2025

Canadian Clinical Biochemistry Syllabus

Contents

Preamble

This syllabus is intended as a guide for those training to become Clinical Biochemists and those involved in training Clinical Biochemists. Clinical biochemistry requires the acquisition, synthesis and application of domain-specific knowledge. The inclusion of Tasks, Competencies and Knowledge Blocks in the syllabus is designed to emphasize the need for knowledge acquisition, synthesis of information and application of concepts.

Tasks, Duties and Activities

The syllabus first compiles examples of tasks, duties and activities performed by practicing Clinical Biochemists. These provide the rationale and context for the subject matter included in the syllabus and allows syllabus users to more readily see how the knowledge outlined in the syllabus is applied in the profession (Figure 1). Similarly, these tasks were used to help focus the content of the syllabus and ensure that content and competencies outlined in the syllabus are relevant to the day-to-day practice of a Clinical Biochemist.

Competencies

Competencies describe the knowledge, skills and behaviors that a trainee needs to *acquire* and *demonstrate* to be able to work independently, safely and successfully as a Clinical Biochemist. Knowledge is information developed or learned through experience, study or investigation. Skill is the result of repeatedly applying knowledge. Behavior is the response of the individual to a situation. Competency statements are used in conjunction with knowledge blocks to clarify the depth of knowledge, skills and behaviours required for subject matter enumerated in the knowledge block.

Competency statements have been organized into groups (Types 1, 2 and 3) to indicate the competency level expected of practicing Clinical Biochemists for the associated subject matter.

- Type 1 subject matter is fundamental to any practicing Clinical Biochemist and therefore has the more complex and advanced competency expectations
- Type 2 contains more specialized subject matter that while necessary, does not required the same depth of knowledge as Type 1
- Type 3 contains more esoteric knowledge that is nevertheless relevant to a practicing Clinical Biochemist

Knowledge Blocks

Clinical Biochemistry requires the ability to synthesize knowledge from many relevant domains to solve problems and support patient care. The syllabus subject matter has been grouped into five general themes: Clinical, Analytical and Pre-Analytical, Post-Analytical and Professionalism. Within these groups, subject matter has been further divided into related blocks of knowledge. Each knowledge block is structured into rows and columns. The type of knowledge is grouped by row, for example a clinical knowledge block will include rows for concepts, conditions and biomarkers. The knowledge block will also include column headers Type 1, Type 3 and Type 3. Subject matter is grouped by column to indicate which set of competencies are expected for the subject matter in that column. Each cell of the knowledge block contains subject matter of a similar type and requires a similar level of competency. Subject matter is listed as short terms or phrases, that must be paired with associated competency statements, to guide users as to the depth and breadth of knowledge required in that subject. In some cases, examples are included to help clarify the subject. Examples take the form of lists “(e.g one, two, three)” . These lists are for clarity only and are not intended to be exhaustive.

Knowledge Synthesis

Subject matter in different knowledge blocks naturally needs to be combined to function as a Clinical Biochemist (Figure 1). Similarly, when using the syllabus to guide study or design curriculum, it is expected that subject matter from different themes will be combined to facilitate learning. For example, when learning about biomarkers used to diagnose a specific clinical condition, exploration of applicable analytical methods, clinical guidelines and special patient populations needing the testing (knowledge blocks in other themes) would support more complex learning.

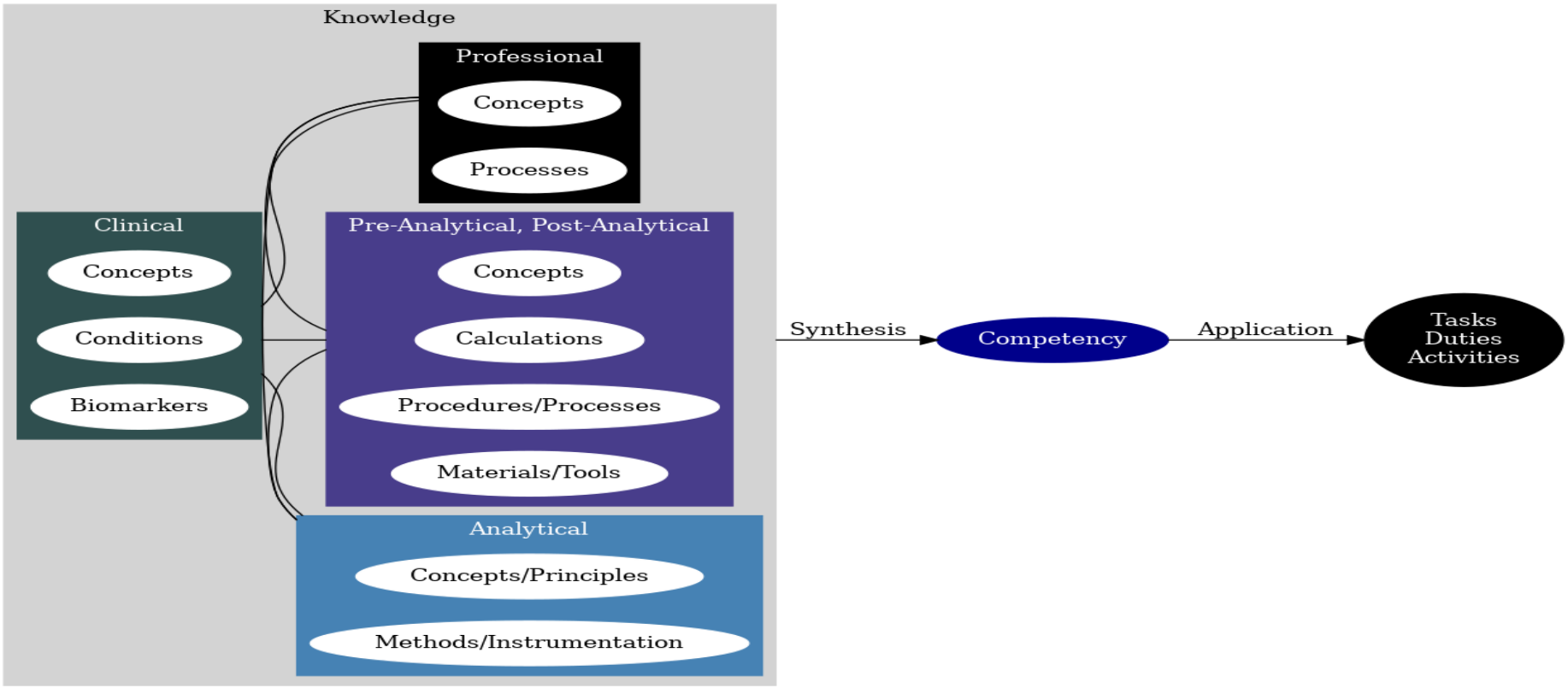

Figure 1. The relationship between knowledge, competencies and the tasks, duties and activities of a Clinical Biochemist.

Tasks, Duties and Activities

The following are examples of daily responsibilities of a Clinical Biochemist, which provide the rationale for the themes and subject matter contained within the syllabus:

- Communicate laboratory results and their meaning.
  - Explain the relationship between a given result and the clinical condition/pathophysiology of the patient
  - Review a patient's chart and/or medical history to identify information that is salient to interpreting a given test result
  - Ensure laboratory reports and other methods of conveying lab results support correct interpretation of results.
  - Effectively provide consultation and advice on follow-up investigations to health care providers and laboratory professionals based on specific laboratory test results.
  - Identify and explain factors that can impact test results and how these can be mitigated or taken into consideration when interpreting results

- Ensure the laboratory is producing accurate, timely and clinically meaningful test results.
  - Verify or validate methods to ensure they are suitable for clinical use.
  - Develop, maintain and evaluate the efficacy of quality management systems.
  - Create, monitor and improve quality control plans for laboratory assays
  - Evaluate proficiency testing results
  - Determine and describe the clinical performance of a specific lab test
  - Provide leadership as a clinical biochemist and subject matter expert in quality management in the lab
  - Summarize the purpose and general process of laboratory accreditation
  - Review and propose appropriate follow-up of non-conforming events and safety events.
  - Develop and monitor key performance indicators in the laboratory

- Investigate causes of discrepant laboratory test results.
  - For a given analyte, outline and explain the analytical mechanisms of common erroneous lab results.
  - Identify and explain patient-specific causes of erroneous test results.
  - Advise on how to mitigate sources of erroneous results for a specific patient situation.

- Advocate for responsible use of laboratory and other health resources and finances.
  - Recommend appropriate test selection and testing frequency in a patient population
  - Describe process improvement tools and how they can be applied to improve laboratory processes.

    - Determine appropriate turnaround times for laboratory tests to meet the clinical needs and advise on different ways this can be achieved.
    - Support the process of budget planning, and funding justification and how they can be applied to improve laboratory processes.

- Evaluate, analyze and interpret laboratory related data.
    - Choose and use appropriate statistical analyses and data visualization methods for a given data set.
    - Determine appropriate follow-up experiments, investigations or actions that are needed based on the findings data analysis
    - Identify what type of data is needed for evaluation and monitoring of various key performance indicators and quality metrics,
    - Use computer software and data visualization tools to effectively analyze, interpret and present data
    - Establish or verify reference intervals
    - Verify fidelity of data communication between instruments, middleware, laboratory information systems and electronic medical records.

- Plan, execute and be responsible for projects in the laboratory.
    - Apply project management tools to plan and monitor a project's progress
    - Identify and collaborate with appropriate project stakeholders
    - Outline major steps of common types of laboratory projects
    - Specify project milestones and deliverables
    - Develop a change management plan and communication strategy

- Advocate for a safe, respectful, ethical and environmentally sustainable clinical laboratory practice.
    - Recognize and respond to situations where dignity, rights, equity and inclusion is not respected
    - Work in a manner that upholds privacy and confidentiality. Ensure that personal health information is collected, used, stored and shared in a way that protects the confidentiality of that information, and the privacy of individuals.
    - Recognize rights and responsibilities in regard to occupational health and wellness and environmental policy

- Educate laboratory staff, trainees and health care providers.
    - Provide education on topics related to lab medicine to several different audiences
    - Evaluate approaches for conveying information related to lab medicine to laboratory staff, administrators, health care providers and patients.
    - Employ innovative teaching methods to improve knowledge transfer and application

- Advance the field of laboratory medicine.
    - Share the findings of original research.
    - Participate in peer review of original research.
    - Translate the findings of original applied research into laboratory service.
    - Evaluate the quality of scientific evidence
    - Promote evidenced based lab medicine practices

- Apply analytical knowledge
    - Explain and compare analytical methods
    - Analyse analytical issues and design a plan to investigate the underlying cause
    - Lead and assess development of analytical methods

Section 1: Clinical

This section outlines concepts, conditions and biomarkers relevant to Clinical Biochemistry. The competency statements below are to be applied to each table detailed subsequently.

