STANDARDS and GUIDELINES FOR
POSTDOCTORAL TRAINING PROGRAMS IN CLINICAL CHEMISTRY

Approved and Adopted by the Commission on Accreditation in Clinical Chemistry (COMACC)
2012

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I. PURPOSE

The Commission on Accreditation in Clinical Chemistry (ComACC) is an independent non-profit organization that accredits training programs in clinical chemistry at the postdoctoral level. The purpose of granting accreditation to training programs is to foster their excellence, to provide recognition to accredited programs, and to attract qualified individuals to training centers of excellence. This process is intended to assure the trainee that the standards of education and training are consistent across programs and are aligned with progress in medicine and clinical laboratory sciences.

These standards and associated guidelines have been established to define the standards of quality in postdoctoral clinical chemistry programs recognized by ComACC accreditation. They are provided for the benefit of fellowship programs and associated institutions to help them to achieve a level of excellence in their educational efforts yet provide flexibility in achieving the standards through program-specific delivery of education material. The program director is considered a critical component to the success of any fellowship program and ComACC will strive to assure that excellence begins with the program leadership and associated faculty.

This document is intended as a guideline/resource for program directors responsible for providing leadership in organizing local resources for postdoctoral training in clinical chemistry and to assist them in assuring that their programs meet the standards and requirements for accreditation by COMACC.

II.PREAMBLE

Clinical chemists are doctoral level scientists and/or physicians who have expertise in clinical chemistry or clinical pathology. Clinical chemistry is a broad field that includes general clinical chemistry, endocrinology, toxicology, therapeutic drug monitoring, nutrition, serology and immunology, biochemical urinalysis, pharmacogenomics, and molecular diagnostics. The principal professional opportunities for graduates of ComACC-approved fellowship programs include Director, Associate/Assistant Director of clinical laboratories in an assortment of medical centers and hospitals, Director or Associate staff in Research and Development departments in pharmaceutical and/or diagnostics industrial firms, Director/Associate or Assistant Director of a commercial laboratory, and Director/Associate or Assistant Director of a public health laboratory. Clinical Chemists are specifically and uniquely trained for the responsibility of oversight of a clinical laboratory, providing expertise in the area of testing, interpretation of laboratory results, and quality management.

The principal objective of a training program should be to educate, train, and prepare clinical chemists to provide leadership in the field of clinical chemistry and other areas of clinical laboratory science, who will be active in research and who will serve the needs of physicians and patients. The training program should be of sufficiently broad scope that it provides the essentials necessary for the trainee to sit for the American Board of Clinical Chemistry Board examination in clinical chemistry or toxicology, and to have career mobility and to be able to succeed in the professional environment. Therefore, in order to prepare the clinical chemist for

these various professional opportunities, the well-balanced program integrates patient care, clinical service, management, research, education, and administration in training.

III. STANDARDS AND GUIDELINES

A. STANDARD I. FACULTY

Educational programs in clinical chemistry must be staffed with adequate, qualified faculty (e.g., clinical chemists and/or clinical pathologists) to assure the quality of the program is consistent with program objectives and education of the trainee is effective.

GUIDELINES

1. PROGRAM DIRECTOR

- **a.** The program must have a director who has ultimate responsibility for oversight and operation of the entire program.
- **b.** Either the Program Director or Co-Director must be a clinical chemist who holds a faculty appointment at the sponsoring institution and who is certified as a Clinical Chemist by the American Board of Clinical Chemistry (ABCC). The program director must be active academically in clinical chemistry research, education, service, and administration at the sponsoring institution. The program director or co-director must have at least five years of academic and service experience (equivalent to a faculty appointment) in the field and with demonstrated teaching expertise at the post-graduate level. If there is a change in directorship, and there is no remaining director/co-director with five years of experience, the program is given up to 12 months to recruit a qualified individual to maintain accreditation. Program Directors are expected to maintain Active Diplomate Status by meeting the requirements for demonstration of continued competency specified by the ABCC. Individuals with certifications in either Toxicological Chemistry or Molecular Diagnostics from the American Board of Clinical Chemistry can be considered for Program Directorships, but must be reviewed by ComACC to assure they are actively participating in and have sufficient experience in general clinical chemistry service, education and research.
- **c.** Program Directors seeking first-time accreditation are encouraged to seek input and mentorship from established programs. Directors of existing programs are expected to provide expertise and guidance as demonstration of their commitment to training.

