SARDAR PATEL UNIVERSITY
University Road P. B. 10
Vallabh Vidhyanagar-388120 (Gujarat)
NAAC accredited with Grade 'A'
(10-01-2023 to 09-01-2028)
Phone: 0692-226808/85; Email: exam_spu@spuvvn.edu; Website: www.spuvvn.edu

National Commission for Allied and Healthcare Professions

Competency Based Curriculum for Medical Laboratory Sciences

As per NCAHP Act 2021

Curriculum -Master of Medical Laboratory Science

Introduction:

The Master of Medical Laboratory Science (MMLS) is specifically aimed at those pursuing a professional career in medical laboratory science. It is designed to provide specialized training both in basic scientific principles of modern laboratory science and in the application of these principles to laboratory diagnosis and management. It is designed as a higher degree program suitable for graduates having experience in Medical Laboratory Science. The program aims to enhance the scientific skills of non-medical graduates with insight into clinical problems that will allow them to work in multidisciplinary teams.

Learning Objectives:

Upon successful completion of the Masters" program, students will

1. **Demonstrate proficiency in a comprehensive range of laboratory procedures**, including advanced techniques in haematology, clinical chemistry, and microbiology.
2. **Identify and troubleshoot issues across all phases of laboratory testing**—pre-analytical, analytical, and post-analytical—to ensure accuracy and reliability of results.
3. **Operate, maintain, and troubleshoot sophisticated laboratory instrumentation**, applying best practices for quality assurance and control.
4. **Interpret complex laboratory data** within the context of pathophysiology and clinical decision-making, with a sound understanding of diagnostic principles related to various organ systems.
5. **Contribute to the innovation and development of diagnostic techniques and laboratory methodologies**, supporting the advancement of evidence-based clinical practice.
6. **Demonstrate readiness for advanced roles** in healthcare, laboratory management, education, and biomedical research through enhanced critical thinking, ethical decision-making, and leadership skills.

Career Opportunities:

Upon successful completion of the course, Post Graduates can have the following career opportunities

- **Clinical labs** – senior scientist, specialist, or lab manager.
- **Research & biotech** – R&D, clinical trials, molecular diagnostics.
- **Academia** – lecturer, trainer, or pursuing PhD.
- **Public health & regulation** – surveillance, quality assurance, accreditation.
- **Industry** – medical science liaison, product specialist, lab informatics.
- **Global & entrepreneurial roles** – international practice, diagnostic startups, or work with WHO/NGOs.

Program Learning Outcomes for Master of Medical Laboratory Science (MMLS) following outcomes reflect the expected competencies and professional capabilities of a graduate upon completion of the program:

Core Program Learning Outcomes:

1. Advanced Laboratory Competence Apply advanced knowledge and technical skills in areas such as clinical chemistry, haematology, microbiology, immunology, transfusion science, molecular diagnostics, and histopathology.
2. Critical Thinking and Problem-Solving Critically evaluate laboratory data, troubleshoot complex testing procedures, and apply evidence-based practices in laboratory decision-making.
3. Research and Innovation Design, conduct, and interpret research studies; contribute to scientific knowledge through research dissemination and potential innovation in diagnostic techniques.
4. Quality Management and Accreditation Demonstrate understanding of quality assurance systems, accreditation processes (e.g., ISO 15189), laboratory safety, and regulatory compliance in clinical laboratory operations.
5. Leadership and Management Exhibit leadership, strategic planning, and effective resource management in laboratory settings; supervise personnel and contribute to operational excellence.
6. Interdisciplinary Collaboration Collaborate with healthcare professionals to provide accurate diagnostic information, participate in interdisciplinary teams, and support patient-centered care.
7. Ethical and Professional Practice Adhere to ethical principles, legal frameworks, and professional standards in all aspects of laboratory science and research.
8. Communication Skills effectively communicate scientific and clinical information to peers, healthcare providers, patients (where applicable), and the broader scientific community.
9. Continuous Learning and Development Engage in lifelong learning and professional development to stay current with advances in medical laboratory science and emerging diagnostic technologies.
10. Global and Societal Impact Awareness Understand the role of medical laboratory science in public health, global health challenges, and the social determinants of health.

Expectations from Future Graduates in Providing Patient Care

Future graduates of medical laboratory science programs are expected to play an increasingly integral role in healthcare delivery. Key expectations include:

1. **Accurate and Timely Diagnostics**: Delivering high-quality laboratory results that are critical for early detection, diagnosis, prognosis, and monitoring of diseases.
2. **Interdisciplinary Collaboration**: Working closely with physicians, nurses, and other healthcare professionals to interpret lab results and support clinical decisions.
3. **Patient-Centered Focus**: Understanding the impact of laboratory findings on patient outcomes and ensuring test appropriateness, especially in personalized and precision medicine.

4. **Continual Learning**: Keeping pace with rapid advancements in diagnostics and adopting innovations that improve efficiency and accuracy.
5. **Public Health Contribution**: Supporting disease surveillance, outbreak investigations, and screening programs, especially in resource-limited settings.
6. **Ethical Practice and Leadership**: Upholding integrity, ensuring patient confidentiality, and leading initiatives in quality improvement, laboratory safety, and policy development.

