

## ComACC Guidelines/Checklist for Accreditation of Clinical Chemistry Training Programs

### Purpose

The Commission on Accreditation in Clinical Chemistry (ComACC) is an independent non-profit organization that accredits training programs in clinical chemistry at the masters, doctoral, and 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 with the progress in medicine and clinical laboratory sciences.

Standards and associated guidelines have been established that define the conditions under which these goals may reasonably be achieved at each level of training. These guidelines are provided for the benefit of institutions to help them to achieve a level of excellence in their educational efforts. The Commission expects the institution to have flexibility in developing programs of quality. It does however consider the program director to be a key to the success of any program and will strive to assure that excellence begins with the program leadership.

This document is intended as a guideline/checklist for program directors who provide the leadership in organizing local resources for training in clinical chemistry and to assist them in assuring that their programs meet the standards and requirements for accreditation by ComACC.

<b>Name of Training Program</b>	
<b>Director of Training Program</b>	
<b>Co-Director(s) of Training Program</b>	
<b>Year Program Created</b>	
<b>Type of Training Program</b>	
<b>What level of training does the Clinical Chemistry Training Program provide?</b>	
<input type="checkbox"/> Master's degree <input type="checkbox"/> Doctoral degree <input type="checkbox"/> Postdoctoral	
<b>Admission Requirements</b>	
<b>Are candidate's transcripts reviewed to ensure they meet the courses requirements to qualify to sit for the American Board of Clinical Chemistry (ABCC) Chemistry Examination?</b>	
<input type="checkbox"/> Yes <input type="checkbox"/> No	
<b>SI</b>	<b>FACULTY OF THE CLINICAL CHEMISTRY TRAINING PROGRAM:</b>
<i>Program Director</i>	
<b>Does the Training Program have a Director who is:</b>	
<input type="checkbox"/> A Diplomate of the American Board of Clinical Chemistry (DABCC)?	
<b>If the Program Director does not meet the requirements indicated above what is the program's plan to comply with these requirements by the year 2010?</b>	
<b>SII</b>	<b>INSTITUTIONAL SUPPORT</b>
<b>Does the parent institution of the Training Program in Clinical Chemistry provide adequate:</b>	
Space	

- Master's degree
- Doctoral degree
- Postdoctoral

- Yes
- No

- A Diplomate of the American Board of Clinical Chemistry (DABCC)?

Yes No

Administrative support

 Yes No

Logistical support

 Yes No***Salary/Fringe Benefits*****Does the postdoctoral trainee receive a salary equivalent to a 1<sup>st</sup>-year Pathology Resident? If not, please explain.** Yes No***Laboratory Facilities*****Does the Training Program provide broad-based training in Clinical Chemistry associated with rotations in:** General chemistry Endocrinology Toxicology Therapeutic drug monitoring (TDM) Nutrition Serology and immunology Urinalysis Pharmacogenomics Molecular diagnostics Other (*specify*): \_\_\_\_\_***Library*****Do trainees have access to a library and/or on-line services that provide an adequate, readily available basic collection of reference materials for the fields in which the Training Program provides training?** Yes No***Computer Services***

Does the institution/department sponsoring the Training Program provide trainees with full access to a personal computer, access to on-line services, including patient-specific data, and a personal e-mail address?

 Yes No***Records*****Can the Training Program provide documentation of:**

Trainee recruitment/selection documentation

 Yes No

Training rotation/course schedules and activity logs

 Yes No

Documentation of clinical consultation (e.g., on-call logs)

- Yes
- No

Trainee performance evaluations

- Yes
- No

Trainee evaluations of the Training Program/faculty

- Yes
- No

List of past trainees, including their certification status and current position

- Yes
- No

### **SIII CURRICULUM AND INSTRUCTION**

**Does the Training Program provide both didactic and practical training in each of the disciplines that constitute the Training Program?**

- Yes
- No

#### ***Program Objectives***

**Does the Training Program provide training sufficient for a trainee to demonstrate competency in:**

Directing clinical services

- Yes
- No

Initiating independent (or collaborative) research projects

- Yes
- No

Teaching residents, graduate students, medical students, medical technologists, etc.

- Yes
- No

Supervised laboratory management as an “Acting Director”

- Yes
- No

Interacting with clinical staff (e.g., physicians, nurses, other allied health professionals)

- Yes
- No

Supervised service as a consultant to physicians in the interpretation of laboratory data (e.g., laboratory test results, biochemical and genetic test findings) and in the recommendation/rationale for the most appropriate laboratory tests in support of a particular disease diagnosis

- Yes
- No

Assessing the laboratory and diagnostic value of the newest tests, disease markers, and technologies in the field of clinical chemistry

- Yes
- No

Discussing the aforementioned information as a presenter at Grand Rounds, staff meetings, Case Review and Call Notes Conferences, etc.