2. TEACHING FACULTY

- **a.** Faculty affiliated with a training program must devote sufficient time to the educational program to fulfill their defined teaching responsibilities. They must have current certification in the specialty they teach and have an appropriate medical/faculty staff appointment. Faculty must participate in teaching trainees, supervising clinical learning experiences and research, evaluating trainee achievement, and evaluating program effectiveness. Non-doctoral staff may assist with instruction of operational tasks, but should not substitute for faculty. Ideally, there will be additional ABCC-certified faculty to provide expertise and assist with the training in basic clinical chemistry topics. Chemistry faculty members are encouraged to maintain Active Diplomate Status by meeting the requirements for demonstration of continued competency specified by the ABCC. Faculty members who are certified in other disciplines are encouraged to maintain certification in the discipline.

b. The ratio of postdoctoral trainees to full time clinical chemistry faculty should, as a general rule, not exceed three (3) trainees to one (1) faculty.

B. STANDARD II. INSTITUTIONAL SUPPORT

The parent institution of an accredited educational program in clinical chemistry shall provide adequate space as well as administrative and logistical support to facilitate the effective, efficient operation of the training activity.

In programs where education is provided in two or more institutions, responsibilities of the sponsoring institution(s) and each affiliate for program administration, instruction and supervision must be documented and signed by both parties. There must be a regular review and renewal process for the agreement, no less frequently than the accreditation cycle. The Program Director must assume overall responsibility for all training not at the sponsoring institution.

GUIDELINES

1. SALARY/BENEFITS

It is recommended that a postdoctoral trainee have the same salary and benefits as that provided for a first year resident in laboratory medicine (clinical pathology). The precise title of the trainee may vary from institution to institution. Whatever the title, training should be the primary activity of all fellows.

2. LABORATORY FACILITIES

- **a.** It is essential that training in clinical chemistry be conducted and associated with a broad based clinical laboratory, with rotations in many specialty areas such as general clinical chemistry, endocrinology, toxicology, therapeutic drug monitoring, nutrition, serology and immunology, biochemical urinalysis, pharmacogenomics, some hematology/coagulation, and molecular diagnostics being available to the trainees where possible.
- **b.** It is highly recommended that postdoctoral trainees have the opportunity to rotate at institutions with special patient populations such as pediatric hospitals, veterans' administration medical centers and/or forensic laboratories and/or other educational modalities. If rotations are not feasible, didactic lectures or other educational modalities may be used to simulate these activities.
- **c.** Any clinical chemistry laboratory used for training shall meet the requirements for local, state or Federal licensure or, where no such requirements exist, be approved by an organization acceptable to the Commission (such as the College of American Pathologists, The Joint Commission, or the Center for Medicare and Medicaid Services). Exceptions to this rule may be made on the basis of the Commission's own findings at the time of a site visit by an inspection team.

3. LIBRARY

Training institutions must have library and/or other services that provide an adequate, readily available basic collection of reference books as well as books in the sciences fundamental to clinical chemistry, pathology, and laboratory medicine. In addition, the library should provide access to a wide range of on-line medical/biochemical journals in the fields of clinical chemistry.

4. COMPUTER SERVICES

The institution will provide the trainee with full access to a personal computer and on-line services. Postdoctoral trainees must have an electronic mail address and access to Medline/PubMed or similar on-line literature search function. It is essential that all trainees have access to any additional computer systems necessary for training and patient care, such as the LIS (Laboratory Information System) and EMR (Electronic Medical Record) and can demonstrate their proficiency for the Commission upon request.

