# Skills as Expected from a Post Graduate in Laboratory Medicine

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# What is Laboratory Medicine ?

- Laboratory Medicine Department is the Tier I of Laboratory Infrastructure of a Medical College Hospital

  The Tier I includes activities of centralised sample collection centre and central hospital laboratory which is engaged in almost 70% of all clinical laboratory investigations for routine and emergency care of in-patients and out-patients ensuring minimum turn-around-time (TAT) and quality.

- Laboratory Med. Dept. is Managed by Laboratory physicians of first contact for both Clinicians and Patients

- Laboratory Medicine as a Discipline is considered to be the Umbrella discipline that includes all laboratory-related departments, which make considerable portion of the backbone of Evidence-based Medical Practice

# What are the Other Tiers?

- Tier I:

  Related to Laboratory Medicine department

- Tier II:

  Encompasses specialty laboratories of Pathology, Microbiology and Biochemistry departments

- Tier III:

  High-end Common Research Facility laboratory in the medical college hospital

# Categories of Skills Laboratory Physician of First Contact is Expected to Have

- Management Skill
- Skill for Basic Laboratory Technology, Procedures & Methods
- Investigation & Operational Skill
- Result Interpretation Skill
- Research Skill

# I. Management Skill

- General Management
- Management of Automation
- Management of Quality
- Point-of-Care Management
- Managerial skill to get Laboratory Accredited
- Management of Education of Staff, Students & Residents

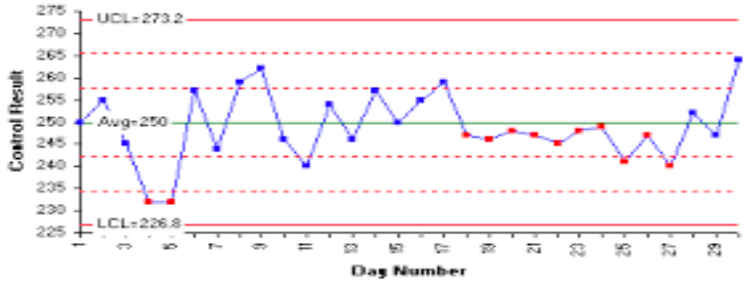

# 1. *General Management*


- Able to 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
- Actively participation in Test selection (ward-round, consultation form from clinicians), Test operation and Test interpretation (acting as laboratory consultant of clinical consultants) and referral to laboratory super-specialist, if necessary
- Ensure laboratory safety by standard, universal and special precautions for managing fire, poisonous/corrosive chemicals, infectious specimens and ensuring post-exposure remedial measures and prophylaxis
- Management of Biomedical Waste, starting from Segregation to Disposal
- Inventory Management; Equipment (Log book) and Reagents (stock, shelf-life)
- Legal Ethical and Social issues of specific Test and Test result

# 2. *Management of Automation*


- **Preanalytical automation**
  - Able to handle the pre-phlebotomy (e.g., LIS, bar coding) and post-phlebotomy automation (e.g., conveyer belt) for collection and transport of samples
- **Analytical automation**
  - Able to handle laboratory Automation / Robotics of all kinds including Tract-based Analyzers, and Creating a Smart laboratory out of automated laboratory (Corrective skill of Laboratory Physician's Autonomy supervenes Automation & AI)
  - Able to check calibration of the equipment and to maintain daily quality control record
  - Able to do troubleshooting, recalibrate the equipment and take corrective measures for the errors detected
  - Able to read "flags" in the result and take appropriate action
  - Able to validate the automatically generated reports
  - Able to manage AI in Laboratory Robots
  - Able to manage Inflatable Lab in Pandemics, in National & International disaster
  - Able to manage Mobile Lab, Lab on the wheels, for remote countryside & far away battlefields
- **Post-analytical automation**
  - Able to dispatch of reports through LIS (Laboratory Information System), if available
  - Able to manage sample preservation for specified period


# 3. *Management of Quality*




- Able to detect laboratory error, its source, its types, and take remedial measures and finally document it in the record book.
- Quality check of Pipettes, Dispenser, Refrigeration Temperature, Temperature of cold lab, Speed of Centrifuge machines etc.
- Able to identify preanalytical variables, perform preventive maintenance of equipment and checking of reagent.
- Able to run and interpret results of high, medium and low controls on daily basis in laboratory robot.
- Able to perform internal quality control and statistical analysis on daily basis for precision check.
- Able to make and interpret Levy Jennings chart for analytes and follow Westgard rules to take corrective action for errors identified before running patient samples.
- Able to participate in an external quality assurance program and proficiency testing, organized by national or international body.
- Able to read and interpret EQAS reports and take corrective action accordingly, when required

