CLINICAL BIOCHEMISTRY DIGITAL SPECIALIST PORTFOLIO MODULES

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Clinical Biochemistry Specialist Portfolio Modules

- Quality (please see separate booklet for learning outcomes)
- Biochemistry Techniques
- Automation and Laboratory Practice
- Fluid and Electrolyte Disorders
- The Kidney in Health and Disease
- Liver Function and Associated Disease States
- Lipids, Lipoproteins and Lipid Metabolism
- Calcium, Magnesium, Phosphate and Bone Markers
- Diabetes and Hypoglycaemia
- Acid-Base and Bicarbonate Balance
- Cardiac Biomarkers
- Specific Proteins
- Cancer Biochemistry and Tumour Markers
- Gastrointestinal Disorders and Malabsorption
- Reproductive Endocrinology
- Pregnancy Biochemistry
- Inherited Metabolic Disorders and Newborn Screening
- Biochemical Nutrition
- Investigation of Thyroid Disease
- Abnormal Pituitary Function
- Investigation of Adrenal Disease
- Therapeutic Drug Monitoring
- Toxicology

Please note
All learning outcomes (LOs) are met through two pieces of evidence, Q&A as agreed with a training officer and an additional piece of work as selected by the candidate.

A statement of work and reflective statement on each module will be required which will include sign off by the trainer stating that the candidate works in accordance with laboratory procedures, the competence for which should be evidenced in-house and is not part of the portfolio submission.

Indicative Content outlines background knowledge that may be required to meet the LOs and/or knowledge and competences expected to be demonstrated across multiple modules. Knowledge of areas highlighted in the indicative content may be examined during the viva.

Module Title	Clinical Biochemistry Techniques
Module code	9258
Rationale/ Aims	Overview of the techniques used within clinical biochemistry. Candidates will gain understanding of core techniques used within clinical biochemistry laboratories including method principle, advantages and limitations. They will be able to critically evaluate the methods and understand when and why different methods are used. The candidate will understand the underlying scientific principles of the methods listed. Candidates will be able to apply knowledge to practical application in the laboratory.
Learning outcomes	1. Explain the principles of methodologies, advantages and limitations used in practice, include: • Ion selective electrodes (ISE) direct/indirect • Spectrophotometry (including different reaction types and indices) • Nephelometry • Turbidimetry • Immunoassay • Competitive and non-competitive • Chemiluminescent immunoassay (CLIA) • Fluorescence immunoassay (FIA) • Enzyme linked immunosorbent assay (ELISA) • Liquid chromatography tandem mass spectrometry (LC-MS/MS) • HPLC • Gas chromatography mass spectrometry (GCMS) 2. Describe the following methods and give an example of where this might be used: • Radioimmunoassay • Particle agglutination 3. Discuss the principles of interferences in methods listed above including haemolysis, icterus, lipaemia, heterophilic antibodies and sample contamination. 4. Explain the generation and use of calibration curves and the calculation of results from a measured signal. 5. Evaluate different methodologies in use for 2 selected analytes and discuss why your laboratory uses your current method. 6. Explain antibody-antigen reaction kinetics, including affinity, avidity, prozone and antigen excess. 7. Define the following terminology and give workplace specific examples: • Qualitative • Quantitative • Analytical sensitivity • Analytical specificity • Clinical sensitivity

	• Clinical specificity • Accuracy • Precision • Linearity • Limit of detection
Indicative Content	Candidates require knowledge and understanding of: Techniques used within clinical biochemistry laboratories including principle, advantages and limitations. Sensitivity and specificity of assays and how this is used to determine when confirmation methods are used. Signal generation and detection methods within assay systems. Antibody-antigen kinetics. Candidates must be able to Run assays, troubleshoot as required and perform all aspects of quality assurance including maintenance, IQC, EQA, calibration, record keeping, non-conformance reporting

Module Title	Automation and Laboratory Practice
Module code	
Rationale/ Aims	This module covers principles of automation in the clinical biochemistry laboratory including, autovalidation, contingency planning, IT interfaces and connectivity including middleware systems. Candidates will gain knowledge and understanding of laboratory IT connectivity, autovalidation processes and contingency planning. Candidates will be able to troubleshoot issues and communicate issues to relevant parties. Candidates will understand the process of verification and validation.
Learning outcomes	1. Discuss the principles of autovalidation include reference and abnormal ranges, delta checks (incorporate biological variation data), within sample checks and rule-based criteria, use examples from practice to demonstrate how these are applied. 2. Discuss your local contingency process, include examples of IT failure and analyser failure and discuss your limits of practice in these processes. 3. Describe the end-to-end use of the instrument software/user interface including the role of “middleware” from sample receipt to result reporting and discuss how issues would be investigated and resolved. 4. Discuss the importance of maintenance procedures and discuss, with examples, why specific maintenance is performed. 5. Demonstrate setting up and running assays on your routine automated analyser. 6. Demonstrate examples of troubleshooting different issues on automated analysers, including the rationale for actions taken. 7. Discuss the process for implementation of a new assay or analyser, identify where verification and/or validation steps are undertaken. 8. Explain the difference between verification and validation and demonstrate a verification or validation undertaken by the candidate.
Indicative Content	Candidates require knowledge and understanding of: How information is passed between the laboratory LIMS system and the analysers including middleware.