5. RECORDS

The institution shall maintain, and have available for inspection by the Commission upon request, the records of faculty and trainees' curriculum offerings, program activities, trainee attendance, and evaluation documents. The records should be prepared in a manner consistent with Federal right to privacy legislation. Records should include, but are not limited to:

- **a.** Recruitment/selection documentation
- **b.** Rotation/course schedules and activity logs
- **c.** Documentation for clinical consultation i.e., on-call experience
- **d.** Trainee performance evaluations by faculty
- **e.** Program and faculty evaluations by trainees
- **f.** Trainee scholarly performance (publications, abstract, presentations), which may be part of CV's provided.
- **g.** List of past trainees, including certification status and current position

C. STANDARD III. CURRICULUM AND INSTRUCTION

The curriculum and instruction, both didactic and clinical, of an accredited training program in clinical chemistry shall demonstrate a pursuit toward excellence and the achievement of preset educational objectives. The curriculum and instruction shall demonstrate, but not be restricted to, compliance with minimum requirements defined by the Commission.

1. PROGRAM OBJECTIVES

The curriculum and instruction, both didactic and clinical, of an accredited training program in clinical chemistry shall demonstrate a pursuit toward excellence and the achievement of preset educational objectives. The curriculum and instruction shall demonstrate, but not be restricted to, compliance with minimum requirements defined by the Commission.

- **a.** A trained clinical chemist should be able to demonstrate competency in directing clinical services and proficiency for initiating independent (or collaborative) research projects.
- **b.** A trained clinical chemist must be able to teach others (residents, graduate students, medical students, medical technologists, etc).
- **c.** A trained clinical chemist should have administrative skills. Most training programs devote part of the program to supervised managerial training, in which a trainee will assume the graduated responsibilities of the laboratory director for a defined period of time (at least 6 months total) with documented goals and objectives.
- **d.** Competency in the following areas is the goal:
    1. A clinical chemist must serve effectively as a consultant to physicians in the interpretation of reported laboratory values and in the relationship of biochemical and genetic findings of disease. He/she should have a cordial relationship with the medical staff.

2. A clinical chemist should be familiar and up to date with the newest tests, disease markers and technologies in the field of clinical chemistry. A clinical chemist should be a source of information in his/her field and educate his/her colleagues about the most recent findings in clinical chemistry by speaking at Grand Rounds, staff meetings, etc. The latter approach can result in an excellent collegial relationship between the laboratory and the medical staff.
3. A clinical chemist must be thoroughly grounded in the theory, operation, and maintenance of instrumentation, methodology, and the quality control measures applicable to the modern clinical laboratory.
4. As an administrator, a clinical chemist must be a reasonably competent manager of people, and have a working knowledge of capital equipment, budgetary resources, the ethics of medicine and science. As the training proceeds, the postdoctoral trainee should be given increasing responsibility for management and supervisory duties with opportunity and responsibility for decision-making increasing as the trainee's proficiency increases.

2. ADMISSION

Postdoctoral trainees in clinical chemistry must hold an earned PhD in a chemical, physical, biological or clinical laboratory science or a MD, DO, DPM or DMD degree from an appropriately accredited university or college. Sufficient courses in chemistry, biochemistry or other acceptable subjects should have been completed to qualify the student for certification eligibility with the American Board of Clinical Chemistry prior to admission into the training program. Students who feel that additional course-work would be of benefit (human physiology, molecular diagnostics, etc.) should be offered the opportunity while in training. Trainee selection should conform to institutional requirements for equal employment opportunity and be based solely on qualifications related to successful completion of the training program.

3. CURRICULUM

Postdoctoral training should be sufficient to allow the trainee to assume immediate responsibility for the clinical chemistry laboratory in a medium sized hospital or to direct a laboratory subject to regulations (local, state, or federal). Specifically:

- The postdoctoral trainee must acquire a competency for independent decision-making and assume a responsible role in providing the most accurate laboratory results and interpretation to his/her medical colleagues. This should include the responsibility of handling calls from technical and medical staff during the training period with appropriate graded responsibilities and oversight.
- The postdoctoral training period must be a minimum of two years in duration. This time usually is required to teach trainees the fundamentals of clinical chemistry, pathophysiology of human diseases, biostatistics, quality assessment, and principles of instrumentation, as well as to provide sufficient exposure to the management and supervisory aspects of a broad based clinical chemistry laboratory.
- Training will consist of didactic and hands on laboratory teaching, supervised decision making responsibilities, design of clinically oriented research projects and development of presentation skills.

