- Jennings and b) Cusum charts. Demonstration of various methods of quality control- Westgard Rules to verify trends, biases, or errors in quality controls.

UNIT 5 QUALITY CONTROL PROGRAMME

9 Hrs.

External quality control, Internal Quality control, Proficiency testing, Total quality management framework, Quality laboratory processes, Quality assurance, Quality assessment, Current trends in laboratory accreditation, ISO certificate, Quality planning and Quality improvement.

Max.

60 Hrs.

COURSE OUTCOMES

On completion of the course, students will be able to know

CO1- Understand the principles of automation.

CO2 - Identify role of automation in flow analyzers.

CO3 - Recognize the types of analyzers and their significance.

CO4 - Apply the theoretical understanding to practical usage.

CO5 - Recognize the latest trends and quality practices.

CO6 - Bridge the gap between clinical and industry in theory and practice of automation.

TEXT / REFERENCE BOOKS

1. Laboratory management – Quality in Laboratory diagnosis – Candis A Kinkus, Demos medical publishers, 2011.
2. Quality control in Laboratory – GaffarSarwarZamman, Intech open publishers, 2011.
3. Clinical Diagnosis and Management by Laboratory Methods, Henry 23rd edition, 2016.

SAMB4003	MOLECULAR PATHOLOGY	L	T	P	EL	CREDITS	TOTAL
		3	0	0	0	3	100

COURSE OBJECTIVE

- To develop an understanding of the basic concepts and terminology in general pathology.
- To understand the methods of microbial staining, media, transport and control of microbial pathogens.

Unit I General Pathology

12Hrs.

Homeostasis and Cellular Adaptations - Normal Cell - Cell Injury - types of cellular adaptations - Cellular adaptations-atrophy, hypertrophy, hyperplasia and dysplasia.

Unit II Cell Injury and Cell Death

12Hrs.

Etiology of cell injury, morphology of cell injury, cellular swelling - Cell death: Types autolysis, necrosis, apoptosis

Unit III Inflammation

12Hrs.

Inflammation - Acute inflammation - vascular event, cellular event, inflammatory cells – Chronic Inflammation - general features, granulomatous inflammation, tuberculoma.

Unit IV Disorders, Neoplasia and Healing

12Hrs.

Haemodynamic Disorders: Oedema, hyperemia, congestion, hemorrhage, circulatory disturbances, thrombosis, ischaemia& infarction - Neoplasia - Definition, how does it differ from hyperplasia, difference between benign tumor and malignant tumor – Healing - Definition, different phases of healing, factors influencing wound healing.

Unit V Molecular Pathology and genetics 12Hrs.

Molecular genetics of hematopoietic neoplasm-lineage probes in the evaluation of hematopoietic neoplasm- Molecular analysis of chromosomal aberrations in leukemias and lymphomas,

Max. 60 Hrs.

COURSE OUTCOMES:

On completion of the course, students will be able to

- CO1: Understand the basic elements in cell injury, and the cellular adaptations.
- CO2: Understand the basic elements in cellular adaptations.
- CO3: Demonstrate about the necrosis, apoptosis of the damaged cells.
- CO4: Describe the role of immune cells in inflammation process.
- CO5: Acquire the knowledge to process various clinical samples and interpret the results.
- CO6: Understand the basic molecular diagnostic procedures

TEXT / REFERENCE BOOKS

1. Textbook of Pathology - Harsh Mohan - 8th Edition (English) Paperback – 1 January 2019
2. Robbins & Cotran Pathologic Basis of Disease: South Asia Edition Paperback – 14 August 2014
3. Henry, John Bernard, Todd Sanford and Davidson, 2002. Clinical diagnosis and management by laboratory methods. W.B. Saunders& Co.