The Arab League
Council of Arab Health Ministers
The Arab Board of Health Specializations
General Secretariat

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مجلس وزراء الصحة العرب
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المجلس العلمي لعلم الأمراض

Scientific Council of Pathology

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Guidebook of Clinical Pathology

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ARAB BOARD OF HEALTH SPECIALIZATIONS
SCIENTIFIC COUNCIL OF PATHOLOGY

INTRODUCTION

Pathologists are an integral component of the health care system specializing in the diagnosis and management of disease processes by laboratory methods. They function as diagnosticians, consultant physicians, teachers, and investigators in clinical and research studies. Pathologists integrate clinical information, scientific knowledge, and understanding of disease models with a wide spectrum of diagnostic modalities.

The **Arab Board of Health Specialization Scientific Council of Pathology** recognizes the crucial role of pathologists in patient care and scientific advancement. The Board aims at setting unified standards of excellence across the Arab world. The Specialty Boards in Anatomic Pathology and Laboratory Medicine represent one component of this goal. Assuring excellent training of pathology residents in certified laboratories and hospital facilities are equally important components of this process.

ARAB BOARD OF HEALTH SPECIALIZATION IN CLINICAL PATHOLOGY

A. CERTIFICATION

Candidates passing the final board examinations in Pathology are awarded the specialty certificate: **Arab Board of Health Specialization in Clinical Pathology (ABHS-CPath).**

B. GENERAL OBJECTIVES

1. Graduate Medical Education programs in Clinical Pathology (Laboratory Medicine) must provide an organized educational experience for qualified physicians seeking to acquire competence as a practicing clinical pathologist. The program must be structured according to international standards of postgraduate training in Clinical Pathology (Laboratory Medicine).

2. Programs must offer residents the opportunity to acquire a comprehensive understanding of Clinical Pathology, especially the consultative role of the pathologist in patient care. These can be in general Clinical Pathology programs or in training programs with combined focus in one area of Clinical Pathology such as Microbiology, Clinical Chemistry, Hematology and Coagulation, Blood Bank & Transfusion Medicine, Laboratory Management & Quality, Cytogenetics & Medical Genetics and Molecular Pathology.

C. SPECIFIC OBJECTIVES

Upon the completion of training, the resident should have demonstrated competencies in the six areas listed below. Toward this end, each program must define the specific knowledge, skills, and attitudes that are required and provide educational experiences as needed to develop these competencies. The program must create and reinforce the concept of life-long learning.

1. PATIENT CARE

Residents must demonstrate a satisfactory level of diagnostic competence and the ability to provide appropriate and effective consultation in the context of Clinical Pathology services:

- Develop a firm understanding of the principles, methodologies and interpretation of clinical laboratory tests.
- Acquire excellent diagnostic acumen for the commonly seen abnormalities in laboratory testing and their clinical relevance.
- Acquire knowledge of the proper utilization of laboratory tests, cost effectiveness and understand the role of ancillary studies in the work up of an abnormal laboratory finding.
- Demonstrate hands-on experience with specimen handling, laboratory procedures and automation.
- Develop good understanding of quality control issues, troubleshooting and laboratory safety policies.

2. MEDICAL KNOWLEDGE (Medical Expert/Clinical Decision-Maker)

Residents must demonstrate knowledge of established and evolving medical sciences and the application of this knowledge to Clinical Pathology.

- Understand the principles of specimen collection, handling, processing and rejection.
- Understand the basic principles of physiology, biochemistry, cell biology, immunology, and microbiology and pathogenesis.
- Demonstrate understanding of the general principles of genetics.
- Demonstrate knowledge of basic molecular biology structure and function of nucleic acids and proteins, replication mechanisms, in vitro synthesis, role of DNA, various RNA classes and proteins in cell biology.
- Understand the principles of specimen collection, handling, processing and rejection.
- Demonstrate ability to interpret data in the areas of electrolytes, acid-base, renal function, hepatic function, gastro-intestinal function, endocrine function, lipids, cardiac function, specific proteins, tumor markers, therapeutic drug monitoring, toxicology, metabolic disorders, antenatal screening, and trace metals.
- Demonstrate understanding of the techniques of specimen collection and preparation for routine hematologic testing, bone marrow aspiration and biopsy interpretation, as well as proper utilization and interpretation of ancillary stains that are used for that purpose.
- Demonstrate ability to perform differential counts on cytospin preparations of body fluids.
- Demonstrate knowledge of the technical aspects of flow cytometry, ability to interpret flow cytometry histograms, correlation of flow cytometry histograms with peripheral blood and bone marrow samples as well as body fluids, and correlation of flow cytometry results with lymph node biopsies in lymphoproliferative disorders.
- Demonstrate knowledge in identification of abnormal hemoglobins and work up of diagnostic tests for that purposes including electrophoresis.
- Demonstrate knowledge of coagulation and appropriate testing for coagulation disorders.
- Demonstrate knowledge of the proper type of specimen needed for the various tests in clinical microbiology, the proper transportation medium, the proper processing of the samples, the identification of common organisms, the understanding of tests and media reactions, interpretation of antimicrobial susceptibility testing, the interpretation of rapid procedure for detection and identification of organisms, correlation with clinical data, and quality control.
- Demonstrate skills in microscopic analysis of urine, stool, synovial fluid and semen specimens.
- Demonstrate knowledge of disinfection, sterilization, hospital infection control, safety in the laboratory.

- Demonstrate knowledge of the various serologic techniques (ELISA, agglutination, precipitation, complement-fixation, and fluorescent antibodies), and of the tests used in the diagnosis of different autoimmune and infectious diseases.
- Demonstrate the ability to perform ABO blood grouping, Rh blood grouping, direct and indirect antiglobulin tests, cross matching (major and immediate spin), component preparation, tube and gel methods, identification of antibody panel, elution and adsorption, selection of least incompatible blood, phenotyping, approach to cord blood analysis, approach to patients with immune hemolytic anemia, apheresis (red cell exchange, etc…), donor screening, preparation, and storage of blood components.
- Demonstrate knowledge of resolution of ABO discrepancies, other major blood groups and their clinical significance, importance of identification of antibodies, elution and adsorption, evaluation of cord blood studies, donor selection, component therapy, transfusion reactions, significance of the work up of transfusion reactions, hemolytic disease of the newborn, autoimmune hemolytic anemia, protocols of massive transfusion, and transfusion practices in the pediatric and neonatal population.
- Demonstrate knowledge of disease processes at the molecular level (solid tumors, hematopoietic tumors, infectious diseases) and methods used for their detection; must be familiar with the general applications of molecular pathology in clonality assays and molecular cytogenetics.
- Demonstrate knowledge and skills in the various molecular techniques such as different types of PCR, real-time PCR, and sequencing (where applicable).
- Demonstrate an in-depth knowledge of specimen collection requirements for cytogenetics and set up for the various types of samples (blood, amniotic fluid, chorionic villi or fetal parts, bone marrow or lymph node, solid tumors), culture maintenance, harvesting and slide making, AND chromosome banding techniques.
- Exhibit skills in chromosome analysis.
- Demonstrate knowledge of fluorescent in-situ hybridization (FISH) technique and ability to interpret its results.

3. PRACTICE-BASED LEARNING AND IMPROVEMENT (Collaborator)

Residents must be able to demonstrate the ability to investigate and evaluate their diagnostic and consultative practices, appraise and assimilate scientific evidence and improve their patient care practices.

