I SEMESTER

MBT-1001: Molecular Diagnostics

Module-I

Introduction and History of diagnostics: Diseases- infectious, physiological and metabolic errors, genetic basis of diseases, inherited diseases. Infection – mode of transmission in infections, factors predisposing to microbial pathogenicity, types of infectious diseases- bacterial, viral, fungal, protozoans and other parasites. Philosophy and general approach to clinical specimens, Sample collection- method of collection, transport and processing of samples, Interpretation of results, Normal microbial flora of the human body, Host - Parasite relationships.

Module-II

Traditional disease diagnosis methods and tools: diagnosis of infection caused by Streptococcus, Coliforms, Salmonella, Shigella, Vibrio, and Mycobacterium., Diagnosis of fungal infections. Major fungal diseases: Dermetophytoses, Candidiosis and Aspergillosis. Diagnosis of DNA and RNA viruses- Pox viruses, Adenoviruses, Rhabdo Viruses, Hepatitis Viruses and Retroviruses. Diagnosis of Protozoan diseases: Amoebiosis, Malaria, Trypnosomiosis, Leishmaniasis. Study of helminthic diseases- Fasciola hepatica and Ascaris lumbricoides. Filariasis and Schistosomiasis.

Module-III

Major Metabolic disorders and its causes: Traditional methods for the diagnosis of metabolic errors. Disease due to genetic disorders - Identifying human disease genes.

Cancer- different types of cancers, genetics of cancer- oncogenes, tumour suppressor genes. Methods available for the diagnosis of genetic diseases and metabolic disorders.

Genetic disorders- Sickle cell anemia, Duchenne muscular Dystrophy, Retinoblastoma, Cystic Fibrosis and Sex – linked inherited disorders.

Module-IV

Molecular Diagnosis: Nucleic acid amplification methods and types of PCR: Reverse Transcriptase-PCR, Real-Time PCR, Inverse PCR, Multiplex PCR, Nested PCR, Alu-PCR, Hot-start, In situ PCR, Long-PCR, PCR-ELISA, Arbitrarily primed PCR, Ligase Chain Reaction.

Proteins and Amino acids, Qualitative and quantitative techniques: Protein stability, denaturation; amino acid sequence analysis

Module-V

Hybridization techniques and DNA sequencing methods in molecular diagnosis: Southern, Northern, in-situ (including FISH), microarrays – types and applications; Protein extraction and analysis (including PAGE and its variations); Western Blot

Automated DNA sequencing- Principles, Methods and Instrumentation- Advances in DNA sequencing- New Generation sequencing Methods, Pyrosequencing, · Microarrays- Personalised Medicine- Pharmacogenomics (ADMET)

Text/References (Latest Edition):

1. Medical Microbiology, Edited by Greenwood, D, Slack, R and Peutherer, J, ELST Publishers.
2. Parasitology, Chatterjee K.D, Chatterjee Medical Publishers.
3. Bailey & Scott's Diagnostic Microbiology, Betty A. Forbes , Daniel F. Sahm, Alice S. Weissfeld , Ernest A. Trevino, Published by C.V. Mosby
4. Jawetz, Melnick, & Adelberg's Medical Microbiology, Geo F. Brooks, Stephen A. Morse, Janet S. Butel.
5. Fundamentals of Molecular Diagnostics. David E. Bruns, Edward R. Ashwood, Carl A. Burtis. Saunders Group.
6. Henry's Clinical Diagnosis And Management By Laboratory Methods Mcpherson
7. Molecular Diagnostics: Fundamentals, Methods & Clinical applications. Lele Buckingham and Maribeth L. Flaws
8. Molecular Diagnostics for the Clinical Laboratorian 2Ed, W.B. Coleman. Humana Press.