Module Title	Fluid and Electrolyte Disorders
Module code	9260
Rationale/ Aims	This module covers knowledge and practice relating to laboratory testing for fluid and electrolyte disorders. Candidates will gain knowledge of water and electrolyte homeostasis and be able to interpret analytical results in the investigation of electrolyte disorders. Candidates will understand the relationship of osmolarity, osmolarity and fluid constituents and how this impacts analytical results obtained. Candidates will understand the water deprivation test and how to interpret results.
Learning outcomes	1. Describe mechanisms of water and electrolyte homeostasis. 2. Demonstrate analysis and interpretation of sodium, potassium and osmolality, in plasma/serum and urine, in the assessment of water and electrolyte homeostasis. 3. Discuss causes of pseudohyponatraemia and their investigation. 4. Discuss causes of pseudohyperkalaemia and how these are investigated. 5. Explain the principles and application of osmolality measurement in the candidates laboratory. 6. Discuss the relationship between osmolality, osmolarity and plasma constituents and demonstrate how to calculate a plasma osmolarity. 7. Explain with examples, discrepancies between calculated osmolarity and measured osmolality. 8. Describe with examples causes of electrolyte/fluid disturbances and how these may be investigated further with additional biochemical testing. 9. Describe the water deprivation test and discuss its use in clinical diagnosis.
Indicative Content	Candidates require knowledge and understanding of: Osmolality measurement and its clinical value Interferences in analytical processes Candidates must be able to : Measure and interpret analytes in the investigation of water and electrolyte imbalance, including maintenance of equipment and quality assurance processes

Module Title	The Kidney in Health and Disease
Module code	9253
Aim of the Module	This module covers the role the kidney plays in eliminating waste and how a decline in function and kidney damage are detected in the laboratory. Candidates will gain knowledge of the anatomy and physiology of the kidney in health and disease and the pathophysiology of acute and chronic kidney disease. Candidates will gain understanding of the routine laboratory tests used in the investigation of kidney function and renal disease and be able to analyse and interpret these results.
Learning outcomes	1. Describe the anatomy of the kidney and discuss how this relates to normal function. 2. Explain the role of the kidney in health and discuss how this alters during the different disease states of acute kidney injury (AKI) and chronic kidney disease (CKD). 3. Discuss the biochemical differentiation between glomerular and tubular renal disease. 4. Discuss the key tests (both analytical and calculated) that aid in the detection of kidney damage or declining function. 5. Discuss the role of the laboratory in implementing clinical practice guidelines for the management of AKI and CKD (e.g., NICE*, KDIGO*). 6. Discuss different methods of creatinine measurement and explain their limitations. 7. Demonstrate interpretation and reporting of kidney function test results, commenting on clinical and/or technical significance. 8. Describe the purpose of kidney stone analysis, including tests requested to aid understanding of the cause of stone formation and discuss what different test results mean for the patient.
Indicative Content	Students require knowledge and understanding of: Kidney anatomy, physiology and function, its relevance in kidney pathogenesis and the subsequent diagnosis of disease. Candidates must be able to : Measure and interpret analytes in the investigation of renal dysfunction and disease, including maintenance of equipment and quality assurance processes

Module Title	Liver Function and Associated Disease States
Module code	9254
Rationale/ Aims	This module provides an overview of the liver, liver disease including inherited conditions impacting liver function and investigation of these conditions. Candidates will gain understanding of the liver in health and disease and of the analytes utilised in laboratory investigations. Candidates will gain knowledge on causes of jaundice and inherited diseases that impact bilirubin. Candidates will be able to analyse, interpret and report on liver function results
Learning outcomes	1. Discuss, the pathophysiology of the following liver diseases; cholestasis, cirrhosis, hepatitis and malignancy. 2. Explain major causes of jaundice with pre-hepatic, hepatic and post-hepatic examples. 3. Discuss common inherited abnormalities of bilirubin including Gilberts syndrome. 4. Identify tests used in the investigation of liver function and associated disease states and explain their analytical role. 5. Demonstrate measuring core analytes in the investigation of liver disease and comment on a range of results obtained. 6. Explain, with examples, the significance of abnormal bilirubin in plasma/ serum and urine. 7. Explain when the following might be measured in the investigation of liver disease and why: • ALP isoenzymes • urine bilirubin and urobilinogen, • ɣ- gamma globulins, • α-fetoprotein • α 1-antitrypsin • copper and ceruloplasmin 8. Discuss the potential impact of Enhanced Liver Fibrosis (ELF) testing on patient pathways.
Indicative Content	Candidates require knowledge and understanding of: The role of the liver in carbohydrate, fat, protein and hormone metabolism; storage; the metabolism and excretion of bilirubin; detoxification of drugs and foreign compounds The metabolism and breakdown of haemoglobin, the excretion and physiological importance of total and direct bilirubin Common liver diseases, their aetiology and how they are investigated in the laboratory Commonly performed liver function tests e.g. total bilirubin, direct (conjugated) bilirubin, total protein, albumin, bile acids, AST, ALT, GGT, ALP (including isoenzymes), amylase