- Contribute effectively to other interdisciplinary team activities.
- Must have experience in clinical medicine and surgery sufficient to achieve a sound understanding of the effects of disease and the role of Clinical Pathology in medical management.
- Demonstrate the ability to advise on the appropriateness of clinical tests in all laboratory disciplines, their clinical significance and the appropriate investigations to follow, if clinically indicated.

4. INTERPERSONAL AND COMMUNICATION SKILLS (Communicator)

Residents must be able to demonstrate interpersonal and communication skills that result in effective information exchange and teaming with other health care providers, patients, and patients' families.

- Establish effective relationships with colleagues and staff.
- Listen effectively.
- Assist in the continuing education of physicians and other staff.
- Understand and be able to communicate the pathology and laboratory information effectively in an oral and written form.

5. PROFESSIONALISM

Residents must demonstrate commitment to carrying out professional responsibilities, adherence to ethical principles, and sensitivity to a diverse patient population.

- Exhibit appropriate personal and interpersonal professional behaviors.
- Demonstrate a professional attitude to colleagues as well as to other laboratory staff.
- Have an appreciation of the crucial role of the clinical pathologist in providing quality patient care. This will include knowledge of individual professional limitations and the necessity of seeking appropriate second opinions.
- Demonstrate adherence to good clinical practice and medical ethics.
- Understand the principles of conducting research studies.
- Understand the importance of continuous professional development and learning.

6. SYSTEMS-BASED PRACTICE (Manager)

Residents must demonstrate an awareness and responsiveness to the larger context and system of health care and the ability to call on system resources to provide pathology services that are of optimal value.

- Demonstrate knowledge of the principles of laboratory management and administration.
- Demonstrate knowledge within the clinical laboratory of the quality system essentials and how to apply to total quality management.
- Demonstrate knowledge of the methods for professional quality assurance/improvement as applied to Clinical Pathology.
- Demonstrate knowledge to assess results from different methods and the requirements for proper method evaluation, validation and implementation in clinical testing.
- Understand the basic principles and standards of accreditation for laboratory certification.
- Demonstrate competence in basic computer skills with emphasis on automated electronic reporting, electronic communication and search strategies.

D. ADMISSION TO THE ARAB BOARD OF HEALTH SECIALIZATION IN CLINICAL PATHOLOGY:

1. The candidate must hold an MD or equivalent degree from an accredited medical school.
2. The candidate shall have successfully completed his/her training in an accredited program in Clinical Pathology (Laboratory Medicine).
3. The application form of the candidate should be endorsed by the Program Director and an Arab Board representative in the Pathology Scientific council.
4. The candidate shall have a good command of the Arabic and English languages.
5. The candidate shall pay the required registration fees
6. The candidate shall comply with the requirements of the Arab Board of Health Specialization in Clinical Pathology.

E. ACCREDITATION OF TRAINING PROGRAMS

a. Requirements:

1. The program should be recognized by local authorities for training purposes.
2. All regulations of the Arab Board accreditation requirements should be met.
3. The training program should possess sufficient volume and quality, and cover all disciplines of Clinical Pathology including Blood Banking and Transfusion Medicine, Clinical Chemistry (Biochemistry), Clinical Hematology, Clinical Microbiology, Molecular Genetics and Cytogenetics, Molecular Pathology and specialized laboratory techniques. The material must form an adequate mix of cases to ensure exposure to common/uncommon and malignant/non-malignant conditions.

4. The program applying for accreditation can be in one hospital / location or group of affiliated departments of Pathology to fulfill the required case mix and volume.
5. The program should be complemented by an acceptable range of specialized techniques such as flow cytometry and molecular diagnostics.
6. Programs should have at least 3 full time consultants, who are holders of recognized qualifications in their specialties with minimum experience of 5 years working as independent pathologists or Laboratory Directors.
7. The number of trainees should not be too small in a manner that compromises the quality of training.
8. The program must ensure adequate resources (e.g., sufficient laboratory space and equipment, classrooms, meeting rooms, computer, internet and statistical consultation services).
9. There must be access to an on-site library or to a collection of appropriate texts and scientific journals.
10. The audiovisual resources available for educational purposes should be adequate to meet the goals and objectives of the program.

b. Structure of the Training Program

1. Duration of the program

a. The duration of the training program is 4 years.
b. The candidate should pass all required evaluation processes in all 4 years at his/her registered/accredited program.
c. Candidates can spend up to 12 months of their training at other accredited programs inside or outside their countries or in other recognized international pathology centers if this will go to enrich their training.

2. General outline of basic rotations

First year

The trainee goes through scheduled 2-3 months rotations in all disciplines of the clinical lab and gain knowledge and experiences in the general laboratory medicine principles and basic requirements of the disciplines as listed in ***Appendix II***.

Second and third year

The trainee goes through scheduled 2-3 months rotations in all disciplines of the clinical lab and gain knowledge and experiences in the advanced laboratory medicine principles, laboratory management, and the advanced requirements of the disciplines as listed in ***Appendix II.***

Fourth Year

The trainee spends longer periods of rotations in disciplines of interest capitalizing on acquired knowledge of earlier years to demonstrate abilities to practice Clinical Pathology, possibly with a focus in one or more disciplines. The trainee should be actively engaged in the research and academic activities of the department, the development plans to introduce new tests and procedures, and the management activities of Clinical Pathology at the training center(s).

3. Training Methods

The following training methods should be utilized to achieve the objectives and requirements of the training program:

a. Daily case review:

Residents and faculty members study all unusual laboratory findings in their respective units and identify those that have teaching benefit to be shared with other residents. Residents participate in review of quality control measures within the unit, where applicable. In Clinical Hematology, for example, there will be daily microscopic review of all bone marrow aspirates and abnormal peripheral smears and correlating findings with biopsy material and other ancillary studies such as flow cytometry, cytogenetics and molecular studies.

b. Regular weekly departmental meetings:

Faculty, trainees and staff participate together in detailed discussion of interesting, instructive and unusual cases to share information and reach consensus diagnosis, when and where applicable. Medical staff from other clinical services (Medicine, Surgery, Obstetrics & Gynecology, Pediatrics and others) are invited contributors to these meetings and other clinical and educational activities.

c. Current Topic Seminars:

Residents are required to present a talk on selected topics suggested by the staff members. Topics are chosen to cover recent advances in Clinical Pathology (Laboratory Medicine) which require a comprehensive review of the most recent literature on the topic. Each resident is required to present a minimum of four talks per year.

d. Journal Club:

Residents are required to present reviews of one article or more published in indexed journals dealing with research studies, investigations, and development of new techniques in pathology or related medical sciences.

e. Didactic lectures and talks by the faculty or consultants.

Faculty or Consultants should design a core curriculum in Clinical Pathology and participate in giving regular talks regarding different laboratory disciplines and instruct the trainees on the proper approaches to laboratory

testing, laboratory administration and quality management programs as they apply to the various disciplines.

f. Research project:
Residents are required to participate in a research project with other staff members or co-author a scientific paper in compliance with the Arab Board regulations.

g. Courses:
Residents are encouraged to take specialized courses such as Clinical Research Methods, Communication Skills courses, Health Management, Laboratory Quality, Safety, laboratory management, etc...

F. FORMAT OF EXAM

1. General information:

The Exams consist of two parts, I & II. The official language of the exams is **English**.