Expected to complete a Certified Quality Control Methodology Course during Senior Residency


# 4. *Point-of-Care Management*

- Able to implement and perform quality check of point-of-care devices
- Able to validate the device against the gold standard test in the laboratory
- Able to validate results of Point-of-care investigations
- Able to manage Inflatable Lab in Pandemics, in National & International disaster
- Able to manage Mobile Lab, Lab on the wheels, for remote countryside & far away battlefields


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

- Able to prepare Quality Manual, Sample collection Manual, Lab safety Manual
- Able to prepare standard operating procedures (SOPs) of investigations and Quality System Procedure (QSP) for different clauses of ISO 15189 along with routine forms and formats
- Able to do Internal Audit of the lab and prepare report.
- Able to correct all non-conformities (NCs) raised during audit and assessment of the laboratory
- Able to monitor Complain Register: documentation of complaints, response from the laboratory, remedial and precautionary measures taken
- Able to write minutes of Management Review Meetings (MRM)

## 6. *Managerial skill on Education and On-site training of laboratory Staff, MBBS and Nursing students and Clinical Residents*

- Participate in motivating, periodic training, education and competency assessment of the Technical staff
- Sensitization of Undergraduates (MBBS) during their laboratory visits
- Sensitization of Nursing Students & clinical postgraduates on the scope and limitations of the laboratory investigations by laboratory rounds and during their laboratory posting

# II. Skill on Basic Laboratory Technology, Procedures and Methods

- Able to check water quality of the laboratory
- Handling of Small Equipment

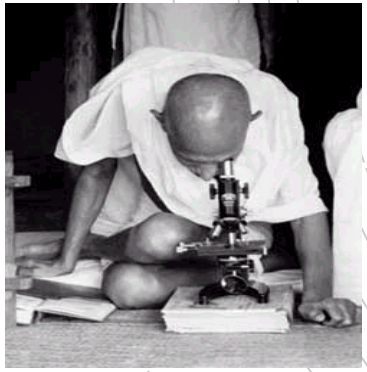
  Different types of Microscopes, Pipettes, Dispensers, Balances, different varieties of Centrifuges, Vortex, pH Meter, Oven, Incubators, BOD incubator, Refractometer, Colorimeter, Spectrophotometer, Nephelometer, Blood Gas Analyzer, Electrolyte Analyzer, different types of Electrophoresis, different types of Chromatography (e.g., HPLC, TLC, GLC), Autoclaves, Sterilizers, etc.
- Preparation of Buffers, Standard solution, Normal solution and Molar Solution
- Handle Sterilization and Disinfection methods

# III. Investigation & Operational Skill

## Microscopy

## &

## Automated Analysis



- Investigations on Body Fluids
- Chemical Investigations of Blood and Body fluids
- Investigations on Blood for Hematological disorders
- Investigation of Bone Marrow
- Investigation as required for basic Transfusion Medicine
- Immunological Investigations
- Investigations for Infective disorders
- Molecular Diagnostics
- Skill on Histo-and cyto-Pathology

# 1. *Investigations on Body Fluids*

- 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 etc.)**

  and, if necessary, to conduct microbiological examinations, to arrive at possible diagnosis of renal and urinary disease, biliary disease, nervous system disease, infertility, pulmonary disease, joint disease, prenatal diagnosis (from Amniotic fluid) etc.

- Able to interpret urinary findings as if, the urine is the "liquid biopsy" of the kidney
- Able to do and interpret pregnancy test in urine in difficult situations
- Able to interpret CSF findings in the context of meningitis caused by different organisms and differentiate from encephalitis, brain abscess and Guillain Barre syndrome
- Interpretation of Exfoliative cytology in the peritoneal, pleural pericardial fluids

# 2. *Biochemical Investigations*

- **a) of Blood/Serum:**
- Analysis of Sugar, Urea, Creatinine, Uric acid, Bilirubin (Total, Direct, Indirect) total Protein, Albumin, Globulin (both Manual & Automated methods)
- Analysis of Serum Enzymes: Transaminases, Gamma glutamyl transferase, Alkaline Phosphatase, Acid Phosphatase, Amylase, LDH, CPK etc.
- Estimation of Serum Electrolytes: $Na^{+}$, $K^{+}$, $Ca^{++}$, $PO_4^{-}$ etc.
- Able to take corrective step in case of hemolyzed, hyperlipidemic and hyperbilirubinimic serum