Clinical Competencies

For each **Type 1** concept, condition and biomarker achieve the following competencies:

- Describe and explain the causes and clinical signs and symptoms of the condition.
- Describe and explain the pathophysiology and biochemical changes associated with the condition.
- Recognize basic treatment modalities for the condition
- Apply recommendations from applicable clinical and laboratory guidelines.
- Recommend and justify biomarkers that are relevant for screening, diagnosis, or monitoring of the condition.
- Interpret biomarker results, including dynamic testing.
- Compare the utility of analytical methods available for biomarker measurement.
- Apply recommendations from relevant clinical practice guidelines
- Explain the associated concepts.

For each **Type 2** concept, condition and biomarker achieve the following competencies:

- Describe the causes and clinical signs and symptoms of the condition.
- Describe the pathophysiology and biochemical changes associated with the condition.
- Recommend and justify biomarkers that are relevant for screening, diagnosis, or monitoring of the condition.
- Interpret biomarker results.
- Compare the utility of analytical methods available for biomarker measurement.
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- Apply recommendations from relevant clinical practice guidelines.
- Explain the associated concepts.

For each **Type 3** concept, condition and biomarker achieve the following competencies:

- Evaluate evidence to recommend biomarkers that are relevant for screening, diagnosis, or monitoring of the disease or disorder.
- List the primary pathophysiology and primary biochemical changes associated with the condition.
- Explain the associated concepts.

Acid-base respiratory function

	Type 1	Type 2	Type 3
Concept	● Henderson-Hasselbach equation ● Control of respiration ○ Compensation for acidosis and alkalosis ● Hemoglobin dissociation curves ● Respiratory and metabolic mechanisms in regulation of acid-base balance ● Calculation of blood gas parameters	● Effect of pH, pO_2 and pCO_2	
Condition	● Metabolic acidosis and alkalosis ● Respiratory acidosis and alkalosis ● Carbon monoxide poisoning ● Renal Tubular acidosis ● Chronic obstructive pulmonary disease ● Congestive heart failure	● Cystic fibrosis ● Ventilatory disorders	● Alpha-1-antitrypsin deficiency ● Amyloidosis
Biomarker	● Blood gas measurements and calculations ● Co-oximetry measurements ● Ketones ● Lactate ● Anion gap ● Osmolar gap ● Osmolality ● Bicarbonate ● Base excess ● Oxygen saturation ● Partial pressure of oxygen and carbon dioxide	● Urine anion gap	● Alpha-1-antitrypsin ● Alpha-1-antitrypsin genotyping and phenotyping ● *CFTR* genotype ● Amyloid protein identification by mass spectrometry

Fluid and Electrolytes

	Type 1	Type 2
Concept	● Volume status ● Volume regulation and distribution ● Principles of correcting fluid losses ● Clinical assessment of extracellular fluid volume ● Osmolytes ● Osmotic, oncotic and hydrostatic pressure ● Anion gap ● Osmolal gap ● Respiratory and renal mechanisms in regulation of acid-base balance ● Compensatory mechanisms and compensation calculations	● Electrolyte transport ● Transudates and exudates ● Water deprivation test ● Body fluids ○ Cerebrospinal ○ Synovia ○ Pericardial ○ Peritoneal ○ Amniotic
Condition	● Hypo, hyper and pseudohypo natremia ● Hypo, hyper and pseudohyper kalemia ● Hypo, hyperchloremia ● Extracellular fluid volume loss ● Dehydration ● Metabolic acidosis and alkalosis ● Respiratory acidosis and alkalosis ● Edema	● Syndrome of inappropriate ADH ● Diabetes insipidus ● Cystic fibrosis ● Polydipsia
Biomarker	● Sodium ● Potassium ● Chloride ● Osmolality ● Bicarbonate ● Base excess ● Blood gases	● Sweat chloride ● ADH ● Copeptin ● Aldosterone ● Renin

Kidney and Urinary Tract

	Type 1	Type 2	Type 3
Concept	● Renal function ● Renal anatomy ● Renal physiology ● Estimated glomerular filtration rate ○ Calculations ● Proteinuria; glomerular permeability, tubular proteinuria ● Creatinine clearance ● Renin-angiotensin-aldosterone system	● Formation of renal calculi ● Renal replacement therapies (e.g. hemodialysis, peritoneal dialysis, kidney transplant) ● Diuretics mechanism of action ● Fractional excretion of electrolytes	
Condition	● Chronic kidney disease ● Acute kidney injury ● Renal tubular acidosis ● Uremia ● Glomerulonephritis ● Nephritic syndrome ● Nephrotic syndrome ● Microalbuminuria	● Hereditary renal tubular disorders	● Primary membranous nephropathy ● Amyloidosis
Biomarker	● Creatinine ● Urea ● Uric acid ● Urinalysis (chemical and microscopic) ● Osmolality ● Urine albumin creatinine ratio ● Urine protein creatinine ratio ● Urine microscopy ● Phosphate, calcium and magnesium	● Cystatin C ● B-2 microglobulin ● Renin ● Aldosterone ● Oxalic acid	● Anti-phospholipase A2 receptor antibodies ● Amyloid protein ● Renal calculi composition ● Citric acid ● Oxalic acid

Endocrine Disorders

	Type 1	Type 2	Type 3
Concept	● Hypothalamic-pituitary-adrenal (HPA) axis ● Adrenal hormone function ● Pituitary hormone function ● Stimulation and suppression testing of the HPA axis ● Thyroid hormone function ● Endocrine system physiology ● Reproductive hormone function ● Primary and secondary causes of endocrine disorders ● Circadian rhythm	● Tanner stage	● Adrenal vein sampling
Condition	● Cushing's disease and syndrome ● Addison's syndrome ● Adrenal insufficiency ● Hyper/hypo thyroidism ● Thyroiditis ● Thyrotoxicosis ● Hashimoto's thyroiditis ● Grave's disease	● Acromegaly/gigantism ● Growth hormone deficiency ● Primary and secondary Hyperaldosteronism ● Premature ovarian failure ● Infertility ● Hypogonadism ● Polycystic ovarian syndrome ● Hirsutism ● Congenital adrenal hyperplasia ● Pheochromocytoma ● Thyroid nodules and goiter ● Hyper/hypo prolactinemia	● Sheehan's syndrome

Biomarker	● LH ● FSH ● TSH ● Free T3 and T4 ● Cortisol	● Growth hormone ● Insulin-like growth factor 1 ● ACTH ● Aldosterone, renin and ratio ● Angiotensin converting enzyme ● Testosterone – total, free, bioavailable ● 17-hydroxyprogesterone ● Estradiol ● Androstenedione ● DHEAS ● SHBG ● Progesterone ● Total T3 and T4 ● Thyroglobulin ● Anti-thyroglobulin antibodies ● Anti-Thyroperoxidase antibodies ● Thyroid receptor antibodies ● Catecholamines ● Metanephrines ● Prolactin	● IGFBP-3 ● Anti-Müllerian hormone

Cardiovascular Disorders and Hypertension

	Type 1	Type 2	Type 3
Concept	● Atherosclerosis ● Universal definition of myocardial infarction ● Continuum of coronary syndromes ● Heart failure classification ● Cardiac risk assessment ● Characteristics of an ideal marker for myocardial infarction ● Pathophysiology of hypertension ● Pathophysiology of stroke	● Cardiac anatomy ● Coronary circulation ● ● Mechanism of cardiac contraction ● Renin-angiotensin-aldosterone system	● Percutaneous coronary intervention ● Coronary Artery Bypass Grafting ● Polygenic risks Type 1s: ○ Coronary artery disease ○ Atrial fibrillation ○ Cardiomyopathies ● Pericardial fluid ● Adrenal venous sampling
Condition	● Acute coronary syndrome ● Myocardial infarction ● Congestive heart failure ● Cardiac amyloidosis ● Hypertension	● Angina	● Inherited cardiovascular diseases ● Amyloidosis
Biomarker	● Troponin and high-sensitivity troponin T and I ● High-sensitivity CRP ● Natriuretic peptides	● Angiotensin converting enzyme ● Aldosterone ● Renin ● Catecholamines ● Metanephrines	● Amyloid protein identification ● CK-MB mass ● Homocysteine

Hematologic Disorders

	Type 1	Type 2	Type 3
Concept	• Blood components • Coagulation • Iron absorption, transport, and storage	• • Hemoglobin biosynthesis • Heme biosynthesis and metabolism • Hyper-coagulable states • Hypo-coagulable states	• Coagulation cascades • Fibrinolytic pathway
Condition	• Iron deficiency anemia • Hemolytic anemia • Pernicious anemia • Hemochromatosis	• Porphyrias • Thalassemia • Hemoglobinopathies	• Leukemias/lymphomas • Myelodysplastic syndromes • Aplastic anemia • Glucose-6-phosphate dehydrogenase deficiency • Fanconi anemia • Coagulopathies • Hemophilias • Von Willebrand's Disease • Disseminated intravascular coagulation
Biomarker	• Complete Blood Count • Iron • Iron binding capacity • Transferrin • Transferrin saturation • Ferritin • Haptoglobin • Vitamin B12 • Folate • Homocysteine	• Hemoglobin fractionation • Aminolevulinic acid • Porphobilinogen • Thrombin time • PT-INR • aPTT • D-dimer • Fibrinogen • Methylmalonic acid	• Porphyrin fractionation • Factor V Leiden • G6PD activity • *G6PD* genotype • Differential leukocyte count • Hemopexin • Anti-factor Xa • Anti-factor IIa • Protein C • Protein S • HFE genotype

Hepatobiliary Disorders

	Type 1	Type 2	Type 3
Concept	• Bilirubin production, metabolism and transport • Liver structure and function		
Condition	• Acute liver failure • Chronic liver failure • Viral hepatitis • Autoimmune liver disease • Alcohol or drug caused liver damage • Non-alcoholic fatty liver disease • Non-alcoholic steatohepatitis • Liver Cirrhosis • Hepatic encephalopathy • Biliary damage and dysfunction • Cholestasis • Primary sclerosing cholangitis • Liver transplantation	• Ascites • Wilson disease • Biliary Atresia • Breast milk jaundice	• Reye's syndrome • Dubin Johnson • Rotor syndrome • Gilbert sydrome • Criger-Najjar syndrome • Lucey-Driscoll syndrome • Budd–Chiari syndrome • Alpha-1-antitrypsin deficiency

