

**NATIONAL MEDICAL COMMISSION
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**GUIDELINES FOR COMPETENCY BASED POSTGRADUATE
TRAINING PROGRAMME FOR MD IN LABORATORY
MEDICINE**

Preamble

Clinical management of patients today is highly dependent on results of laboratory investigations which has seen rapid advances in technology and automation. The presence of a Central laboratory to handle majority of laboratory investigations, quick receipt of quality investigation reports and access and availability of laboratory physicians in the Laboratory Medicine Department to consult helps the consulting clinician in the rapid diagnosis, management and follow-up of patients. Further, the MD in Laboratory Medicine course would assist in bringing newer techniques from research to the diagnostic level.

The MD Laboratory Medicine course is consistent with the 3-tier laboratory concept of an ideal tertiary care hospital attached to a medical college/institute. Tier I is related to laboratory medicine department itself. Tier II encompasses specialty laboratories of Pathology, Microbiology, Biochemistry, Hematology, Endocrinology and Immunology departments while tier III is the high-end research facility laboratory in the medical college hospital. The creation of an MD laboratory Medicine course would help in the availability of Laboratory physicians of first contact for both clinicians and patients thus helping in the treatment and management of patients.

SUBJECT SPECIFIC LEARNING OBJECTIVES

A post graduate student upon successfully qualifying for MD in Laboratory Medicine, should be able to demonstrate following clinical, teaching and research skills:

A. Clinical Skills:

1. Demonstrate competence in skills related to different sections of disciplines of Laboratory Medicine.
2. Interact effectively with allied departments by rendering services in basic and in advanced laboratory investigations.

3. Demonstrate application of laboratory medicine techniques in a variety of clinical settings to solve diagnostic and therapeutic problems.
4. Demonstrate understanding of instrumentation including automation and maintenance of various laboratory equipment.
5. Interact with clinical colleagues during ward round, clinical combined round and clinico-laboratory conference.
6. Contribute along with the clinical colleagues in the formulation of the panel of investigations, whenever the requirement arises.
7. Actively participate in interpretation of test results, further refer for other investigations, if necessary, and help in comprehensive decision making in patient's management and follow up.
8. Collect specimens by routinely performed procedures such as venipuncture, finger-prick, and bone-marrow aspiration. Whenever necessary must be able to provide appropriate help to colleagues performing an invasive procedure.

B. Teaching skills:

1. Sensitize the undergraduate students on the importance of diagnostic laboratory in patient management.
2. Guide the clinical post graduate students on test selection and its interpretation, rational use of laboratory facilities, and make them aware of pre-analytical, analytical and post-analytical sources of error in laboratory investigations.
3. Acquire the skill of guiding their junior colleagues and managing laboratory staff.
4. Present relevant topics in seminar and review published articles during Journal club
5. Participate in case discussions.
6. Learn the operational and quality management of the investigations in the Laboratory Medicine Department and guide the technical staff on the same.
7. Develop communication skills to interact with patients, relatives, peers and paramedical staff and present reports and opinions effectively.

C. Research:

1. Identify a research problem for conducting research in basic or applied aspects.
2. Clearly state the objectives in terms of what is expected to be achieved in the end.

3. Design study taking care of adequate no. of cases with age and gender-matched controls with full awareness of the statistical validity of the size of experimental material.
4. Carry out the technical procedures required to conduct the research topic.
5. Accurately, systematically and objectively record the results and observations made during the course of research.
6. Analyze the data with the aid of an appropriate statistical methodology.
7. Interpret the observations in the light of existing knowledge and highlight how the study has advanced existing knowledge on the subject and what further remains to be done.
8. Prepare the data for publication in an indexed scientific journal.
9. Write the thesis or a scientific paper in accordance with prescribed instructions in a journal of international standards.
10. Present one poster, read one paper at a national/state conference and present one research paper which should be published/accepted for publication/sent for publication during the period of his postgraduate studies so as to make him eligible to appear at the postgraduate degree examination.

D. Group Approach:

1. Participate in group discussion of cases by attending undergraduate multidisciplinary seminars, clinical rounds and contributing to the Journal Club.
2. Participate in instructing and guiding the technical staff of the laboratory, in operational aspects of the tests and quality management.
3. Acquire knowledge on Quality Assurance, Accreditation, Laboratory Audit, Laboratory safety, legal aspects of Laboratory Medicine, Laboratory Management, training of technicians and allocation of work.

SUBJECT SPECIFIC COMPETENCIES

A. Cognitive domain

At the end of the training in M.D. Laboratory Medicine, the post graduate student should acquire knowledge and competence in conducting relevant procedures in: i) Medical Biochemistry, ii) Pathology and Hematology, iii) Medical microbiology, iv) Endocrinology,

v) Blood Banking, vi) Immunology, and vii) Molecular diagnostics as related to the discipline of Laboratory Medicine.

The student should be able to:

1. acquire knowledge about the normal body systems and pathological basis of disease.
2. understand and identify morphological disorders in tissues and cells from test results.
3. acquire knowledge about how and why the use of histological, cytological and biochemical and immune-histological techniques can be helpful in the diagnosis and management of diseases.
4. acquire knowledge about the rationality and relevance of choosing diagnostic investigations (biochemical / hematological / microbiological / immunological / molecular/ endocrinological) in the management of disorders.
5. understand the specific biochemical principles which are being used to measure or determine test substances.
6. acquire competence to perform the specified tests in medical biochemistry, microbiology, pathology, hematology, immunology, molecular biology and endocrinology at the *operational level* with a high order of accuracy.
7. interpret the test results in the context of clinical setting and with knowledge of reference intervals/ abnormal values/ critical Alert values.
8. co-ordinate Laboratory and Hospital Information System (LIS & HIS) with validation of test results on time.
10. evaluate the medical validity of the results of the test, i.e. quality of analysis in comparison to the medical problem.
11. Ensure routine conduct of External Quality Assurance Program & Internal Quality Control Programs and take corrective steps, when needed. The post graduate student should be aware of the principles and the need for quality control of tests performed at the bedside of the patients as Point-of-Care (POC) investigations e.g., ABG in Emergency room or a glucometer in a ward.
9. acquire knowledge on medical auditing of individual and panel of Laboratory Investigations.
12. acquire knowledge of various kinds of Laboratory Auditing methods and is required to attend the course of ISO 15189.