# 2. *Biochemical Investigations*

- **a) of Blood/Serum:**
- Estimation of Lipid profiles: Total Cholesterol (manual and automated method), LDL-Cholesterol, HDL-Cholesterol, VLDL and Triglycerides
- Analysis of Blood Gas parameters and pH
- Analysis of Serum Hormones: TSH, T4, T3, ACTH, Cortisol, FSH, LH. GH, Prolactin, Testosterone, Estrogen, ADH etc.
- Analysis of Vitamins (e.g., Vit D, B12, Folic acid etc.) and Trace Elements
- Analysis of Cardiac Markers: Troponin-I, Troponin-T, CK-MB, Myoglobin. LDH1 & II
- Analysis of Tumor Markers: Colonic Cancer (CEA, CA19-9), Pancreatic Cancer (CA19-9), Ovarian Cancer (CA125), Hepatic Cancer (alpha-feto protein), Trophoblastic Tumor (Beta HCG) etc.
- Analysis of Drugs and Toxins, when necessary

# 2. *Biochemical Investigations*

- **b) of Urine:**
- Analysis of Urinary $Na^{+}$, $Ca^{++}$, $PO_4^{-}$, Creatinine, Albumin, Uric acid
- Analysis of Substances excreted in inborn error of metabolism
- Analysis of Tumor Markers in urine
- Analysis of Porphyrins and related metabolites

# 2. *Biochemical Investigations*

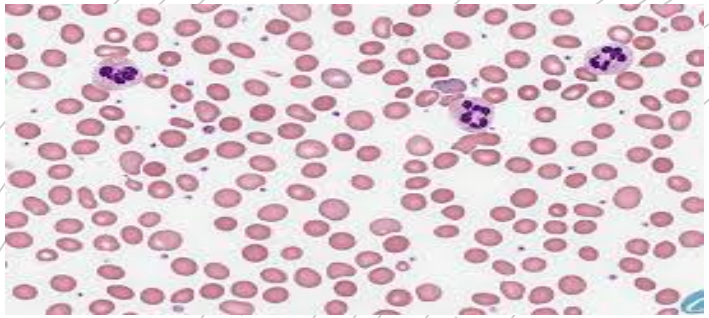
- c) of CSF:
  Analysis of Sugar, total Protein, Albumin, Globulin, Certain Enzymes etc.
- d) Fecal fat estimation for diagnosis of malabsorption and other studies for malabsorption
- e) Able to conduct (i) Plasma electrophoresis for investigation of cause of hypoproteinemia, (ii) Serum electrophoresis for 'M' spike, (iii) Hemoglobin electrophoresis for investigation of hemoglobinopathies, (v) Urine electrophoresis for specific protein
- f) Able to Evaluate Liver Functions, Renal Functions, Endocrine Functions, GI function etc.

# 2. *Biochemical Investigations*

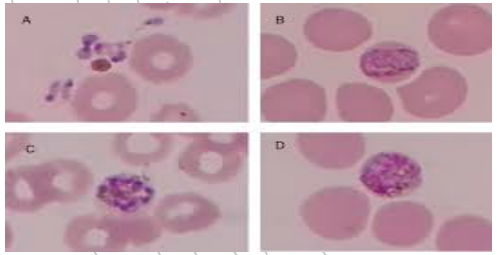
- Able to select and perform Investigations for laboratory Diagnosis of

  Diabetes mellitus (Diagnostic Criteria), Metabolic Syndrome, Metabolic Bone Disease, Hepatitis and other diseases of liver.