Eligibility for admission:

1) Candidate must have **passed Bachelor of Medical Laboratory Science (B.MLS) on regular mode** from any recognised Indian University.
2) Admission to MMLS shall be made on the basis of **University entrance exam followed by interview**. No direct Admission will be entertained.
3) Entrance exams will be conducted based on the syllabus of BMLS. Successful candidates who cleared Exam should be called for the interview
4) Interview panel should have Dean/Principal/Head of the department (Chairman of the board) Professor/ Associate professor and other members as per the policy of the institution whose recommendations shall be final for the selection of students
5) **Medical Fitness Certificate** is mandatory to submit and it is to be endorsed by Government Medical Officer.
6) Reservation policy for admission in postgraduate programme shall be as per Gov. of Gujarat.
7) Postgraduate Entrance Criteria required to be compulsory registered member of NCAHP.

Duration of the program

- Duration of the program is 2 years or 4 semesters with 1340 hours of Lecture & 900 hours of practical Training.

Total number of hours: 2240
Total Credits: 86

Medium of instruction:

- English shall be the medium of instruction for all the subjects of study and for examination of the course.

Attendance:

A candidate has to secure minimum -
1. 80% attendance in theoretical
2. 80% in Skills training (practical) for qualifying to appear for the final examination.

No relaxation, whatsoever, will be permissible to this rule under any ground including indisposition etc.

Assessment:

Cognitive Assessment

Structured logbook; Viva-voce examination.
Structured case presentation
Formative assessment
Summative assessment; Case presentation

Psychomotor Assessment

Objective Structured Clinical Examination (OSCE)
Objective Structured Practical Examination (OSPE)
Mini Clinical Evaluation Exercise (Mini-CEX)
Direct Observation of Procedural Skills (DOPS)
Simulation-based assessment

The Government of India notified **the National Commission for Allied and Healthcare Professions (NCAHP)** Act on **March 28, 2021**. As a common regulatory body, the NCAHP Act provides for regulation and maintenance of standards of education and services by Allied and Healthcare Professionals.

Medical Laboratory Sciences (MLS)

Teaching Learning Methodologies

- **Didactic Teaching (Foundational Knowledge):** Lectures & Seminars, Interactive Tutorials, E-learning & Flipped Classroom
- **Laboratory-Based Learning (Skill Development)** : Demonstrations & Hands-On Practicals, Simulation-Based Training, Objective Structured Practical Examinations (OSPE)
- **Problem-Based & Case-Based Learning:** Problem-Based Learning (PBL), Case Discussions, Error Analysis Workshops
- **Clinical Exposure & Work-Integrated Learning:** Clinical Rotations/Internships; Workplace-Based Assessments; Interdisciplinary Collaboration
- **Research and Innovation-Oriented Learning:** Capstone Projects; Evidence-Based Learning; Innovation Challenges
- **Professionalism and Soft Skills Training :** Communication Skills Workshops; Ethics & Biosafety Training; Team-Based Learning

Assessment methods

- **Knowledge-Based Assessment (Cognitive Domain – Bloom's):** Written Exams; Case-Based Questions (CBQs); Online Quizzes & Open-Book Tests
- **Practical/Skill-Based Assessment (Psychomotor Domain – Miller's "Shows How"):** Objective Structured Practical Examination (OSPE); Direct Observation of Procedural Skills (DOPS); Simulation-Based Assessment
- **Workplace-Based Assessment:** Logbooks & Portfolios; Mini-Clinical Evaluation Exercises (Mini-CEX): Case Presentations & Viva Voce; Workplace Performance Evaluation
- **Research & Innovation Assessment:** Capstone/Research Projects; Poster/Oral Presentations; Quality Improvement Projects
- **Professionalism & Affective Domain:** Peer Assessment; Reflective Writing/Portfolios; Supervisor Feedback (360° Evaluation)

Mode of education for all allied and healthcare program: All programs should be delivered in full-time mode

- The curriculum is to be devised in a semester system. All programs must have a mandatory internship. It is recommended that a faculty and student ratio of 1:15 is to be followed for the undergraduate programmes and 1:10 for the Post graduate programmes.

Minimum Standard Recommendations:

- Classrooms with smart board and internet facilities for audio visual teaching.
- **Laboratories:** Anatomy & Physiology laboratory; Biochemistry laboratory; Microbiology laboratory; Haematology and clinical pathology laboratory; Histopathology and cytopathology laboratories
- **Library:** Text books/reference books, periodicals and Journals
- **Computer facility:** At least fifteen (15) desktop computers with internet access for students

Master of Medical Laboratory Science

Career Opportunities:

Upon successful completion of the course, Post Graduates can have the following career opportunities

⇒ **Clinical labs** – senior scientist, specialist, or lab manager.

⇒ **Research & biotech** – R&D, clinical trials, molecular diagnostics.

⇒ **Academia** – lecturer, trainer, or pursuing PhD.

⇒ **Public health & regulation** – surveillance, quality assurance, accreditation.

⇒ **Industry** – medical science liaison, product specialist, lab informatics.

⇒ **Global & entrepreneurial roles** – international practice, diagnostic startups, or work with WHO/NGOs.

MARKS QUALIFYING FOR A PASSING

- For University examination subjects: **50% in internal assessment**, **50% in university theory examination**, **50% in university practical examination** and **50% in aggregate**
- For thesis and defence: For successful thesis defence, the candidate will make a brief presentation of about 30 minutes followed by viva-voce. A candidate must secure at least **50% marks to pass**.