13. acquire knowledge of infection control policies and procedures to the extent of action to be taken in case a MRSA (Methicillin resistant Staph aureus), MDR (multi drug resistant) TB, XDR (extensively drug resistant) TB, VRE (Vancomycin resistant enterococci) is isolated in the Laboratory.
14. give priority status to different tests in case of emergency.
15. design and conduct research in the discipline of Laboratory Medicine.
16. acquire knowledge on Biostatistics for conducting research, writing thesis and publication of scientific papers.
18. acquire knowledge and conduct budgeting and costing of all laboratory tests.
19. acquire knowledge of the underlying principle/s and design of important laboratory instruments, their use and annual maintenance (AMC).
20. acquire knowledge on different kinds of safety measures in the laboratory.
21. acquire knowledge on infection control programs including antimicrobial stewardship and response to epidemics.
22. supervise and train technical staff of the department.
23. acquire knowledge about management of a large multidisciplinary laboratory services program.

B. Affective Domain:

The post graduate student should be able to:

1. function as a part of a team, develop an attitude of cooperation with colleagues, and interact with patients, clinicians or other colleagues to provide the best possible opinion.
2. adopt ethical principles and maintain proper etiquette in dealings with patients, relatives and other health personnel and to respect the rights of the patient including the right to information and second opinion.
3. develop communication skills to word reports and professional opinion as well as to interact with patients, relatives, peers and paramedical staff, and for effective teaching.
4. work as an effective team member and leader. The student should also demonstrate attitude and communication skills while handling clinical material, reports and with patients or their relatives.

C. Psychomotor domain

At the end of the course, the student should have acquired following skills:

I. Management Skills

1. General Management

The student should be able to:

- (i) manage a multidisciplinary central hospital laboratory of the medical college/institute a) with patient-centric view, one window solution of their problems b) with minimum Turn-Around-Time (TAT) of investigations and c) assurance of quality d) covering Total Testing (Pre-analytical, Analytical and Post-Analytical) phases of investigation.
- (ii) actively participate in test selection (ward-round, consultation with clinicians), test operation and test interpretation (acting as laboratory consultant for clinicians) and referral to laboratory super-specialist, when felt necessary.
- (iii) ensure laboratory safety by ensuring standard universal and special precautions for managing fire, poisonous/corrosive chemicals, infectious specimens and by post-exposure management and prophylaxis.
- (iv) ensure management of biomedical waste, starting from segregation to disposal.
- (v) conduct inventory management of equipment (Log book) and reagents (stock, shelf-life) and proper storage.

2. Management of Automation

The student should be able to:

a) Pre-analytical automation

handle the pre-phlebotomy (e.g., LIS, bar coding) and post-phlebotomy automation for collection and transport (e.g., conveyer belt) of samples.

b) Analytical automation

- (i) handle laboratory automation / robotics of all types including tract-based analyzers, and converting the automated laboratory into a smart laboratory.
- (ii) check calibration of the equipment and to maintain daily quality control record.
- (iii) trouble shoot, recalibrate the equipment and take corrective measures for errors detected.
- (iv) read “flags” in the result and take appropriate action.
- (v) validate laboratory reports.

c) Post-analytical automation

- (i) dispatch of reports through Laboratory Information System (LIS), if available.

- (ii) ensure preservation of patient samples as and when necessary.

3. *Management of Quality*

- (i) detect laboratory errors, its source, types, and take remedial measures and finally document it in the record book.
- (ii) maintain calibration of pipettes, dispensers, refrigerators, centrifuges and allied equipment.
- (iii) identify pre-analytical variables, perform preventive maintenance of equipment and testing and verification of reagents.
- (iv) run and interpret results of high, medium and low controls on daily basis in laboratory .
- (v) perform internal quality control and statistical analysis on daily basis for precision check.
- (vi) plot and interpret Levy Jennings chart for analytes and follow Westgard rules to take corrective action for errors identified before running patient samples.
- (vii) participate in an external quality assurance program and proficiency testing organized by national or international agencies.
- (viii) read and interpret EQAS reports and take corrective action accordingly.

4. *Point-of-Care Management*

- (i) calibrate, maintain and perform quality checks of Point-of-Care devices.
- (ii) validate the device against a gold standard test.
- (iii) validate results of point-of-care investigations.

5. *Managing to prepare and get the Laboratory accredited by National and International Accreditation body (NABL, CAP)*

- (i) prepare Quality Manual, Sample collection Manual, Lab Safety Manual.
- (ii) design Standard Operating Procedures (SOPs) of investigations and Quality System Procedure (QSP) for different clauses of ISO 15189 along with routine forms and formats.
- (iii) conduct Internal Audit of the lab and prepare report.
- (iv) correct non-conformities raised during audits and assessment of the laboratory.
- (v) monitor Complaint Register; documentation of complaints, response from the laboratory, remedial and precautionary measures taken.
- (vi) write Minutes of Management Review Meetings (MRM).

6. *Management of onsite training of staff, MBBS and nursing students & clinical residents*

- (i) Participate in motivating, periodic training and competency assessment of the Technical staff.
- (ii) Sensitize undergraduate and nursing students about laboratory tests during their laboratory visits.
- (iii) Sensitize post graduates from clinical departments on the scope and limitations of the laboratory investigations during their laboratory rounds and laboratory postings.

II. Skills in Basic Technology

- (i) check water quality of laboratory
- (ii) handle equipment including:
different types of microscopes, pipettes, dispensers, balance, different types of centrifuges, vortex mixer, pH meter, oven, incubators, BOD incubator, refractometer, colorimeter, spectrophotometer, nephelometer, blood gas analyzer, electrolyte analyzer, different types of electrophoresis equipment, different types of chromatography (e.g., HPLC, TLC, GLC) equipment, autoclaves, sterilizers, ELISA equipment etc.
- (iii) prepare buffers, standard solutions, normal solutions and molar solutions.
- (iv) handle sterilization and disinfection methods.