	Referral tests and the methodologies used Non-biochemistry tests that may be used with biochemistry results in the investigation of liver disease

Module Title	Lipids, Lipoproteins and lipid metabolism
Module code	9270
Rationale/ Aims	This module provides an overview of lipids, lipid disorders and their involvement in cardiovascular disease as well as analytical considerations in lipid analysis. Candidates will gain knowledge and understanding of the classification of lipids and lipoproteins, lipid metabolism and abnormalities, Candidates will gain knowledge of the role of lipids in diagnosis and monitoring of disease and the role of lipid measurements in prevention of cardiovascular disease. Candidates will understand analytical methods available for measurement and calculation of lipids and lipoproteins and their limitations.
Learning outcomes	1. Describe classification of lipids and lipoproteins. 2. Describe primary lipid disorders and their classification, discuss the laboratory investigation of one of these. 3. Describe secondary causes of lipid abnormalities, discuss the laboratory investigation of one of these. 4. Explain how lipid measurements are used to assess risk of cardiovascular disease in association with other factors. 5. Discuss the treatment and management of cardiovascular disease risk, e.g. role of statins. 6. Demonstrate reporting samples for lipaemia and comment on the results. 7. Demonstrate calculating LDL-cholesterol, and non-HDL cholesterol and discuss the limitations. 8. Explain rationale for fasting and non-fasting lipid requests. 9. Discuss non-pathological causes of lipaemia.
Indicative Content	Candidates require knowledge and understanding of: Normal lipid metabolism Lipid disorders and treatments. Sample interferences Candidates should be able to: Analyse samples for lipid analysis, including maintenance of relevant equipment and ensuring quality assurance processes are carried out Interpret and report lipid results

Module Title	Calcium, Magnesium , Phosphate and Bone Markers
Module code	9262
Rationale/ Aims	This module covers the roles and regulation of calcium, magnesium and phosphate, disorders of calcium, magnesium and phosphate and their investigation. Candidates will gain knowledge of the structure, function and regulation of bone formation and resorption including the role of vitamin D, PTH and calcitonin in calcium, magnesium and phosphate homeostasis. Candidates will be able to classify, diagnose and identify typical treatment of calcium, magnesium and phosphate disorders.
Learning outcomes	1. Describe the roles, distribution, and metabolic regulation of calcium, phosphate, and magnesium ions in the human body. 2. Discuss, with examples, causes and consequences of disorders of calcium, phosphate, and magnesium homeostasis. 3. Discuss the application of different laboratory tests utilised in investigating disorders of calcium, phosphate, and magnesium homeostasis, include why they are used. 4. Explain the difference between total and ionized calcium measurement, the role of calcium correction and why this is required. 5. Discuss the limitations and interferences that may affect measurement of analytes involved in the investigation of calcium, magnesium and phosphate homeostasis. 6. Describe the process of bone formation and resorption. 7. Discuss analytes utilised in the investigation of metabolic disorders affecting bone.
Indicative Content	Candidates require knowledge and understanding of: The roles and regulation of calcium, magnesium and phosphate. The most common diseases associated with metabolic bone disease and disorders of calcium, magnesium and phosphate homeostasis. Understand the principles of analysis of tests involved in the investigation of bone disease and know the reference ranges for commonly performed tests. Able to run analysers and processes associated with analytes measured including EQA as appropriate and application of internal quality processes including troubleshooting.