- Able to diagnose Metabolic / Respiratory/ Mixed Acidosis and Alkalosis (Uncompensated / Compensated)
- Able to identify the cause(s) of Hypo- and Hypernatremia, Hypo- and Hyperkalemia, Hypo- and Hypercalcemia
- Able to investigate Inborn Error of Metabolism
- Able to investigate Prenatal fetal defects
- Able to guide clinicians in progress and regress of cancer from tumor markers



# 3. *Investigations on Blood for Hematological disorders*



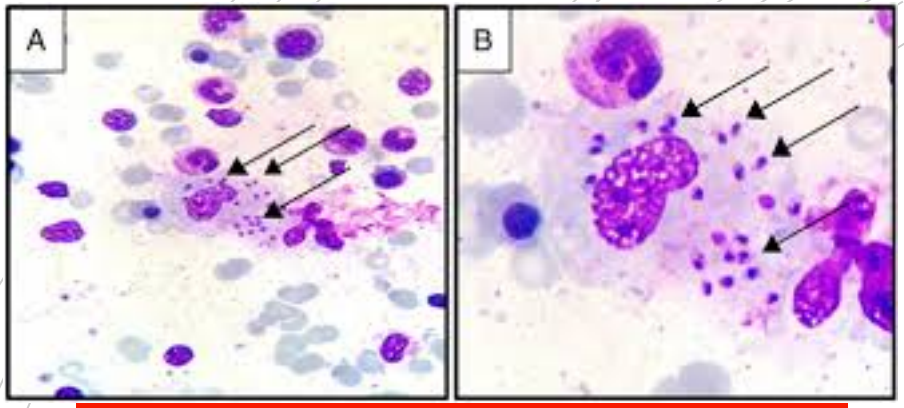
- Collection, transport and processing of blood samples for different hematological investigations in specified vial with adequate amount of specific anticoagulant
- Able to perform  manual methods of Blood Cells count, Make peripheral smear and staining
- Able to perform Hematocrit, Reticulocyte count, measure ESR (Westergren and Wintrobe methods) manually and prepare Buffy coat.
- Able to read  and interpret Hemogram and histogram  from Automated blood cell counter
- Able to 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
- Able to demonstrate Hemo-parasites; malaria, babesia, microfilaria etc.

# 3. *Investigations on Blood for Hematological disorders*

- Able to Investigate in details the etiology of Anemia; nutritional deficiency, hemolytic, hypoplastic and others
- Able to select investigations and work up for Nutritional Anemia
- Able to select investigations and work up for Hemolytic Anemia
- Able to demonstrate sickle cell, G6PD deficiency and identify cold agglutinin
- Able to prepare hemolysate and estimate Hb F manually and $HbA_2$ by column chromatography
- Able to do Hb-variant analysis, interpret electrophoresis and the result of chromatographic study
- Able to diagnose Thalassemia and conduct further study to classify it
- Able to investigate for Leukocyte disorders (quantitative and functional disorders)

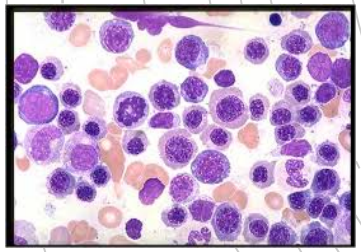
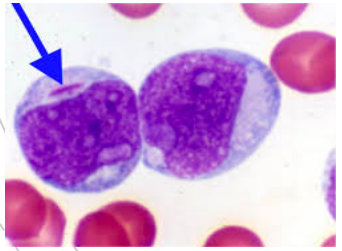
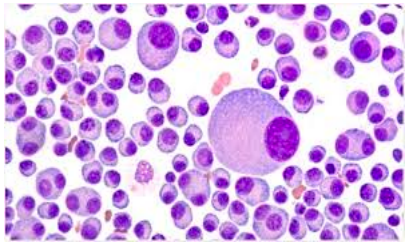
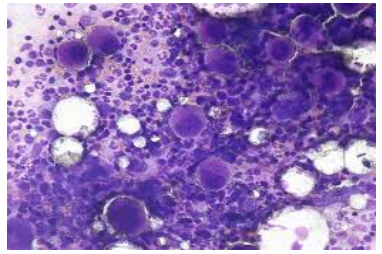
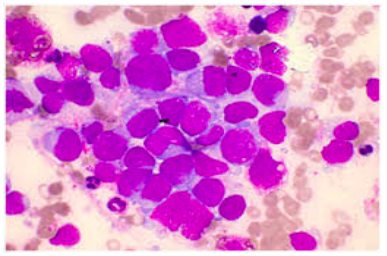
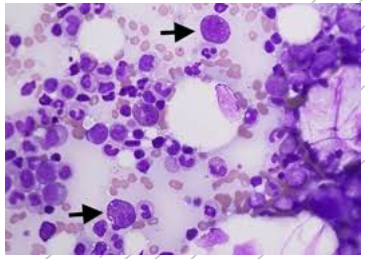
# 3. *Investigations on Blood for Hematological disorders*

- Able to investigate for and diagnose different Leukemias with cytochemistry, immunophenotyping and genetic analysis
- Able to 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
- Able to investigate Platelet functions (Platelet adhesion, aggregation and release defect)
- Able to investigate prothrombotic state: Assay of Anti thrombin III, Factor V-leiden, Protein C, Protein S etc.