9. Molecular Pathology in Clinical Practice, D. G. B. Leonard.
10. Microbial Functional Genomics by J.Zhou, D.K. Thomson. Y.Xu. J.M. Tiedje. J.Wiley & Sons Publishers.
11. Human Molecular Genetics- Tom Strachan
12. Concepts of Genetics- William s. Klug
13. Emery's Elements of Medical Genetics- Robert F. Mueller & Ian D. Young

MBT-1002: Genetic Counselling and Prenatal/Postnatal Diagnosis

Module-I

Screening and diagnosis: invasive and non-invasive methods: Prenatal, neonatal, postnatal and perinatal diagnosis, embryo, foetal sampling methods, aminocentesis, fetoscopy, CVS, cordocentesis, maternal blood sampling, karyotyping, DNA investigation, Biochemical, immunological and enzymatic analysis, Presymptomatic and predictive testing - Genetic Registers - Population screening, carrier screening, Two step screening - Advantages and disadvantages of testing

Module-II

Pedigree studies & Genetic Counselling: Symbols used in pedigree studies, Pedigree analysis & construction, Pedigree analysis for the inheritance pattern of genetic diseases, Aspects – components - Prospective and retrospective genetic counselling - Genetic counsellor - Preconceptional genetic counselling - Psychological counselling - Scenario based decision - Person centred approach

Module-III

Management and Remedial measures for genetic disorders: Conventional approach , Application of recombinant methods, Multi speciality approach, foetal medicine, foetal vaccination, recurrent loss of pregnancy, Foetal therapy - Antenatal and postnatal surgical anomalies, Management of inherited metabolic disorders in India, The role of prenatal pathologists , Gene therapy, hormonal replacement therapy.

Module-IV

Population education: individual, families, society, Awareness programme - policy markers, community influences, Training of medical/para medical/health care providers, Pharmacogenetics and ecogenetics

Module-V

Ethical and Legal issues: Ethics in prenatal diagnosis and subsequent abortion, Ethical problems faced by the counselor, Ethical guidance in genetic counseling, Eugenics – Euthenics – Positive and negative euthenics - Euphenics – ELSI.

Text/References (Latest Edition):

1. Genetic Diagnosis of Endocrine Disorders, Roy E. Weiss, Samuel Refetoff, Academic Press.
2. Genetic Disorders and the Fetus: Diagnosis, Prevention and Treatment, Aubrey Milunsky, Jeff Milunsky, John Wiley & Sons
3. The Encyclopedia of Genetic Disorders and Birth Defects, James Wynbrandt, Mark D. Ludman, Infobase Publishing.
4. Genes, Chromosomes, and Disease: From Simple Traits, to Complex Traits, to Personalized Medicine, Nicholas Wright Gillham, FT Press.
5. P. Kaushal, D. R. Malaviya and A. K. Roy. Ethical aspects in genetic counseling
6. Preventive Genetics by Gogate, Jaypee Brothers, Medical Publishers
7. Basic Human Genetics, V. Kapur, R. K. Suri, Jaypee Brothers Publishers

MBT-1003: Molecular Therapeutics

Module-I

Gene therapy: Intracellular barriers to gene delivery; Overview of inherited and acquired diseases for gene therapy; Retro and adeno virus mediated gene transfer; Liposome and nanoparticles mediated gene delivery

Module-II

Cellular therapy: Stem cells: definition, properties and potency of stem cells; Sources: embryonic and adult stem cells; Concept of tissue engineering; Role of scaffolds; Role of growth factors; Role of adult and embryonic stem cells; Clinical applications; Ethical issues

Module-III

Recombinant therapy: Clinical applications of recombinant technology; Erythropoietin; Insulin analogs and its role in diabetes; Recombinant human growth hormone; Streptokinase and urokinase in thrombosis; Recombinant coagulation factors

Module-IV

Immunotherapy: Monoclonal antibodies and their role in cancer; Role of recombinant interferons; Immunostimulants; Immunosupressors in organ transplants; Role of cytokine therapy in cancers; Vaccines: types, recombinant vaccines and clinical applications

Module-V

Gene silencing technology: Antisense therapy; siRNA; Tissue and organ transplantation; Transgenics and their uses; Cloning; Ethical issues

Text/References (Latest Edition):

1. Bernhard Palsson and Sangeeta N Bhatia, Tissue Engineering, Prentice Hall.

2. Pamela Greenwell, Michelle McCulley, Molecular Therapeutics: 21st century medicine, Sringer.

MBT-1004: LAB-I

1. Bioinformatic tools for genome and proteome analysis.
2. Isolation of genomic DNA from peripheral blood.
3. Agarose gel electrophoresis
4. Determinations of DNA Quality & Concentration by spectrophotometry
5. PCR
6. Southern hybridization
7. Preparation of competent cells and transformation
8. Plasmid preparation.
9. Construction of recombinant DNA and Cloning
10. RNA isolation
11. cDNA Synthesis
12. PAGE and Western Blot
13. DNA sequencing
14. Molecular diagnosis of Human Immunodeficiency virus (HIV) by RT- PCR
15. Molecular diagnosis of Human Immunodeficiency virus (HIV) by Western Blotting