Biomarker	• Bilirubin
	  ○ Total
	  ○ Conjugated
	  ○ Unconjugated
	  ○ Delta
	• ALT
	• AST
	• LD
	• ALP
	• GGT
	• Alpha-fetoprotein
	• Ceruloplasmin
	• Albumin
	• Hepatitis A, B and C serology
	• Ammonia
		• Copper
		• Ceruloplasmin
		• Bile acids
		• Non-invasive multi-marker algorithm for liver fibrosis, NAFLD and NASH
			• Alpha-1-antitrypsin
			• Alpha-1-antitrypsin genotyping and phenotyping

Gastrointestinal and Pancreatic Disorders

	Type 1	Type 2	Type 3
Concept	• Intestinal absorption of macronutrients and micronutrients • Endocrine and exocrine functions of the pancreas	• Malabsorption • Body fluids: ascites	
Condition	• Acute and chronic pancreatitis • Pernicious anemia • Colorectal cancer • Diarrhea • Gastrointestinal bleeding	• H. pylori infection • Celiac disease • Crohn's disease • Inflammatory bowel disease • Ulcerative colitis • Peptic ulcers • Intestinal malabsorption • Lactose intolerance	• Neuroendocrine tumors • Zollinger-Ellison syndrome
Biomarker	• Amylase • Lipase • Fecal occult blood • Fecal immunochemical testing • Carcinoembryonic antigen • Cancer Antigen 19-9	• Xylose absorption test • Fecal elastase • Transglutaminase autoantibodies • Endomysial antibodies • Gliadin autoantibodies • Fecal calprotectin • Colon cancer genetic risk • Stool antigen • CO_2 urea breath test for H. pylori • Serotonin and 5'HIAA • Chromogranin A • Hydrogen breath test • Gastrin	• Secretin stimulation test • Fecal Osmotic Gap • Fecal pH • Fecal fat analysis •

Musculoskeletal and Rheumatic

	Type 1	Type 2	Type 3
Concept	● Muscle physiology ● Joint structure and physiology ● Autoimmunity	● Smooth muscle ● Skeletal muscle ● Autoantibodies	● ANA patterns and associated diseases
Condition	● Arthritis ● Systemic lupus erythematosus ● Rhabdomyolysis ● Osteoarthritis ● Gout ● Uricemia	● Vasculitis ● Goodpasture's syndrome ● Antiphospholipid syndrome ● Duchenne muscular dystrophy ● Becker muscular dystrophy	● Lesch-Nyhan syndrome
Biomarker	● Creatine Kinase ● Myoglobin ● Rheumatoid factor ● Anti-cyclic citrullinated peptide antibodies ● Uric acid ● C-reactive protein	● Antinuclear antibodies ● Extractable nuclear antigen antibodies ● anti-dsDNA ● Anti-neutrophil cytoplasmic antibodies ● MPO antibodies ● PR3 antibodies ● Anti-beta 2 glycoprotein ● Anti-cardiolipin antibody ● Lupus anticoagulant	● Anti-parietal cell antibodies ● Anti-smooth muscle antibodies ● Anti-mitochondrial antibodies ● Myositis autoantibodies ● Synovial fluid crystals

Neurology and Psychiatry

	Type 1	Type 2	Type 3
Concept	• Blood Brain Barrier • Neurodegenerative disease	• CSF sample collection	
Condition		• Multiple sclerosis • Meningitis • Myasthenia gravis • Epilepsy • CSF fluid leak	• Paraneoplastic syndrome • Encephalitis • Bipolar disorder • Parkinson's disease • Alzheimer's disease • Neuromyelitis spectrum disorder
Biomarker		• CSF glucose • CSF protein • Oligoclonal banding • Beta-2-transferrin • Beta-trace protein	• Paraneoplastic antibodies • Anti-Hu antibodies • Anti-Yo antibodies • Anti-NMDA antibodies • Anti-acetylcholine receptor antibodies • Anti-GAD65 antibodies • Anti-NMO antibodies • ApoE genotype

Diabetes Mellitus

	Type 1	Type 2	Type 3
Concept	● Etiology of Type 1, Type 2, gestational and inherited forms ● Complications of diabetes ○ microvascular and macrovascular ● Glucose tolerance testing ● Regulation of blood glucose	● Self monitoring of blood glucose ● Insulin tolerance testing	● Insulin pumps ● Continuous glucose monitoring
Condition	● Hypoglycemia and hyperglycemia ● Diabetic ketoacidosis ● Metabolic syndrome	● Non-ketotic hyperosmolar coma ● Diabetic nephropathy	
Biomarker	● HbA1c ● Glucose ● Insulin ● Urine Albumin creatinine ratio ● Ketones (serum and urine) ● Oral glucose tolerance test	● C-peptide ● Glucagon ● Fructosamine ● Osmolality ● Sodium ● Potassium	● Autoantibodies in diabetes ● Pro-insulin

Lipids and Lipoprotein Disorders

	Type 1	Type 2	Type 3
Concept	● Lipid absorption, transport and metabolism ● Lipoprotein composition ● Lipoprotein metabolism pathways: ○ Endogenous ○ Exogenous ● Fatty acid transport and oxidation ● Apolipoproteins ○ Functions ○ Receptors ● Cardiovascular disease risk calculations	● Therapeutic modalities for lipoprotein disorders	
Condition	● Atherosclerosis ● Hyperlipidemia ○ Non-inherited disorders ● Hypercholesterolemia ● Metabolic syndrome	● Familial hypercholesterolaemia ● apolipoprotein B deficiency ● Lipoprotein lipase deficiency	● Recessive X-linked ichthyosis ● LCAT deficiency
Biomarker	● Total cholesterol ● LDL cholesterol – direct and calculated methods ● HDL cholesterol ● Non-HDL cholesterol ● Triglycerides ● Apolipoprotein A ● Apolipoprotein B	● Lipoprotein (a) ● High sensitive CRP ● Genotyping ○ LDL receptor*(LDLR)* ○ Lipoprotein lipase (*LPL*) ○ PCSK9 (*PCSK9)*	● Lipoprotein ultracentrifugation ● Lipoprotein-X by lipoprotein electrophoresis ● Hypertriglyceridemia genetic panels ● Hypercholesterolemia genetic panels

Bone and Mineral Metabolism

	Type 1	Type 2	Type 3
Concept	• Regulation of calcium and phosphate • PTH regulation and metabolism • Bone metabolism • Metabolism of vitamin D • Primary versus secondary hyper/hypo calcemia • Circulating forms of calcium		
Condition	• Hypocalcemia • Hypercalcemia • Hyperparathyroidism • Hypoparathyroidism • Osteoporosis • Hypophosphatemia • Hyperphosphatemia • Hypermagnesemia • Hypomagnesemia • Rickets / Osteomalacia	• Hypophosphatasia • Hypophosphatemic rickets • Paget's disease • Familial hypocalciuric hypercalcemia • Pseudohypoparathyroidism • Renal osteodystrophy	• Osteogenesis imperfecta • Achondroplasia
Biomarker	• PTH • Calcium – total and ionized • Phosphate • 25-hydroxy vitamin D • 1, 25-dihydroxy vitamin D • Magnesium • Alkaline phosphatase	• PTHrp • Osteocalcin • Alkaline phosphatase isoenzymes • C- and N-telopeptides	• FGF23 • PINP • PICP • Pyridinolines

Genetics

	Type 1	Type 2	Type 3
Concept	● Nuclear DNA ● Messenger RNA ● Chromosomes ● Gene structure ● Modes of inheritance ● Polymorphisms ● Complex traits ● Inherited and acquired genetic variation ○ Somatic ○ Germline	● Mitochondrial DNA ● Expressivity ● Penetrance ● Chromosomal rearrangement ● Variant classification ○ VUS ○ Path ○ Likely Path ○ Benign	● Linkage/linkage disequilibrium ● Homoplasmy and heteroplasmy ● *De novo* mutations ● X-inactivation ● Mosaicism ● Chimerism ● Epigenetics
Condition		● Disorders of Chromosome number ● Structural defects in chromosomes	● Mosaic ● Chimera
Biomarker			● Karyotype ● Copy number variants ● Single nucleotide polymorphisms ● Single or small nucleotide changes ● Promoter methylation

Pregnancy and prenatal screening

	Type 1	Type 2	Type 3
Concept	● Physiology and anatomy of pregnancy ● Biochemical, hematological and endocrine changes during pregnancy ○ Multiples of the median ● Rh isoimmunization and hemolytic disease of the newborn ● Gemelar pregnancy ● Amniotic fluid ● Meconium	● Assisted reproductive technology ● Fetal lung maturity ● Maternal serum screening ○ First trimester screening ○ Second trimester screening ○ Integrated screening ○ Non-invasive prenatal testing	
Condition	● Gestational diabetes ● Pre-eclampsia and eclampsia ● HELLP syndrome ● Pre-term labour ● Premature rupture of membranes ● Ectopic pregnancy	● Molar pregnancy ● Trophoblastic disease ● Choriocarcinoma ● Polyhydramnios ● Open neural tube defects ● Anencephaly ● Rh isoimmunization ● Cholestasis of pregnancy ● Hyperemesis gravidarum ● Trisomy 13, 18 and 21, and Turner syndrome	
Biomarker	● hCG and isoforms ● AFP ● Fetal fibronectin ● Nitrazine test ● Pre-eclampsia and HELLP syndrome: ○ Creatinine, urea, AST, ALT ○ Urinary proteins ○ Platelets ● Total bile acids ● Thyroid function in pregnancy: ○ TSH ○ FT4/FT3 ○ Anti-TPO	● PAPP-A ● Inhibin A ● Unconjugated estriol ● Plasma nucleic acids ● Biomarkers in amniotic fluid ○ Acetylcholinesterase ○ AFP ○ Karyotype ○ Bilirubin ● sFlt-1 ● PIGF ● Prenatal Cell-Free DNA screening	● Fetal scalp pH ● Fetal scalp lactate ● LH ● FSH ● seminal fluid ● IGFBP-1 ● Fetal lung maturity testing