Module Title	Diabetes and Hypoglycaemia
Module code	9259
Rationale/ Aims	This module covers glucose metabolism and the laboratory investigation of hyper and hypoglycaemia. Candidates will gain knowledge of glucose regulation and metabolism and the conditions resulting from hyper and hypoglycaemia . Candidates will gain understanding of analytes measured during investigation of hypo and hyperglycaemia and be able to interpret the results.
Learning outcomes	1. Describe the mechanism and function of the following: gluconeogenesis, glycogenolysis, glycolysis, ketogenesis. 2. Describe the homeostatic control of blood glucose concentration including the counter- regulatory hormones: glucagon, cortisol, adrenaline, and growth hormone, and identify the target tissues of insulin. 3. Discuss different sample types and how they are used in the investigation and monitoring of hyperglycaemia and hypoglycaemia. 4. Describe the clinical utility of the glucose tolerance test and glycated haemoglobin and demonstrate with examples interpretation of results. 5. Describe common clinical features of diabetes mellitus and discuss the diagnostic criteria. 6. Discuss the different types of diabetes and associated treatment strategies. 7. Discuss the long-term complications of diabetes and monitoring processes. 8. Define insulin resistance and the metabolic syndrome. 9. Discuss the role of c-peptide and insulin measurement in the investigation of hypoglycaemia. 10. Discuss the mechanisms and laboratory diagnosis of: diabetic ketoacidosis, hyperosmolar hyper-glycaemic syndrome, and hypoglycaemia.
Indicative Content	Candidates require knowledge and understanding of: Physiology and homeostasis of glucose metabolism and control. Common diseases and complications associated with insulin resistance. Principles of analysis of tests involved in the investigation of diabetes and know the reference ranges for commonly performed tests. Candidates must be able to: Run analysers and processes associated with analytes measured including EQA as appropriate and application of internal quality processes including troubleshooting.

Module Title	Acid-Base and Bicarbonate Balance
Module code	9261
Rationale/ Aims	This module covers acid-base balance and how this is impacted by physiological factors, homeostatic and compensatory mechanisms. Candidates will gain knowledge of acid base homeostasis and the impact of different conditions on acid-base balance. Candidates will gain knowledge of the compensatory mechanisms and how changes to acid base impact other analytes and their measurement. Candidates will gain knowledge of metabolic and respiratory conditions affecting acid-base and how these are investigated. Candidates will understand methodologies of analyte measurement and the different uses of blood gas analytes
Learning outcomes	1. Describe homeostasis and physiological significance of buffer systems. 2. Describe normal acid-base balance including bicarbonate reabsorption and hydrogen ion excretion, including the transport of carbon dioxide and oxygen. 3. Discuss the following with an example condition: • Metabolic acidosis • Metabolic alkalosis • Respiratory acidosis • Respiratory alkalosis 4. Discuss the physiological compensatory mechanisms in each of the above disorders. 5. Discuss, with an example, a condition that gives rise to a mixed acid base disorder. 6. Discuss sample requirements for blood gas analysis and explain possible complicating pre-analytical errors for abnormal blood gas. 7. Identify the analytes measured on blood gas analysers and discuss how this compliments laboratory analysis. 8. Describe the methodology of the following: • Direct ISE • Amperometry • pH electrode • Co-oximetry 9. Demonstrate interpretation of a blood gas result.
Indicative Content	Candidates require knowledge and understanding of: Impact of acid-base on analyte measurement Sample requirements for blood gas analysis Difference between analytes measured on blood gas analysers and in the laboratory

Module Title	Cardiac Biomarkers
Module code	9267
Rationale/ Aims	Candidates will gain understanding of the use of biomarkers to assist in diagnosis of cardiac disease and the use of guidelines for assessment of patients with heart disease. Candidates will understand the laboratories role in analysis, diagnosis and monitoring cardiac disease.
Learning outcomes	1. Define the term Acute Coronary Syndrome (ACS) and describe cardio-vascular changes that may lead to ACS 2. Explain the rationale for using troponin to detect cardiac muscle damage. 3. Explain with reference to guidelines how troponin is used in conjunction with clinical assessment for diagnosis of myocardial infarction (MI). 4. Demonstrate actions taken when analysing and reporting on troponin results and give examples of situations when clinical communication is required. 5. Describe the term congestive heart failure (CHF) and explain associated physiological changes. 6. Discuss laboratory investigations of diagnosing and monitoring of CHF, explain the rationale of these investigations. 7. Explain with reference to guidelines the interpretation of BNP and potential follow up investigations. 8. Discuss cardiac and non-cardiac causes of elevated CK. 9. Discuss the range of POCT cardiac markers in use.
Indicative Content	Candidates require knowledge and understanding of: Structure and physiology of the heart Cardiac disorders Candidates should have an awareness of national guidelines relating to investigation of heart disease Candidates must be able to: Measure and interpret analytes in the investigation of cardiac function, including maintenance of equipment and quality assurance processes