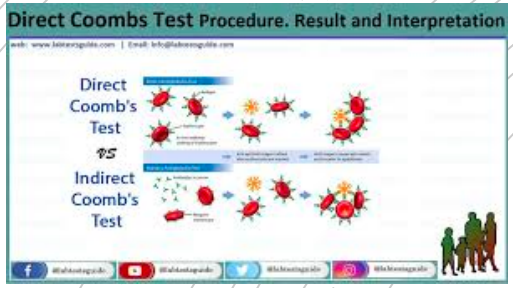

# 4. *Investigation of Bone Marrow*

- Collection, transport and processing of Bone marrow samples for different investigations and diagnosis
- Ability to interpret normal and abnormal bone marrow
- Ability to 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 and others

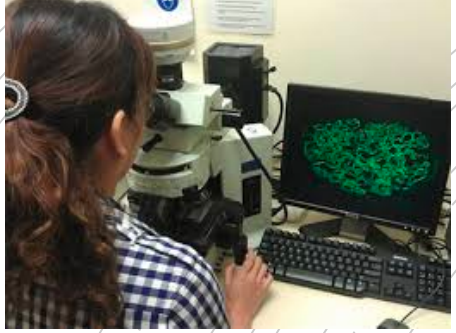
# 5. *Investigation as required for basic Transfusion Medicine*


- Get familiar with National and State legislation policies on Blood Banking
- Able to screen blood donors
- Able to perform phlebotomy on a healthy blood donor and collect blood in different specified bags
- Able to screen for Transfusion Transmitted Diseases in a blood donor
- Able to  perform cell grouping of major ABO & Rh blood groups and interpret findings by tube method
- Able to  perform serum cell grouping of major ABO blood groups and interpret findings by tube method
- Able to  perform cell grouping and serum cell grouping for minor blood groups
- Able to identify Secretory status of the Subject

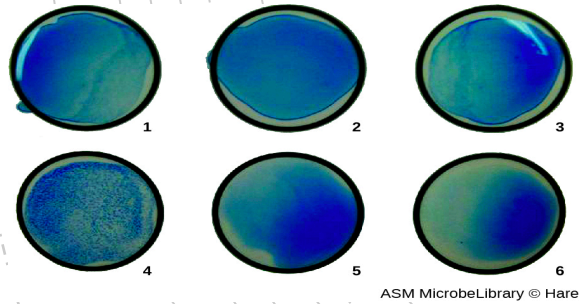



# 5. *Investigation as required for basic Transfusion Medicine*

- Able to perform cell and serum crossmatching
- Able to do Antiglobulin (Coombs) test; direct and indirect
- Able to investigate a case of Blood Transfusion Reaction
- Able to 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 and others, store those components according to standard protocols and use those in appropriate clinical conditions
- Able to do Therapeutic phlebotomy when necessary.
- Able to select subject for Apheresis and conduct the procedure



# 6. *Immunological Investigations*




- Able to perform basic immunological techniques

  Immunofluorescence microscopy

  Immunoassays; Immunoprecipitation, immunofixation different kinds of ELISA, ELISPOT assays Chemiluminescence analysis, Western blotting etc.

  Serological techniques; CFT, different types of Agglutination reactions, IHA etc.

- Able to perform immunophenotyping by Flowcytometry
- Able to measure and interpret CRP, RF, ANF etc.
- Able to evaluate Cellular immune system:

  Able to count B cell, T cell, T cell subsets; CD4 & CD8

- Able to perform T cell function test

  Able to in-vitro demonstration of CMI, Blast transformation.