Newborn Screening and Inborn Errors of Metabolism

	Type 1	Type 2	Type 3
Concept	● Dried blood spot samples ● Population based screening ● ● Essential amino acids ● Steroid biosynthesis	● Fatty acid beta-oxidation ● Urea cycle ● Electron transport chain ● Branch chain amino acid metabolism ● Glycolysis ● Gluconeogenesis	● Congenital hyperinsulinism ● Hereditary fructose intolerance ● Wilson and Jungner criteria for screening
Condition	● Congential hypothyroidism ● Congential adrenal hyperplasia ● Cystic Fibrosis	● Fatty acid oxidation defects ○ Medium acyl-CoA dehydrogenase deficiency ○ Very long Acyl-CoA dehydrogenase deficiency ● Organic acidemias ○ Propionic acidemia ○ Methylmalonic acidemia ○ Isovaleric acidemia ○ Glutaric aciduria type 1 ● Amino acidopathies ○ Phenylketonuria ○ Maple syrup urine disease ○ Tyrosinemia type 1 and 2 ● Urea cycle disorders ○ Argininosuccinate synthase deficiency ○ Argininosuccinate lyase deficiency ○ Ornithine transcarbamylase deficiency ● Classical Galactosemia	● Lysosomal storage diseases ● Electron transport chain defects
Biomarker	● Thyroid stimulating hormone ● Ammonia ● Lactate ● Beta-hydroxybutyrate ● Glucose ● Immunoreactive trypsinogen	● Pyruvate ● 17-hydroxyprogesterone ● Androstenedione ● Cortisol	● Plasma amino acids ● Plasma acylcarnitines ● Urine organic acids

Pediatrics

	Type 1	Type 2	Type 3
Concept	● Growth and development ● Cord blood ● Bilirubin production, metabolism and transport ● Bilirubin nomograms	● Tanner stages	
Condition	● Neonatal hypoglycemia ● Neonatal hyperbilirubinemia ● Failure to thrive ● Congenital thyroid disease ● Diabetes mellitus ● Hemolytic disease of the newborn	● Respiratory distress syndrome ● Cystic fibrosis ● Delayed puberty ● Precocious puberty ● Disorders of sex development ● Growth hormone deficiency ● Neuroblastoma ● Celiac disease	● Kawasaki disease
Biomarker	● Bilirubin ○ Total ○ Conjugated ○ Unconjugated ○ Delta	● Catecholamines ● Metanephrines ● Sweat chloride	

Immunology

	Type 1	Type 2	Type 3
Concept	• Innate immunity • Adaptive immunity • Antibody mediated immunity • Cell-mediated immunity • Acute phase reaction • Allergens • Antibody isotypes	• Complement system • IgG subclasses	• Human leukocyte antigen
Condition	• Acute inflammation • Hypogammaglobulinemia • IgA deficiency • Polyclonal gammaglobulinemia	• Cryoglobulinemia • ANCA associated vasculitis	• Complement disorders • IgG4-related disease • Hypersensitivity pneumonitits
Biomarker	• C reactive protein • Immunoglobulins (IgA, IgG, IgM)	• C3 and C4 • Cryoglobulin • Cryofibrinogen • Immunoglobulin E • Allergen specific IgE and component testing • IgG subclasses (IgG1, IgG2, IgG3, IgG4) • MPO, PR3	• Total complement activity measurement • C1 esterase inhibitor • Immunoglobulin D

Oncology

	Type 1	Type 2	Type 3
Concept	● Cell-cycle ● Apoptosis ● Tumor staging ● Metastasis ● Benign vs malignant neoplasms ● Properties and utility of a tumor biomarker: ○ Screening ○ Diagnosis ○ Monitoring ○ Recurrence		● Hereditary cancer syndromes
Condition	● Solid tumors ● Monoclonal gammopathies ● Multiple myeloma ● Light chain myeloma	● Amyloidosis ● Waldenström's macroglobulinemia ● Cryoglobulinemia ● Lymphoma	● Lynch syndrome ● Familial adenomatous polyposis syndrome ● Hereditary breast and ovarian cancer syndrome ● Li-Fraumeni syndrome ● Cowden syndrome ● POEMS (Polyneuropathy, organomegaly, endocrinopathy, monoclonal gammopathy, and skin changes) syndrome

Biomarker	• Carcinoembryonic antigen • Alpha fetoprotein • Human chorionic gonadotropin • Total and free Prostate specific antigen • Cancer antigen 19-9 • Cancer antigen 15-3 • Cancer antigen 125 • Calcitonin • Thyroglobulin, anti-thyroglobulin antibodies • Monoclonal immunoglobulins • Serum protein electrophoresis • Free light chains • Urine protein electrophoresis • Urine light chains	• Parathyroid hormone-related protein • 5-hydroxyindoleacetic acid • Chromogranin A • Vasoactive intestinal peptide • Beta-2-microglobulin • Metanephrines	• HER2/Neu • Vascular endothelial growth factor • Alkaline phosphatase isoenzymes • Lactate dehydrogenase isoenzymes

Nutrition, Vitamins, Trace Elements

	Type 1	Type 2	Type 3

Concept	• Absorption, metabolism and function of:
	  ○ Vitamin B9 (folate)
	  ○ Vitamin B12
	  ○ Vitamin D
	• Monitoring nutritional status
	• Total parenteral nutrition
		• Essential and non-essential metals
		• Absorption, metabolism and function of:
		  ○ Vitamin A
		  ○ Vitamin B1
		  ○ Vitamin B2
		  ○ Vitamin B6
		  ○ Vitamin E
		  ○ Vitamin K
			• Absorption, metabolism and function of:
			  ○ Vitamin B7
			  ○ Vitamin B3
			  ○ Vitamin C
			• Biological exposure index

Condition	• Vitamin B12 deficiency • Folate deficiency • Vitamin D deficiency • Malnutrition • Malabsorption	• Copper deficiency/excess • Wilson's Disease • Vitamin deficiencies	• Menkes syndrome • Cadmium poisoning

Biomarker	• Vitamin B12 • Vitamin B9 (folate) • Vitamin D • Albumin • Prealbumin • Total protein • Iron	• Ceruloplasmin • Homocysteine • Methylmalonic Acid • Vitamin A • Vitamin E • Carotene • Prothrombin time • Intrinsic factor antibody • Lead • Zinc • Copper	• Arsenic • Chromium • Cobalt • Cadmium • Aluminium • Manganese • Iodine • Titanium • Vitamin B6 • Thiamine • Vitamin C • Vitamin K • Delta amino levulinic acid

Pharmacology and Therapeutic Drug Monitoring

	Type 1	Type 2	Type 3

Concept	• Pharmacokinetics
	  ○ Liberation
	  ○ Absorption
	  ○ Distribution
	  ○ Metabolism
	  ○ Excretion
	• Pharmacodynamics
	• Compliance
	• Therapeutic index
	• Does optimization
	• Free drug measurement
		• Zero order kinetics
		• First order kinetics
		• Peak vs. trough
		• Steady-state
		• One-compartment model
		• Multi-compartment model
			• Pharmacogenetics
			  ○ Cytochrome P450 superfamily
			  ○ Azathioprine
			  ○ Warfarin
			• Drug interactions
			• Biopharmaceuticals

Condition	● Compliance and non-compliance ● Adverse drug reactions ● Toxicity		
Biomarker	● Antibiotics ● Antidepressants ● Lithium ● Cyclosporine ● Tacrolimus ● Sirolimus ● Mycophenolic acid ● Methotrexate and rescue	● Thiopurine metabolites ● Anti-epileptic drugs ● Anti-convulsants ● Anti-psychotic drugs ● Cardioactive drugs	● Thiopurine methyltransferase phenotype and genotype ● Monoclonal antibody based therapeutics ● Anti-drug antibodies ● Antifungals

Toxicology

	Type 1	Type 2	Type 3
Concept	● Toxidromes ● Drug overdose ● Drug withdrawal ● Acetaminophen nomogram	● Compliance Monitoring ○ Drug diversion ● Metabolism of drugs of abuse ○ Opioids and opiates ○ Tetrahydrocannabinol ○ Cocaine ○ Benzodiazepine ○ Barbiturates ○ Amphetamine ○ Phencyclidine ○ Tricyclic antidepressants ● Toxic and non-toxic metals ● Drug screens vs. confirmatory tests ● Antidotes for overdose ● Sampling considerations	● Synthetic and designer drugs ● Regulated and unregulated drug supply ● Medicolegal use of tests ● Forensic use of tests
Condition	● Acetaminophen toxicity ● Salicylate toxicity ● Toxic alcohol poisoning ● Carbon monoxide poisoning	● Lead poisoning ● Mercury poisoning ● Iron poisoning	Digoxin toxicity Methotrexate toxicity
Biomarker	● Urine drugs of abuse panel ● Anion gap ● Osmolal gap ● Blood gases ● Acetaminophen ● Salicylate ● Ethanol ● Methanol ● Ethylene glycol ● Isopropanol ● Serum Osmolality ● Carboxyhemoglobin	● Specimen validity testing ● Drugs of abuse confirmatory tests ● Long term markers for ethanol abuse ● Iron ● Lead ● Mercury	● Broad spectrum drug screen ● Cholinesterase activity ● Aluminium ● Arsenic ● Chromium ● Cobalt ● Cadmium ● Titanium

Infectious Diseases

	Type 1	Type 2	Type 3
Concept	● Universal precautions ● Biosafety levels ● Aseptic technique for sample collection and handling ● Antibiotic resistance	● Antibiotic stewardship ● Screening and confirmatory tests ● Public health application of testing	
Condition	● Sepsis ● Sexually transmitted infections ● Viral hepatitis A, B and C infections ● Tuberculosis ● H. pylori	● HIV infection ● CMV infection ● HSV infection ● COVID-19 infection ● Influenza ● Syphilis ● Fungal infections	● Viral hepatitis D and E
Biomarker	● C-reactive protein ● Procalcitonin ● Antigen and antibody tests ● Viral nucleic acid tests ● Hepatitis A, B and C serology ● Lactate	● TORCH screen ○ Toxoplasma gondii ○ Rubella ○ Cytomegalovirus ○ Herpes simplex virus ● HIV testing ● Syphilis serology ● IgE ● Anti-streptolysin O ● Body fluids testing	

Section 2: Analytical

This section outlines concepts,principles, methods and instrumentation relevant to Clinical Biochemistry. The competency statements below are to be applied to each table detailed subsequently.

Analytical Competencies

For each **Type 1** concept, principle, method, instrument achieve the following competencies:

1. Describe, explain and discuss concepts and principles
2. Detail the major components of methods/instrumentation
3. Explain how methods and instruments function
4. Identify advantages, disadvantages and limitations of each method/instrument
5. Justify the selection of an instrument or method for a given clinical need
6. Develop experience with methods/instruments through direct observation or hands-on work
7. Troubleshoot and investigate issues with methods/instrumentation
8. Perform calculations, plot data, interpret and explain results and output of methods and instrumentation
9. Recall causes and mechanisms of method interference and be able to assess if interference is present.