III. Operational and Investigation Skills

1. *Investigations on Body Fluids*

- (i) conduct physical, chemical and microscopic examination of:
Urine, CSF, peritoneal, pleural, pericardial and synovial fluids, semen, sputum, feces, amniotic fluids, lavage fluids (e.g., BAL, gastric lavage) and, if necessary, conduct microbiological examinations, to arrive at possible diagnosis.
- (ii) interpret urinary findings.
- (iii) perform and interpret pregnancy test in urine.
- (iv) interpret CSF findings in the context of meningitis caused by different organisms and differentiate from encephalitis, brain abscess and Guillain Barre syndrome.
- (v) interpret exfoliative cytology in the peritoneal, pleural and pericardial fluids.

2. a) **Blood/Serum:**

The student should be able to take corrective steps while testing hemolysed, hyperlipidemic and hyperbilirubinemic serum.

b) **The student should be able to carry out biochemical investigations of :**

- (i) sugar, urea, creatinine, uric acid, bilirubin (total, direct, indirect) total protein, Albumin, Globulin (both manual & automated methods)
- (ii) serum enzymes
- (iii) serum electrolytes
- (iv) Lipid profile: total cholesterol (manual and automated method), LDL-cholesterol, HDL-cholesterol, VLDL and triglycerides
- (v) Blood gas parameters and pH
- (vi) hormones: TSH, T₄, T₃, ACTH, Cortisol, FSH, LH, GH, Prolactin, Testosterone, Estradiol, ADH
- (vii) vitamins (e.g. Vit D, B₁₂, Folic acid) and trace elements
- (viii) cardiac markers: Troponin-I Troponin-T, CK-MB, myoglobin. LDH 1 & II
- (ix) tumor markers: Colonic cancer (CEA, CA19-9), pancreatic cancer (CA19-9), ovarian cancer (CA125), hepatic cancer (alpha-fetoprotein), trophoblastic tumor (BHCG).
- (x) drugs and toxins, when necessary.

b) Urine:

The student should be able to analyse:

- (i) urinary Na^+ , Ca^{++} , PO_4^- , creatinine, albumin, uric acid
- (ii) tumor markers
- (iii) substances excreted for inborn errors of metabolism
- (iv) porphyrins and related metabolites

c) CSF:

sugar, total protein, albumin, globulin and enzymes.

- (i) Fecal fat estimation for diagnosis of malabsorption,
- (ii) Conduct (a) Plasma electrophoresis for investigation of cause of hypoproteinemia, (b) serum electrophoresis for 'M' spike, (c) hemoglobin electrophoresis for investigation of hemoglobinopathies, (d) urine electrophoresis for specific protein.
- (iii) evaluate liver functions, renal functions, endocrine functions, GI functions.
- (iv) select and perform investigations for laboratory diagnosis of diabetes mellitus, metabolic syndrome, metabolic bone disease, hepatitis and other diseases of liver, inborn Errors of metabolism, prenatal fetal defects.
- (v) Diagnose metabolic/respiratory/mixed acidosis and alkalosis (uncompensated /compensated).
- (vi) identify the cause/s of hypo- and hypernatremia, hypo- and hyperkalemia, hypo- and hypercalcemia.
- (vii) guide clinical post graduates on progress and regress of cancer from tumor markers.

3. Investigations on Blood for hematological disorders

- (i) collect, transport and processing of blood samples for different hematological investigations in specified vial with adequate amount of specific anticoagulant.
- (ii) perform manual methods of blood cell count, make peripheral blood smear and its staining.
- (iii) perform Hematocrit, Reticulocyte count, measure ESR (Westergren and Wintrobe methods) and prepare Buffy coat.
- (iv) read and interpret hemogram, histogram from automated blood cell counter.
- (v) examine and interpret stained peripheral blood smear and to arrive at possible diagnosis of disorder of red cells, white cells and platelets, sepsis and drug effects.
- (v) demonstrate Hemo-parasites; malaria, babesia, microfilaria etc.
- (vii) investigate in detail the etiology of Anemia: nutritional deficiency, hemolytic, hypoplastic and other causes.
- (viii) select investigations and perform tests for nutritional Anemia.
- (ix) select investigations and perform tests for hemolytic Anemia
- (x) demonstrate sickle cell, G6PD deficiency and identify cold agglutinin.
- (xi) diagnose Thalassemia and conduct further study to classify it.
- (xii) investigate for Leukocyte disorders (quantitative and functional disorders).

- (xiii) investigate for, and diagnose different types of Leukemia with cytochemistry, immunophenotyping and genetic analysis.
- (xiv) investigate and diagnose bleeding disorders by screening coagulation tests (BT, CT, PT, APTT, TT, Platelet count, Clot retraction), DIC work up including estimation of D-Dimer, diagnose specific Factor deficiency by Mixing study, Adsorption study, Factor Assay.
- (xv) investigate platelet functions (platelet adhesion, aggregation and release defect).
- (xvi) investigate prothrombotic state: Assay of anti-thrombin III, factor V-leiden, protein C, protein S.

4. *Investigation of Bone Marrow*

- (i) Collect, transport and processing of bone marrow samples for different investigations and diagnosis.
- (ii) interpret normal and abnormal marrow.
- (iii) diagnose hematological and systemic disease from bone marrow examination especially reactive marrow, megaloblastic anemia, all kinds of leukemia, myelodysplastic disorders, plasma cell dyscrasia, megakaryocytic and non-megakaryocytic thrombocytopenia, pure red cell aplasia, hypoplastic marrow, metastatic deposits, viscera leishmaniasis, Parvo virus infection.