Part I exam:

1. The Council shall determine the Exam dates and venues based on the number of applicants and the location of their training centers.
2. A trainee is eligible to sit for Part I Exam after completing 20 months of training in an accredited program.
3. The application to sit for the exam should have the Scientific Council approved *Competency Assessment Form* filled and submitted as well.
4. The exam is conducted through the electronic platform in the centers designated and approved by the member countries at the same date and time announced by the Scientific Council.
5. Failure to sit for the exam within a period of two years from the start of the accredited training leads to cancelation of the application record automatically.
6. Part I Exam is offered twice per year.
7. A trainee is eligible to sit for Part I Exam for four (4) times. The attempts are counted from the date of the first attempt of taking the exam after completion of 20 months of training in an accredited program approved by the Arab Board, or from the date of the first attempt after the approval of part of the training.
8. It is possible to accept, and for one time only, a request to delay sitting for an exam, if the applicant submits a valid reason at least 15 days prior to the exam date. This will not be counted as an attempt.
9. The Part I exam is graded over 100 and the passing grade is 60%.

Part II exam:

1. A trainee is eligible to sit for the Part II Exam after completing 4 years of training in an accredited program and after passing successfully Part I Exam or being exempted from it and presenting a document confirming successful completion of the accredited training and specialty requirements.
2. Part II exam is composed of two parts: Written and Practical. The applicant will sit for both exam parts without the prerequirement to pass the *Written* part. Grading will be as follows:
   - Final *Written* exam weight is 40%
   - Final *Practical* exam weight is 60%
   - The total passing score for Part II exam is 60%
   - The passing score in each of the *Written* and *Practical* exam parts is 50%.
   - If the applicant scores less than 60% as a total for Part II exam or less than 50% in any of the *Written* or *Practical* exams, he or she will have to take both *Written* and *Practical* exams again.
3. Part II exam is held once per year in October-November with the possibility of an additional exceptional session during the same if requested by the Scientific Council Chairman.
4. The exam is conducted through the electronic platform in the centers designated and approved by the member countries at the same date and time announced by the Scientific Council.
5. Failure to sit for the exam within a period of two years from the completion of the accredited training leads to cancelation of the application record automatically.
6. A trainee is eligible to sit for the Part II Exam for four (4) times counted from the date of the first attempt of taking the exam after completion of the accredited training.
7. A trainee who has been exempted from Part I and approved for the required years of training is eligible to sit for the Part II Exam for four (4) times counted from the date of the first attempt after approval of the exemption.
8. It is possible to accept, and for one time only, a request to delay sitting for an exam, if the applicant submits a valid reason at least 15 days prior to the exam date. This will not be counted as an attempt.
9. If the 4 allowed attempts to sit for the exam have been utilized, the trainee may be granted two additional attempts within two years after repeating the last training year in the accredited program approved by the Arab Board.
10. A trainee is granted the Arab Board certification in Clinical Pathology after passing the Part II exam.

2. Part I Exam

The exam will be prepared by the Examination Committee of the Council and it is a multiple-choice exam (MCQs). It covers general principles that govern Clinical Pathology and its subspecialties of Clinical Hematology and Coagulation, Blood Bank and Transfusion Medicine, Clinical Microbiology, Clinical Immunology and Serology, Clinical Chemistry, Molecular Pathology and Cytogenetics. The exam also covers laboratory and analytical quality management commensurate with level of training, instrumentation, and laboratory safety.

3. Part II Exam

Is prepared by the Examination Committee of the Council and it is a multiple-choice exam. There are two options for Part II examination: the first is an examination for general Clinical Pathology certification that covers broadly all its subspecialties of Clinical Hematology and Coagulation, Blood Bank and Transfusion Medicine, Clinical Microbiology, Clinical Immunology and Serology, Clinical Chemistry, Molecular Pathology and Cytogenetics. The second is an examination for certification in one of the Clinical Pathology subspecialties: Clinical Hematology, Clinical Chemistry, Clinical Microbiology, and Blood Bank & Transfusion Medicine.

Part II Examination for the two options above consists of two components:

1. Theory component: It covers all aspects of training, and Clinical Pathology disciplines, instrumentation and technological aspects, quality management, laboratory management, clinicopathological correlations, and tests for knowledge of general and organ-specific clinical pathology.
2. Practical component: It covers practical cases in Clinical Pathology subspecialties of Clinical Hematology, Blood Banking and Transfusion Medicine, Molecular Pathology and Cytogenetics, Clinical Chemistry, Clinical Immunology and Clinical Microbiology and Serology. Where applicable, it utilizes virtual microscopy technology of selected cases that cover a wide range of hematological disorders or others, special stains, molecular tests, and technologies used in these Clinical Pathology specialties.
3. For subspecialty exams in Part II, the emphasis of questions in these two components will be more pertinent to the sought Clinical Pathology subspecialty certification.

Appendix I

OBJECTIVES AND EXPECTATIONS OF TRAINING IN CLINICAL PATHOLOGY

Basic Learning Objectives

1. Gain knowledge and technical skills to recognize, interpret, and explain pathologic processes in the clinical practice.
2. Effectively communicate pathologic findings to colleagues and provide consultative information regarding patient management.
3. Effectively direct and manage the Clinical Pathology laboratory in all its aspects and provided services.

Basic Programmatic Expectations of Residents

1. Develop an understanding of basic pathologic processes.
2. Acquire skills needed to interpret laboratory data and make clinicopathologic correlations.
3. Communicate effectively and share expertise with peers and colleagues.
4. Develop investigative skills to better understand pathologic processes as they apply to both individual patients and the general patient population.
5. Acquire knowledge and experience in laboratory direction and management.
6. Assume leadership roles in education of other physicians and allied health professionals.

Specific Skills that Apply to All Areas of Clinical Pathology

1. Ability to obtain pertinent information from the patient's clinical record.
2. Demonstrate knowledge of information that is necessary to provide adequate clinical history on submission forms for Clinical Pathology specimens.
3. Demonstrate knowledge of the general principles and terminology for processing Clinical Pathology specimens, including patient identification, proper specimen handling and safe transportation to the clinical laboratory.
4. Demonstrate familiarity with the detailed organization, equipment, and techniques of the respective clinical laboratories.
5. Where applicable, such as in Clinical Hematology and Clinical Microbiology, to list common histochemical and immunohistochemical stains used for microscopic sections, as well as their indications and the expected results for various tissue or specimen types.
6. Ability to enumerate the elements of satisfactory sections, specimen preparation and stains, and identify the possible reasons for unsatisfactory preparations.
7. Ability to select appropriate fixatives for special histologic or specimen preparations.
8. Demonstrate knowledge of the specimens that commonly require special handling and /or testing (flow cytometry, microbiological cultures, cytogenetics, recovery of crystals, electron microscopy, immunohistology, etc…).
9. Ability to collect and preserve appropriate tissues and body fluids for immunofluorescence, molecular testing and flow cytometric studies.
10. Proficiency in performing special hematological studies, including touch preparations (where applicable), cytospins, and blood smears.

11. Proficiency in initiating routine microbiological studies, including appropriate cultures, smears, and stains, and knowledge of methods of collection and preservation, if needed.
12. Demonstrate knowledge of basic principles of tissue banking.
13. Ability to present cases at conferences with clarity, completeness, and high quality illustrations, and to reach reasonable interpretative conclusions.
14. Demonstrate knowledge of the appropriate storage and disposal of tissues, chemicals, fixatives and reagents.
15. Demonstrate knowledge of the common pathogens that can be transmitted to laboratory personnel in the clinical laboratory, as well as basic safety precautions to be taken in the Clinical Pathology laboratory, including universal precautions for infectious agents and the role of the pathologist in institutional infection control.
16. Ability to take suitable gross and microscopic photographs using digital filming technology.
17. Know current regulations emanating from the health insurance, governmental regulations, and hospital policies regarding protection of patient confidentiality; demonstrate knowledge of how such rules impact the Clinical Pathology laboratory, and means for their implementation in the handling of human tissues and body fluid specimens/samples for diagnostic work and research.