For each **Type 2** concept, principle, method, instrument achieve the following competencies:

1. Describe and explain concepts and principles
2. Be familiar with how the concepts and principles are applied in the clinical laboratory
3. Outline the components of the methods/instrumentation
4. Identify advantages and disadvantages of the method/instruments

For each **Type 3** concept, principle, method, instrument achieve the following competencies:

1. Describe the general concepts and principles
2. Identify when a method/instrument may be required the clinical laboratory

General techniques and Related Instrumentation

	Type 1	Type 2
Concepts/Principles	● Water purification and quality ● Selection and preparation of buffers ● Preparation of laboratory reagents and solutions	● System suitability checks
Methods	● Volumetric techniques ● Pipetting techniques ● Gravimetric techniques ● pH determination ● Sample pre-treatment methods: ○ Filtration ○ Extraction ○ Pre-concentration ○ Centrifugal ultrafiltration ○ Dialysis ○ Selective precipitation ○ Centrifugation	

Analytical and Clinical evaluation of laboratory tests

	Type 1	Type 2
Concepts/Principles	● Validation and verification of methods and instruments ● Test performance of quantitative and qualitative methods ● Clinical test performance. ● Analytical performance specifications/goals ● Reference intervals and medical decision limits	● Diagnostic efficiency, clinical efficacy
Methods	● Quantitative and qualitative analytical method validation methods: ○ Precision ○ Accuracy ○ Linearity and calibration verification ○ Interference studies ○ Dilution recovery ○ Carryover ○ Analytical measurement range ○ Reference interval verification ○ Lot-to-lot variability ○ Sensitivity limits ■ Limit of blank ■ Limit of detection ■ Limit of quantitation ○ Method agreement ○ Interpretive cut-offs (e.g. positive, negative, indeterminant) ● Clinical method validation: ○ Clinical validity, clinical utility (e.g. diagnosis, screening, monitoring, prognosis, predictive) ○ Sensitivity, specificity ○ Positive and negative predictive values	

Metrology

	Type 1	Type 2
Concepts/Principles	● Metrological traceability chain ○ Reference standards ○ Definitive methods ○ Reference methods ● Method Standardization ● Method Harmonization ● Measurement Uncertainty ● Units of measurement ● Calibration	● Sample commutability ● Method transference ● Internal standard materials
Methods	● Calculation of measurement uncertainty ● Unit conversions ● Calibration curves	● Internal standards ● External standards

Optical techniques and Spectroscopy

	Type 1	Type 2	Type 3
Concept/Principles	● Spectrophotometry ○ Absorbance ○ Transmittance ○ Beer-lambert law ○ Molar absorptivity ● Reflectance photometry ● Light scattering ○ Nephelometry ○ Turbidimetry ● Luminescence ○ Chemiluminescence ○ Electrochemiluminescence ○ Fluorescence ● Microscopy ● Refractometry	● Anisotropy ○ Fluorescence polarization ● Fluorescence resonance energy transfer ● Time-resolved fluorescence	● Bioluminescence ● Phosphorescence ● Nuclear Magnetic Resonance ● Atomic spectroscopy ●
Method/Instrumentation	● Spectrophotometer ○ Light sources ○ Wavelength selectors ○ Wavelength filters ○ Photodetector diode ○ Photomultiplier tube ● Reflectometer ○ Instrument geometry ○ Light sources ● Nephelometer and turbidimeter ● Luminometer ● Co-oximeter ● Optical microscopy ○ Bright field	● Flow cytometer ● Fluorescence microscope ● Refractometer ● Infrared spectrophotometer ● Fluorometer ● Excitation source ○ Monochromators ○ Detectors ● Optical microscope ○ Polarized light ○ Phase contrast ○ Automated microscopy ○ Image analysis	● Flame photometer ● Optical emission spectrometer ● Electron microscope ● Interference contrast microscope ● X-ray diffractometer ● Flame or flameless atomic absorption spectrophotometer ● Surface Plasmon Resonance ● Microscope ○ Fluorescence ○ Confocal ○ Deconvolution

Electrochemistry

	Type 1	Type 2	Type 3
Concepts/Principles	● Potentiometry ● Amperometry	● Coulometry ● Conductivity	● Voltammetry ● Impedance
Methods/Instrumentation	● Ion selective electrode ○ Direct methods ○ Indirect methods ● Amperometric biosensors ● Blood gas instruments ● Glucose meters ● Continuous glucose monitoring devices	● Coulometric chloride titrator ● Sweat conductivity analyzer ● Complete blood count analyser ○ Impedance measurements for RBC and platelet count, hematocrit ○ Hematocrit conductivity sensor	

Enzymology

	Type 1	Type 2	Type 3
Concepts/Principles	● Enzymes ○ Enzyme classes ○ Cofactors, coenzymes ○ Isoenzymes ○ Stability of enzymes ● Enzymes as reagents (e.g. Antibody conjugates, CEDIA or EMIT assays) ● Enzymes as biomarkers ● Coupled enzymatic reactions	● Enzyme kinetics ○ Michaelis Menton equation ● Intracellular vs extracellular enzymes	
Methods/instrumentation	● Immobilized enzyme assays (e.g biosensors) ● Enzyme and isoenzyme measurement methods: ○ Mass and activity concentration units	● Equilibrium (endpoint) methods ● Kinetic (reaction rate) methods ● Zero-order assays for enzyme activity ● First-order assays for substrate concentration	● Isoenzyme fractionation techniques ● Immunoinhibition or chemical inactivation assays

Immunoassay

	Type 1	Type 2	Type 3
Concepts/Principles	● Principles of immunoassay: ○ Antibody structure ○ Antibody-Antigen interaction ○ Affinity, avidity, valency, clonality ● Types of immunoassay ○ Competitive ○ Non-competitive ○ Homogenous ○ Heterogeneous ● Immunoassay detection strategies ● Specificity/cross-reactivity ● High dose hook effect		● Antibody development and production
Methods/instrumentation	● Applications on automated analyzer (e.g.microparticle IA, enzyme IA, sandwich IA) ● Manual/batch formats (e.g. ELISA) ● Lateral flow	● Indirect immunofluorescence ● Lineblot ● Multiplex immunoassays	● Chip based microarrays ● Radioimmunoassay ● Immunoprecipitation assay

Separation techniques

	Type 1	Type 2	Type 3
Concepts/Principles	● Chromatography: ○ Theory of ○ Types of ○ Internal standards ○ Calibration ○ Detection modalities (ex. UV-Vis, FID, MS) ○ Chromatogram analysis ● Electrophoresis: ○ Theory ○ Types ○ Calibration ○ Detection modality (ex. Staining, immunofixation, western blot, densitometry, peak integration) ○ Electropherogram interpretation		
Methods/Instrumentation	● Liquid chromatography ● Gas chromatography ● Gel Electrophoresis ● Capillary electrophoresis ● Isoelectric focusing	● Extraction and purification methods(eg. Solid phase, liquid-liquid, supported liquid, affinity-based extraction, precipitation, filtration)	● Planar chromatography (eg. Paper, thin-layer) ● Size exclusion chromatography ● Centrifugal filters ● Ultracentrifugation ● Gradient centrifugation

Mass spectrometry

	Type 1	Type 2	Type 3
Concepts/Principles	● Sample preparation (e.g. dilution, derivatization, digestion, purification) ● Assay Calibration ● Ionization ○ Theory ○ Types ○ Ion suppression/matrix effects ○ Single vs multiple charge states ● Mass Analysis ○ Theory ○ Types ○ Stable isotope Internal standard ○ Mass calibration ○ Dwell time ○ Fragment ion formation ○ Analyte identification ○ Ion ratios ○ Mass spectra ■ total ion chromatogram ■ extracted ion chromatogram	● Mass analyzer accuracy ● Mass analyser resolution ● Targeted protein analysis: ○ Peptide-level analysis ○ Protein-level analysis ● Charge state deconvolution (multi charges, isotopes) ● Epimers, isomers, polyatomic ions, adducts and in-source losses	Applications in other clinical lab areas: ● Genomic/Molecular ● Microbiology ● Anatomic pathology/tissue
Methods/Instrumentation	● General components of a mass spectrometer ○ Sample introduction system ○ Ion source/inlet ○ Mass analyzer ○ Ion Detector ○ Vacuum system ○ Computer ● Ionization methods ○ ESI	Mass analyzers ● Ion trap ● Time of flight	● Ionization Methods ○ MALDI ○ DESI ○ REIMS ● Other ion separation methods ○ Ion Mobility

	○ APCI ○ ICP ● Mass analyzers ○ Quadrupole ○ Tandem quadrupole ● Common modes of analysis (eg. SIM, MRM, precursor ion scan)		

Molecular Diagnostics

	Type 1	Type 2	Type 3
Concepts/ Principles		• DNA and RNA structure and function • Plasma (cell-free) nucleic acids • Nucleic acid amplification • Nucleic acid sequencing • Nucleic acid detection and discrimination • Variant nomenclature • Variant classifications • Laboratory and workflow design • Approaches to preventing contamination	• Cytogenetics • miRNA, cDNA and mtDNA structure and function • Copy number variation • Single and multi-nucleotide variation (e.g. SNPs, indels, expansions) • Variant interpretation • Mosaicism • Chimerism • Polymorphism • Epigenetics • Nucleic acid hybridization (e.g. Southern blotting, chip arrays) • Molecular techniques used to detect copy number changes or large repeats (e.g multiplex ligation-dependent probe amplification)

Methods/ instrumentation	● DNA and RNA isolation and purification ● Polymerase chain reaction (PCR) methods ● Real time PCR ● Quantitative PCR ● Melting point analysis	● Sequencing methods: o Sanger sequencing ○ Next generation sequencing ○ Long-read sequencing ○ RNA sequencing ● Sample pooling and other throughput approaches ● POCT applications of molecular diagnostics	● Karyotype analysis ● Genotype analysis ● Fluorescent in situ hybridization ● Nucleic acid fragmentation techniques (e.g.Restriction fragment length polymorphism) ● DNA chips/microarrays ● Methylation analysis ● Copy number and large repeat detection ● Paternity and forensic testing approaches

Section 3: Pre-Analytical

This section outlines concepts, procedures/processes and tools/materials related to pre-analytical functions of the laboratory. The competency statements below are to be applied to each table detailed subsequently.