GUIDELINES

1. The specific content of the training program curriculum is left largely up to the Program Director and Teaching Faculty. However, the curriculum for an effective training of

clinical chemists should provide the necessary education, training, and practice (where feasible) in the essential areas of clinical chemistry and laboratory practice that are outlined in Appendices I through IV. It is recognized that not all programs will be able to provide hands-on training in all areas. The use of off-site rotations and visits to specialty organizations is an effective way to provide additional training, but is not required.

2. Additional guidance for development of a training program curriculum may be found on the ComACC web-site and include recommendations for assessment of competencies in clinical pathology based on the six areas of competency defined by the Accreditation Council for Graduate Medical Education (ACGME) – patient care, medical knowledge, practice-based learning and improvement, interpersonal and communication skills, professionalism, and systems-based practice.
3. Trainee experiences must be educational and balanced so that all competencies can be achieved. Trainees are expected to be students first with priority in the allotment of trainee time and energy given to the didactic and clinical education of the trainee. The learning objectives of the program must not be compromised by reliance on trainees to fulfill service obligations.
    - Moonlighting within or outside of the institution must be clearly separated from the training program experiences and not interfere with the ability of the trainee to achieve the goals and objectives of the program. If moonlighting or performance of billable clinical activities is allowed during the training period, there must be a defined policy outlining the scope of such activities.
    - Any program wishing to enroll Fellows part-time or in a research track must develop detailed policies and procedures to assure that the trainee receives the same level of training as those who are full time. These policies must demonstrate how the modules, rotations, on-call activities and other trainee experiences are measured and found to be equal to full-time clinical fellows.

STANDARD IV. PROGRAM EVALUATION

There must be an assessment process for continually and systematically reviewing the effectiveness of the program.

GUIDELINES

1. The program should define a series of outcome measures from the last four active years. The data must be documented, analyzed, and used in the program evaluation.
2. Examples of outcome measures include publications by trainees, practice certification examinations, certification examination results (ABCC or others), and/or surveys of graduates, their current employers, or staff who interact with the trainees or graduates.

STANDARD V. MAINTAINING ACCREDITATION

Programs are required to comply with administrative requirements for maintaining accreditation including:

1. Submission of the self-study report or any required progress reports as determined by ComACC.
2. Payment of accreditation fees as determined by ComACC.
3. Notification of changes to administrative and operational information provided to ComACC within 60 days. Information includes program director(s), mailing addresses, email, phone numbers, clinical affiliates indicated at the last inspection, or institutional names.

4. Submission of all reports and responses requested by ComACC within established deadlines. Failure after 30 days to meet any deadline will result in a suspension of accreditation for 30 days followed by revocation of accreditation status if no response is received within that time period. Notification will be sent to ABCC and NRCC of revocation. After revocation, the program will be required to apply as a new program for accreditation by ComACC.

APPENDICES

APPENDIX I. FUNDAMENTAL CONCEPTS AND PROCEDURES

LABORATORY MANAGEMENT, ORGANIZATION AND OPERATION

- Principles of leadership and organization
- Laboratory facilities and design
- Centralized versus Point-of-Care Testing
- Laboratory test ordering and reporting systems
- Medico-legal requirements (confidentiality, record keeping)
- Accreditation requirements
- Workload reporting and cost accounting
- Billing and reimbursement concepts and issues
- Preparation and maintenance of proper laboratory manuals
- Quality management, including day to day quality control and quality assurance and long-term quality improvement.
- Informatics (EMR, HIS, LIS)

LABORATORY SAFETY

- Fire, chemical, radiation and infection control
- Waste disposal regulations
- Blood and body fluid precautions
- Applicable OSHA/JCAHO regulations and requirements
- Material Safety Data Sheets (MSDS) interpretation
- Any other laboratory or institutional safety practices and policies in effect (e.g., ergonomics)