5. *Investigation required for basic Transfusion Medicine*

- (i) familiar with National and State legislation policies on blood banking.
- (ii) screen blood donors.
- (iii) perform phlebotomy on a healthy blood donor and collect blood in different specified bags
- (iv) screen for transfusion transmitted diseases in a blood donor.
- (v) perform cell grouping of major ABO & Rh blood groups and interpret findings by tube method.
- (vi) perform serum cell grouping of major ABO blood groups and interpret findings by tube method.
- (vii) perform cell grouping and serum cell grouping for minor blood groups.
- (viii) identify secretory status of the donor and recipient.
- (ix) perform cell and serum cross matching.
- (x) perform antiglobulin (Coombs) test: direct and indirect.
- (xi) investigate a case of blood transfusion reaction.
- (xii) perform fractionation of whole blood into various components such as cryoprecipitate, platelet concentrate, fresh frozen plasma, single donor plasma, Red Blood Cell concentrates, Leucocyte-depleted component, store the components according to standard protocols and use those in appropriate clinical conditions.
- (xiii) select subject for apheresis and conduct the procedure.

6. *Immunological Investigations*

- (i) perform basic immunological techniques including Immunofluorescence microscopy & Immunoassays; immune-precipitation, immune-fixation, different kinds of ELISA, ELISPOT assays, chemi-luminescence analysis, Western blotting.

- Serological techniques; CFT, different types of agglutination reactions, IHA.
- (ii) perform immune-phenotyping by flowcytometry.
 - (iii) evaluate collagen vascular disorders, autoimmune disorders, immunodeficiency status (primary and secondary).
 - (iv) measure and interpret CRP, RF, ANF.
 - (v) evaluate cellular immune system including count B cell, T cell, T cell subsets; CD4 & CD8. Able to perform T cell function test; *in-vitro* demonstration of CMI, Blast transformation, *in vivo* test e.g., Intradermal inoculation.
 - (vi) evaluate humoral immune system including B cell function evaluation and immunoglobulin estimation.
 - (vii) estimate level of complements.
 - (viii) estimate cytokines in blood and fluids.
 - (ix) perform HLA-typing of cells and organs.
 - (x) evaluate collagen vascular disorders, autoimmune disorders, immunodeficiency status (primary and secondary).
 - (xi) apply laboratory approach for investigation of various hypersensitivity and allergic disorders.

7. Investigations for Infective disorders: the student should be able to:

- (i) take care of pre-analytical variables to increase the yield of infectious agents.
- (ii) perform and interpret rapid diagnostic tests (e.g., Malaria, Leishmania and HIV)
- (iii) demonstrate microorganisms by using common stains like Gram, Giemsa, Albert and AFB stains, and India ink preparation by means of appropriate microscopic procedures.
- (iv) prepare culture media and inoculation of the sample specimen in the media and recording the outcome.
- (v) conduct drug sensitivity tests in culture.
- (vi) perform biochemical tests for microbial identification and their serotyping (including Widal test).
- (vii) conduct cell culture studies for the diagnosis of viral & other microbial infections.
- (viii) maintain specific strains of microbes in the laboratory, as required.
- (ix) perform and interpret TORCH screening
- (x) perform and interpret the markers of different kind of viral hepatitis.
- (xi) diagnose Tuberculosis including drug-resistant tuberculosis.
- (xii) investigate the infections and infestations in an immune-compromised host.
- (xiii) examine body fluids and excreta (stool, urine) for parasites including protozoa, nematodes, cestodes and trematodes and their diagnosis by gross, microscopic (concentration method, when necessary), special staining, and serological & culture methods.
- (xiv) diagnose amoebiasis, giardiasis, leishmaniasis, toxoplasmosis & malaria.
- (xv) identify opportunistic parasites in the immune-compromised host.
- (xvi) identify common mycotic organisms by microscopy and special stains.
- (xvii) participate in Hospital Infection Surveillance program.

8. Molecular Diagnostics: the student should be able to:

- (i) set up of a molecular diagnostic laboratory.

- (ii) extract DNA from cell homogenate and use nanodrop spectrophotometer for DNA isolation.
- (iii) perform Nucleic acid amplification techniques: PCR, RT-PCR (including Melting Curve analysis), LCR, LAMP, digital PCR, and Non-PCR based Isothermal amplification and probe amplification.
- (iv) Post-translation analysis including electrophoresis, hybridization (solid phase and solution phase) assays, microarray, dot-blot, line probe assay.
- (v) read gel electrophoresis in gel documentation unit.
- (vi) perform investigations on chromosomal and genetic disorders
- (vii) develop familiarity with New Generation Gene Sequencer (NGS), if available.

9. Skills on Histo- and Cyto-pathology: the student should be able to:

- (i) diagnose from H/E-stained histopathology slides common lesions like acute appendicitis, fatty liver, secretory and proliferative endometrium, gestational products, amyloidosis (of kidney), colloid goiter, TB lymphadenitis, fibroadenoma breast, leiomyoma uterus, squamous cell carcinoma skin/lung, adenocarcinoma breast, mucin-secreting adenocarcinoma colon/stomach/ovary, metastatic carcinoma in lymph node and in bone marrow.
- (ii) perform FNAC of cervical lymph node, thyroid, skin & oral lesions and breast lump and do liquid-based cytology and interpret the PAP smear.

IV Skill of reporting the result of investigations

- (i) acquire the skills for integrative reporting taking consideration of (a) clinical context (b) results of all chemical, hematological and microbiological investigations of the patient sent to the lab, (c) reference interval of values, (d) the specificity and sensitivity of the methods, (e) prevalence of disease in defined populations and (f) Positive and negative predictive value (PPV and NPV) of the test.
- (ii) develop the skill of communication of the result to the patient and to clinical colleagues.
- (iii) advice further series of investigations.
- (iv) maintain confidentiality of the report.
- (v) counseling of patients.
- (vi) develop the skill of Error-disclosure.

V Research Skills

- (i) identify research problem, formulate research hypothesis/question, design appropriate study method with requisite no of cases & controls, select laboratory methods of analysis, tabulation and statistical analysis of the results and prepare report.
- (ii) apply the available statistical tools for analysis of the result.
- (iii) identify the strength and limitation of the study.