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MMLS Semester I –Common for all specialisations

Code	COURSE NAME	L/P	C	Hours	IA	ESE	Total
M01COMLS01	Medical Laboratory Management	4	4	60	30	70	100
M01COMLS02	Cell and Molecular Biology	4	4	60	30	70	100
M01COMLS03	Advanced Molecular Diagnostic Techniques	4	4	60	30	70	100
M01COMLS04	Research Methodology & Biostatistics	2	2	30	30	70	100
M01COMLS05	Digital Health Technologies	2	2	30	30	70	100
	Practical						
M01COMLS06	Research Methodology & Biostatistics Practical	2	2	60	30	70	100
M01COMLS07	Advanced Molecular Diagnostic Techniques Practical	2	2	60	30	70	100
M01COMLS08	Lab Management & Molecular Biology Practical (Elective)*	2	2	60	30	70	100
	Total	**22**	**22**	**420**	**240**	**560**	**800**

L: Lecture, T: Tutorial; P: Practical, C: Credit; I: Internal Assessment; ESE: End Semester Examination

Semester II- Medical Biochemistry

Code	COURSE NAME	L/P	C	Hours	IA	ESE	Total
M02MLSMB01	Bioorganic & Biophysical Chemistry	4	4	60	30	70	100
M02MLSMB02	Instrumentation in Biochemistry	4	4	60	30	70	100
M02MLSMB03	Enzymology & Nutrition	4	4	60	30	70	100
M02MLSMB04	Intermediary Metabolism	4	4	60	30	70	100
	Practical						
M02MLSMB05	Bioorganic & Biophysical Chemistry Practical	4	2	60	30	70	100
M02MLSMB06	Instrumentation Practical	4	2	60	30	70	100
M02MLSMB07	Clinical posting	4	2	90	30	70	100
	Total	**28**	**22**	**450**	**210**	**490**	**700**

L: Lecture, T: Tutorial; P: Practical, C: Credit; I: Internal Assessment; ESE: End Semester Examination

Semester III- Medical Biochemistry

Code	COURSE NAME	L/P	C	Hours	IA	ESE	Total
M03MLSMB01	Clinical Biochemistry I	4	4	60	30	70	100
M03MLSMB02	Clinical Biochemistry II	4	4	60	30	70	100
M03MLSMB03	Immunology	4	4	60	30	70	100
M03MLSMB04	Endocrinology & Biochemistry of aging	4	4	60	30	70	100
	Practical						
M03MLSMB05	Clinical Biochemistry I Practical	2	2	60	30	70	100
M03MLSMB06	Clinical Biochemistry II Practical	2	2	60	30	70	100
M03MLSMB07	Immunology Practical	2	2	60	30	70	100
	Total	**22**	**22**	**420**	**210**	**490**	**700**

L: Lecture, T: Tutorial; P: Practical, C: Credit; I: Internal Assessment; ESE: End Semester Examination

Semester II- Medical Microbiology

Code	COURSE NAME	L/P	T	C	Hours	IA	ESE	Total
M02MLSMM01	Essential and Applied Microbiology	3	1	4	60	30	70	100
M02MLSMM02	Systematic Bacteriology	3	1	4	60	30	70	100
M02MLSMM03	Medical Entomology and Parasitology	3	1	4	60	30	70	100
M02MLSMM04	Immunology and Immunodiagnostics	3	1	4	60	30	70	100
	Practical							
M02MLSMM05	Systematic Bacteriology practical	4	0	2	60	30	70	100
M02MLSMM06	Medical Entomology and Parasitology practical	4	0	2	60	30	70	100
M02MLSMM07	Immunology and Immunodiagnostics practical	4	0	2	60	30	70	100
	Total	**24**	**04**	**22**	**420**	**210**	**490**	**700**

L: Lecture, T: Tutorial; P: Practical, C: Credit; I: Internal Assessment; ESE: End Semester Examination

Semester III Medical Microbiology

Code	COURSE NAME	L/P	T	C	Hours	IA	ESE	Total
M03MLSMM01	Medical Virology	3	1	4	60	30	70	100
M03MLSMM02	Medical Mycology	3	1	4	60	30	70	100
M03MLSMM03	Public Health Microbiology	3	1	4	60	30	70	100
M03MLSMM04	Advances in Microbial Informatics	3	1	4	60	30	70	100
	Practical							
M03MLSMM05	Medical Mycology & Virology practical	4	0	2	60	30	70	100
M03MLSMM06	Public Health Microbiology practical	4	0	2	60	30	70	100
M03MLSMM07	Clinical posting	4	0	2	90	30	70	100
	Total	**24**	**4**	**22**	**450**	**210**	**490**	**700**

L: Lecture, T: Tutorial; P: Practical, C: Credit; I: Internal Assessment; ESE: End Semester Examination