  Able to in-vivo test: Intradermal inoculation

# 6. *Immunological Investigations*

- Able to evaluate Humoral immune system;

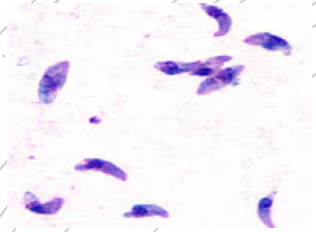
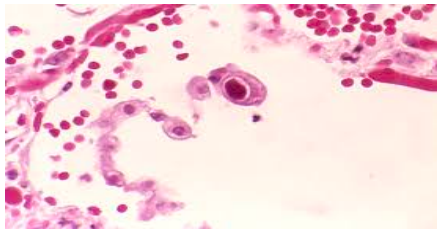
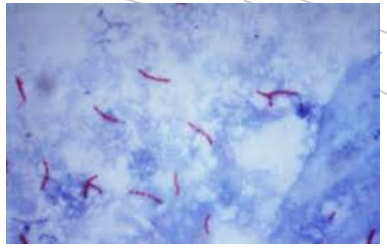
  B cell function evaluation and immunoglobulin estimation.

  Able to estimate Complements level

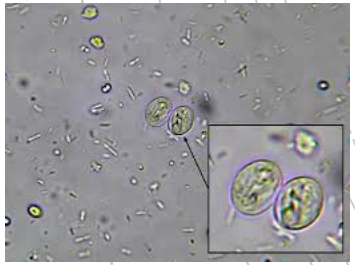
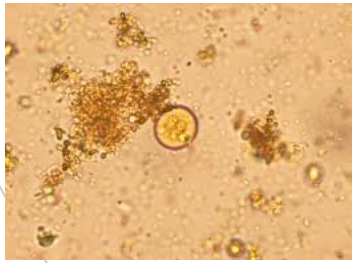
- Able to estimate Cytokines in blood and fluids
- Able to perform HLA-typing of cells and organs
- Able to evaluate collagen vascular disorders, autoimmune disorders, immunodeficiency states (primary and secondary)
- Able to investigate Hypersensitivity Reactions
- Able to investigate Organ-specific and Non-organ-specific Immunological diseases

# 7. Investigations for Infective disorders

- Able to identify and correct the preanalytic variables (normal microflora, faulty collection, contaminants, faulty transport, timing of collection, importance of sample volume etc.) that determine the quality and yield of microbiologic testing
- Able to perform and interpret Rapid Diagnostic Tests for microorganism as available (e.g., HIV)
- Able to demonstrate microorganisms by Microscopy (bright field, dark ground, phase contrast, fluorescence microscope etc.) using stains like Grams, Giemsa, Romanowsky, AFB, Kinyoun stain, India-ink preparation, Albert's special stains for spores, capsules, inclusion bodies, stains for parasites & fungi etc.
- Able to prepare culture media and inoculation of the sample specimen in the media and finally reading the outcome
- Able to conduct drug sensitivity tests in culture
- Able to perform biochemical tests for microbial identification
- Able to perform their serotyping (including Widal test)
- Able to conduct cell culture studies for the diagnosis of viral & other microbial infection
- Able to maintain specific strains of microbes

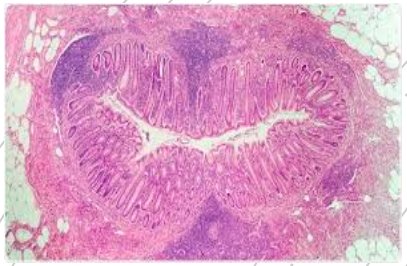
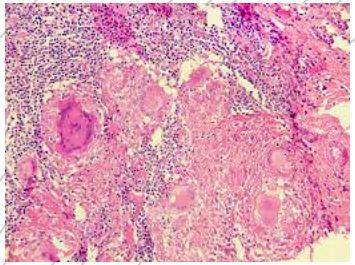
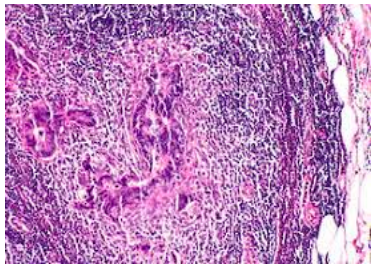
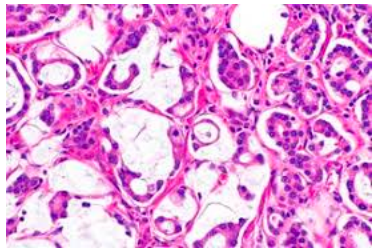
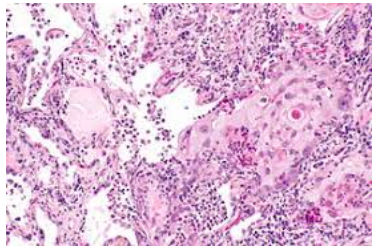
# 7. Investigations for Infective disorders