SYLLABUS

A. Cognitive Domain:

The post graduate student must acquire knowledge in the following:

1. ORGANIZATION OF THE LABORATORY

- Spatial organization: flooring, ventilation, air-conditioning, sanitation, drainage
- Disposal of waste in differently colored bags; from collection, segregation to disposal
- Laboratory Safety:
 - Prevention of physical, chemical & biological hazards
 - First Aid in laboratory accidents; management and post exposure prophylaxis
 - Understanding of different levels of biosafety; BSL I, BSL, II and BSL III.
- Financing, budgeting and cost accounting of investigations
- Management of laboratory stores
- Special reference to glassware, chemicals (AL, LR) & storage of dangerous poisonous chemicals
- Personal management and training of technical staff
- Streamlining of in-put and output of lab investigations, specimen collection and dispatch of report (TOT, One point solution to patients)
- Understanding of POC testing in the wards
- Computerization of laboratory services (LIS and its connection with HIS)
- Legal aspects of laboratory services.

2. QUALITY CONTROL & QUALITY ASSURANCE

- Sources of errors in laboratory results a) pre- analytical b) analytical c) post- analytical.
- Methods of detection of errors
- Types of error
- Corrective measures to minimize the errors
- Method of documentation of the whole procedures
- Onward transmission of the knowledge and skill to the other laboratory
- Preparation of internal 'control'
- Proficiency testing program, participation in E.Q.A.P. & preparation of biological standards
- Procurements of 'Standards' and 'Control' for Hematology, Clinical Chemistry and immunoassays
- Quality assurance in microscopy

- To check the calibration of Pipettes, speed of centrifuge, temperature of freezer, incubator, oven etc.

3. INSTRUMENTATION

Acquire knowledge on i) principle, ii) parts, iii) working manual, and iv) preventive maintenance of the following instruments:

A. Major Instruments:

- Photoelectric Colorimeter
- Spectrophotometer
- Centrifuge machines (table top, high speed, cold centrifuge)
- Blood Cell Counter
- ELISA Reader & Washer
- Autoanalysers
- Flame-photometer & Electrolyte analyzer
- Blood Gas Analyzer
- Microscopes: Light, Fluorescent, Dark ground, Phase contrast
- Electrophoresis apparatus,
- Densitometer,
- Culture hood & Biosafety hood
- Thermocycler and Gel doc.
- Microbial culture system,
- TB culture system
- Urine analysis system
- BOD Incubator
- Immunoassay analyzer
- -20⁰ C and -80⁰ C deep freezer
- Refrigerated centrifuge machine.

B. Minor Instruments:

- Different types of shakers, roller mixer, Cyclomixer etc.
- Thermometer
- Different kinds of refrigerators (4°, -20°C, -80°C)
- Incubators (including BOD incubator)
- Ovens
- Water-baths
- Distillation plant
- Deionizer plant
- RO System

- Auto pipettes
- pH meter
- Auto-dispensers
- Analytical balance
- Table top centrifuge.

C. The principles and working manual of following techniques:

- Chromatography of different kinds particularly HPLC, TLC and GLC,
- Flow Cytometry
- Chemi-luminescence analysis
- Scanning and Transmission Electron microscopy,
- Beta & Gamma Counting.

4. PHYSICAL CHEMISTRY & CLINICAL BIOCHEMISTRY

a) Physical Chemistry

- Molecular weight, Atomic weight, Equivalence weight, Log table, Periodic table
- Water of crystallization, colloid, crystalloid, osmolality, osmolarity, normality, specific gravity.

b) Clinical Biochemistry:

- Carbohydrate chemistry: identification, metabolism and disorders of metabolism; diabetes Mellitus, hypoglycemia
- Structure, function and physiological roles of different proteins, metabolism, hypo- and hyper-proteinemia
- Amino acids & related metabolites, aminoaciduria
- Glycoproteins, proteoglycans and collagen
- Porphyrins
- Lipids, lipoproteins, apoproteins
- Enzymology: diagnostic values of enzymes & isozymes in health and disease
- Acid-base and Electrolyte imbalance and regulation
- Tumor markers
- DNA-RNA chemistry
- Vitamins, & Trace elements and other important metals
- Biochemistry of various body fluids
- Functions of endocrine organs such as hypothalamus, pituitary, thyroid, parathyroid, adrenal, pancreas and gonads
- Bone and GI tract as endocrine organ
- Biochemistry of hormone synthesis, degradation and excretion, assay methods
- Neurochemistry: neurotransmitters, neuromodulators and neurohormones; their synthesis and functions

5. PHYSICAL, CHEMICAL AND MICROSCOPIC EXAMINATION OF BODY FLUIDS

Physical, chemical and microscopic examination of various excretory / secretory fluids e.g. (i) urine (ii) CSF (iii) peritoneal, pleural, pericardial, synovial, (v) amniotic (vi) semen (vii) sputum and (viii) feces.

6. HAEMATOLOGY & TRANSFUSION MEDICINE

A. Hematology

- Detection and typing of anemia
- Polycythemia
- Neutrophilia, eosinophilia, basophilia, lymphocytosis, neutropenia, Lymphopenia, Agranulocytosis
- Leukemia classification, cytochemistry immunophenotyping, cytogenetics, clinico-pathological correlation
- Thrombocytosis, thrombocytopenia, platelet functions
- Investigation of bleeding disorders
- Investigation of prothrombotic state
- Automation in hematology: difference with automation in clinical chemistry
- Bone marrow physiology and pathology

B. Transfusion Medicine

- Basic immunohematology
- ABO and Rh grouping
- Clinical significance of other blood groups
- Transfusion therapy including the use of whole blood, RBC concentrates and Blood component therapy
- Rationale of pre-transfusion testing
- Transfusion transmitted Infections
- Adverse reactions to transfusion of blood and blood components
- Quality control in blood bank

7. INVESTIGATIONS OF INFECTIOUS DISEASES

- Medically important microbes in general. Enterobacteriaceae and other gram negative bacilli like *Salmonella*, *Shigella*, *E coli*. Gram-positive cocci & bacilli and Mycobacteria, in particular, their general behavior, life history, metabolism, genetics and mode of infection