Module Title	Specific Proteins
Module code	9256
Rationale/ Aims	This module covers knowledge and practice relating to laboratory testing for common proteins measured in clinical chemistry laboratories. Candidates will gain knowledge of proteins measured in clinical biochemistry and the relationship of proteins in different body fluids. Candidates will be able to interpret protein electrophoresis results and understand why different proteins are analysed in investigations.
Learning outcomes	1. Explain why each of the following proteins might be measured in a laboratory: Beta-2 microglobulin CRP Procalcitonin Alpha-1-antitrypsin Ceruloplasmin Immunoglobulins Complement Cryoglobulins Carbohydrate Deficient Transferrin Serum free light chains 2. Discuss the relationship of proteins in serum, plasma, urine, CSF and other fluid types. 3. Demonstrate interpretation of serum electrophoresis and the patterns expected in different conditions using examples from practice. 4. Evaluate the role of protein analysis in myeloma diagnosis and monitoring. 5. Discuss the relationship between MGUS and myeloma. 6. Discuss the role of CSF protein analysis, including electrophoresis in the investigations of different conditions for example, multiple sclerosis. 7. Discuss the clinical relevance of cryoglobulin analysis and evaluate the techniques used to collect, prepare and analyse them. 8. Discuss the role of serum electrophoresis in the analysis of AAT phenotypes and how this impacts patient management. 9. Discuss the potential impact of B-amyloid and Tau protein in the investigation of dementia.
Indicative Content	Candidates require knowledge and understanding of: Basic chemical and physical properties of protein molecules. Synthesis of immunoglobulins Assess suitability of samples for analysis. Demonstrate analysis of specific protein(s) as described in local SOP.

	follow laboratory procedures for reporting of results, including acting on significant/abnormal results Common interferences with protein assays. Candidates must be able to: Evaluate specific protein EQA report.

Module Title	Cancer Biochemistry and Tumour Markers
Module code	9263
Rationale/ Aims	This module covers causes of cancer and biochemical markers that can be used in screening, diagnosis and monitoring. Candidates will gain knowledge of the biochemical and metabolic changes associated with tumour development and common cancers and their biomarkers. Candidates will gain understanding of the laboratory tests available for screening, diagnosis and monitoring of tumour development and how these are interpreted.
Learning outcomes	1. Describe causes of cancer and discuss, where relevant, how these lend themselves to biochemical investigation. 2. Discuss attributes an ideal tumour marker in relation to screening, diagnosis and monitoring and evaluate biochemistry tumour markers against this ideal. 3. Describe the role of different biochemical biomarkers involved in cancer staging. 4. Discuss possible biochemical consequences of tumour growth such as ectopic hormone production. 5. Discuss how different methods and standards can impact results obtained. 6. Discuss sample collection considerations in relation to tumour marker measurement. 7. Demonstrate with examples reporting tumour markers and commenting on the results. 8. Discuss possible future advances in cancer biochemistry and molecular diagnostics.
Indicative Content	Candidates require knowledge and understanding of: Hormonal and biochemical changes in tumour development and metastasis. Common carcinomas and their symptoms. Principles of analysis of tests involved in the screening, diagnosis, monitoring and classification of tumours. GI tumour markers, e.g. 5HIAA Candidates must be able to: Run analysers and processes associated with analytes measured including EQA as appropriate and application of internal quality processes including troubleshooting.

Module Title	Gastrointestinal Disorders and Malabsorption
Module code	9264
Rationale/ Aims	This module covers the physiology of the gastrointestinal (GI) tract and the analytes used in investigation of GI disorders. Candidates will gain knowledge of the structure and function of the GI tract and the major organs involved and understanding of the classification, diagnosis and treatment of GI disorders. Candidates will understand the key biochemical tests associated with GI disease diagnosis and monitoring and be able to explain results obtained.
Learning outcomes	1. Explain the physiology of absorption in the GI tract and explain the different functions of acid in the stomach and bile acids in the small intestine. 2. Explain the functions of secretin and cholecystokinin in nutrient digestion. 3. Describe the following conditions and discuss their investigation: GI bleed • Coeliac Disease • Inflammatory Bowel Disease (IBD) • Irritable Bowel Syndrome (IBS) • Gastric surgery with bypass or gastric banding • Thyrotoxicosis • Pancreatic insufficiency • Bile salt insufficiency • Cystic Fibrosis 4. Discuss the use of amylase and lipase in the investigation of Pancreatitis. 5. Describe the symptoms and laboratory diagnosis of gut hormone-secreting tumours. 6. Discuss the advantages and limitations of the faecal elastase test as a measure of exocrine pancreatic disease and describe the alternative tests available. 7. Demonstrate reporting and interpretation of abnormal results in the investigation of gastrointestinal disease.
Indicative Content	Candidates require knowledge and understanding of: The GI structure and function The secretion and absorption processes. The most common diseases associated with the GI tract. Principles of analysis of tests involved in the investigation of GI disorders. Candidates must be able to: Run analysers and processes associated with analytes measured including EQA as appropriate and application of internal quality processes including troubleshooting.