II SEMESTER

MBT-2001: Quality Control and Testing of Recombinant Drugs

Module-I

Industrial aspects: Stability studies of biotechnology derived products, Effects of various environmental /processing on stability of the formulation and techniques for stabilization of product against the same regulatory requirement related to stability testing with emphasis on matrixing bracketing techniques, Climatic zones

Module-II

Recombinant DNA Technology and production of protein drugs: Review of protein biosynthesis in prokaryotic and eukaryotic cells, Regulation of gene expression, methods of creating recombinant DNA, isolation of cloned genes, cDNA cloning, genomic DNA cloning, expression of recombinant proteins, host cells, expression vectors, strategies in design of recombinant plasmids for pharmaceuticals

Module-III

Analysis of Recombinant proteins: Total protein assay: Quantitative amino acids analysis, Folin-Lowry protein assay, BCA assay, UV spectrophotometry etc. Purity: Protein impurities, contaminants, electrophoretic analysis, HPLC based analysis, DNA content analysis, immunological assays for impurities, combined immunological and electrophoretic methods, host-cell impurities etc. Test procedures: ICH guidelines. Potency assays: In-vitro biochemical methods. cell-Iine derived assays, whole animal assays etc.

Module-IV

Industrial application of biotech products: Industrial enzymes (examples), immobilization of enzymes, their applications in industry, Immobilized Enzyme engineering, Kinetics of immobilized enzymes, novel methods for enzyme and vaccine production; Steroid production, analgesics etc.

Module-V

Quality control of crude drugs: Quality control of natural medicine products including organoleptic, microscopical, physical, chemical and biological

evaluation of crude drugs, Quality control and in process Quality control of Tablets, Capsules, Liquid dosage forms - parenteral & sterile preparations, ointments, creams, suppositories and controlled release products.

Text/References (Latest Edition):

1. Jens T. Cartensen and C. T. Rhodes, Drug stability principle and practice, 3 rd ed. Vol. 107, Marcel Dekker
2. Rodney pealman, Y. John wang, formulation characterization and stability of protein drugs.
3. Eugene J. McNally, Jayne E. Hasted, protein formulation and delivery 2nd Ed. Informa-healthcare.
4. Sven frokjaer and lars hovgaard, pharmaceutical formulation development of peptides and proteins. Taylor and Franceis
5. Sarfaraz K. Niazi, Handbook of Preformularion, Informa Healthcare
6. Practical Biochemistry: Principles and Techniques, Fifth Edition, K. Wilson and J. Walker
7. Experimental Biochemistry, R. L. Switzer and L. F. Garrity W. H. Freeman and Company

MBT-2002: Bio-Preservation and Biobanking

Module-I

Bio-Preservation & Biobanking: Blood banking, Selection of blood bags for component preparation, preparation of red cell concentrate, Fresh Frozen plasma, platelet concentrate, cryoprecipitate, washed red cells, Frozen red cells **Plasma Fractionation:** Principles, manufacturing of different plasma derivatives, Component Testing, Labeling, Transportation and storage of blood components, Preparation of leukoreduced blood products, Leukocyte filters, component extractors, Metabolic changes in blood components during storage, release of cytokine during storage, Inventory management and maintenance of blood stock, Irradiated blood components , Blood substitutes, Measurement of factor VIII level in FFP, Measurement of fibrinogen level in FFP, Sterility test on platelet

concentrates, Sterility test on Whole blood, Measurement of pH and other platelet parameters

Module-II

Umbilical cord stem cell banking: Specimen collection, Processing of Cord Blood, Cryopreservation of Cord Blood and banking of umbilical cord stem cell, Human specimen repositories, Cord blood banks: public use banks & family use banks, autologous transplant and allogenic transplant.