- Epidemiology of infectious diseases
- Hospital Acquired Infections/Nosocomial infections
- Medically important parasites
- Medically important viruses
- Medically important fungi
- Systemic Microbiology: Gastroenteritis and bacterial food poisoning, septicemia, wound infection, burn associate infections, U.T.I., R.T.I., C.N.S. infection including meningitis, encephalitis, STDs/ AIDS, opportunistic infections, congenital infections and infections in vulnerable groups e.g. AIDS patients, cancer patients, Geriatrics, premature babies, pregnancy & post-transplantation.
- Vaccines for infectious diseases
- Laboratory acquired infections
- Diagnosis & prevention of infection
- Lab. Safety: Blood borne diseases including-Viral Hepatitis & HIV, air borne infections, Universal standard precautions, Principles of bio-safety
- Medico-Legal aspects of infectious diseases including postmortem findings and evidence based opinion on criminal cases in regard to infections/vaccines.
- Notifiable disease

8 CLINICAL IMMUNOLOGY

- Physiology of Immune System
- Hypersensitivity reactions
- Autoimmune diseases
- Transplantation immunology
- Host-Parasite interaction

9. CLINICAL PHYSIOLOGY

ORGAN FUNCTION TESTS:

- Liver function tests
- Kidney function tests
- Gastric function tests
- Pancreatic function tests
- Splenic function tests
- Tests for malabsorption
- Respiratory function tests
- Cardiac function tests, and
- Endocrine function tests.

10. MOLECULAR BIOLOGY

- Structure of DNA & RNA

- Genetic configuration of commonly used genomic vectors/host and their uses in molecular biology
- Blotting technology (Southern, Northern, Western)
- DNA hybridization
- RNA hybridization
- Polymerase Chain Reaction (PCR) and its variants in various diseases
- LCR (Ligase Chain Reaction)
- NASBA (Nucleic acid sequence based amplification)
- Micro-array technology
- Chromosomal analysis
- HLA typing
- Principles of bioassays, Bio-chips
- Cell culture technology.

11. ANATOMIC PATHOLOGY

- Theory and methods of biopsy, processing of tissue
- Basic and general Pathology like degeneration, necrosis, inflammation, growth disorders, circulatory disturbance, hypersensitivity reaction, deficiency disease.
- Histopathology techniques, Cytopathology techniques, Histochemistry techniques, Immuno-histochemistry techniques, Electron Microscopy.
- Study of common histo-pathological lesions such as:
 - Proliferative, secretory and menstruating endometrium
 - Gestational products
 - Common skin lesions such as psoriasis, lichen planus, pemphigus vulgaris, squamous cell carcinoma
 - TB lymph adenitis
 - Acute appendicitis
 - Fatty liver
 - Amyloidosis (of kidney)
 - Colloid goiter
 - Benign tumors, such as fibroadenoma breast, leiomyoma uterus
 - Malignant tumors such as squamous cell carcinoma of skin/lung, adenocarcinoma of breast, mucin secreting adenocarcinoma colon/stomach/ovary, metastatic carcinoma in lymph node and in bone marrow.

B. PSYCHOMOTOR DOMAIN

The post graduate student should acquire following skills:

1. GENERAL

- Preparation of standard, normal & molar solution

- Preparation of buffers
- Preparation of Laboratory reagents
- Handling of corrosives, poisonous chemicals.

2. CHEMISTRY

- Manual method of estimation of sugar, urea, bilirubin, protein (total and fractional), creatinine, cholesterol, uric acid, amylase, acid and alkaline phosphatases,
- Automated methods of estimation of: a) above substances b) SGOT, SGPT, LDH, CPK, Calcium, Phosphate.
- Measurement of blood pH & arterial blood gases,
- Electrolytes estimation (Na, K, Ca, Cl)
- Lipids, apo-proteins and lipoproteins,
- Tumor markers
- Chemical analysis of body fluids, (CSF, Peritoneal/pleural/synovial fluid)
- Practical exercises on quality assurance in a clinical biochemistry laboratory.
- Endocrine organ function tests.

3. HAEMATOLOGY & TRANSFUSION MEDICINE

Hematology

- Collection, transport and processing of blood samples for different hematological investigations
- Performance of routine hemogram: Hb, TLC, DLC, ESR.
- Preparation, staining and interpretation of peripheral blood smear, Reticulocyte count, buffy coat preparation, Hematocrit measurement
- Aspiration of bone marrow, preparation of touch smear and bone biopsy. Staining and interpretation of marrow
- Cytochemistry of blood smear and bone marrow smear and their interpretation,
- Nutritional Anemia Study: Serum iron, folate and vitamin B₁₂ estimation
- Hemolytic studies e.g. osmotic frangibility, sickling test, estimation of HbF, HbA₂, Comb's test vii) Leukocyte function test
- Screening coagulation and DIC studies. BT, CT, PT, APTT, clot stability
- Investigation of prothrombotic states. Protein C, Protein S, Antithrombin III, Lupus anticoagulant
- Demonstration of common blood parasites
- Understanding automation in hematology: advantage and limits.

B. Transfusion Medicine

- Selection and bleeding of donors

- ABO and Rh grouping
- Resolving ABO grouping problems by secretor status in saliva and expanded panel of minor blood groups
- Familiarity with antibody screening by; a) LISS (Low-ionic salt solution) b) Enzymes c) AHG (Anti-Human Globulin)
- Steps to be taken if the above are positive
- Demonstrate familiarity with cross-matching by; a) LISS (Low-ionic salt solution) b) Enzymes c) AHG (Anti-Human Globulin)
- Steps to be taken if there is incompatibility
- Preparation of blood components i.e. cryoprecipitate, platelet concentrate, fresh frozen plasma, single donor plasma, Red Blood Cell concentrates
- Demonstrate familiarity with antenatal and neonatal techniques a) Direct antiglobulin test b) Antibody screening and titer c) selection of blood for exchange transfusion
- Demonstrate familiarity with principle and procedures involved in, a) resolving ABO grouping problems, b) identification of RBC antibody, c) investigation of transfusion reaction d) testing of blood for presence of (i) HBV (Hepatitis B Virus Markers) (ii) HCV (Hepatitis C Virus Markers) (iii) HIV (Human Immunodeficiency Virus markers) (iv) VDRL, and xi) investigation of hemolytic jaundice of adult and new born.