BASIC STATISTICS

- Descriptive statistical measures, e.g., mean, median, mode and standard deviation
- Comparative statistics, e.g., confidence limits, t-test, F-test, analysis of variance, Chi-square, linear and other regression and difference plots
- Concepts of parametric and non-parametric statistics

APPENDIX II. PRINCIPLES OF ANALYSIS AND TECHNIQUES USED IN CLINICAL CHEMISTRY

SPECIMEN COLLECTION AND PROCESSING

- Specimen collection, identification, transport, delivery, preparation and preservation
- Patient preparation for tests
- Special collection requirements, e.g., neonates

- Anticoagulants, preservatives and gel separators
- Regulations and precautions regarding transport of biological specimens
- Pre-analytical errors
- Special considerations for specimens other than blood (urine, CSF, body fluids)

PRINCIPLES OF ANALYSIS

- Solute/solvent concepts and calculations
- Units of measurement – Conventional, SI, and unit conversions
- Basic laboratory techniques, e.g., pipetting, weighing, filtering, centrifugation
- Fundamental analytic concepts such as spectrophotometry and other optical techniques, electrochemistry, electrophoresis, chromatography, mass spectrometry, enzymology, immunochemistry, radioimmunoassay, etc.
- Chemicals, water, primary and secondary standards; reference materials (International reference materials) and reference methods
- Internal and external quality control concepts and procedures
    - Control charts (e.g. Levey-Jennings)
    - QC rules (e.g. Westgard)
    - Moving averages
- Proficiency testing – external, internal
- Principles of new method introduction:
    - Principles of analytic error assessment
    - Assessment of accuracy, precision, interferences, sensitivity and limits of detection, method bias, total allowable error, etc.)
    - To include including regulatory requirements for introduction of a new method (FDA-approved, and laboratory developed tests (LDTs), and analyte specific reagents (ASRs)
- Principles of instrumentation and automation and strategies to select appropriate instruments

TECHNIQUES USED IN CLINICAL CHEMISTRY

- General Techniques: Volumetric techniques, weighing, filtration, liquid-liquid and solid-phase extractions, partition coefficients; selection and preparation of buffers; freeze drying; dialysis; concentration, desalting, ultra-filtration; preparation of derivatives; calibration techniques
- Spectrophotometric Techniques: Molar absorptivity, reflectance, absorbance, transmittance, fluorometry, fluorescence polarization, bioluminescence, chemiluminescence, electroluminescence, nephelometry and turbidimetry
- Electrochemistry: Potentiometry, ion-selective electrodes, voltammetry and amperometry, conductometry, coulometry and biosensors
- Electrophoresis: Conventional, capillary, microchip, polyacrylamide, capillary zone, isotachophoresis, isoelectric focusing, immunofixation, two dimensional (2D)
- Chromatography: Planar vs. column, gas vs. liquid, adsorption, affinity, ion-exchange, partition and size-exclusion techniques, direct and reverse phase liquid chromatography, highperformance liquid chromatography, solid phase extraction techniques, gas chromatography
- Mass spectrometry: GC-MS, LC-MS, LC-MS-MS, MALDI-TOF, SELDI, ICP-MS
- Clinical Enzymology: Enzyme kinetics, enzymes as reagents, coupled enzymatic reactions, zero-order (enzyme) assays, first-order (substrate) assays
- Immunoassay techniques: Preparation, assessment and storage of antisera, methods of assessing analytical sensitivity and specificity, standardization issues, isotopic and non-

isotopic, liquid or solid-phase, competitive, non-competitive or immunometric, specific techniques (radioreceptor, immunodiffusion, immunoelectrophoresis, immunoblotting and immunofixation, enzyme-linked immunoassays, nephelometric, turbidimetric, chemiluminescent and fluorometric immunoassays