Semester II Haematology and Transfusion Medicine

Code	COURSE NAME	L/P	C	Hours	IA	ESE	Total
M02MLSHT01	Haematology and Haematological Disorders	4	4	60	30	70	100
M02MLSHT02	Haemostatic Disorders	4	4	60	30	70	100
M02MLSHT03	Applied Immunopathology in Haematology	4	4	60	30	70	100
M02MLSHT04	Clinical Pathology	2	2	30	30	70	100
	Practical						
M02MLSHT05	Haematology and Haematological Disorders Practical	2	2	60	30	70	100
M02MLSHT06	Haemostatic Disorders Practical	2	2	60	30	70	100
M02MLSHT07	Applied Immunopathology in Haematology Practical	2	2	60	30	70	100
M02MLSHT08	Clinical Pathology Practical	2	2	60	30	70	100
	Total	**22**	**22**	**450**	**240**	**560**	**800**

L: Lecture, T: Tutorial; P: Practical, C: Credit; I: Internal Assessment; ESE: End Semester Examination

Semester III- Haematology and Transfusion Medicine

Code	COURSE NAME	L/P	C	Hours	IA	ESE	Total
M03MLSHT01	Blood Banking and Immunohematology	4	4	60	30	70	100
M03MLSHT02	Transfusion Medicine	4	4	60	30	70	100
M03MLSHT03	Molecular Hematology	4	4	60	30	70	100
M03MLSHT04	Advanced Haematological Techniques	2	2	30	30	70	100
	Practical						
M03MLSHT05	Blood Banking and Immunohematology Practical	2	2	60	30	70	100
M03MLSHT06	Transfusion Medicine Practical	2	2	60	30	70	100
M03MLSHT07	Molecular Hematology Practical	2	2	60	30	70	100
M03MLSHT08	Advanced Haematological Techniques Practical	2	2	60	30	70	100
	Total	**22**	**22**	**450**	**240**	**560**	**800**

L: Lecture, T: Tutorial; P: Practical, C: Credit; I: Internal Assessment; ESE: End Semester Examination

Semester II- Histology and Cytopathology

Code M02MLSHC	COURSE NAME	L/P	C	Hours	IA	ESE	Total
M02MLSHC01	Translational Anatomy and Cell Dynamics	4	4	60	30	70	100
M02MLSHC02	Essentials of Histology	4	4	60	30	70	100
M02MLSHC03	Essentials of Cytopathology	4	4	60	30	70	100
M02MLSHC04	Cancer epidemiology and Digital Pathology	2	2	30	30	70	100
	Practical						
M02MLSHC05	Translational Anatomy and Cell Dynamics Practical	2	2	60	30	70	100
M02MLSHC06	Essentials of Histology Practical	2	2	60	30	70	100
M02MLSHC07	Essentials of Cytopathology Practical	2	2	60	30	70	100
M02MLSHC08	Cancer epidemiology and Digital Pathology Practical	2	2	60	30	70	100
	Total	**22**	**22**	**450**	**240**	**560**	**800**

L: Lecture, T: Tutorial; P: Practical, C: Credit; I: Internal Assessment; ESE: End Semester Examination

Semester III- Histology and Cytopathology

Code	COURSE NAME	L/P	C	Hours	IA	ESE	Total
M03MLSHC01	Diagnostic Histopathology	4	4	60	30	70	100
M03MLSHC02	Cytological Techniques	4	4	60	30	70	100
M03MLSHC03	Immunohistochemistry & Diagnostic Markers	4	4	60	30	70	100
M03MLSHC04	Molecular Techniques in Histopathology & Cytology	2	2	30	30	70	100
	Practical						
M03MLSHC05	Diagnostic Histopathology Practical	2	2	60	30	70	100
M03MLSHC06	Cytological Techniques Practical	2	2	60	30	70	100
M03MLSHC07	Immunohistochemistry & Diagnostic Markers Practical	2	2	60	30	70	100
M03MLSHC08	Molecular Techniques in Histopathology & Cytology Practical	2	2	60	30	70	100
	Total	**22**	**22**	**450**	**240**	**560**	**800**

L: Lecture, T: Tutorial; P: Practical, C: Credit; I: Internal Assessment; ESE: End Semester Examination

Semester IV –COMMON FOR ALL SPECIALIZATION

No	**SEMESTER IV**	**Credits**	**Contact Hours**	**IA**	**EAE**	**Total**
M04MLSCOD1	Dissertation	22	990	200	400	600
Total		**22**	**990**			

No	**Course Name**	**Continuous assessment**	**End Semester Examination**	**Total**
1	Dissertation viva	100	200	300
2	Dissertation Logbook	100	200	300
Total				**600**

⇒ **Credit Distribution**: Each semester would consist of a minimum of 22 credits. The credit distribution hours for Lecture, Tutorial, Practical, and Clinics are as follows:
Credit Details:
Lecture / Tutorial: 1 credit = 15 hours; Practical: 1 credit = 30 hours; Clinical/ Lab Posting: 1 credit = 45 hours (Credit Includes: L – Lectures, T- Tutorials, P- Practical)

⇒ Post graduate Program Requirements: A minimum of **88** credits is required for the MMLS

⇒ A program of 2 years duration, inclusive of six months research dissertation.

Promotion Criteria to higher semesters:

The eligibility for promotion to the next academic year is subject to securing the minimum academic performance as specified below

⇒ First to second year: a minimum of 70% of the credits at the end of the first year (includes first and second semester)

⇒ Students will be eligible for internship research dissertation only after successful completion of the entire coursework, i.e. 100% credits to be accrued by the end of the third semester.

⇒ The student must complete all the coursework requirements within a maximum of double the program duration. For example, in a 2-year program, all the academic coursework needs to be completed within 4 years. Failure to do so will result in exit from the program.