SKILL EXPECTED PER LEVEL OF TRAINING

PART ONE (YEAR 1)

SKILLS

1. To be involved in the processing of laboratory specimens in all units of Clinical Pathology including Clinical Hematology and Coagulation (to be familiar with staining procedures), Clinical Microbiology, Clinical Chemistry, Clinical Immunology and Serology, Cytogenetics, Molecular Pathology, Blood Banking and Transfusion Medicine.
2. To be able to set up the microscope correctly.
3. To learn basics in morphological identification of peripheral blood cells, bone marrow cells and microbes.
4. To initiate reports on simple routine cases.
5. To learn the importance of ancillary tests.
6. To be aware of different resource materials and how to use them.
7. To start basic preparation for Part I exam.

KNOWLEDGE

1. Basis of tissue and cell fixation, specimen processing, and staining, where applicable such as in Clinical Hematology and Clinical Microbiology.
2. Pathological basis of diseases.
3. Common pathological changes that affects the hematopoietic system.
4. Understand pathological changes at cellular level.
5. Basic principles of analysis in Clinical Chemistry and knowledge of the routine chemistry analytes and the techniques employed for their testing.

6. Principles of electrophoresis and the utilization of this technology in diagnosing abnormal proteins such as serum proteins, immunoglobulins, hemoglobin and others.
7. Basic principles of automation.
8. Basis of ancillary techniques including immunohistochemistry, cytogenetics and molecular diagnostics.
9. Basic principles of blood grouping, immunohematology and transfusion medicine.
10. Basic principles of platelet pheresis and therapeutic plasma pheresis.

ATTITUDE

1. Appreciate the importance of specimen handling and block selection.
2. Seek advice and help when appropriate and needed.
3. Appreciate the role of clinical pathologists as an integral part of clinical decision making.
4. Realize the importance of turn around time in reporting.
5. Positive attitude toward team working environment.
6. Familiarity with laboratory quality, health and safety regulations.
7. Adherence to basic principles of patient confidentiality and medical ethics.

PART TWO (YEARS 2,3,4)

SKILLS

1. To write interpretation reports of specialized tests and procedures and sign out with the supervising clinical pathologist.
2. To perform and supervise specialized procedures such as pheresis.
3. To consolidate knowledge on Molecular Pathology, Cytogenetics, and Flow Cytometry.
4. To prepare for and attend multidisciplinary medical meetings or conferences.
5. To be involved in the Quality Management program of the department and be familiar with the methodology of test development and validation.
6. To be involved in research in conjunction with the Clinical Pathology faculty and staff as well as specialists from other disciplines. An effort should be made to publish research and investigative work or case reports, etc…
7. To have the opportunity to participate in discussion of matters related to the management of the department
8. To participate in the education of medical students, medical laboratory technology program students and other trainees.
9. Trainees should be encouraged to seek second opinions from colleagues and show around cases.
10. To prepare for Part II exam.

KNOWLEDGE

1. Understand principles of examination of all major specimens and sampling to enable completion of standardized testing and reporting.
2. Possess sufficient general clinical knowledge including major changes in trends of diagnosis and treatment.
3. To have sufficient clinical and pathology knowledge to enable integration of clinical data and pathological features.

4. Have good knowledge of the sensitivity, specificity, positive predictive value and negative predictive value of diagnostic tests and those that are used for screening purposes.
5. Advanced understanding of the principles, application and interpretation of special histochemical, immunohistochemical and common molecular methods.
6. Knowledge of features of infections and microorganisms as they relate to laboratory testing, clinical management of the patients, and infection control.
7. Knowledge of transfusion medicine and the appropriate utilization of blood bank resources in clinical medicine.
8. Understand the role of integration of different ancillary techniques in transplantation immunology and diagnosing the wide spectrum of hematological disorders, neoplastic and non-neoplastic.
9. Understand the integration of different ancillary studies in diagnosing microbial agents and consequently infectious diseases.
10. Understanding the basic principles of laboratory management, quality assurance and safety issues.
11. Understanding the principles of performing research studies.

ATTITUDE

1. Understand the importance of continuing professional development.
2. Understand the importance of integration of clinical and pathological data for accurate diagnosis.
3. Understand the importance of ensuring that request form and specimen identification are accurate and the requirement to identify and resolve any error or discordance.
4. Demonstrate an understanding of the importance of Clinical Pathology to clinicians and patients (e.g. Timeliness and accuracy of reporting).
5. Understand cost-benefit issues and proper laboratory utilization when considering the use of additional techniques.
6. Appreciate the available molecular technologies and their advances and how they can contribute to patient care.
7. Hold positive attitude toward team working environment.
8. Acquire familiarity with laboratory quality, health and safety regulations.
9. Adhere to basic principles of patient confidentiality and medical ethics.
10. Develop proper ways to communicate with other members of the Laboratory Medicine department, other departments and clinical teams.
11. Demonstrate motivation to learn about common disease processes through all available diagnostic resources.

Appendix II

COMPETENCIES IN CLINICAL PATHOLOGY; Necessary Evaluation of Resident Applicant to Board exam:

Residents must be evaluated for competencies in the six areas below to the level expected of a new practitioner.

The Resident should be graded on a scale of 1 3 5 7 9

1-3 Unsatisfactory
5 Satisfactory
7 Good
9 Superior

Only residents with grades of 5 or greater on each of the 6 competencies below will be eligible to take the Board exam.

1. **PATIENT CARE**
   Residents must demonstrate a satisfactory level of diagnostic competence and the ability to provide appropriate and effective consultation in the context of Clinical Pathology services.

2. **MEDICAL KNOWLEDGE**
   Residents must demonstrate knowledge about established and evolving medical sciences and the application of this knowledge to Clinical Pathology (Laboratory Medicine).

3. **PRACTICE-BASED LEARNING AND IMPROVEMENT**
   Residents must be able to demonstrate the ability to investigate and evaluate their diagnostic and consultative practices, appraise and assimilate scientific evidence and improve their patient care practices.

4. **INTERPERSONAL AND COMMUNICATION SKILLS**
   Residents must be able to demonstrate interpersonal and communication skills that result in effective information exchange and teaming with other health care providers, patients, and patients' families.

5. **PROFESSIONALISM**
   Residents must demonstrate a commitment to carrying out professional responsibilities, adherence to ethical principles, and sensitivity to a diverse patient population.

6. **SYSTEMS-BASED PRACTICE**
   Residents must demonstrate an awareness and responsiveness to the larger context and system of health care and the ability to call on system resources to provide Clinical Pathology services that are of optimal value.