- Isotope Techniques: Physical principles and types of radioactive isotopes, counting techniques and their statistical evaluation, half-life and specific activity concepts and calculations, units of radioactivity, radioimmunoassay techniques, radiation safety and legal requirements for storage and disposal
- Molecular Diagnostics: Principles and methods of DNA and RNA isolation, purification, polymerase chain reaction (PCR); DNA probes (radioactive and non-radioactive labels), hybridization, restriction fragment length polymorphism (RFLP), blotting techniques, DNA chips/microarrays, sequencing, Real Time PCR, fluorescent in situ Hybridization (FISH), other methods of genomic analysis
- Proteomics and Protein Arrays: Qualitative and quantitative methods for proteome characterization such as 2-D gel electrophoresis, SELDI-TOF MS, MALDI-TOF MS, protein profiling, fluorescence resonance energy transfer (FRET), and surface plasmon resonance (SPR)

APPENDIX III. INSTRUMENTATION IN CLINICAL CHEMISTRY

The following are examples of the array of instruments often found in a clinical laboratory and with which the trainee should be familiar. For those programs not possessing a broad array of instrumentation, trainees are nevertheless expected to develop an understanding of the principles and potential uses for the instruments listed below. In addition, program directors should provide opportunities for trainees to visit other laboratories in order to broaden their instrumentation/automation exposure and experience.

- Amino-acid analyzer
- Atomic absorption spectrophotometers
- Automated and semi-automated analyzers for general chemistry, automatic sampling and pipetting devices, immunologic techniques, chemiluminescence, fluorescence polarization; random access and batch analyzers; reagent cassette and thin film analyzers
- Blood gas apparatus and co-oximeters
- Capillary zone electrophoresis and immuno-fixation electrophoresis
- Electrophoresis and densitometer equipment
- Flow cytometers
- Fluorometers
- Gas chromatographs with FID, NPD and mass detection
- General laboratory equipment such as centrifuges, dry and water baths, balances, microscopes, pH meters, shakers, thermometers, vortex mixers, etc.
- High performance liquid chromatographs and associated detection systems
- Infrared spectrophotometers
- Ion specific electrodes (electrolyte measurement and other applications
- Isoelectric focusing
- Laboratory automation (front-end, track systems, back-end/storage and retrieval)
- Liquid scintillation and gamma counters
- Mass spectrometers (quadrupole and tandem)
- Nuclear magnetic resonance
- Osmometers
- Polymerase chain reaction cyclers and other amplification instruments
- Refractometers
- Small instruments for satellite and point-of-care testing

- Spectrophotometers, reflectometers and nephelometers
- Tonometers
- Ultracentrifuge
- Water purification systems, stills, de-ionizers, reverse osmosis units

APPENDIX IV. PRINCIPLES OF LABORATORY MEDICINE RELATIONSHIP OF THE LABORATORY TO MEDICAL PRACTICE

- Understand the roles (screening, diagnosis, monitoring) and limitations for laboratory testing in clinical practice
- Understand the structure, use and limitations of the medical record (paper or electronic); develop proficiency in extracting and interpreting laboratory and medical information
- Be able to design studies and appropriately analyze and interpret data related to determination of diagnostic performance:
    - Design and performance of outcome studies
    - Sensitivity, specificity, predictive value, odds ratio, hazard ratios, and ROC studies
    - Economic evaluation of diagnostic testing and application of principles of evidence-based laboratory medicine
- Understand the principles and application of evidence-based laboratory medicine in test implementation and patient evaluation
- Implementation of appropriate test utilization practices

INTERPRETATION OF LABORATORY TEST RESULTS

- Understand the establishment and appropriate use of reference ranges and critical values
- Understand the sources and effects of analytic variables on laboratory tests
- Understand the sources and effects of physiological variables (diurnal and individual variations, rest, exercise, age, gender, fasting and the pharmacologic effects) on test results
- Understand the effects of disease on test results and recognize typical disease patterns
- Recognize the use and limitations of current disease-related testing strategies/algorithms, e.g., use of cardiac markers for AMI and ACS, lipid screening, for CHD, diabetes screening, PSA screening, etc.
- Develop and demonstrate (via activity logs) application of the above skills through liaison and consultative interaction with medical staff and other laboratory professionals; participate in service rounds, autopsy reports and related seminars and case reports
- Understand the principles of screening, confirmatory and reflex testing