Pre-Analytical Competencies

For each topic below, be able to:

- Explain how each concept relates to the quality and accuracy of clinical laboratory testing
- Explain why each concept is important in the clinical laboratory
- Apply guidelines and regulations applicable to these concepts in the clinical lab
- Translate these concepts and tools into laboratory policies and procedures
- For each "**Type 1**" condition, biomarker and analytical method (in the Clinical or Analytical sections of the syllabus) list and describe any unique pre-analytical concepts and procedures applicable to that condition/biomarker/method, and how they influence result validity
- Identify relevant pre-analytical concepts and procedures that should be combined with post-analytical processes to improve test results and patient care

For **Type 1** topics be able to:

- Describe in detail how, and for what purpose a procedure or process is performed
- Recall important considerations and key steps in the process and explain why they are important and the implications on test results and patient care if these key considerations are missed
- Design, analyze and interpret the results of experiments to assess the impact or confirm appropriateness of the pre-analytical process, procedure or material on test results
- Provide instructions and justification for use of a specific procedure or material in the context of the total testing process

For **Type 2** topics be able to:

- Provide a general outline of how and why a procedure or process is performed
- Recall important considerations and key steps in the process
- Provide instructions and justification for use of a specific procedure or material in the context of the total testing process

For **Type 3** topics be able to:

- Describe what the topic is and its relevance in the clinical laboratory

Patient Intake and Test ordering

	Type 1	Type 2	Type 3
Concepts	● Positive patient identification ● Patient information required for testing ● Health Care provider information required ● Test-specific patient preparation information (e.g. time of last dose, fasting time) Methods of generating lab test requests: ● Computerized provider order entry ● Requisition forms ● Standing orders ● Order sets ● Test codes and nomenclature ● Test batteries or panels ● Add on testing ● Reflex testing	● Unidentified patients ● Patient in isolation ● Trauma ● When patient anonymity must be protected (eg. sexual assault) ● Referred out testing	● Identifying patient-specific safety risks (e.g. violent patient, patients taking hazardous drugs) ● Patient paid testing ● Third party testing ● Direct to Consumer ● testing ● Bloodwork for research and clinical trials
Procedures	● Patient identification ● Specimen labeling requirements ● Incident, Hazard and Near Miss Reporting Policy and Procedure. ● Standard Infection Control Precautions Procedure		● Anonymized patient testing (e.g. HIV)
Materials and tools	● Armband scanning ● Laboratory requisitions ● Order sets ● Standing Orders ● Specimen labelling ● Laboratory Information System ● Hospital Information System		

	● Electronic Health Record Healthcare Information System ● Privacy Impact Assessment		

Specimen Collection

	Type 1	Type 2	Type 3
Concepts	Types of biological specimens (sample type) and related collection procedures ● whole blood; serum; plasma ○ vein, artery, or capillary/blood spot ○ umbilical cord ○ intraoperative ○ adrenal vein ● urine ○ random, first morning, 12h, 24h ● feces and meconium ● breath ● other fluids: synovial, amniotic, pleural/asitic, pericardial, saliva,cerebrospinal fluid, wound/drain, sweat, intraosseous ● swabs: nasal, oral, nasopharyngeal Preanalytical variables and biological variation ● Controllable preanalytical variable (posture, prolonged bed rest, exercise, physical training, circadian variation, travel, diet, drug intake, tourniquet use, fist clenching) ● Uncontrollable preanalytical variable (e.g. age, sex, race, disease state) ● Environmental factors: altitude, ambient temperature, geographical location, and seasonal influences. Patient preparation needed for specific tests ● time of day, fasting, supine, modified diets Timed sample collections	Patient-centered laboratory care Laboratory versus non-laboratory collections Patient-specific sample collection considerations ● preferred venipuncture sites ● preferred sites of arterial puncture, ● contraindications to sample collection at preferred sites ● collection from catheters and intravenous lines ● maximum volume/day	Chain of custody

	● Therapeutic drug monitoring ● Dynamic testing ○ Suppression and stimulation tests Phlebotomy ● Tourniquet, fist clenching, venous stasis ● Order of draw/sampling ○ components in evacuated tubes and indication for use (e.g. tube materials, surfactants, additives, separators) ○ Evacuated blood tubes, syringe ● Needle gauge selection Urine Collection ● specimen handling, container and preservatives		
Procedures	Phlebotomy technique ● tourniquet time ● fist pumping ● needle gauge ● patient posture Urine sample collection ● Random ● First catch ● 24 hour Dynamic testing (e.g suppression and stimulation tests)	● Validation and verification of consumables used for sample collection ● Assisted urine collection	● Hemodialysis/ peritoneal dialysis ● Intraosseous sampling ● Adrenal vein sampling ● Parathyroid Venous Series ● Post-mortem ● Nail and hair ● Arteriovenous Fistula ● Pericentesis/Thoracocentesis ● Spinal tap/CSF collections ● Saliva collection

Materials and tools	Blood collection supplies Non-blood collection supplies and instructions Requisitions and order sets		

Specimen Handling and Transport

	Type 1	Type 2	Type 3
Concepts	Processing ● Maintenance of specimen identification ● Sample preservation ● Biomarker specific requirements ● Centrifugation Internal transport ● Pneumatic tube systems ● Manual delivery ● Robotic track External Transport ● Sample handling and stability for short and long distances ● Mode of transportation ● Routes and frequency Transport requirements ● Specimen packaging ● Specimen lists ● Specimen and shipment tracking ● Stability and preservation in transit ● Regulations	● Biohazard and lab safety of handling biological specimens ● Universal precautions ● Transportation of Dangerous Goods regulations ● Handling considerations for highly infectious samples (e.g. Creutzfeldt-Jakob disease, Ebola virus, MPox)	● Transport considerations for Hub-and-spoke, centralization or other lab network models ● New technologies for specimen transport (e.g. robots, drones)

Procedures	• Separation and labeling of plasma/serum • Sharing, aliquoting and splitting specimens	Biomarker or sample-specific handling procedures • Chilled centrifuge • Warm water bath • Heat inactivation or other pretreatment • pH adjustment	Shipping schedules and transport times

Automation

	Type 1	Type 2	Type 3

Concepts	• Tasks and processes amenable to automation
	• Components of total laboratory automation systems
	  ○ Sample identification/barcodes
	  ○ Track systems
	  ○ Centrifugation
	  ○ Sample loading/unloading
	  ○ Capping/decapping
	• Monitor automation performance
	• Justification and benefits of automation; limitations
		• Total laboratory automation,
		• Task-targeted automation
		• Subtotal automation
		• Workflow analysis
			• Preanalytical automation:
			  ○ barcode readers,
			  ○ transport and sorting tracks
			  ○ centrifugation
			  ○ decapping/recapping
			  ○ aliquoting
			  ○ specimen integrity checks
			• Metrics to be considered for automation (e.g. space, throughput requirements, analytical considerations, maintenance, cost, staff)

Sample Integrity and Interferences

	Type 1
Concepts	● Analyte stability limits ● Sample storage conditions ● Interference mechanisms of common assay interferences such as: ○ Hemolysis, Icterus, Lipemia ○ Abnormal immunoglobulins and immunoglobulin complexes ○ Drugs ○ Supplements ○ Biologics ○ Electrolyte exclusion effect ○ Total parenteral nutrition ○ Intravenous fluid contamination ○ Clotted specimens ● Effect of additive on underfilled/overfilled tubes ● Wrong container or wrong additive ● Expired tubes
Procedures	● Evaluation and establishment of stability and interference claims ● Sample acceptance/ rejection criteria ● Approaches for mitigation of interferences
Materials and tools	● Investigations for interferences ● Laboratory investigations for wrong sample type

Referral laboratory/send-out testing

	Type 1	Type 3
Concepts	● Criteria for test referral ● Referral laboratory qualifications (e.g turn around time, method, regulatory authorization, cost, accreditation, customer support) ● Test utility and stewardship	● Contracts and billing ● Report retention policies
Procedures	● Sample storage and shipping requirements ● Ordering process for referral tests ● Review and approval process ● Results transmission and reporting ● Process for communicating critical results	● Out of province or country testing
Processes and tools	● Evaluation of referral laboratory performance	

Section 4: Post Analytical

This section outlines concepts, procedures/processes and tools/materials related to post-analytical functions of the laboratory. The competency statements below are to be applied to each table detailed subsequently.

Post-Analytical Competencies

For each topic in the tables below:

- Be aware of guidelines, regulations or best-practice applicable to these concepts and procedures in the clinical laboratory
- Incorporate these concepts and tools into laboratory policies and procedures

For each **Type 1** topic be able to:

- Explain and illustrate the importance of each concept/procedure/tool to the quality of clinical laboratory testing
- Compare and contrast different ways that lab test results are interpreted
- Recall and perform any calculations relevant to topics outlined here
- Design, analyze and interpret the results of studies that evaluate the function of or monitor a process related to each topic
- Provide instructions and justification for use of a specific concept, procedure or material/tool in the context of the total testing process
- When various options for a given procedure or tool may exist, compare and contrast their use on result quality and/or process impact
- Outline key steps of process/procedure and how to use a specific material/tool

For each **Type 2** topic be able to:

- Explain the significance of each topic, in the words context of laboratory testing
- Recall important considerations and key steps in a process
- Where applicable, interpret the results of studies to assess the impact or confirm appropriateness of the post-analytical process, procedure or material on test results

For each **Type 3** topic be able to:

- Define or describe why each topic is relevant in the clinical laboratory

Evaluation of Patient Results and Result Reporting

	Type 1	Type 2	Type 3
Concepts	● Instrument interfaces, automation and autoverification: ○ Middleware ○ Laboratory Information System ○ Healthcare Information System ○ Electronic Health Record ● Elements and parameters of a laboratory report ● Reference intervals ● Result comments and interpretation ● Medical decision limits ● Critical values ● Units of measurement (SI, US customary units) ● Qualitative, semi-quantitative and quantitative results ● Significant figures ● Autoverification rules ○ Delta checks ○ Absurd checks ○ Reporting limits ○ Indices check ○ Instrument errors	● Information flow between instrument and information systems ● Direct reporting to patients (patient portals) ● Result reporting when electronic systems are down	● Emerging methods for verifying patient results ● Communication standards ● Medical legal requirements for release of results
Procedures	● QC flags ● Instrument errors ● Identification and investigation of common assay interferences and absurd values	● Units ● Verification of laboratory test results ● Reporting of laboratory test results	● Nomenclature ● Standardization between information systems ● Security measures and privacy

	• Critical value definition, communication, and documentation • Autoverification rules • Validation and scenario testing (user acceptance testing) for middleware and LIS		

Materials and tools	• Laboratory Report Elements
	  ○ Patient identifier
	  ○ Prescriber/healthcare provider identification
	  ○ Patient location
	  ○ Test name
	  ○ Examination procedure, if applicable
	  ○ Measuring unit
	  ○ Reference interval/medical decision limit
	  ○ Comments (alerts or interpretative)
	  ○ Critical result
	• Autodilution
	• Calculations
	• Reflex and reflective testing
	• Delta check
	• HIL indices
	• Turnaround time monitoring and tracer studies
			• IT network components (e.g. modem, server, client, firewall)
			• Health Level 7 (HL-7) standards
			• Logical Observation Identifiers Names and Codes (LOINC)