4. INFECTIOUS DISEASE LABORATORY

- Methods of collection, transportation and techniques used for clinical samples: a) blood b) bone marrow, splenic, liver, lymph Node aspirates c) CSF, pus from closed cavities & open wounds d) urine e) stool f) semen g) sputum h) saliva i) swabs (nasal, pharyngeal, rectal, conjunctival.)
- Demonstration of microorganisms by microscopy (bright field, dark ground, phase contrast, fluorescence.)
- Commonly used stains in microbiology: Grams, Giemsa, Romanowsky, A.F.B, Kinyoun's, Albert's special stains for spores, capsules, inclusion bodies, parasites & fungi.
- Culture media: their preparation, inoculation, and uses
- Antibiotic sensitivity testing including automation in Microbiology and interpretation of antibiograms vi) Serological techniques e.g. Widal, VDRL, CFT, ID, ELISA, IFA, RIA etc. In-vitro demonstration of CMI (cell mediated immunity), Complement cycles, Blast transformation, Monoclonal antibodies, and skin test
- Biochemical tests for microbial identification
- Serotyping of microbes
- Bed side tests: FNA, intradermal tests, cord blood, lumbar puncture etc.
- Animal inoculation studies
- Egg inoculation, cell culture studied for the diagnosis of viral & other microbial infection

- Human parasites including Protozoa, Nematodes, Cestodes and Trematodes and their diagnosis by gross, microscopic and serological & culture techniques. Diagnosis of amoebiasis, giardiasis, Leishmaniasis, Toxoplasmosis & Malaria
- fungal infections in human and their diagnosis
- Hospital infection surveillance
- Maintenance of strains.

5. CLINICAL IMMUNOLOGY

- Demonstration of T and B cell.
- Functional evaluation of T and B cell. CD4 & CD8 counting
- Immunoglobulin estimation
- Serological techniques like (a) CFT (b) Agglutination test (c) IHA & (d) ELISA with particular, reference to microbial serology, interleukin, ANF, RF, CRP
- Radioimmunoassay
- Immunoglobulins in health and disease
- Complements level determination.

6. ANATOMIC PATHOLOGY

- FNAC procedure, processing, staining and microscopy
- Biopsy and gross specimens handling
- Processing of tissue: manual, automated
- Common histo-pathological staining
- Microscopy of common lesions

THESIS

The post graduate student must submit their research protocol within 04 months of joining the MD course. The thesis should be submitted at least 6 months before the date of commencement of the theory examination. The thesis shall be examined by a minimum of three examiners, one internal and two external examiners, who shall not be the examiners for theory and practical; on the acceptance of the thesis by two examiners, the candidate shall appear for the final examination.

TEACHING AND LEARNING METHODS

Postgraduate teaching program

Teaching methodology

Learning in a PG program is primarily self-directed. MD course in Laboratory Medicine consists of laboratory and academic work. The formal sessions are merely meant to supplement this core value. The acquisition of practical competencies is the cornerstone of post graduate medical education in Laboratory Medicine so that they become the Laboratory physician of first contact for the clinicians and the patients in test selection, test operation and test interpretation.

Formal teaching sessions

In addition to laboratory work, at least 06 hrs of formal teaching per week is necessary. The department may select a mix of the following departmental sessions and interdepartmental sessions (see below):

Journal club	Once a week
Seminar	Once a week
Practical exercise	Once a week
Case discussions	Once a week

Note: These sessions may be organized as an institutional activity for all postgraduates.

- Sessions on basic sciences, biostatistics, research methodology, teaching methodology, hospital waste management, health economics, medical ethics and legal issues related to experimentation are suggested.
- The post graduate students shall be required to participate in the teaching and training program of undergraduate students and interns.

Log book: During the training period, the post graduate student should maintain a Log Book giving details of experimentation done and skills acquired. The Log book shall be used to aid the internal evaluation of the student. The Log book shall be checked and assessed periodically by the faculty members imparting the training.

- Department should encourage e-learning activities.

Formal interactive Teaching with other Departments

1. Weekly Combined seminar with residents of Pathology/ Microbiology / Biochemistry/ Immunology/ Endocrinology departments.
2. Interaction with clinical colleagues

During the course of 03 years, the students are expected to interact with each other and with faculty of clinical disciplines continuously regarding in-patients as well as out-patients. They are advised to participate actively in pre-test and post-test counselling of the patients. The post graduate students are encouraged to take ward round at least once a week with respective Head of the Department of Pediatrics and Medicine, Surgery, Gynecology & Obstetrics.

3. Weekly Interdepartmental Case discussion

There will be weekly interdepartmental rounds and case discussion on selected cases whose investigations have been done over the week in different sections of the laboratory,

particularly with the following departments viz., Medicine, Pediatrics, Surgery, Gastroenterology, Endocrinology, Gynecology and Obstetrics, Neurology, Casualty and I.C.U.

4. Weekly participation in combined round and grand round of the Institution

During the weekly combined round and grand round, the post graduate students of Laboratory Medicine will actively participate for discussion on the investigative aspects of the case presented.

Attending and Participating in Workshop, Symposia, CME

- Attend accredited scientific meetings (CME, symposia, and conferences).
- A postgraduate student of a post graduate degree course in broad specialties would be required to present one poster presentation, to read one paper at a national/state conference and to present one research paper which should be published/accepted for publication/sent for publication during the period of his post graduate studies so as to make him eligible to appear at the postgraduate degree examination.

RECOMMENDED POSTING SCHEDULE FOR THREE YEAR TRAINING

Posting	Ist year	2nd year	3rd year
Fluid and Excretion Laboratory	2 months	-----	2 months
Hematology Laboratory	4 months	2 months	2 months
Chemistry laboratory	3 months	2 months	3 months
Infectious disease laboratory	3 months	2 months	2 months
Dept. of Pathology	-	3 months	-
Dept. of Microbiology	-	2 months	-
Dept. of Transfusion Medicine	-	1 month	1 month
Other special lab, as required (e.g. Chromosomal and genetic lab, HLA Lab, Stem cell Lab etc.)		-	2 months

ASSESSMENT

FORMATIVE ASSESSMENT i.e., Assessment during the training

Formative assessment should be continual and should assess medical knowledge, patient care, procedural and academic skills, interpersonal skills, professionalism, self-directed learning and ability to practice in the system.