Module-III

Techniques for Bio-Preservation: Stem cell banking approaches: cord blood, cord tissue, adipose tissue, sedimentation efficacy studies, extended stability studies, Hypothermic storage and testing.

Laser Scanning Microscopy and Micro-Spectroscopy for Cryobiology and Cryopreservation,

Module-IV

Applications of stem cell banking: Overview of embryonic and adult stem cells for therapy Neurodegenerative diseases; Parkinson's, Alzheimer, Spinal Cord Injuries; Tissue system Failures; Diabetes; Cardiomyopathy; Kidney failure; Liver failure; Cancer; Hemophilia etc.

Module-V

Human Embryonic Stem Cells and Society Human stem cells research: Ethical consideration; Stem cell religion consideration; Stem cell based theories: Pre clinical regulatory consideration and Patient advocacy.

Text/References (Latest Edition):

1. David T. Harris Stem Cell Banking for Regenerative and Personalized Medicine Biomedicines 2, 50-79

2. Biopreservation and biobanking Volume 14, Number 2, 2016 ª Mary Ann Liebert, Inc.
3. David McKenna & Jayesh Sheth Umbilical cord blood: Current status & promise for the future Indian J Med Res 134 pp 261-269

MBT-2003: Clinical Embryology

Module-I

Introduction to mammalian embryology: Differentiation , morphogenesis, growth, reproduction, evolution, environmental effects on fetal development, different approaches for the study of fetal development, methods used to study developmental biology, principles and processes of DNA and RNA in embryonic development, signals & signaling system that induce fetal development, intercellular connections and oraganogenesis in the embryo, fertilization

Module-II

Assisted Reproduction: Overview of invitro fertilization, Quality control testing of culture media, Surgical items and labware, Culture media and sperm preparation for IVF, Egg retrieval and insemination, Semen analysis, anti-sperm antibodies, cryopreservation and thawing of semen, and sperm washing.

Module-III

Embryo culture: Fertilization evaluation, Embryo culture and transfer and assisted hatching, intra cytoplasmic sperm injection, Cumulus cell coculture techniques, Pre implantation genetic diagnosis (PCR, FISH, Micro array technology and karyotyping), embryo cryopreservation and vitrification

Module-IV

Advanced ART Techniques: Assisted hatching by laser or chemical (Tyrode's) method, single cell biopsy of embryo (laser and chemical)**, Pre implantation**

genetic diagnosis: setting up of the micromanipulator, biopsy of embryos, use of laser and acid Tyrode's for zona drilling, blastomere and polar body aspiration and fixation techniques, cell spreading, fixation techniques

Module-V

Regulation and ethics in Assisted reproductive technology: Current major legislative and non-legislative schemes for regulating IVF, regulatory bodies and their requirements for licensing, accrediting and approving clinical and ART related research, legal and ethical issues surrounding IVF, gamete and embryo donation, embryo experimentation, surrogacy, cloning, stem cell research and genetic selection and manipulation, role of ethics in health care and legal decision-making, main ethical frameworks and principles used in analysing conflicts and solving problems, the ethical concerns raised by current ART practices and the future prospects for this technology around the world

Text/References (Latest Edition):

1. Developmental biology. Gillbert. S., Sinauer Associates, Inc.
2. Veterinary Embryology. T.A. McGeady, P.J Quinn et al. Blackwell publishing
3. Principles of Development. Wolpert. L, et al. Oxford Univ.Press,

4. MBT-2004: LAB-I

1. Density gradient based separation of peripheral lymphocytes, Lymphocyte culture and detecting proliferation on mitogenic stimulus
2. Chick embryo fibroblast cell culture
3. Functional protein identification
4. Karyotype using Human lymphocyte culture a. Q-banding b. G-banding c. C-banding d. NOR-banding
5. Genetic counseling (pedigree analysis in disease conditions, risk calculation)
6. Isolation of cells from blastocyst
7. Preparation of feeder cell culture.
8. Culturing of Stem cell line.
9. Growing mesenchymal stem cell.
10. Preservation of cord blood.

11. Stem cell isolation from umbilical cord.
12. Stem cells –Identification of cells by staining of bone marrow – (Animal example)

MBT-2005: 3 months internship on the latest techniques in medical biotechnology in reputed hospitals, healthcare industries and CSIR/ICMR laboratories