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SEMESTER I

Medical Laboratory Management Credit = 4 (60 hours)

Course Rationale: This course will enable the student to manage resources, understand and follow GCLP, minimize errors, implement and maintain quality control measures, maintain equipment and promote a safe working environment, develop good communication skills, foster team work and develop leadership skills.

Learning outcomes: At the end of the course the student should be able to

⇒ Understand the need for efficient and effective laboratory operations, including resource allocation, personnel management, equipment and reagent purchase and maintenance.

⇒ Comprehend knowledge of relevant regulations, standards, and best practices for overall improvement of laboratory services for patient care

UNIT	M01COMLS01 Medical Laboratory Management	C=4 (60 hr)
I.	**Principles of Lab management:** Financial management, human resource management and space and facility management. Organisational structure of lab. Laboratory design: functional components of laboratory, Various types of laboratory. A standardized clinical laboratory set up, Factors affecting productivity of a laboratory **Training of technical staff in Clinical laboratory:** Areas of training. Role of lab supervisors in training. Job description of various levels. Hands on approach to various laboratory practices	6
II.	**Work- Flow** of a Clinical Laboratory – sample reception, registration, barcoding, centrifuging, sample processing, result checking, result release, sample storage Scope of laboratory services	4
III.	**Good Clinical laboratory practices (GCLP)** • Standard operating procedures (SOP): importance of SOP's in a clinical laboratory • Laboratory personnel: Role of lab personnel in a medical Laboratory • Laboratory sample management: request form, sample labelling, sample register, sample storage, sample disposal • Laboratory equipment: Equipment procurement and evaluation. Details of specific instruments / devices for analyte estimations (routine chemistry, hormones, tumour markers, electrolytes, drugs, metals, blood gases, amino acids,) • Laboratory reagents and kits: Procuring kits, inventory, storage, validation	8
IV.	**Laboratory errors**: Root cause analysis and CAPA (corrective action, preventive action) **Phases of errors** in clinical Laboratory testing process Preanalytical variables	8

	Analytical variables- Use of stable reference materials-calibrators & controls, LJ charts and Westgard rules. **Standardization / Calibration processes:** Calibration of basic equipment by laboratory personnel. Calibration of methods-colorimetric and enzymatic. Post analytical variables: transfer of results, documentation, competence and various laboratory processes	
V.	**Total Quality management:** ➢ Fundamental principles. TQM framework ➢ External Quality Assessment Schemes ➢ Internal QC Procedures, Use of Internal Quality Control material. Care and procedural steps in reconstitution of commercial controls.	**6**
VI.	**Biological Reference Intervals**: Definition. Establishment. Validation of reference intervals. Diagnostic efficacy. **Documentation** in Laboratory/Maintenance of records: Patient entry registers, Procedure manuals, Registers of Reagents, consumables and accessories, quality control data, patient data and all relevant lab records	**8**
VII.	**Clinical laboratory informatics**: Computer basics. Word processing, spreadsheets, data-base, graphics, statistics, Laboratory Information Systems (LIS).	**4**
VIII.	**Laboratory Accreditation and Audit:** ISO guidelines, NABL 15189 standards, Audit in a Medical Laboratory: Introduction and Importance, Responsibility, Planning, internal audit, Horizontal, Vertical and Test audit, Frequency of audit, Documentation. Overview of JCI & CAP.	**6**
IX.	**Public relations**: Interpersonal skills at work place, communication with patients, Leadership management, conduction of seminar and CME programs, performance appraisal of staff, Laboratory approach to patient community, patient/clinician feedback forms, Hospital organization and interactions between the laboratory service and the rest of the hospital	**4**
X.	**Risk Management and safety measures:** Safety responsibility-employer and employee - Safety in a clinical laboratory: personal protection, Laboratory hazards, Laboratory safety- fire, chemical, electrical, radiation, Laboratory infection control, Hazardous waste and transport of Hazardous material, biomedical waste management, HIV: pre- and post-exposure guidelines, Hepatitis B & C: pre- and post-exposure guidelines, drug Resistant Tuberculosis, Needle prick injury and follow-up, Accident documentation and investigation	**4**

Suggested Readings:

1. MacMillan, D., & Lewandrowski, K. B. The Clinical Laboratories.
2. Chou, D. (2007). Henry's clinical diagnosis and management by laboratory methods. *JAMA*, *297*(16), 1827-1833.
3. Rifai, N. (2017). *Tietz Textbook of Clinical Chemistry and Molecular Diagnostics-E-Book: Tietz Textbook of Clinical Chemistry and Molecular Diagnostics-E-Book*. Elsevier Health Sciences.

4. Mrinalini Sant (2022) Textbook of Medical Laboratory Technology 2nd Edition 2022
5. Godkar, P. B., & Godkar, D. P. (2006). *Textbook of medical laboratory technology*. Bhalani publishing house.

Cell and Molecular Biology Credit = 4 (60 hours)

Course Rationale: Molecular Biology knowledge is essential for a Medical Laboratory Science scholar as it provides the foundation to the professional in understanding the latest techniques in Biotechnology. It empowers the graduate to use advanced techniques in disease diagnosis and progression and also in analyzing genetic information which explains genetic and molecular basis of many diseases affecting mankind

Comprehend in-depth understanding of fundamentals.