CLINICAL PATHOLOGY AND LABORATORY EVALUATION OF DISEASE

Understand basic human biochemistry and physiology, specific biochemical alterations and laboratory tests and testing strategies for the following:

1. **Cardiovascular and related diseases**
    a. Biochemistry and physiology of normal circulatory function
    b. Pathophysiology, clinical features and recommended laboratory tests for diagnosis and management of acute myocardial infarction, acute coronary syndromes and congestive heart failure
    c. Role of the laboratory in diagnosis and management of primary and secondary hypertension
2. **Endocrine disorders**

a. Biochemistry and physiology of endocrine hormones, including:
    i. Pituitary- hypothalamic
    ii. Adrenal
    iii. Thyroid
    iv. Parathyroid
    v. Pancreatic endocrine
    vi. Ovarian, placental and testicular hormones
b. Pathophysiology, clinical features and recommended laboratory tests for diagnosis and management of disorders of the above listed systems
c. The use of stimulation/suppression tests in the assessment of endocrine function

3. Gastro-intestinal and exocrine pancreatic disease

a. Biochemistry and physiology of GI metabolites and hormones, including:
    i. Pancreatic digestive enzymes
    ii. Hydrochloric acid and bicarbonate
    iii. Gastro-intestinal hormones
b. Pathophysiology, clinical features and recommended laboratory tests for diagnosis and management of gastro-intestinal and exocrine pancreatic disease, including:
    i. Malabsorption
    ii. Secretory disorders (neoplastic and non-neoplastic)
    iii. Immunologic disorders (e.g. celiac disease)
c. The use of stimulation/suppression tests in the assessment of gastric function/disease

4. Genetic diseases

a. Gene structure, mechanisms of damage and repair and phenotypic manifestations
b. Specific genetic defects, inheritance patterns and biochemical, cytogenetic, and molecular diagnostic approaches for genetic diseases
c. Recommended tests and newborn screening strategies for inherited disorders

5. Hematologic/coagulation disorders

a. Principles of blood homeostasis and morphology and function of cellular elements of blood
b. Pathophysiology, clinical features and recommended laboratory tests for diagnosis and management of hematologic diseases and disordered hemostasis with biochemical implications including:
    i. Hemolysis, hemoglobinopathies and thalassemias
    ii. Coagulopathies, primary and secondary causes
    iii. Porphyrias
    iv. Isoimmunization (Rh/ABO)
    v. Anemias and disordered iron metabolism
c. Interpretive skills for evaluation of electrophoretic and HPLC results for the diagnosis of hemoglobinopathies and thalassemias

6. Infectious Diseases

a. Principles of infectious diseases
b. Pathophysiology, clinical features, and recommended laboratory test for diagnosis and management of (per CDC and/or local guidelines):
    i. HIV
    ii. Hepatitis A
    iii. Hepatitis B
    iv. Hepatitis C
c. Interpretation of all results

7. Hepatobiliary diseases

a. Hepatic structure, physiology and biochemistry

b. Pathophysiology, clinical features and recommended laboratory tests for diagnosis and management of hepatobiliary diseases, including:
    i. Hepatocellular diseases
    ii. Cholestatic disorders
    iii. Immunologic and neoplastic liver diseases
    iv. Inherited disorders of bilirubin metabolism

8. Immune system disorders

a. Immunoglobulin production, structure and function
b. Principles of cellular and humoral immune reactions
c. Pathophysiology, clinical features and recommended laboratory tests for diagnosis and management of immunologic diseases/alterations in immune function, including:
    i. Immunoglobulin deficiency/overproduction (e.g. immune deficiency syndromes, monoclonal gammopathies, cryoglobulinemia)
    ii. Immunologic impact of transplantation
    iii. Autoimmune diseases
    iv. Allergy testing
d. Interpretive skills for evaluation of electrophoretic and immunofixation results in serum, urine and CSF for monoclonal and/or oligoclonal gammopathies.