Module Title	Reproductive Endocrinology
Module code	9265
Rationale/ Aims	This module covers hormones required for reproduction, causes of infertility and the biochemical investigations of these. Candidates will gain knowledge of the role of hormones involved in reproductive endocrinology in the female, hormonal changes in the menstrual cycle and control mechanisms involved and the hormonal interrelationships in male reproductive function. Candidates will gain understanding of the key biochemical tests associated with investigation of pregnancy, infertility, assisted conception and menopause.
Learning outcomes	1.Describe the hormonal changes in the menstrual cycle, the control mechanisms involved and explain why menstrual cycle day information is necessary for accurate result interpretation. 2.Explain causes of amenorrhoea and discuss the role of the laboratory in its investigation. 3. Discuss the causes and biochemical investigations of male and female infertility. 4. Describe how and why ovulation may be inhibited or induced for therapeutic purposes. 5. Discuss the significance of results (E2/prog) in assisted conception patients and Ovarian Hyperstimulation Syndrome (OHSS). 6. Discuss the relationship of free hormones and their binding proteins. 7. Explain the significance of measuring free and total hormone values and their binding proteins to laboratory investigations. 8. Discuss the implications of laboratory investigations for transgender patients.
Indicative Content	Candidates require knowledge and understanding of: Physiological mechanisms of hormone control and action on target organ Control and function of hypothalamic/pituitary/gonadal axis. Principles of analysis of biochemical tests involved in the investigation of infertility and menopause Laboratory procedures for reporting of results, including acting on significant/abnormal results The laboratory role in the investigation of infertility and in assisted conception Candidates should be able to: Run analysers and processes associated with analytes measured, including EQA as appropriate and application of internal quality processes including troubleshooting.

Module Title	Pregnancy Biochemistry
Module code	9268
Rationale/ Aims	This module covers changes in biochemistry during pregnancy. Candidates will gain knowledge of biochemical and metabolic changes associated with pregnancy and common pregnancy disorders. Candidates will understand the laboratory tests available for screening, diagnosis and monitoring of pregnancy and common pregnancy-related disorders. Candidates will understand the different laboratory methods used in prenatal screening and diagnosis, and their limitations.
Learning outcomes	1. Describe hormonal and metabolic changes in pregnancy. 2. Discuss effects pregnancy can have on common laboratory tests. 3. Describe common biochemical disorders in pregnancy. 4. Discuss the role of laboratory tests in the screening, diagnosis and monitoring of preeclampsia, cholestasis, thyroid disease and iron deficiency in pregnancy. 5. Discuss the role of biochemistry in the diagnosis of gestational diabetes and the impact on patient management. 6. Describe the changes of HCG levels in pregnancy and discuss how these are used in normal, ectopic and molar pregnancy confirmation. 7. Discuss the role of biochemistry in pre-natal screening.
Indicative Content	Candidates require knowledge and understanding of: Hormonal and biochemical changes in pregnancy Common pregnancy related disorders, e.g. gestational diabetes Principles of analysis of tests involved in the prenatal screening and the investigation of pregnancy disorders Candidates must be able to: Run analysers and processes associated with analytes measured including EQA as appropriate and application of internal quality processes including troubleshooting.

Module Title	Inherited Metabolic Disorders and Newborn Screening
Module code	9266
Rationale/ Aims	This module covers inherited metabolic disease and investigations undertaken in the clinical biochemistry laboratory. Candidates will gain knowledge of modes of inheritance different types of inherited metabolic disease. Candidates will gain understanding of laboratory tests available for screening, diagnosis and monitoring of inherited metabolic disease.
Learning outcomes	1. Explain the genetic basis of inherited metabolic disease and modes of inheritance. 2. Discuss the pathogenesis and role of the laboratory in the following; Cystic Fibrosis (CF) Alpha 1 anti-trypsin deficiency and porphyrias. 3. Describe, with examples, different types of inherited metabolic disorders. 4. Explain with an example the effects of a metabolic block and its significance in disease detection. 5. Discuss with examples treatment strategies for inherited metabolic disorders and the requirement for ongoing monitoring. 6. Discuss with examples initial investigations undertaken when inherited metabolic disorders are suspected and describe sample requirements. 7. Describe the role of the laboratory in diagnosis confirmation and monitoring of inherited metabolic disorders including when referrals are necessary. 8. Explain the requirement for monitoring antenatal patients with inherited metabolic disorders. 9. Discuss sample requirement for newborn screening, disorders detected and limitations of testing.
Indicative Content	Candidates require knowledge and understanding of: Genetic inheritance Different types of inherited metabolic disorders Principles of analysis of tests involved in newborn screening and the investigation of inherited metabolic disorders Candidates must be able to: Run analysers and processes associated with analytes measured including EQA as appropriate and application of internal quality processes including troubleshooting.