- Able to perform and interpret TORCH screening
- Able to perform and interpret the markers of different kind of Viral Hepatitis
- Able to diagnose Tuberculosis including drug-resistant tuberculosis
- Able to investigate the infections and infestations in a immunocompromised host
- Able to 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
- Able to diagnose Amoebiasis, Giardiasis, Leishmaniasis, Toxoplasmosis & Malaria etc.
- Able to identify common mycotic organisms by microscopy and special stains
- Able to participate in Hospital Infection Surveillance

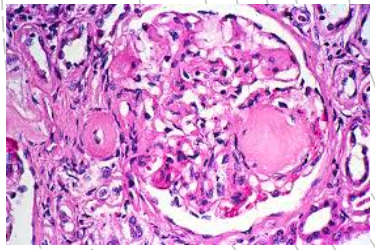
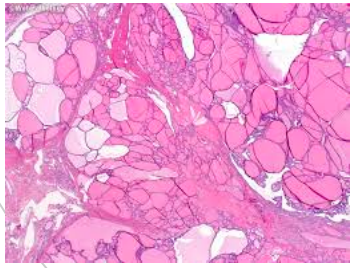
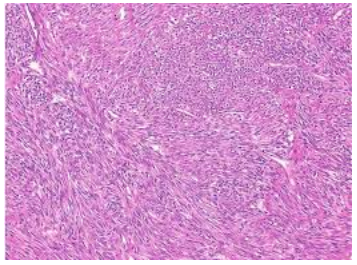
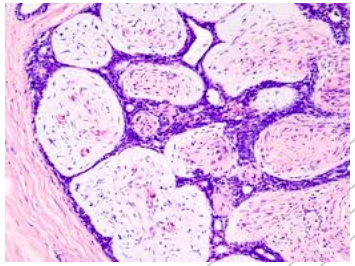
# 8. Molecular Diagnostics

- Able to set up of a diagnostic molecular laboratory
- Able to extract DNA from cell homogenate and use nanodrop spectrophotometer for DNA isolation
- Able to 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
- Post-translation analysis: Electrophoresis, Microarray, Dot-blot, Line probe assay etc.
- Able to read Gel Electrophoresis in Gel Documentation unit
- Able to do chromosomal and cytogenetic study, Hybridization (solid phase and solution phase) assays, fluorescence in- situ hybridization, comparative genomic hybridization with the limitations of each test and sources of false-positive and false-negative genetic tests
- Develop familiarity with NGS, if available, Pyro-sequencing and sequencing-based tests

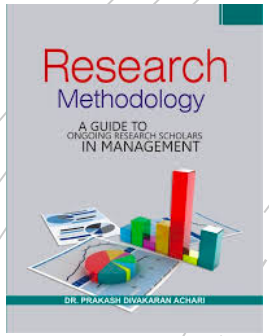
# 9. *Skill on Histo-, and Cyto-Pathology*

- Able to 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 etc.
- Able to do FNAC of Cervical lymph node, Thyroid, Skin and Oral lesions, Breast lump and do liquid-based cytology and interpret the PAP smear
- Exfoliative cytology is mentioned in the Fluid sections (in slide no 14)

# IV. Skill of reporting the result of investigations

- Acquisition of the skill of integrative reporting taking consideration of (i) clinical context (ii) results of all chemical, hematological and microbiological investigations of the patient sent to the lab, and (iii) Reference interval of values, (iv)the specificity and sensitivity of the methods, (v) prevalence (prior probability) of disease in defined populations (Bayes' theorem) and (vi) Positive and negative predictive value (PPV and NPV) of the test
- Develop the skill of communication of the result to patient, and to clinical colleagues regarding Threshold value, Critical value of the given parameter
- Make the clinical colleagues understand the burden of Unnecessary investigations
- If felt required, advice further series of investigations
- Develop the skill of maintaining confidentiality of the report
- If required, counseling of patients
- Develop the skill of Error-disclosure





# V. Research Skill

- Able to identify research problem, do the review of literature finding out the explanatory gaps and on this basis formulate research question, develop research hypothesis
- Able to design appropriate type of study method with requisite no of cases & age-and gender-based controls, select laboratory methods for analysis
- Able to tabulate and do the statistical analysis of the results to conclude and generalize the outcome, if possible
- Able to identify the strength and limitation of the study

Expected to complete a Certified Basic Research Methodology Course during Senior Residency

# CONCLUSION

# Thank You