ASSESSMENT OF COMPETENCIES IN CLINICAL PATHOLOGY

In addition, each resident should be assessed **for each of the following 5 categories** as:

Novice
Advanced beginner
Competent
Proficient
Expert

Only applicants with an assessment of **Competent or above** would be eligible to take the board exam:

GENERAL LABORATORY BASIC PRINCIPLES:

- Knowledge of accreditation standards/requirements for specimen submission and handling within laboratory setting
- Knowledge of accreditation standards regarding safety, occupational hazards/infection control
- General principles of analytical laboratory testing and their applications to individual disciplines
- Use of special techniques such as immunohistology, flow cytometry, cytogenetics, molecular genetics, culture techniques and others.
- Storage/disposal of specimens and hazardous chemicals
- Basic computer skills in Clinical Pathology

MICROSCOPIC EXAMINATION

1. **Basic**
   - Accurate clinical and laboratory data collection
   - Reasonable diagnosis/differential diagnosis
   - Basic elements of information required in all reports
   - Preparation of written report
   - Prepared/organized for sign out sessions with senior staff
   - Correlation with ancillary tests findings when applicable

   More advanced
   - Formulate an accurate diagnosis or recognize need for consultation
   - Selection of special stains and ancillary studies, when appropriate
   - Interpretation of various assays and knowing their limitations and artifacts
   - Knowledge/use of classifications and grading systems of tumors and disease
   - Use of synoptic reports (as appropriate)
   - Amended/addendum reports
   - Proper handling of consultation cases
   - Microscopy
   - Digital technology (where applicable)

2. CLINICAL MICROBIOLOGY:

Basic

- Demonstrate knowledge of the identification of microbes by:
    - Routine stains for the identification of microbes (e.g. Gram stain, acid fast stain, Ziehl Neelsen)
    - Proper media for the variety of microbes such as aerobic, anaerobic bacteria, Mycobacteria and fungi.
    - Major biochemical characterization of bacteria
    - Principles of antimicrobial testing and in vitro antibiotic sensitivity
- Precautions in handling microbial agents
- Demonstrate the ability to integrate theoretical basic knowledge with gained practical skills in the performance of laboratory tests for reliable diagnosis of infectious etiologies and accurate interpretation of test results.
- Identify appropriate specimens and select the most appropriate investigation to detect the most likely involved infectious agent(s) for the individual patient.
- Demonstrate the ability to follow an SOP in performing test procedures to obtain accurate results in an effective and efficient manner to achieve an optimal turnaround time.
- Demonstrate ability of producing a laboratory report containing correct results and appropriate interpretative comments, together with using appropriate IT systems to release results.

More advanced

- Advanced knowledge of biochemical profile of bacteria including uncommonly encountered microorganisms
- Know the commonly occurring infections due to yeasts and fungi.
- Recognize the gross and microscopic culture characteristics of the yeast/fungi. For example, Cryptococcus neoformans, Candida albicans, Rhizopus spp./Mucor spp, Aspergillus fumigatus, dimorphic fungi, Dematiaceous fungi
- Understand the methods employed for the identification of yeasts and mold fungi.
- Be able to describe specimen processing needed for mycobacterial cultures such as concentration and digestion. Know why and when this is needed.
- Know the grouping of non-tuberculosis mycobacteria.
- Understand the methodology and the limitations for direct detection of M. tuberculosis in clinical specimens.
- Be acquainted with the *Clinical and Laboratory Standards Institute* (CLSI) standards and guidelines for antimicrobial testing and be able to interpret different testing methods.
- Understand which variables affect susceptibility testing.
- Be able to recognize different/ unusual susceptibility results and how to verify the results.
- Be able to interpret the listed serologic and molecular tests used for diagnosis of viral infections.
- Describe the mechanisms of the common antiviral agents such as acyclovir, amantidine, oseltamivir, ATZ, gancyclovir and others.

- Molecular testing for microbes. For example, HIV testing using Western blot and viral load detected by PCR
- Understand mechanisms of transmission of nosocomial infections.
- Communication/dialogue with the clinical team for the appropriate care of patients with microbial infections.

3. CLINICAL MICROSCOPY-PARASITOLOGY-URINALYSIS-SPEROGRAM

a. Intestinal Parasites & Biochemical Examination of Stool

- Collection and handling of stool specimens e. g. general approach, scotch tape technique, and rectal swab technique.
- Macroscopic examination of the stool: consistency, presence of mucus, blood, round worms, tape worms or their segments.
- The different methods for fixation (preservation) of stool specimens e.g. PVA, 10% formalin, 5% formalin saline solution, MIF Schaudinn's as well as the advantages and disadvantages of each method.
- The different techniques (advantages and disadvantages of each) for preparation and examination of stool specimens for parasites:
  i. The wet mount preparation (direct saline smear or Lugol's iodine smear).
  ii. The concentration methods using zinc sulfate flotation, formalin ether sedimentation, and the formalin ethyl acetate sedimentation.
- The preferred approach of combination technique using fixation (preservation) with PVA and the subsequent concentration by formalin ethyl acetate sedimentation prior to examination.
- The commercially available systems for concentration of stool specimens e.g. FPC.
- The different staining techniques used for visualizing intestinal amoeba and flagellates, e.g. trichrome stain and the iron hematoxylin stain, as well as the interpretation of findings in these stain.
- The Modified Acid Fast (Kinyon acid fast) staining procedure for detection of coccidian parasites such as Cryptosporidium, Isospora and others and the interpretation of findings.
- The proper use of the microscope and the micrometer for examination and interpretation of prepared smears and determination of the size of the parasite or its stages.
- The culture technique for the detection of parasites e.g. Strongyloides stercolaris (Haradu Mori filter strep Culture), and Trichomonas.
- The immunoserologic methods used for diagnosing parasitic infections of the GI tract e.g. Giardia and hepatic amoebiasis.
- The biochemichal methods used for determining the presence of fat (Sudan III).
- The quality control exercised in checking the reagents e.g. occult blood test, FPC and others.
- The chromatographic immunoassay for the qualitative determination of human calprotectin and lactoferrin in stool sample.
- The chromatographic immunoassay for the qualitative determination of human occult blood in stool sample. (e.g. *Hemosure*).
- The Wright Stain performance and reading for detection of PMN in stool.

b. Microscopic & Biochemical Investigation of Urine & Body Fluids

- The proper collection of urine specimens for microscopic and chemical examination.
- The macroscopic examination of the specimen.
- The routine chemical investigations (Dipstick) e.g. pH, protein, sugar, glucose, urobilinogen and acetone, as well as the interpretation of results and correlation with disease, and the mechanism of reaction in each.
- The performance and interpretation of results for manual tests and their implication in diseases.
- The preparation of urinary sediment for microscopic investigation to detect WBC, RBC, crystals and parasites as well as their correlation with disease conditions.
- The proper quality control for *Combur 10 test* strips.
- The proper use and interpretation of polarizing microscopy for crystals.
- The proper use and interpretation of phase contrast microscopy for RBC morphology.
- The proper use and interpretation of Automated Urine Analyzer (Cobas) as well as the daily QC for it.

c. Semen Analysis & Examination (Spermogram)

- The instructions to patients for the proper collection of specimens.
- The proper containers, labeling, time of collection and prompt delivery to the laboratory.
- The macroscopic examination for color, volume and liquefaction.
- The proper preparation and examination of specimen for motility, the presence of RBC, crystals and Trichomonas vaginalis.
- The proper preparation and staining (Giemsa or Papanicolaou) of specimen for examination of sperm morphology and the differentiation between WBC and spermatocytes.
- The proper staining and interpretation of Eosin stains to differentiate dead from live sperms.
- The proper preparation, dilution (1:20) and counting of total number of sperms using hemocytometer, as well as the proper calculation to report sperm counts as millions per ml.
- The proper preparation, incubation and examination of specimen for viability.
- pH of semen using *Combur 10* dipstick.