9. Kidney and urinary tract diseases

a. Biochemistry and physiology of normal kidney function
b. Pathophysiology, clinical features and recommended laboratory tests for diagnosis and management of acute and chronic kidney diseases, including:
    i. Glomerular dysfunction
    ii. Renal tubular disease
    iii. Diseases of renal endocrine dysfunction
    iv. Diabetic nephropathy
c. The physiologic basis and limitations of various renal clearance tests and estimates of glomerular filtration rate

10. Lipid and lipoprotein disorders

a. Structure, synthesis and metabolism of the various lipoprotein classes
b. Pathophysiology, clinical features and recommended laboratory tests for diagnosis and management of primary and secondary lipid disorders
c. Pathophysiology and utility of various testing modalities (e.g., lipid panel, apolipoproteins, lipoprotein subfractions) for risk stratification and management of coronary heart disease

11. Mineral and bone disorders

a. Biochemistry of calcium, phosphorus and vitamin D metabolism and of bone formation/resorption
b. Pathophysiology, clinical features and recommended laboratory tests for diagnosis and management of primary and secondary bone diseases (e.g. osteoporosis, Paget's disease, lytic bone diseases)

12. Nutrition and protein disorders

a. Biochemistry of plasma proteins and amino acids
b. Pathophysiology, clinical features and recommended laboratory tests for diagnosis and management of:
    i. Dysproteinemias and dysproteinurias
    ii. Malnutrition
    iii. Genetic and acquired amino acid disorders
    iv. Vitamin deficiencies
c. Interpretive skills for evaluating plasma protein patterns from electrophoretic testing of serum and urine

13. Pregnancy and reproductive disorders

a. Biochemistry and physiology of normal pregnancy
b. Pathophysiology, clinical features and recommended laboratory tests for diagnosis and management of obstetrical complications and diseases of the prenatal and perinatal period
c. Recommended laboratory screening tests and testing strategies for prenatal diagnosis of inherited disease (e.g., trisomy 21)
d. Recommended laboratory tests and testing strategies for fetal lung maturation
e. Tests for risk of preterm labor and/or rupture of fetal membranes

14. Toxicology and clinical pharmacology

a. Classification of major classes of drugs and toxins and their biochemical/physiologic effects
b. Appropriate sample collection, laboratory test methods, testing sequence and interpretive guidelines for workup of suspected poisoning or toxic exposures by various classes of toxins
c. Understanding of pharmacokinetics and pharmacodynamics
d. Pharmacogenetics
e. Appropriate sample collection and timing, laboratory test methods, testing sequence and interpretive guidelines for therapeutic drug monitoring, work-place drug testing, and testing in support of pain management programs

15. Water, electrolyte and acid-base disorders

a. Basic intracellular and extracellular fluid and electrolyte homeostasis
b. Pathophysiology, clinical features and recommended laboratory tests for diagnosis and management of fluid and electrolyte disorders, including:
    i. Dehydration (e.g. fluid deprivation, diabetes insipidus)
    ii. Water excess (e.g., SIADH)
    iii. Hyper-/hyponatremia; hyper-/hypokalemia
    iv. Oncotic disorders (e.g., edema and ascites)
c. The physiologic basis, use and limitations of various fluids/electrolytes formulae (e.g., anion gap, osmolar gap, serum/urine electrolyte ratios) for detection and differentiation of various fluid and electrolyte abnormalities)

16. Pediatric Clinical Chemistry

a. Considerations and requirements for pediatric testing as related to:
    i. Sample collection requirements and limitations
    ii. Reference intervals
b. Pathophysiology, clinical features and recommended laboratory tests for diagnosis and management of diseases of childhood (e.g., respiratory distress syndrome, hyperbilirubinemia, neuroblastoma, congenital hypothyroidism)
c. Develop interpretive skills for evaluating urine/plasma amino acid and organic acid patterns characteristic of inherited pediatric metabolic disorders

17. Laboratory evaluation of neoplasia

a. Etiology and clinical manifestations of cancer
b. Recommended laboratory tests for screening, diagnosis, staging and management of specific human cancers, including:
    i. Biochemical markers
    ii. Biogenic amines
    iii. Oncofetal tumor markers
    iv. Enzymes
    v. Cellular markers
    vi. Genetic screening both for risk assessment and treatment modalities
c. Clinical performance and limitations of tumor markers