Understand and apply techniques for disease diagnosis with extreme accuracy and precision

Develop research attitude that can further help in developing newer techniques in molecular Biology

Learning objectives: At the end of the course students will be able to

UNIT	M01COMLS02 Cell and Molecular Biology	C=4 (60 hr)
I.	Basic Concept Of Cell Structure, Function And Processes a) Cell Organelles And Their Functions b) Cell Division, Cell Cycle And Apoptosis	6
II.	The Central Dogma Of Molecular Biology-Transfer Of Genetic Information From Dna To Rna To Protein Synthesis, Dna Replication Transcription-The Process Of Transcription, Inhibition Of Transcription, Reverse Transcriptase, Post Transcriptional Modification Translation- The Process Of Translation, Post Translational Modifications Like Folding, Glycosylation Etc. Inhibitors Of Protein Synthesis	12
III.	Gene Expression-Regulation And Significance	6
IV.	In Situ Hybridization-To Study Gene Expression Pattern, Localize Gene Amplification, Gene Location	6
V.	Concept Of Gene Switching, Gene Transposition, Somatic Recombination	8
VI.	Cell Culture: Introduction, Significance, Cell Culture Lab – Instruments, Aseptic Techniques, Media Preparation And Filtration For Cell Culture, Media Composition And Supplements, Types Of Cell Culture- Primary, Secondary. Adherent, Suspension Cells, Commonly Used Cell Lines, Cell Culture Procedure, Contamination In Cell Culture Lab, Biosafety Levels, Ethical Issues. Waste Disposal	12
VII.	Basic Principles And Applications Of Molecular Techniques : Recombinant DNA Technology: Restriction Endonuclease, DNA Ligase, Vectors, Chimeric Molecules, Cloning, Gene Library, Cloning Strategies, In-Situ Hybridization, Blot Techniques And Applications, RFLP, Gene Therapy,	10

	Tran Genesis, DNA Finger Printing, DNA Sequencing, PCR, DNA a Probes, Hybridoma Technology.	

Suggested books

1. Veer Bala Rastogi (2015) Principles of Molecular Biology
2. Wilson, K., Hofmann, A., Walker, J. M., & Clokie, S. (Eds.). (2018). Wilson and Walker's principles and techniques of biochemistry and molecular biology. Cambridge university press.
3. Satyanarayana, U. (2013). Biochemistry. Elsevier Health Sciences.
4. Lodish, H. F. (2008). Molecular cell biology. Macmillan.
5. Karp, G. (2009). Cell and molecular biology: concepts and experiments. John Wiley & Sons

Advance Molecular Diagnostics Techniques Credit = 4 (60 hrs)

Course Rationale: This course provides students with a comprehensive understanding of the advanced molecular techniques and enable them to apply advance methods in the diagnosis

Learning outcome: At the end of the course students should be able to:

comprehend knowledge and clinical skills of molecular techniques

Use accurate and advance diagnostic tools

UNIT	M01COMLS03 Advance Molecular Diagnostics Techniques	C=4 (60 hr)
I.	**Principle & Role of Molecular Diagnostics:** Basic principles in molecular diagnostics and organizations of molecular diagnostics laboratory. Role of molecular diagnostics in present diagnostic era, Ethical issues related to molecular diagnostics, future of molecular diagnostics, Historical aspects advantage of DNA over traditional serology.	**8**
II.	**PCR and its modifications:** Principle of PCR, types of PCR: Primer designing, Reverse Transcriptase-PCR, Real-Time PCR, Inverse PCR, Multiplex PCR, Nested PCR, In situ PCR, Long-PCR, PCR-ELISA, arbitrarily primed PCR. Applications of PCR in Diagnosis and research. **PCR modifications**: Ligase Chain Reaction, isothermal amplification, nucleic acid sequence-based amplification (NASBA), transcription mediated amplification, strand displacement amplification. Specimen collection, advantages and disadvantages of techniques, key factors affecting the performance and reliability.	**12**
III.	**Quantitative and Qualitative estimations:** Protein stability, denaturation; amino acid sequence analysis, Hybridization techniques – Southern, Northern, in-situ (including FISH), line probe assay, microarrays – types and applications; Protein extraction and analysis (including PAGE and its variations); Western Blot	**12**

IV.	Instruments and Techniques: Spectrophotometry, HPLC, MS, ELISA, Chemiluminescent, FIA, Flow cytometry, and specific applications; Electron microscopy and its application, Immunohistochemistry, Immunoflourescenes, Immunocytochemistry– principle and techniques	**12**
V.	Recombinant DNA technology: Restriction endonuclease, DNA ligase, vectors, chimeric molecules, cloning, gene library, cloning strategies, and applications, RFLP, Gene therapy, Trangenesis, DNA finger printing, DNA probes, hybridoma technology	**8**
VI.	Definition, application and advantages of Genomics, Next-generation sequencing technology, Proteomics, Transcriptomics, Metabolomics	**8**

Suggested Readings:

- Wilson, K., Hofmann, A., Walker, J. M., & Clokie, S. (Eds.). (2018). Wilson and Walker's principles and techniques of biochemistry and molecular biology. Cambridge university press.
- Godkar, P. B., & Godkar, D. P. (2006). *Textbook of medical laboratory technology*. Bhalani publishing house.
- Carson, S., Miller, H. B., Srougi, M. C., & Witherow, D. S. (2019). *Molecular biology techniques: a classroom laboratory manual*. Academic Press.
- Tagu, D., & Moussard, C. (Eds.). (2006). *Techniques for molecular biology*. Science Publishers.
- Coleman, W. B., & Tsongalis, G. J. (Eds.). (2007). *Molecular diagnostics: for the clinical laboratorian*. Springer Science & Business Media.