4. CLINICAL CHEMISTRY (BIOCHEMISTRY):

Basic

- Demonstrate the knowledge of general technical and managerial skills to operate a clinical chemistry laboratory.
- Demonstrate the basic principles of Clinical Chemistry and the knowledge of proper scientific procedures for assessment and evaluation of methodologies to be used for patient testing.
- Demonstrate knowledge for testing for routine analytes such as blood glucose, lipids, liver function tests, cardiac biomarkers, renal function tests, pancreatic enzymology, electrolytes and acid base, proteins, and hormones (pituitary,

thyroid, parathyroid, reproductive, growth, adrenal glands, and different suppression and stimulation tests).

- Demonstrate knowledge for testing and assessment of assays and analytes such as blood glucose, lipids, liver function tests, cardiac biomarkers, renal function tests, pancreatic enzymology, electrolytes and acid base, proteins, and hormones (pituitary, thyroid, parathyroid, reproductive, growth, adrenal glands, and different suppression and stimulation tests).
- Demonstrate knowledge in testing for vitamins and minerals and as they relate to various physiologic and pathophysiologic conditions such as in bone metabolism and metabolic bone disease.
- Demonstrate knowledge of basic principles of laboratory automation.
- Describe the basic components of nephelometric and turbidimetric systems
- Apply knowledge of basic principles of chromatographic separation to selection of methods for analysis in the clinical laboratory
- Explain the basic physiochemical principles of electrophoresis
- Describe principle desirable characteristics of capillary zone and isoelectric focusing electrophoresis
- Recognize the several categories of immunoassays
- Recognize the advantages and disadvantages of different antigen and antibody labels
- Demonstrate knowledge of continuous quality assurance and regulatory compliance methodologies and application of quality management in various phases of the workflow: pre-analytical, analytical, and post-analytical.
- Select appropriate control materials that will reliably evaluate method performance
- Establish control rules that will detect significant variation from baseline performance that may affect patient care or proficiency test success, but that minimize false signals
- Review control results to detect significant changes from baseline performance and investigate causes
- Evaluate proficiency testing results to detect issues in the testing process that must be corrected to meet regulatory requirements
- Establish appropriate limits for agreement between different instruments performing
- Describe the basic components of a simple (single beam) photometer
- Apply Beer`s Law, absorbance, and percent transmittance to concentration of a measured analyte
- Employ serum hemolysis, icterus, and lipemia "indices" to assist in identification of specimens with significant interferences
- Develop expertise regarding the several types of interferences in immunoassays and some protocols that may be useful for detecting interferences
- Demonstrate knowledge of testing for selected analytes in body fluids other than blood and serum.
- Utilize statistical concepts, such as analytical sensitivity and specificity, bias, and variance, and techniques such as linear regression analysis, in evaluating performance characteristics of laboratory methods
- Identify and, when possible, account for analyte specific biologic variables

- Ensure appropriate procedures are in place for proper labeling of specimens and aliquots
- Employ or advocate delta checking to warn of potential specimen artifacts or specimen identify issues
- Recognize common, unstable analytes measured in the laboratory like ammonia, lactate and blood gases.
- Communicate proper handling of blood gas specimens, including influences of plastic syringes and specimen preservation on ice.

Advanced
- Demonstrate knowledge of tumor markers for screening, diagnosis and monitoring.
- Demonstrate knowledge of therapeutic drugs: knowledge of drug metabolism, pharmaco-kinetics, and pharmacodynamics for different classes and for proper therapeutic monitoring.
- Learn about toxicology: laboratory evaluation and management of overdosed or poisoned patients and laboratory evaluation of drugs of abuse.
- Demonstrate knowledge of antenatal screening for chromosomal abnormalities using different ultrasound, biochemical, and genetic markers.
- Recognize protein electrophoresis investigations and interpretation as well as correlation with other laboratory parameters.
- Recognize amino acids by HPLC, organic acids by GC/MS, tandem mass spectrometry, and other methods used for screening and investigation of inborn errors of metabolism.
- Trace metals analysis by atomic absorption spectroscopy or ICPMS.
- Principles and applications of point-of-care testing (POCT).
- Laboratory information system.
- New method evaluation and validation, quality control, quality assurance, and basic laboratory statistics. Introduction to various softwares used in method evaluation and quality management (Example, *EP Evaluator*).
- Laboratory results evaluation and interpretation: reference values and decision making.
- Utilize statistical concepts such as clinical sensitivity, clinical specificity, predictive value, and ROC curve analysis in evaluating the diagnostic performance of laboratory tests
- Define and be able to utilize statistical techniques such as arithmetic mean, geometric mean, standard deviation, and percentile rank for evaluation of population-derived data to establish reference intervals; select correct type of statistical tool depending on the distribution of data observed
- Describe the statistical techniques used to monitor significant changes in a patient`s lab results
- Establish or validate appropriate reference interval based on patient population
- Differentiate basic methodologic and process issues impacting importing reference intervals by transference versus establishing them by patient study
- Examine reports for possible non-random, post-analytic variables, for example, loss or alteration of information from truncation, round-off, units conversion, re-formatting, data loss or corruption via transmission, and determine appropriate follow-up

- Generate clear, accurate, and complete reports that effectively communicate test results and treatment implications where appropriate
- Set, monitor, and modify chemistry auto verification rules
- Work with other medical care professionals to define appropriate critical values and notifications
- Discuss current results and patient issues with clinicians and multidisciplinary health care teams
- Record, investigate, resolve (when indicated), and respond to reports of laboratory errors by the clinical staff
- Apply appropriate ion creation/fragmentation methods, particularly MALDI, electron impact, and electrospray to a wide range of analyte measurement
- Match the advantages of TOF-MS, single quadrupole MS, and tandem MS with analytical problems
- Become familiar with the analytical power and challenges presented by GC-MS and LC-MS.
- Adopt, when possible, techniques such as curve resolution, retention time adjustment, and custom built mass spectral libraries to improve quantitation and certainty of peak identifications
- Use isotope dilution for high accuracy calibration where appropriate

5. BLOOD BANK:

Basic

Basic immunohematology
- ABO and Rh: antigen typing
- Direct antiglobulin test-poly and monospecific
- Antibody screen: Method and principles
- Antibody identification: Method and principles
- Reagent red cell panel; selected cell panel; antibody elution and adsorption
- Enhancement techniques for antibody identification
- Crossmatch: Major crossmatch versus immediate spin

ABO Discrepancies:
- Causes and clinical significance
- Methods of resolution

Blood Group Antigens:
- Rhesus, Kell Duffy, Kidd, Lewis, MNSs, P, Lutheran, I
- Biochemistry and clinical significance of the antibodies to these blood group antigens

Blood Component Therapy:
- Preparation and storage of blood components
- Clinical use of blood components
- Therapeutics effect and methods for monitoring

Transfusion Reactions:

- Types of transfusion reactions
  (Pathophysiology, laboratory findings, clinical presentations, treatments, prognosis, and prevention):
  - Acute hemolytic transfusion reaction
  - Delayed hemolytic transfusion reaction
  - Anaphylactic and allergic transfusion reaction
  - Allergic reactions
  - Hemolysis due to passive transfer of antibody
  - Febrile non-hemolytic transfusion reactions
  - Transfusion related acute lung injury
  - Transfusion transmission infections
  - Adverse effects during transfusions due to citrate overload, hypocalcemia, hypothermia, hyperkalemia, iron overload
  - Graft versus host disease
  - Post transfusion thrombocytopenic purpura
  - Laboratory evaluation of transfusion reactions