Test Result Interpretation

	Type 1	Type 2	Type 3
Concepts	● Reference intervals ○ Advantages/limitations ○ Types and statistical approaches ○ Partitions and biological changes ○ Comparison to clinical decision limits ○ Comparison to cut-offs for qualitative reporting ○ Standardization/harmonization ● Biological variation ● Specimen commutability ● Gold standard/reference methods ● Interferences ● Reference change values ● Uncertainty of measurement		● Meta-analysis ● Systematic reviews
Procedures	● Reasons for interpretative comments ○ Manual interpretation ○ Analytical ○ Pre-analytical ○ Cancellations ● Reference intervals: establish, transfer or verify	● Consultation with physicians ● Additional tests for confirmation	
Materials and tools	● Total allowable error ● Reference change value ● Measurement of uncertainty ● Biological variation ● Index of individuality ● Clinical performance parameters ○ Sensitivity	● Bayes' theorem ● Interpretive guidelines	

	○ Specificity ○ Positive predictive value ○ Negative predictive value ○ Likelihood ratios ○ Efficiency ○ ROC curve analysis		

Sample Storage and Disposal

	Type 1	Type 2	Type 3
Concepts	● Sample stability during storage ● Separation from cells ● Aliquoting, sharing and splitting specimens ● Primary versus aliquot container storage ● Add-on testing ● Reflex testing ● Sample identification/de-identification	● Secondary use of specimens for quality assessment or research	● Chain of custody ● Medical waste regulations ● Biosafety and regulatory requirements for storage and handling
Procedures	● Sample retention time (policies and procedures, exceptions) ● Verification of sample stability and storage condition claims ● Indexing/tracking specimen locations	● Waste segregation ● Solid vs liquid waste ● Disposal of known hazardous specimens ● Automated storage and retrieval	● Process and requirements for release of samples to: coroner, medical examiner or law enforcement ● Biobanking ● Frequency of waste removal ● Labeling waste ● Spills and waste exposures
Materials and tools	● Pending lists ● Sample storage containers ● Sample storage locations ● Frost-free/non-cycling freezers ● Temperature monitors ● Biohazard waste containers, secondary containers		● Methods for disposing of laboratory specimens ● PPE requirements for waste handling

Section 5: Professional

This section outlines concepts related to a broad range of overarching laboratory knowledge. Due to the diverse nature of the content, specific competency statements related to each table are detailed alongside the table.

Point of Care Testing

Competency Statements for POCT Knowledge Block

For each **Type 1** topic be able to:

- Explain the importance of each concept, consideration and process to the quality of point of care testing
- Be aware of applicable point of care testing guidelines, regulations and best-practices
- Incorporate these elements into laboratory and institutional policies and procedures
- Provide a comprehensive outline of how to incorporate each item into a POCT program
- Outline how each consideration compares or contrasts to laboratory testing

For each **Type 2** Column 2 item:

- Recall the relevance to point of care testing
- Incorporate these elements into laboratory and institutional policies and procedures

	Type 1	Type 2
Concepts	• Definition(s) and scope of POCT • Multidisciplinary POCT committee/Management group • Clinical governance • Device complexity levels • Types of users • Non-laboratorian personnel training	

Considerations	● Benefits and risks of POCT ● Device/test selection and evaluation ● User training and competency assessments ● Accreditation/regulatory requirements ● Preanalytical, analytical and post-analytical factors ● Transcutaneous measurements (e.g. bilibrubin, pulse oximetry) ● Positive patient identification in POCT ● Analytical performance and comparability ● Quality management, assurance and control programs ● Instrument and user support models ● Instrument maintenance and calibration ● Connectivity and middleware ● Result reporting ● Types of POC devices	● Testing in specific populations ○ remote locations ○ outreach or non-healthcare settings ○ vulnerable populations ● Patient self-testing
Processes	● Evaluation of need and clinical utility ● Comparability assessment amongst POC devices and with laboratory methods ● Policies and Procedures appropriate for end users (e.g. respiratory technologists, nurses) ● Cleaning and disinfection ● Inventory management	● Cost-effectiveness evaluation ● Testing on patients in isolation

Laboratory Data Analysis and Statistical Techniques

(Calculations and Interpretation)

For each topic in the tables below:

- Define the meaning of each concept in the table
- Explain how each concept is applied in the clinical laboratory

For **Type 1** topics:

- Be able to perform calculations and data analysis techniques
- Critically analyze and interpret the output of the data analysis
- Understand what data analysis technique is appropriate for a given scenario and why

For **Type 2** topics:

- Be familiar with the concepts listed and their role in the clinical laboratory
- Evaluate output of calculations or data analysis techniques

	Type 1	Type 2
Concepts	● Method validation ● Clinical performance of laboratory tests ● Statistical distributions ● Parametric versus non-parametric statistics ● Reference intervals ● Probability ● Systematic and random error ● Statistical significance ● Significant figures/digits ● Types of data: dichotomous ,continuous, ordinal;	● Statistical outlier ● Data transformations ● Bayes' theorem ● Types of studies ○ case series ○ case-control ○ cohort ● Evidence-based laboratory medicine ● Meta-analysis
Calculations	● Descriptive statistics (e.g. mean, median, mode, standard deviation, coefficient of variation, standard deviation index, Z-score; range quantiles, interquartile range)	Inferential statistics ● Parametric: t-test, F-tests, analysis of variance (ANOVA) ● Non-parametric: Chi-square test,

	● Regression (e.g. least squares, Deming, Passing-Bablock) ● Statistics for evaluating quantitative test performance (e.g. accuracy, precision, linearity, total allowable error) ● Statistics for qualitative tests (e.g. concordance, McNemar test for symmetry, Cohen's Kappa) ● Sensitivity, specificity, positive predictive value, negative predictive value, likelihood ratio, prevalence ● Receiver operating characteristic (ROC) curves and related calculations (AUC, Youden's index) ● Confidence intervals ● statistical quality control ● Biological variation and related statistics (ex. CVi, CVg, Reference change value) ● Measurement Uncertainty ● Dilutions, serial dilutions, titres ● Recovery studies ● Unit conversions and calculation with units of measure	Wilcoxon rank-sum test ● Outlier detection ● Heteroskedasticity/homogeneity tests ● Moving averages ● Statistics used in external quality assessment and proficiency testing Clinical studies: ● Relative Risk Ratio ● Odds ratios ● Hazard ratios ● Number needed to treat
Processes	● Visual representation and inspection of data (e.g. scatter plot, histogram, box plot, Bland-Altman, Youden and bias plot)	● Data formatting (e.g. delimited text files) ● Specialized graphical data analysis (e.g. forest plot, bubble plot, volcano plot, rose plot)

Total Quality Management

Competency Statements for Total Quality Management Knowledge blocks

For each topic in the tables below, be able to:

- Define and illustrate the importance of each concept/procedure/tool to the accuracy of clinical laboratory testing
- Explain why each concept is important in improving quality in the clinical laboratory
- Incorporate these concepts and tools into laboratory policies and procedures
- Understand the importance of professional quality roles in laboratory medicine

For each **Type 1** topic be able to:

- Design, analyze and interpret the results of each quality parameter, tool, or metric outlined
- Outline key steps of each process/procedure and how to use the specific tools or metrics
- Be aware of guidelines, regulations or best-practice applicable to these concepts and procedures in the clinical laboratory
- Provide instructions and justification for use of a specific concept, procedure or material/tool in the context of the total testing process

For each **Type 2** topic be able to:

- Provide a general outline of how and why a procedure or process is performed or why a tool is used

Quality Control

	Type 1	Type 2
Terms and concepts	● QC program development ● Analytical Quality goals, total allowable error ● Stockholm consensus hierarchy ● Multi-rule QC (e.g. Westgard rules) ● Type of error (random vs systematic) ● Target values (e.g mean, standard deviation) ● QC frequency ● QC review and troubleshooting ● Levey Jennings charts and QC patterns ● QC material format (e.g. liquid vs lyophilized, concentration, stability, matrix effects) ● Peer group means ● Process in the event of out-of-control QC results t	● Patient based real-time quality control ● Rolling mean/averages ● Sigma metric ● False acceptance and false rejection rates

Quality Assurance

	Type 1	Type 2
Terms and concepts	● External quality assurance/Proficiency Testing (EQA/PT) survey type (wet, dry, patterns of practice) ● EQA/PT survey report interpretation and result follow up (bias, calibration verification, linearity, precision, interference) ● EQA/PT Warning/Flags ● Interlaboratory comparisons (all methods mean, instrument mean, reference value) ● Intra-laboratory comparisons ● Commutability and traceability ● Investigation of discordant results and corrective action ● Measurement uncertainty	● Laboratory accreditation requirements ● Laboratory standards and guidelines

Quality Improvement

	Type 1	Type 2
Terms and concepts	● Quality improvement paradigm ● Non-conforming and adverse event documentation and monitoring	● LeanSix Sigma methodology ○ Project charter ○ Multidisciplinary teams ○ Voice of client ○ Interventions/change initiatives ○ Goal development ○ Family of measures ○ Root cause analysis ○ Plan, Do, Check, Act cycles ○ Performance boards ○ Communication Plan ○ Process mapping ○ Process problem detection ○ Pareto chart ○ Run charts ○ Fishbone diagram

Quality Plan

	Type 1	Type 2

Terms and concepts	● Healthcare quality ● Quality system essentials ● Total quality management ● Policies, processes and procedure development ● Quality manual ● Standard operating procedures ● Key performance indicators ● Post implementation monitoring ● Risk Assessment	● Quality Director ● Organizational chart ● Inventory management ● Contingency planning

Quality Process

	Type 1	Type 2
Terms and concepts	● Occurrence management ● Process Improvement ● Internal quality and safety audits ● Process control ● Document control ● Performance assessments ● Preventive maintenance ● Records: validation, purchasing, inventory, temperature, accession ● Laboratory Information System	● Staff training ● Competency maintenance ● Safety reports ● Customer Service

Laboratory Accreditation and Regulation

Competency statements for Accreditation and Regulation Knowledge block

For each item in the table below, be able to:

- Define and explain the significance of each term/concept to the accreditation and functioning of a clinical laboratory

In addition, be able to:

- Describe major steps of the accreditation process
- List some of ways the laboratory ensures preparedness for accreditation
- Find relevant discipline-related information in standards and regulation documents
- Interpret and synthesize standards requirements to make them actionable
- Recognize how total quality management relates to each concept listed here

Concepts and processes	● Accreditation and regulation ● Accreditation bodies ● Accreditation standards ○ Structure, domains and sections (eg. analytical and technical standards, systems and organizational standards)
	Accreditation process ● Self-assessment/self-audits ● External audit/inspection cycle ● Demonstration of compliance ● Corrective actions/non-conformity management ● Personnel and resources involved in accreditation preparation