- Yes
- No

Understanding the theory, operation and maintenance of instrumentation, test methodologies, and quality assurance (QA) and quality control (QC) practices

- Yes
- No

Understanding the skills required to be a competent manager of people and resources (e.g., capital equipment and budget)

- Yes
- No

Understanding the ethics of medicine and science

- Yes
- No

**Does the Training Program provide the opportunity for increased administrative, managerial, and supervisory responsibilities?**

- Yes
- No

**Does the Training Program provide the opportunity for training in the essential areas of clinical chemistry and laboratory practice indicated in the attached Appendices A through D?**

- Yes
- No

**APPENDIX A: 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

**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

**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, difference plots, linear and other regression techniques
- Concepts of parametric and non-parametric statistics

**APPENDIX B: 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

**Principles of Analysis**

- Solute and 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,
- Chemicals, water, primary and secondary standards; reference materials (International reference materials) and reference methods
- Internal and external quality control concepts and procedures
- Proficiency testing – external, internal
- Principles of analytic error assessment, evaluation of methods, and method validation (assessment of accuracy, precision, interferences, sensitivity and limits of detection, method bias, total allowable error, etc.)
- Point-of-care testing (POCT) concepts
- Point-of-surgery testing (POST) concepts
- Principles of instrumentation and automation and strategies to select appropriate instruments (*See Appendix C*)

**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
- Turbidimetry

### **Electrochemistry**

- Potentiometry
- Ion-selective electrodes
- Voltammetry and amperometry
- Conductometry
- Coulometry
- 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
- High-performance 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

- Immunometric
- Radioreceptor
- Immunodiffusion
- Immuno-electrophoresis
- Immunoblotting
- Immunofixation
- Enzyme-linked immunosorbent
- Nephelometric
- Turbidimetric
- Fluorometric

### **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 and purification
- Polymerase chain reaction (PCR)
- DNA probes (radioactive and non-radioactive labels)
- Hybridization
- Restriction fragment length polymorphism (RFLP)
- Blotting techniques
- DNA chips
- Fluorescence in situ hybridization (FISH)
- Proteomics
- Protein arrays
- Methods of genomic analysis, including DNA/RNA, protein, and antibody microarrays

**APPENDIX C: 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 ana-
- 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
- Liquid scintillation and gamma counters
- Mass spectrometers (quadrupole and tandem)
- Nuclear magnetic resonance
- Osmometers
- Polymerase chain reaction cyclers and other amplification instruments
- Refractometer.
- Small instruments for satellite and point-of-care testing
- Spectrophotometers, reflectometers and nephelometers
- Tonometer
- Ultracentrifuge
- Water purification systems (stills, de-ionizers, reverse osmosis units)
- Laboratory automation. Trainees should understand the principles of front-, back-end, and full-automation. They should be familiar with advantages and shortcomings associated with automation and be able to assess the appropriateness and feasibility of adapting automation for a given laboratory

## APPENDIX D: 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, and ROC studies
- Economic evaluation of diagnostic testing and application of principles of evidence-based medicine

### Interpretation Of Laboratory Test Results

- 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

### 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:

- Cardiovascular and related diseases
- Biochemistry and physiology of normal circulatory function
- Pathophysiology, clinical features and recommended laboratory tests for diagnosis and management of acute myocardial infarction, acute coronary syndromes and congestive heart failure
- Role of the laboratory in diagnosis and management of primary and secondary hypertension

### Endocrine Disorders

Biochemistry and physiology of endocrine hormones, including:

- Pituitary-hypothalamus
- Adrenal
- Thyroid
- Parathyroid

- Pancreatic endocrine
- Ovarian, placental and testicular hormones
- Pathophysiology, clinical features and recommended laboratory tests for diagnosis and management of disorders of the above listed systems
- The use of stimulation/suppression tests in the assessment of endocrine function

### **Gastro-Intestinal And Exocrine Pancreatic Disease**

Biochemistry and physiology of GI metabolites and hormones, including:

- Pancreatic digestive enzymes
- Hydrochloric acid and bicarbonate
- Gastro-intestinal hormones

Pathophysiology, clinical features and recommended laboratory tests for diagnosis and management of gastro-intestinal and exocrine pancreatic disease, including:

- Malabsorption
- Secretory disorders (neoplastic and non-neoplastic)
- Immunologic disorders (e.g. celiac disease)
- The use of stimulation/suppression tests in the assessment of gastric function/disease