Advanced

- Platelet Transfusion refractoriness: Diagnosis, management, and laboratory testing
- Autoimmune hemolytic anemia: Laboratory workup, selection and release of red cell components
- Hemolytic disease of the newborn: Prevention, diagnosis and treatment
- Massive transfusions: Definition and management
- Use of specifically processed blood components:
  - Gamma irradiation
  - CMV negative
  - Leukocyte depletion
  - Washed blood component
- Preparation of leukocyte depleted cell concentrates: Compare and contrast different methods
- Blood utilization review
- Donor questionnaire, deferral
- Collection of whole blood
- Collection and therapeutic apheresis: Types, applications and outcomes
- Institution transfusion committee: structure and responsibility

6. CLINICAL HEMATOLOGY:

Basic

- Instrumentation and methodology
- Complete blood count and red cell indices
- Reticulocyte count
- Examination of peripheral smear, basic morphology:
  - Identification of normal red cells, white cells and platelets, as well as non-neoplastic abnormalities
  - Identification of blood parasites such as Plasmodium and Trypanosoma

- Erythrocyte sedimentation rate
- Sickling test
- Coagulation and hemostasis tests: PT, PTT, TT, bleeding time, D-dimer
- Cell counts in body fluids and CSF
- Bone marrow aspirate interpretation, basic morphology:
  - Quality
  - Different stages of maturation of normal marrow cells as well as maturational abnormalities and dysplastic changes
- Basic principles of flow cytometry:
  - Know about utility and the different applications of flow cytometry
  - Sensitivity, specificity and Limitations of flow cytometry testing
  - Specimen handling
  - Knowledge about basic flow techniques
  - Basic gating strategies
  - Common markers used in flow cytometry testing

Advanced

- Common and uncommon red blood cell disorders: presentation and morphologic changes
- Common and uncommon white blood cell disorders: presentation and morphologic changes
- Familiarity with various hematological malignancies as per the most recent WHO classification: acute leukemias, chronic leukemias, lymphoid neoplasms and plasma cell dyscrasias
- Integration of interpretation of peripheral smears and bone marrow aspirates with integration of ancillary studies such as cytochemical stains, flow cytometry, cytogenetics and molecular studies
- Identification of abnormal cells in the marrow, such as those associated with metabolic disorders, infectious and neoplastic disorders other than hematological neoplasms
- Interpretation of gated flow cytometry plots for immunological and hematological disorders
- Advanced cell identification in body fluids
- Hemoglobin electrophoresis: familiarity with different hemoglobinopathies
- Hemostasis and thrombosis:
  - Coagulation tests: Clotting factors, S-protein, C-protein, testing for clotting factors inhibitors, platelet function assays
  - Common and uncommon platelets disorders: presentation and morphologic changes
  - Common and uncommon coagulopathies: presentation and testing

7. MOLECULAR DIAGNOSTICS/CYTOGENETICS:

Basic

- Learn the various techniques available for the diagnosis, monitoring and prognostication of neoplastic diseases, particularly hematolymphoid disorders and solid tumors.

- Learn the basic and standard techniques utilized in the diagnosis of infectious diseases and common heritable disorders as well as those for transplantation immunology.
- Acquire the principles and limitations of conventional polymerase chain reaction (PCR), reverse transcriptase polymerase chain reaction (RT-PCR), both conventional and quantitative, Fluorescence in situ hybridization (FISH), western blot, karyotyping, and DNA sequencing.
- Assess variable issues of troubleshooting and quality control in using and maintaining these techniques and their corresponding equipment.

a. Nucleic Acid Hybridization

- Discuss the roles of base pairing and the double-stranded structure of DNA molecules.
- Explain the role of complementary base pair association in determining the specificity of nucleic acid hybridizations
- Understand the concept of melting temperature and applications to nucleic acid hybridizations
- Identify environmental conditions which can affect the strength and specificity of nucleic acid hybridizations as well as the melting temperature of the hybridized product

b. Amplification of Nucleic Acids Using the Polymerase Chain Reaction (PCR)

- Describe the three basic steps involved in a typical nucleic acid amplification carried out using the polymerase chain reaction
- List the basic components (reagents) used in a polymerase chain reaction and identify those which have a significant effect on the target specificity of the amplification
- Compare and contrast the appropriateness and potential limitations of each of the following sample types for analysis by polymerase chain reaction: 1) blood specimen with EDTA anticoagulant, 2) heparinized blood specimens, 3) fresh or frozen tissue sample, 4) formalin fixed paraffin embedded tissue sample.
- Identify the most common inhibitors of the polymerase chain reaction encountered in a clinical laboratory setting
- Explain the purpose of physically separating pre-amplification and post-amplification areas of laboratories which perform testing using the polymerase chain reaction
- Understand the fundamental difference between target amplification and signal amplification techniques for nucleic acid analyses

c. Mutation Detection Technologies

- Describe the technique of allele specific polymerase chain reaction and explain the difference between this and a standard, non-allele specific polymerase chain reaction
- Understand the basic biochemical processes underlying the Sanger method of DNA sequencing

- Describe the limitations of Sanger sequencing for the detection of whole exon deletions and duplications
- Explain the analytical level variability in the detection of somatic mutations in tumor tissue identified in a biopsy specimen versus mutations in the germline sequence of an individual

d. Interpretation of Sequence Variants

- Distinguish between the terms: Mutation, Polymorphism and Sequence variant
- Describe each of the following types of mutations:
    i. Single nucleotide substitution
    ii. Nucleotide deletion
    iii. Nucleotide insertion
- Explain the functional effects of the following types of mutations on the protein product of a gene:
    i. Nonsense mutations
    ii. Missense mutations
    iii. Frameshift mutations
- Understand the possible effects of splice site mutations on the protein product

e. Real Time PCR

- Understand the different chemistries utilized (DNA binding dyes vs. target specific probes) and the fluorescence detection technology used in real-time PCR
- Understand the distinction between the exponential and plateau phases of PCR amplification and the concept of CT (threshold cycle)
- Compare the advantages of real-time PCR over end-point PCR (Dynamic range, precision of quantification, sensitivity)
- Explain the importance of appropriate selection of internal controls for sample normalization
- Recognize the different applications of real-time PCR in molecular diagnostics

f. Reverse Transcription PCR (RT-PCR)

- Understand the technical importance of handling of RNA to avoid degradation
- Describe why genomic DNA contamination of template RNA is problematic and address the means to correct the occurrence.
- Describe the basic steps in RT-PCR (including vital reagents used, choice of primers and amplicon size)
- Understand the meaning of Complementary DNA (cDNA)
- Recognize the importance of real-time RT-PCR in molecular diagnostics

g. FISH and Array CGH (aCGH)

- Describe the basic principles of Fluorescence in situ Hybridization (FISH) and aCGH (differential labeling of normal and reference DNA and co-hybridization to the array)
- Identify the various probes utilized in FISH techniques (telomeric, subteloremic, etc.)