Digital Health Technologies Credit = 2 (30 hours)

Course Rationale: This course aims to equip students with foundational knowledge and practical insights into the application of digital health technologies in the medical laboratory setting. Understanding the course will make students competent in understanding and integrating these technologies essential to enhance diagnostics, quality assurance, data management, and patient care.

Learning outcomes: At the end of the course the student should be able to: 1.) Understand digital technologies shaping medical laboratory practices. 2.) Apply digital tools for laboratory data management and quality control. 3.) Explore AI and machine learning in laboratory diagnostics. 4.) Assess the role of telehealth and remote diagnostics in laboratory medicine. 5.) Evaluate digital health standards, data security, and regulatory considerations.

UNIT	**M01COMLS04** **Digital Health Technologies**	**C=2** **(30 hr)**
I.	Introduction to Digital Health in Laboratory Medicine: Definition and scope of digital health, Evolution and historical perspectives, Current healthcare, big data, and machine learning, artificial intelligence in healthcare applications,	**6**

	predictive analytics in healthcare, WHO classification of digital health interventions,	
II.	Artificial Intelligence and Machine Learning in Diagnostics: AI in hematology: automated WBC differential, RBC morphology, AI in histopathology and cytopathology: image classification and tumor grading, AI in microbiology: colony morphology analysis, resistance prediction, AI in biochemistry: predictive analytics from lab trends (e.g., sepsis prediction), AI in molecular diagnostics: variant classification and pathogenicity prediction, Digital Epidemiology and Health Surveillance	**6**
III.	Telehealth medicine: Definitions and distinctions: Telehealth vs. Telemedicine vs. Remote Patient Monitoring, trends in telemedicine, Types of telehealth modalities: synchronous, asynchronous, and hybrid, Components of a telehealth ecosystem (software, devices, connectivity, data platforms), Role of laboratory medicine in remote monitoring (e.g., chronic disease management), AI Applications in Remote Patient Monitoring, Mobile Health (mHealth) and Health Apps	**6**
IV.	Digital Health: Definition and scope of digital health, Key stakeholders: healthcare providers, patients, policymakers, IT developers, Global and national digital health strategies (e.g., WHO Digital Health Strategy, NDHM India), Digital health ethics and data governance, lectronic Health Records (EHR) and Laboratory Information Systems (LIS), Structure and function of EHR systems, Data security and patient confidentiality, Clinical decision support systems (CDSS) integration with LIS, Case studies on digitized lab workflows	**6**
V.	Ethical and legal challenges of artificial intelligence-driven healthcare: Regulatory classification of AI-powered RPM devices (e.g., FDA SaMD, CDSCO), Requirements for clinical validation and safety assessment, Ethical considerations in autonomous health monitoring, Challenges of algorithmic bias and AI transparency, Legal responsibility in automated decision-making	**6**

Suggested Readings:

1. Topol, E. (2019). Deep medicine: how artificial intelligence can make healthcare human again. Hachette UK.
2. Bohr, A., & Memarzadeh, K. (Eds.). (2020). Artificial intelligence in healthcare. Academic Press.
3. World Health Organization. (2023). Classification of digital interventions, services and applications in health: a shared language to describe the uses of digital technology for health. World Health Organization.
4. Global strategy on digital health 2020-2025, WHO

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Course Name: Research Methodology & Biostatistics …..Credit = 2 (30 hours)

Course Rationale: This course enables students in medical laboratory science with the knowledge and skills to conduct scientific research and apply biostatistical methods in clinical and laboratory settings.

Learning Objectives: At the end of the course, students will be able to Understand the fundamentals, types of research in health sciences, formulate research problems and hypotheses relevant to laboratory medicine.

Design appropriate research studies and select suitable data collection methods

Apply statistical tools for data analysis and interpretation

UNIT	M01COMLS05 Research Methodology & Biostatistics	C=2 (30 hr)
I.	**Introduction to Statistics and Data** Definition and Scope of Statistics in Health Sciences Uses of Statistics in Clinical and Preventive Medicine Types of Variables: ● Qualitative vs Quantitative Discrete vs Continuous Scales of Measurement: Nominal, Ordinal, Interval, Ratio Measures of Central Tendency: Mean, Median, Mode ● Definitions, Properties, Applications Measures of Dispersion: ● Range, Quartile Deviation, Interquartile Range, Standard Deviation, Variance, Coefficient of Variation Quartiles and Percentiles	**6**
II.	**Probability, Distributions, and Sampling** • Normal and Standard Normal Distribution: Properties and Applications • Probability Concepts and Calculations (mean ± SD intervals) • Skewness and Kurtosis: Definitions and Interpretation • Parameters vs Statistics • Population, Sample, Sampling Frame • Sampling Distribution and Central Limit Theorem • Standard Error: Mean, Proportion, Differences • Confidence Intervals for Means and Proportions	**6**
III.	**Hypothesis Testing and Statistical Inference** • Hypothesis Testing: Null and Alternative Hypotheses • Type I and II Errors • One-tailed vs Two-tailed Tests • p-value, Significance Level, Power • Parametric Tests: Paired and Unpaired t-tests • One-way and Repeated Measures ANOVA • Non-parametric Tests: Mann-Whitney U, Wilcoxon Signed Rank, Kruskal-Wallis, Friedman's ANOVA • Chi-square Test and McNemar's Test: Concepts and Applications	**6**