Module Title	Biochemical Nutrition
Module code	9255
Rationale/ Aims	This module covers key conditions which cause nutritional insufficiency and their typical symptoms and laboratory tests available for screening, diagnosing and monitoring nutritional status. Candidates will gain knowledge and understanding of how nutritional status impacts health and which analytes are most commonly measured. Candidates will be able to analyse samples, explain the results, report the results and take actions based on results as required.
Learning outcomes	1. Describe the nutritional requirements of the following and their transport proteins in health: • Copper • Zinc • Selenium • B12 • Folate • Iron • Vitamins A and E 2. Discuss conditions and related symptoms which may arise from or cause insufficiency or excess of those analytes listed in LO1. 3. Discuss the role the laboratory plays in diagnosing and monitoring conditions discussed in LO2. 4. Demonstrate with examples from candidates practice investigation and reporting of nutritional status. 5. Identify sample requirements and factors that may impact sample integrity and discuss corrective action(s). 6. Explain Total Parenteral Nutrition (TPN) and discuss the laboratory role in patient monitoring. 7. Discuss treatment strategies for nutritional insufficiency and the potential impact on result interpretation and further testing. 8. Demonstrate, relevant to candidates practice, the ability to analyse samples, interpret results, and for abnormal results take appropriate action(s) explaining the rationale for decisions.
Indicative Content	Candidates require knowledge and understanding of: Different macro and micronutrients required for normal physiology. Common nutritional disorders and their symptoms. Principles of analysis of tests involved in the screening, diagnosis, monitoring of nutritional insufficiency. Candidates must be able to: Run analysers and processes associated with analytes measured including EQA as appropriate and application of internal quality processes including troubleshooting.

Module Title	Investigation of Thyroid Disease
Module code	9271
Rationale/ Aims	This module looks at the role of the thyroid and investigation of thyroid dysfunction/disease. Candidates will gain knowledge of thyroid anatomy and function and understanding of thyroid disease and its investigation in the laboratory. Candidates will be able to interpret results of thyroid investigations.
Learning outcomes	1. Describe the anatomy of the thyroid gland and discuss the physiological role of the thyroid hormones and their target organs. 2. Describe the mechanisms of thyroid hormone synthesis and homeostatic control as part of the hypothalamic-pituitary-thyroid-axis. 3. Discuss the clinical significance of free thyroid hormone concentration and the carrier proteins involved in thyroid hormone transport. 4. Discuss different types of thyroid disease, their causes and typical symptoms. 5. Discuss laboratory tests involved in the investigation of thyroid disease including autoantibody measurement. 6. Demonstrate with examples result interpretation in the investigation of hyper and hypothyroid disease. 7. Describe different treatment strategies for thyroid disease and possible complications that may result.
Indicative Content	Candidates require knowledge and understanding of: The physiology and homeostasis of pituitary hormone production and the negative feedback loop. The most common diseases and complications associated with thyroid dysfunction. Principles of analysis of tests involved in the investigation of thyroid disease and know the reference ranges for commonly performed tests. Significance of thyroid disease in pregnancy Candidates must be able to: Run analysers and processes associated with analytes measured including EQA as appropriate and application of internal quality processes including troubleshooting.

Module Title	Abnormal Pituitary Function
Module code	9269
Rationale/ Aims	This module covers the physiology and functions of the pituitary gland and the laboratory investigation of pituitary disorders. Candidates will gain knowledge of the structure and function of the pituitary gland and its relationship to the hypothalamus and understanding of causes of pituitary dysfunction and the laboratory tests utilised to investigate. Candidates will also understand how dynamic function tests are used to aid these investigations and will be able to interpret results.
Learning outcomes	1: Describe the physiology and relationship of the hypothalamus and pituitary. 2: Discuss the classification, transport and mechanism of action of pituitary hormones. 3: Explain the synthesis, homeostatic control and function of Growth Hormone, Prolactin ACTH, TSH, LH and FSH. 4: Describe conditions that may lead to abnormal pituitary hormone production. 5: Demonstrate using an example from practice the laboratory investigation of hyperprolactinaemia. 6: Describe the role of dynamic function tests and discuss with examples how these are used to assess pituitary function. 7: Identify sample requirements and factors that may impact sample integrity and discuss appropriate corrective action(s).
Indicative Content	Candidates require understanding of: Human physiology and homeostatic mechanisms including those related to pituitary function Considerations of sample requirements, analytical requirements and quality assurance processes in clinical biochemistry Principles of analysis of tests involved in the investigation of pituitary dysfunction Candidates must be able to: Run analysers and processes associated with analytes measured, including EQA as appropriate and application of internal quality processes including troubleshooting