- Identify the relation between array resolution and target clone size and density
- Recognize the variable applications of aCGH including:
    i. Detection of copy-number variations (CNVs)
    ii. Loss of heterozygosity (LOH)
- Understand the concept of copy number polymorphisms (CNPs)
- Recognize the chromosomal aberrations where aCGH is not useful like:
    i. Balanced translocations
    ii. Inversions

h. Next Generation Sequencing (NGS)

- Describe the basic principles of NGS including library preparations, clustering, and sequencing
- Identify two major examples of platforms and technologies available (Example, Sequencing by Synthesis and pH-nanotechnology)
- Recognize the applications of NGS in molecular diagnostics and research
- Understand the concept of Single Nucleotide Variations (SNVs)
- Recognize the various NGS applications:
    i. Whole Exome Sequencing (WES)
    ii. Whole Genome Sequencing (WGS)
    iii. RNA Sequencing (RNA-Seq)

Advanced

- Ability to correlate molecular findings with other laboratory parameters and clinical findings
- Ability to complete a full karyotype analysis using regular and automated techniques
- Ability to interpret a PCR/RT-PCR report using both conventional (gel-based) and quantitative (real-time) assays with adequate reporting skills including:
    i. Writing comments
    ii. Correlation with other reported test results
    iii. Clinical significance

a. Specimen Handling

- Ensure effective communication between the medical or surgical oncologist, surgical pathologist and molecular pathologist to facilitate appropriate specimen collection including the types, quantities, and specimen handling requirements of samples that are needed at the time of diagnosis
- Determine the most appropriate collection and type of samples for chromosomal and molecular testing
- Ensure adequate quantity and quality of specimens for the necessary morphologic and molecular testing
- Ensure that the specimen is appropriately preserved for the anticipated testing, with appropriate documentation of specimen handling conditions
- Establish policies and procedures to ensure specimens are of sufficient quantity and appropriately fixed to permit ancillary testing

b. Patient Selection

- Identify which neoplasms can be better classified with ancillary molecular testing
- Assess the utility of molecular testing for determining treatment options for various neoplasms
- Determine whether the primary or metastatic tumor should be submitted for molecular testing
- Recognize the indications for molecular testing so that patients who can potentially benefit from them will be treated appropriately
- Assess the importance of Liquid Biopsy and Circulating Tumor DNA (ctDNA)
- Realize the importance of genetic counseling in selection of patients for proper genetic testing
- Assess the clinical cases through genetic pedigrees inspection for the proper identification of eligible patients for testing

c. Analytical Concerns

- Recognize sources of analytical error for various molecular tests and the measures to reduce them
- Ensure that the specimen contains enough tumor for RT-PCR analysis (snap frozen) or for conventional cytogenetic analysis (fresh tissue)
- Identify the tumor tissue of interest on a corresponding H & E stained slide that is adjacent to the unstained slides submitted for in situ hybridization (ISH) molecular analysis so that the appropriate area may be dissected and the appropriate cells are scored for in situ assays
- Consider the clinical and imaging studies when establishing the diagnosis for any bone or soft tissue tumor

d. Test Prioritization

- Determine the need to allocate limited tissue appropriately for immunohistochemical and molecular testing to ensure optimal specimen utilization
- Recognize the advantages and limitations of molecular testing as an adjunct to cytopathologic evaluation of cellular specimens
- Recognize the advantages and limitations of molecular approaches commonly used in the assessment of mesenchymal neoplasms:
    i. New cytogenetic and molecular variants continue to be discovered
    ii. Cytogenetic variant translocations (rearrangement of one consistent gene with differing chromosomal translocation partners)
- Recognize that assays are frequently complementary
- Use clinicohistopathologic impression to determine what tests should be performed.
- Identify the most common genetic approaches used to identify tumor-specific abnormalities:
    i. Conventional cytogenetics
    ii. Molecular cytogenetics (in situ hybridization (ISH))
    iii. Sequencing
    iv. Reverse transcription-polymerase chain reaction (RT-PCR) analyses

8. CLINICAL IMMUNOLOGY:

Basic

- Describe the organization of the immune system (Cells and Organs)
- Describe the function of the immune system cells and organs
- Describe and understand the function and structure of the Human Leucocyte Antigen (HLA) molecules system
- Describe and understand the function and structure of the Immunoglobulin heavy and light chains receptors, and antibody classes
- Describe and understand the function and structure T-cell Receptor (TcR)
- Describe and understand the function different cytokines
- Describe the clinical and laboratory characteristics of a range of autoimmune disease
- Recognize and characterize congenital and acquired immune deficiency disorders
- Recognize and characterize asthma, and other allergic diseases and conditions
- Describe immune system reaction to organ/tissue transplantation
- Recognize clinical presentations and diagnose malignancies of the immune system

Advanced

- Autoimmune liver disease (AILD). List autoantigens associated with autoimmune liver disease, explain principles behind assays, their relative diagnostic merits, interpret results in clinical context
- Celiac disease – explain immunopathogenesis, list relevant antibodies and explain methods for detection and their relative merits, evaluate role of HLA typing in the diagnosis of celiac disease
- Autoantibodies in endocrine diseases - list relevant antibodies and explain methods for detection and their relative merits for Type 1 diabetes, autoimmune thyroid diseases, Addison's disease, pernicious anemia/atrophic gastritis
- Autoantibodies in bullous skin disorders - list autoantigens associated with these skin disorders, explain principles behind assays, their relative diagnostic merits, interpret results in clinical context
- Autoantibodies in renal disease and renal transplantation
- Autoantibodies in myositis and scleroderma
- Autoantibodies in neurological diseases
- Autoantibodies in inflammatory bowel disease
- Autoantibodies associated with miscellaneous rheumatic conditions
- HLA and disease association
- Indications for allergy testing
- Immunophenotyping of B-cell lymphoproliferative disorders
- Immunophenotyping of T-cell lymphoproliferative disorders
- Immunophenotyping of NK-cell lymphoproliferative disorders
- Immunophenotyping of myeloid disorders and malignancies
- Assessment of minimal residual disease by flow cytometry
- Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)
- Investigation and interpretation of tests in patients with suspected immunodeficiency including B-cell immunodeficiency disorders, T-cell

immunodeficiency disorders, Complement disorders, Neutrophil disorders, and NK cell disorders

9. LABORATORY MANAGEMENT:

- Explain and apply the use of calibrators and controls in lab assays
- Explain the contribution of interference in lab assays
- Be familiar with quality control principles in clinical laboratory
- Interpret quality assurance (QA) reports and discuss sources of variation in the results of assays in different laboratories
- Apply, review and plan quality assurance strategies for monitoring processes and outputs in the laboratory.
- Apply laboratory-specified work flow procedures and participate in evaluations to determine whether they are optimal
- Recognize, report and analyze quality problems when they arise in the laboratory
- Apply pre-analytical quality control procedures to sample handling, including collection, identification, acceptance, storage and disposal
- Apply internal quality control procedures, including reference ranges and applications- principles and usage of SI units, basic statistics as applied to quality control, and measurement of uncertainty
- Apply external quality assurance procedures, adverse reaction reporting, audit and quality improvement.
- Participate in the implementation of plans for testing and evaluating new technology or advances that may improve the quality of laboratory practice and patient care
- Recognize and rectify causes of error in laboratory assays.
- Document, notify and apply corrective actions, employing laboratory information systems where appropriate, in the event of incidents, errors and adverse events
- Explain the concepts of risk management in the laboratory
- Explain basic laboratory safety principles regarding universal precautions
- Explain specific aspects of maintaining a safe working environment
- Explain basic aspects of ergonomics in the workplace
- Demonstrate knowledge of local, national and international regulatory frameworks surrounding the collection, packaging, transport, storage and disposal of laboratory specimens.
- Basic understanding of Accreditation (e.g. CAP, ISO) standards for laboratory certification
- Understand cost-effective practice of Clinical Pathology (laboratory medicine)
- Understand diagnostic coding/billing procedures
- Demonstrate basic government laws (including compliance) applicable to pathology
- Learn principles of laboratory information system

10. GENERAL SKILLS:

- Use of appropriate terminology and nomenclature in reports
- Appropriate communication with referring clinicians (or patients/family as appropriate)
- Timeliness/turnaround time/indications to rush cases
- Resolution of diagnostic disagreement

- Seeking internal/external consultation
- Training junior residents
- Ability to make an independent case presentation