General Principles

Internal assessment should be frequent, cover all domains of learning and used to provide feedback to improve learning; it should also cover professionalism and communication skills. The internal assessment should be conducted in theory and practical/clinical examination.

Quarterly assessment during the MD training should be based on:

1. Journal based / recent advances learning
2. Patient based /Laboratory or Skill based learning
3. Self-directed learning and teaching
4. Departmental and interdepartmental learning activity
5. External and Outreach Activities / CMEs

The student to be assessed periodically as per categories listed in postgraduate student appraisal form (Annexure I)

SUMMATIVE ASSESSMENT, ie., assessment at the end of training

The summative examination would be carried out as per the Rules given in POSTGRADUATE MEDICAL EDUCATION REGULATIONS, 2000.

The postgraduate examination shall be in three parts:

1. Thesis

Thesis shall be submitted at least six months before the Theory and Clinical / Practical examination. The thesis shall be examined by a minimum of three examiners; one internal and two external examiners, who shall not be the examiners for Theory and Clinical examination. A post graduate student shall be allowed to appear for the Theory and Practical/Clinical examination only after the acceptance of the Thesis by the examiners.

2. Theory examination

The examinations shall be organized on the basis of 'Grading' or 'Marking system' to evaluate and to certify post graduate student's level of knowledge, skill and competence at the end of the training. Obtaining a minimum of 50% marks in 'Theory' as well as 'Practical' separately shall be mandatory for passing examination as a whole. The examination for M.D./ MS shall be held at the end of 3rd academic year.

There shall be four theory papers.

Paper I. Basic Sciences as applied to laboratory medicine including management, equipment, automation, quality assurance and accreditation, General Pathology, Cytology and Histology

Paper II. Hematology, Transfusion Medicine, Immunology, Endocrinology and Molecular diagnostics

VIVA VOCE:

Viva voce will include selection, operational and interpretative aspects of tests performed.

Grand viva will be on day 2 at the end for 2 hours for overall assessment.

RECOMMENDED READING MATERIALS

Books (latest edition)

1. Clinical Diagnosis and Management by Laboratory Methods, Henry JB, WB Saunders. (Indian Edition, Eastern Press, Bangalore).
2. Clinical Laboratory Medicine, Editor Kenneth D. McClatchey, Lippincott Williams & Wilkins.
3. Laboratory Medicine Test Selection and Interpretation, Ed. Joan H. Howanitz & Peter J. Howanitz. Churchill Livingstone.
4. An Introduction to Clinical Laboratory Science, Clerc.
5. Widmann's Clinical Interpretation of Laboratory Tests, Sacher.
6. Clinical Laboratory Science Education & Management, Wallace.
7. Most Commons in Pathology and Laboratory Medicine, Goljan.
8. Advances in Pathology and Laboratory Medicine, Graham.
9. Interpretation of Diagnostic Tests, Wallace.
10. Delmar's Guide to Laboratory & Diagnostic Test, Deniels.
11. A Manual of Laboratory & Diagnostic Tests, Fischbach.
12. General Pathology JB Walter, MS Israel. Churchill Livingstone, Edinburgh.
13. Robin's Pathologic Basis of Disease Ramzi S. Cotran, Vinay Kumar, Stanley L Robbins WB Saunders Co., Philadelphia.
14. William's Hematology Beutler E, Lichtmann MA, Coller BS, Kipps TJ, McGraw Hill, New York.
15. Postgraduate Hematolog, Hoffbrand AV, Lewis SM, Tuddenham EGD, Butterworth Heinemann, Oxford.
16. Wintrobe's Clinical Hematology, Lee GR, Foerster J, Lupeus J, Paraskevas F, Gveer JP, Rodgers GN, Williams & Wilkins, Baltimore.
17. Practical Hematology, Dacie JV, Lewis SM, Churchill Livingstone, Edinburgh.
18. Bone Marrow Pathology, Bain BJ, Clark DM, Lampert IA, Blackwell Science, Oxford.
19. WHO Classification of Hematolymphoid Neoplasm
20. Fundamental of Clinical Chemistry, N. W. Teitz WB Saunders Company, Philadelphia.
21. Varley's Practical Clinical Biochemistry, JR Mc Murray, DM McLaunchlan, Heinemann Professional publishing, Oxford.
22. Glossary of Biochemistry and Molecular Biology, Glick.
23. Diagnostic Microbiology, Bailey & Scott's.
24. Koneman's color atlas and text book of Diagnostic Microbiology

25. Medical Microbiology, Mackie and McCartney.
26. Immunology, Roitt, Brostoff, Male, Bailliere Tindall, Churchill Livingstone, Mosby, W.B. Saunders.
27. Harrison's Principles of Internal Medicine, McGraw Hill
28. Mandell's Principle & Practice of Infectious Disease.

Journals

03-05 international Journals and 02 national (all indexed) journals

Postgraduate Students Appraisal Form
Pre / Para /Clinical Disciplines

Name of the Department/Unit :

Name of the PG Student :

Period of Training : FROM.....TO.....

Sr. No.	PARTICULARS	Not Satisfactory			Satisfactory			More Than Satisfactory			Remarks
		1	2	3	4	5	6	7	8	9	
1.	Journal based / recent advances learning										
2.	Patient based /Laboratory or Skill based learning										
3.	Self directed learning and teaching										
4.	Departmental and interdepartmental learning activity										
5.	External and Outreach Activities / CMEs										
6.	Thesis / Research work										
7.	Log Book Maintenance										

Publications

Yes/ No

Remarks*

***REMARKS: Any significant positive or negative attributes of a postgraduate student to be mentioned. For score less than 4 in any category, remediation must be suggested. Individual feedback to postgraduate student is strongly recommended.**

SIGNATURE of ASSESSEE

SIGNATURE OF CONSULTANT

SIGNATURE OF HOD