IV.	**Regression, and Advanced Analysis** • Correlation: Types, Scatter Diagrams, Pearson's and Spearman's Coefficients • Coefficient of Determination • Regression Analysis: Simple and Multiple Linear Regression • Logistic Regression: Concepts and Applications • Diagnostic Test Evaluation: Sensitivity, Specificity, Positive Predictive Value (PPV) and Negative Predictive Value (NPV) • Receiver Operating Characteristic (ROC) Curve • Agreement and Reliability: Bland-Altman Plot and Kappa Statistics	**6**
V.	**Research Methodology and Epidemiological Applications** ● Research Process and Types of Research Designs ● Data Collection Methods and Sources ● Qualitative Research and Content Analysis ● Test Construction: Reliability, Validity, Norms ● Sample Size Estimation for Means and Proportions ● Rates, Ratios, and Proportions: Definitions and Calculations ● Epidemiological Study Designs: ● Case Reports, Case Series, Cross-sectional, Case-Control, Cohort Studies ● Confounding and Methods to Control ● Randomized Controlled Trials (RCTs), Randomization, Blinding	**6**

Suggested Reading:

- Mahajan, B. (2004). Methods of Biostatistics: For Medical Student and Research work. New Delhi: Jaypee Brothers.
- Essentials of Research Methodology for all Physiotherapy and Allied Health Sciences Students by Ramalingam Thangamani A
- Ramalingam, T. A., & Kumar, S. N. (2018). Essentials of research methodology for all physiotherapy and Allied Health Sciences Students. Jaypee Brothers Medical Publishers.
- Dawson, B. and Trapp, R.G. (2001) Basic & Clinical Biostatistics. Lange Medical Books/ McGraw-Hill, New York.
- Rosner, B. A. (2006). Fundamentals of biostatistics (Vol. 6). Belmont, CA: Thomson-Brooks/Cole.
- Armitage, P., Berry, G., & Matthews, J. N. S. (2013). Statistical methods in medical research. John Wiley & Sons.
- Daniel, W. W. (2004). Biostatistics: A Foundation for Analysis in the Health Sciences 8th Edition (Wiley Series in Probability and Statistics).

Practicals

	M01COMLS06 **Advance Molecular Diagnostics techniques Practical**	**C=2** **(60 hr)**

Students will gain practical skills necessary for various laboratory techniques required for the molecular diagnosis

1. DNA Isolation
2. RNA Isolation
3. Polymerase chain reaction
4. PAGE
5. ELISA
6. Demonstration of western blot
7. HPLC
8. Spectrophotometer analysis- protein Analysis
9. Immunohistochemistry
10. Demonstration of electron microscope

	M01COMLS07 **Research Methodology & Biostatistics Practical**	**C=2** **(60 hr)**

Course Rationale: This course provides students in health sciences with practical skills to design, conduct, and analyse scientific research relevant to clinical & laboratory settings.

Data Handling & Descriptive Statistics

1. Collect raw data from a lab or clinical setting.
2. Classify variables (qualitative/quantitative, discrete/continuous).
3. Organize data into frequency tables.
4. Calculate and interpret: Mean, median, mode Range, standard deviation, variance
5. Create visual representations: Bar charts, histograms, pie charts, box plots

Probability & Distributions

1. Plot and interpret normal distribution curves.
2. Calculate probabilities using mean ± 1SD, 2SD, 3SD.
3. Identify skewness and kurtosis from datasets.

Sampling & Estimation

1. Demonstrate random sampling techniques (simple, stratified, cluster).
2. Calculate standard error and confidence intervals.
3. Estimate population parameters from sample data

Hypothesis Testing: Perform and interpret:

1. One-sample and two-sample t-tests
2. Paired t-test
3. Chi-square test (2x2 table)
4. ANOVA (one-way)
5. Use SPSS/R to run tests and interpret outputs.

	M01COMLS08 **Lab Management & Molecular Biology Practical (Elective)***	**C=2** **(60 hr)**

1. Sample collection, accessioning, barcoding, labeling and specimen rejection criteria
2. Laboratory Information System (LIS): Patient Registration and Sample Accession
3. Preparation and interpretation of Internal Quality Control (IQC) charts (Levey–Jennings and Westgard Rules)
4. Generation and Validation of Digital Laboratory Reports
5. Biomedical Waste segregation and disposal according to BMW Management Rules
6. Estimation of DNA purity and concentration using NanoDrop/Spectrophotometer
7. Agarose Gel Electrophoresis of DNA samples and interpretation
8. Cell viability assessment using Trypan Blue Exclusion Method
9. AI-Based Classification of Normal Blood Cells
10. Prepare Chart: Identification of common chromosomal abnormalities (Down syndrome, Turner syndrome, Klinefelter syndrome) using karyograms