Master of Medical Laboratory Science – MMLS

Syllabus

Year/Semester – I/ I &II
Academic Scheme & Credit Framework

APPROVED SYLLABUS

2025

Ministry of Health & Family Welfare

Master of Medical Laboratory Science – MMLS
Two Year Degree Program (Including six months research dissertation)

1. Program Duration

The Master of Medical Laboratory Sciences – MMLS program shall be of two (2) years duration, consisting of:

- 2 years of academic instruction.
- Inclusive of six months research dissertation
- The academic program is divided into four (04) semesters.

2. Semester-wise Distribution of Instructional Hours

Year	Semester	Instructional Hours per Semester
First Year	Semester I	420
	Semester II	420
Second Year	Semester III	420
	Semester IV	990
Total Program Hours		**2250**

3. Credit System (As per NCAHP Guidelines)

The credit system shall be adopted to define the instructional workload of a course.

4. Credit Nomenclature

Abbreviation	Description
CL	Credit for Lecture
CP	Credit for Practical / Laboratory
L	Lecture Hours per Semester
P	Practical / Laboratory Hours per Semester

5. Dissertation (Fourth Semester)

Semester IV (6 months) is exclusively dedicated to the dissertation, enabling students to undertake independent research under faculty supervision. The dissertation provides hands-on experience in research methodology, data analysis, scientific writing, and presentation, fostering critical thinking and evidence-based laboratory practice in accordance with NCAHP curriculum guidelines.

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

Curriculum Outline
FIRST YEAR

First Semester

S. No.	Course Code	Course Title	Lecture	Practical	Total
1	MMLS 001	Medical Laboratory Management	4	0	60
2	MMLS 002	Cell and Molecular Biology	4	0	60
3	MMLS 003	Research Methodology & Biostatistics	2	0	30
4	MMLS 004	Advance Molecular Diagnostic	4	0	60
5	MMLS 005	Digital Health Technique	2	0	30
6	MMLS 006	Research Methodology & Biostatistics Lab	0	2	60
7	MMLS 007	Advanced Molecular Diagnostics - Lab	0	2	60
8	MMLS 008	Elective course	0	2	60
	TOTAL		**16**	**6**	**420**

Non-university exams

CURRICULUM MAPPING & CREDIT MANAGEMENT
Credits and Assessments Outline
FIRST YEAR

First Semester

S.NO	Course code	Course Titles	Credits/Week			Contact Hours	Assessments		
			L	T	P		I.A	UE	Total
1	MMLS001	Medical Laboratory Management	4	0	0	60	30	70	100
2	MMLS002	Cell and Molecular Biology	4	0	0	60	30	70	100
3	MMLS003	Research Methodology & Biostatistics	2	0	0	30	30	70	100
4	MMLS004	Advance Molecular Diagnostic	4	0	0	60	30	70	100
5	MMLS005	Digital Health Technique	2	0	0	30	30	70	100
6	MMLS006	Research Methodology & Biostatistics Lab	0	0	2	60	30	70	100
7	MMLS007	Advanced Molecular Diagnostics - Lab	0	0	2	60	30	70	100
8	MMLS008	Elective course	0	0	2	60	30	70	100
Total			**16**	**0**	**6**	**420**	**240**	**420**	**800**

Non-university exams

Semester -1

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	Topic	Hours
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

Unit	Topic	Hours
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 ➢ Analytical variables- Use of stable reference materials-calibrators & controls, LJ charts and Westgard rules. Standardization / Calibration processes**:** Calibration of basic equipments by laboratory personnel. Calibration of methods-colorimetric and enzymatic. ➢ Postanalytical variables: transfer of results, documentation, competence and various laboratory processes	8
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

Unit	Topic	Hours
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 followup, Accident documentation and investigation	4
	Total	**60**

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

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

- 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

Unit	Topic	Credit Hours
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

Unit	Topic	Credit Hours
VI	Cell Culture: Introduction, Significance, Cell Culture Lab – Instruments, Aseptic Techniques, Media Preparation And Filteration 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, Tran Genesis, Dna Finger Printing, Dna Sequencing, Pcr,Dna Probes, Hybridoma Technology.	10

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	Topic	Hours
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**

Unit	Topic	Hours
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 stratagies, 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**
	Total	**60**

Advance Molecular Diagnostics techniques Practical Credit = 2 (60 hrs)

Course Rationale: 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

***Clinical laboratory rotation/observation can be incorporated wherever possible**

Suggested Readings:

1. 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.
2. Godkar, P. B., & Godkar, D. P. (2006). *Textbook of medical laboratory technology*. Bhalani publishing house.
3. Carson, S., Miller, H. B., Srougi, M. C., & Witherow, D. S. (2019). *Molecular biology techniques: a classroom laboratory manual*. Academic Press.
4. Tagu, D., & Moussard, C. (Eds.). (2006). *Techniques for molecular biology*. Science Publishers.
5. Coleman, W. B., & Tsongalis, G. J. (Eds.). (2007). *Molecular diagnostics: for the clinical laboratorian*. Springer Science & Business Media.
6. Greene, J. (Ed.). (1998). *Recombinant DNA principles and methodologies*. CRC Press.

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	Topic	Hours
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, predictive analytics in healthcare, WHO classification of digital health interventions,	6
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

Unit	Topic	Hours
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
	Total	**30**

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
5. LIM., C. P., Vaidya, A., Jain, K., Mahorkar, V. U., & Jain, L. C. (2022). Handbook of artificial intelligence in Healthcare. Springer International Publishing.

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	Topic	Hours

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

Unit	Topic	Hours

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	

IV	**Correlation, 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

Unit	Topic	Hours

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

Research Methodology & Biostatistics Practical **Credit = 2 (60 hours)**

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

1. **Data Handling & Descriptive Statistics**
   - Collect raw data from a lab or clinical setting.
   - Classify variables (qualitative/quantitative, discrete/continuous).
   - Organize data into frequency tables.
   - Calculate and interpret: Mean, median, mode
   - Range, standard deviation, variance
   - Create visual representations: Bar charts, histograms, pie charts, box plots
2. **Probability & Distributions**
   - Plot and interpret normal distribution curves.
   - Calculate probabilities using mean ± 1SD, 2SD, 3SD.
   - Identify skewness and kurtosis from datasets.
3. **Sampling & Estimation**
   - Demonstrate random sampling techniques (simple, stratified, cluster).
   - Calculate standard error and confidence intervals.
   - Estimate population parameters from sample data
4. **Hypothesis Testing:** Perform and interpret:
   - One-sample and two-sample t-tests
   - Paired t-test
   - Chi-square test (2x2 table)
   - ANOVA (one-way)
   - Use SPSS/R to run tests and interpret outputs.

Suggested Reading:

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