Module Title	Investigation of Adrenal Disease
Module code	9272
Rationale/ Aims	This module covers the physiology of the adrenal, its relationship to other glands, causes and impact of adrenal dysfunction and its investigation. Candidates will gain knowledge of the structure and function of the adrenal gland and its relationship to the hypothalamic and pituitary glands and the role of aldosterone, cortisol, ACTH and catecholamine's in adrenal function and dysfunction. Candidates will gain understanding of the disease states associated with adrenal dysfunction and the potential affects they have on other body systems and the key biochemical tests associated with adrenal function investigation including dynamic testing.
Learning outcomes	1. Describe the physiology of the adrenal cortex and medulla and their normal functions. 2.Explain the synthesis, control, function and metabolism of aldosterone, cortisol, ACTH and catecholamine's in health. 3.Explain changes in aldosterone, cortisol, ACTH and catecholamine results as relevant to the following conditions; Cushing's Syndrome, Conn's Syndrome, Addison's disease and phaeochromocytoma. 4. Discuss the effects of adrenal dysfunction on electrolyte balance. 5. Identify sample requirements (in the investigation of adrenal disorders) and discuss factors that may impact sample integrity and appropriate corrective action. 6. Discuss the rationale of tests selected for the assessment of adrenal function, including dynamic function tests. 7. Demonstrate with an example from candidates practice the identification of abnormal results in the investigation of adrenal disease and explain any actions taken.
Indicative Content	Candidates require knowledge and understanding of: The physiology of the adrenal cortex and medulla The regulation of the adrenal hormones and neurotransmitters Common diseases and conditions associated with irregular adrenal function Principles of analysis of tests involved in the investigation of adrenal disorders and the reference ranges for commonly performed tests Candidates must be able to: Run analysers and processes associated with analytes measured including EQA as appropriate and application of internal quality processes including troubleshooting.

Module Title	Therapeutic Drug Monitoring
Module code	9273
Rationale/ Aims	This module covers the importance of therapeutic drug reporting, their significance and physiological requirements Candidates will gain knowledge of pharmacokinetics and pharmacogenetics and understand how this is important to drug monitoring. Candidates will gain understanding of drugs measured, and when and why they are measured. Candidates will understand the importance of therapeutic ranges and factors which can affect interpretation of results.
Learning outcomes	1. Discuss why therapeutic drug testing is important and explain why this is not suitable for all drugs. 2. Discuss the role, applications and limitations of pharmacokinetics and pharmacogenetics. 3. Explain elimination half-life and how it relates to clearance, volume of distribution, and attainment of 'steady-state' conditions. 4. Describe the therapeutic role, mode of entry, metabolism, transport and excretion of the following drugs and their relevant metabolites: Digoxin, Theophylline, Phenytoin, Lithium, Carbamazepine, Methotrexate and anti-rejection drugs. 5. Discuss the significance of results outside the therapeutic range. 6. Describe the therapeutic role of the following antibiotics and why they are monitored: Amikacin Vancomycin Gentamicin Teicoplanin 7. Discuss with examples, factors affecting interpretation of therapeutic drug monitoring results.
Indicative Content	Candidates require knowledge and understanding of: Organs involved in metabolism and excretion of drugs Pharmacokinetics and factors affecting drug excretion. Laboratory techniques used in the measurement of drug analysis including EQA and application of internal quality processes including troubleshooting as appropriate Candidates must be able to: Assure the quality and validity of results produced for analytes measured

Module Title	Toxicology
Module code	9274
Rationale/Aims	This module examines the role of the laboratory in diagnosis and monitoring of poisoned patients and the drugs of abuse that are analysed. Candidates will gain understanding of assessment of patients with suspected poisoning. Candidates will gain knowledge and understanding of the commonly analysed drugs of abuse, their reporting and the implications of screening and confirmation. Candidates will gain knowledge of testing that supports diagnosis and monitoring of poisoned patients, and assessment of drugs of abuse.
Learning outcomes	1. Discuss the role of the laboratory in the assessment of a suspected poisoned patient within 24hours of presentation. 2. Discuss with examples when patient samples may be referred to specialist toxicology laboratories. 3. Identify drugs that are abused and discuss the role of the laboratory in screening and confirmation. 4. Discuss why assay specificity and accuracy is compromised when screening for drugs of abuse and why a urine screening test for a drug may be reported as positive but the confirmation is reported as negative. 5. Describe the metabolism of common over the counter drugs at therapeutic and overdose levels. 6. Describe drug kinetics and discuss the effect this may have upon the timing of samples post dose and the establishment of therapeutic and/or toxic ranges. 7. Discuss which laboratory tests may identify an undiagnosed paracetamol overdose and explain what actions would be taken in this case. 8. Discuss the role of the laboratory in the diagnosis of ethylene glycol, ethanol, and methanol poisoning. 9. Discuss the use of masking agents and sample tampering and how laboratories can identify this. 10. Discuss with examples tests used to monitor the treatment and recovery of the poisoned patient and explain why.
Indicative Content	Candidates require knowledge and understanding of: Planning reintroduction of therapy post overdose whether accidental or not. Confirmation of diagnosis Patient management

	Guidelines for laboratory analyses for poisoned patients in the United Kingdom National Poisons Information Service Candidates should have awareness of: The role of FBC, UE, calcium, magnesium, INR, LFT, anion gap, plasma osmolality, ABG, CK and glucose in the investigation and monitoring of poisoned patients or those being tested for drugs of abuse Investigations for overdose of paracetamol, salicylate, ethanol, carbon monoxide Novel psychoactive substances

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