Laboratory staff training and competency

Competency statements for training and competency Knowledge block

For each topic in the table below, be able to:

- Define or explain the concept in the context of the clinical laboratory

In addition, be able to:

- Contribute to the design of staff training and competency assessments
- Facilitate teaching opportunities for laboratory personnel
- Compare the scope of practice of different laboratory personnel, including clinical biochemists, medical technicians, technologists and technical specialists

Concepts	● Definition of competency ● Scope of practice ● Medical staff privileges ● Routine versus specialized training and skills ● Education and certification requirements of different laboratory personnel ● Continuing education requirements ● Maintenance of competency ● Training guide and standard operating procedures ● Competency assessments and compliance audit ● Clinical peer review ● Annual performance review

Interprofessional collaboration and other laboratory specialties

Competency statements for interprofessional knowledge block

- Recognize when and how clinical biochemistry intersects with other laboratory and medical specialties
- Be familiar with the general scope of practice of other laboratory specialities and seek consultation, collaboration and involve other specialists when appropriate
- Be aware of laboratory testing and instrumentation outside the scope of clinical biochemistry, but requires Clinical Biochemist oversight
- Effectively communicate and work as part of interprofessional teams

Relevant terms and concepts	Laboratory specialties ● Core/multidisciplinary lab ● Hematology ● Blood bank and transfusion medicine ● Microbiology ● Pathology ● Molecular diagnostics ● Biochemical Genetics? Clinical/medical specialities ● Nutrition ● Pharmacy ● Respiratory therapy ● Dialysis ● Infection Prevention and Control ● Nursing Non-hospital healthcare collaborations ● Public health ● Naturopaths ● Midwives ● Coroner Hospital and laboratory disaster and emergency response

Leadership Skills and Structures

Competency statements for leadership knowledge block:

- Be familiar with some strategies and tools that support effective leadership
- List ways leaders can support productivity and growth of team members
- Identify areas for future personal leadership development

Terms and Concepts	● Personnel Management Techniques ● Approaches for team motivation ● Effective communication skills ● Decision making models ● Goal setting and strategic planning ● Time management ● Delegation ● Team building ● Medical-operational dyad ● Change management
Procedures	● Giving and receiving feedback ● Staff evaluations ● Performance management ● Hiring processes
Materials and tools	● Organizational charts ● Job descriptions

Laboratory Management

Competency Statements for lab management knowledge block:

For each **Type 1** topic be able to:

- Define and describe how the concept relates laboratory operations
- Summarize how each process is executed and, if applicable, how its output is created and/or evaluated
- Recall key personnel and stakeholders that need to be involved in these processes

For each **Type 2** topic be able to:

- Explain what the concept or process is, and explain its relevance to laboratory management

For each **Type 3** topic be able to:

- Recall the meaning of each term and how it is used in laboratory and personnel management

	Type 1	Type 2	Type 3
Processes and Concepts	Justification/business case for: ● instrument; test; test repatriation; referred-out testing/change in test menu Equipment acquisition and contracting processes: ● Request for information ● Request for proposal ● Reagent rental ● Capital acquisition	● Organizational chart ● Strategic planning ● Capital equipment justification ● Financial management and metrics ○ Budgeting ○ Fiscal planning ○ Return on investment ○ Cost analysis ○ Cost per test ○ Cost per reportable result ○ Overhead ○ Capital and operational costs ○ Work load statistics ○ Full time equivalent	● Billing ● Human resource management ● Labour unions ● Human Resource policies ● Credentialing ● Performance review ● Performance management

Environment and Laboratory/workplace safety

Competency Statements for Workplace safety:

For each item in the table, be able to:

- Define and explain the importance of each concept to the clinical laboratory and for personal and patient safety
- Be aware of guidelines, regulations or best-practice applicable to these concepts in the clinical lab
- Incorporate these elements into laboratory or institutional policies and procedures

Concepts and tools	Environmental Safety ● Control of Lab access/security ● Environmental control ● Fire prevention ● Fire drill, evacuation procedure and muster point ● Waste management and disposal ● Broken equipment labelling and instrument decommissioning ● Electrical and radiation safety ● Emergency code chart Control of Hazards ● Health and safety standards ○ Universal precautions ● Safety policies and procedures ● Chemical and biological safety cabinets ● WHMIS ● Chemical product inventory tracking system ● Chemical and biohazard decontamination procedures ● Safety audit Personal Safety ● Personal protection equipment ● First aid ● Hand hygiene Ergonomics Eyewash stations and emergency showers

Equity, diversity, inclusion and accessibility

Competency statements for EDI knowledge block:

- Be familiar with the meaning and definition of the terms in the table, and how they intersect with laboratory services
- Be familiar with the related terms and identify additional terms and issues that continue to evolve or may be unique to your specific laboratory context
- Appreciate how equity, diversity, inclusion and social justice in healthcare impact patient care
- Incorporate the terms and concepts in the table into laboratory policies, procedures and daily functioning to foster working and training environments that actively promote equity, diversity, inclusion and quality patient care in laboratory medicine
- Recognize existing gaps and limitations in systems design and processes that limit access to laboratory services
- Adopt strategies that promote equity, diversity and inclusion and that counter discrimination and bias[1]
- Appreciate how these terms and concepts are important to high professional standard principles

Related terms	Ableism, ageism, accessibility, anti-oppression, decolonization, diversity, equity, homophobia, inclusion, intersectionality, meritocracy, racism, sexism, genderism
Factors impacting EDI	Historical, social, cultural, economical, political, environmental, structural, systemic
Concepts	● Anti-racism policies ● Implicit and Explicit Bias ● Cultural Safety ● Social Justice ● Access to healthcare (all types): ○ resources and services ○ physical access ○ remote vs urban access ● Truth and reconciliation with indigenous communities ● Trauma-informed care ● Vulnerable populations ● Patient test instructions (e.g.languages, ease of reading) ● LIS limitations (e.g. gender diversity) ● Patient-centered care Biological differences in diverse populations

	● Inclusion of gender-diverse needs in the lab ● Pediatric and patient-specific phlebotomy support

Ethics

Competency statements for ethics knowledge block:

- Identify and appropriately respond to ethical issues in laboratory medicine
- Appreciate how these terms and concepts are important to high professional standard principles
- Be familiar with local/jurisdictional health information privacy laws and research ethics processes
- Incorporate these terms and concepts into laboratory policies, procedures and daily functioning

Terms and concepts	● Confidentiality ● Impartiality ● Professionalism ● Beneficence ● Avoidance of maleficence ● Conflicts of interest ● Local or institutional ethics policy or code of deontology ● Civility and respect in the workplace ● Public trust and protection ● Informed consent ● Ethics in molecular diagnostics and prenatal screening ● Research ethics and research involving the use of laboratory specimens

Sustainability

Competency statements for sustainability knowledge block:

- Be aware of the definition, pillars, and barriers of sustainability in laboratory medicine[1]
- For pre-analytical, analytical, and post-analytical testing phases, identify major causes of laboratory impact to the environment and suggest strategies to improve sustainability through technical, digital and organizational solutions.

Concepts	● Pillars of sustainability in laboratory medicine ● Definition and barriers to sustainability in healthcare ● Laboratory contribution to emissions and carbon footprint ● Energy, water and other resource use ● Reducing, reusing, and recycling consumables ● Digital and automation solutions ● Test stewardship to improve laboratory utilization ● Minimizing non value-added tasks and causes of poor quality processes

Laboratory Information Management

Competency Statements for lab information management:

For each **Type 1** topic be able to:

- Describe what it is and explain its function in laboratory information management
- Describe how each item impacts information flow within and between health information systems
- Diagram the relationship between each term or concept and result reporting
- Design, analyze and interpret the results of studies that evaluate the function or monitor a process related to each topic
- Be aware of guidelines, regulations or best-practice applicable to these concepts and procedures in the clinical laboratory
- Incorporate these concepts and practices into laboratory policies and procedures when appropriate

For each **Type 2** topic be able to:

- Be familiar with each item and its purpose in laboratory information management
- Explain how each concept impacts information flow within and between health information systems
- Incorporate these concepts and practices into laboratory policies and procedures when appropriate

For each **Type 3** topic be able to

- Be familiar with each item and its purpose in laboratory information management
- Incorporate these concepts and practices into laboratory policies and procedures when appropriate

	Type 1	Type 2	Type 3
Terms and concepts	Components of laboratory information: ● Laboratory information system ● Document control system ● Inventory control system ● Middleware ● Data stored on instruments ● Networked file storage Information system validation ● User acceptance testing ● Interface verification	● Data privacy ● Data exchange and standards (e.g. Health Level 7 (HL7)) ● Logical Observation Identifier Names and Codes (LOINC) ● Systematized Nomenclature of Medicine (SNOMED) ● International Classification of Diseases (ICD) ● Instrument to LIS interfaces	● Data warehousing ● Secondary data use (e.g. clinical, education, operational, research, business) ● LIS to LIS integration

Medico-legal

Competency statements for Medico-legal section:

- Be familiar with each item and identify how it may relate to clinical laboratories

Concepts and Principles	● Chain of custody ● Testing for non-clinical indications ● Requirements for forensic toxicology testing purposes ● Specimen types for post-mortem and forensic analysis: ○ Esoteric biological specimens ○ Non-biological specimens ○ Specimen validity (e.g. specimen stability and integrity) ● Storage and handling of materials ● Release of results and specimens ● Specimen and results records retention specifications

Research

Competency statements for Research section:

- Be able to define the terms, and how it may apply to the clinical laboratory

Concepts and Principles	● Types of research studies ● Evidence based lab medicine ● Consent process ● Anonymization, de-identification ● Confidentiality ● Ethics in research studies and ethics approvals ● Processes for the approval of research studies ● Material transfer agreements ● Data analysis and management ● Research versus clinical laboratories ● Biobank

Lab Stewardship

Competency statements for Lab Stewardship:

- Define the terms, and how they apply to the clinical laboratory
- Be aware of guidelines or best-practice applicable to these concepts in the clinical laboratory

Concepts	● Principles and rationale for best practices for laboratory utilization ● Choosing Wisely Canada initiatives ● Best practices for laboratory stewardship oversight ● Laboratory stewardship metrics ● Test selection ● Test utilization
Processes	● Governance ● Engagement ● Interventions ● Data extraction and monitoring ● Continual assessment

Teaching Skills

Competency statements for Teaching:

- Define and apply the terms

Concepts	● Communication and interpersonal skills ● Instructional techniques ● Educational resources ● Learning styles
Processes	● Setting learning objectives ● Design of curriculum, laboratory rotations and projects ● Coaching and mentoring ● Evaluation ● Giving, receiving and responding to feedback