### **Genetic Diseases**

- Gene structure, mechanisms of damage and repair, and phenotypic manifestations
- Specific gene derangements, inheritance patterns and biochemical and molecular diagnostic approaches for genetic diseases
- Recommended tests and newborn screening strategies for inherited disorders

### **Hematologic/Coagulation Disorders**

- Principles of blood homeostasis and morphology and function of cellular elements of blood

Pathophysiology, clinical features and recommended laboratory tests for diagnosis and management of hematologic diseases and disordered hemostasis with biochemical implications including:

- Hemolysis, hemoglobinopathies and thalassemias
- Coagulopathies, primary and secondary causes
- Porphyrrias
- Isoimmunization (Rh/ABO)
- Anemias and disordered iron metabolism

### **Hepatobiliary Diseases**

- Hepatic structure, physiology and biochemistry

Pathophysiology, clinical features and recommended laboratory tests for diagnosis and management of hepatobiliary diseases, including:

- Hepatocellular diseases
- Cholestatic disorders

- Immunologic and neoplastic liver diseases

### **Immune System Disorders**

- Immunoglobulin production, structure and function
- Principles of cellular and humoral immune reactions

Pathophysiology, clinical features and recommended laboratory tests for diagnosis and management of immunologic diseases/alterations in immune function, including:

- Immunoglobulin deficiency/overproduction (e.g. immune deficiency syndromes, monoclonal gammopathies, cryoglobulinemia)
- Immunologic impact of transplantation
- Autoimmune diseases
- Allergy testing
- Interpretive skills for evaluation of electrophoretic and immunofixation results in serum, urine and CSF for monoclonal and/or oligoclonal gammopathies

### **Kidney And Urinary Tract Diseases**

- Biochemistry and physiology of normal kidney function

Pathophysiology, clinical features and recommended laboratory tests for diagnosis and management of acute and chronic kidney diseases, including:

- Glomerular dysfunction
- Renal tubular disease
- Diseases of renal endocrine dysfunction
- Diabetic nephropathy
- The physiologic basis and limitations of various renal clearance tests and estimates of glomerular filtration rate (GFR)

### **Lipid And Lipoprotein Disorders**

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

### **Mineral And Bone Disorders**

- Biochemistry of calcium, phosphorus and vitamin D metabolism and of bone formation/resorption
- 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)

### **Nutrition And Protein Disorders**

- Biochemistry of plasma proteins and amino acids

Pathophysiology, clinical features and recommended laboratory tests for diagnosis and management of:

- Dysproteinemias and dysproteinurias

- Malnutrition
- Genetic and acquired amino acid disorders
- Interpretive skills for evaluating plasma protein patterns from electrophoretic testing of serum and urine

### **Pregnancy And Reproductive Disorders**

- Biochemistry and physiology of normal pregnancy
- Pathophysiology, clinical features and recommended laboratory tests for diagnosis and management of obstetrical complications and diseases of the prenatal and perinatal period
- Recommended laboratory screening tests and testing strategies for prenatal diagnosis of inherited disease (e.g., trisomy 21)
- Recommended laboratory tests and testing strategies for fetal lung maturation

### **Toxicology And Clinical Pharmacology**

- Classification of major classes of drugs and toxins and their biochemical/physiologic effects
- Appropriate sample collection, laboratory test methods, testing sequence and interpretive guidelines for workup of suspected poisoning or toxic exposures by various classes of toxins
- Understanding of pharmacokinetics and pharmacogenetics
- Appropriate sample collection and timing, laboratory test methods, testing sequence and interpretive guidelines for therapeutic drug monitoring

### **Water, Electrolyte And Acid-Base Disorders**

- Basic intracellular and extracellular fluid and electrolyte homeostasis
- Pathophysiology, clinical features and recommended laboratory tests for diagnosis and management of fluid and electrolyte disorders, including:
- Dehydration (e.g. fluid deprivation, diabetes insipidus)
  - Water excess (e.g., SIADH)
  - Hyper-/hyponatremia; hyper-/hypokalemia
  - Oncotic disorders (e.g., edema and ascites)
  - 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)

### **Pediatric Clinical Chemistry**

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

### **Laboratory Evaluation Of Neoplasia**

- Etiology and clinical manifestations of cancer

Recommended laboratory tests for screening, diagnosis, staging and management of specific human cancers, including:

- Biochemical markers
- Biogenic amines
- Oncofetal tumor markers
- Enzymes
- Cellular markers
- Genetic screening
- Clinical performance and limitations of tumor markers

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