



JOHANNESBURG ACADEMIC OFFICE

December 2018

THE COLLEGE OF PATHOLOGISTS OF SOUTH AFRICA

R E G U L A T I O N S

FOR ADMISSION TO THE FELLOWSHIP OF THE COLLEGE OF PATHOLOGISTS OF SOUTH AFRICA IN CLINICAL PATHOLOGY

FC Path(SA) Clin

1.0 COMPONENTS

The examination comprises a single exit examination

2.0 PURPOSE OF ASSESSMENT

This qualification forms part of a process to accredit medical practitioners, as specialists in Clinical Pathology. The Health Professionals Council of South Africa (HPCSA) stipulates training requirements including a minimum period of experiential training. It is usual for the examination to be taken and passed prior to the completion of supervised learning specified by the HPCSA. The aim of this qualification is to meet the needs for formal examination certification, as well as to set standards nationally for such a qualification.

3.0 ADMISSION TO THE EXAMINATION

- 3.1 A candidate must hold a post-internship qualification to practise medicine which has been registered or is registrable with the Health Profession Council of South Africa
- 3.2 A candidate must have completed a minimum of 4 years (48 months) of approved training in pathology by the time of the written examination.
- 3.3 At least 14 months of the 48 months (4 years) must have been spent in each department of Chemical Pathology, Haematology and Microbiology and six months in Virology.
- 3.4 From the second semester 2014 the submission of your Portfolio at the time of making your application is compulsory for all candidates who entered into their Registrar post from 1 January 2011. It is recommended that all candidates entering into their registrar training from 1 January 2019 use the LogBox online portfolio. This is a free service and the app is available in both Apple and Android format. Please register at www.logbox.co.za.¹

¹ LogBox recommendation effective for new Registrars – 1 January 2019

4.0 FORMAT OF THE EXAMINATION

- 4.1 Three written papers of three hours each: one in each of chemical pathology, haematology and medical microbiology. The sub minimum is 50% in each paper.
- 4.2 Practical examination
The practical examination in clinical pathology will last over 3 days with an examination in each of the three disciplines. The sub minimum for each practical is 50%.
- 4.3 An oral examination.
This will be a single oral examination with examiners from each discipline. The sub minima for the oral examination is 50%

5.0 ADMISSION AS A FELLOW

5.1 Only candidates who have completed training in a CMSA recognised registrar post may be awarded a fellowship if successful in the examination.

5.2 **Candidates who have written the examination as a prerequisite from the HPCSA for inclusion on the specialist register are not eligible to be awarded a Fellowship but will be sent a letter confirming their success in the examinations**

I, the undersigned, do solemnly and sincerely declare

that while a member of the College I will at all times do all within my power to promote the objects of the CMSA and uphold the dignity of the CMSA and its members

that I will observe the provisions of the Memorandum and Articles of Association, By-laws, Regulations and Code of Ethics of the CMSA as in force from time to time

that I will obey every lawful summons issued by order of the Senate of the said CMSA, having no reasonable excuse to the contrary

and I make this solemn declaration faithfully promising to adhere to its terms

Signed at this day of
..... 20

Signature

Witness

(who must be a Founder, Associate Founder, Fellow, Member, Diplomate or Commissioner of Oaths)

5.3 A two-thirds majority of members of the CMSA Senate present at the relevant meeting shall be necessary for the award to any candidate of a Fellowship

5.4 A Fellow shall be entitled to the appropriate form of certificate under the seal of the CMSA

5.5 In the event of a candidate not being awarded the Fellowship (after having passed the examination) the examination fee shall be refunded in full

5.6 The first annual subscription is due one year after registration (statements are rendered annually)

APPENDIX A

1.0 AIMS OF THE TRAINING PROGRAMME

1.1 The goals of the training period in Clinical Pathology are:

- To gain extensive knowledge of both common and serious conditions, especially in relation to the South African context, and to develop an integrated approach to the diagnosis, management of patient-care and interpretation skills for these conditions
- To consult with clinicians on appropriate selection and interpretation of laboratory tests
- Interpretive and report writing skills
- Communication and interpersonal skills
- To develop an understanding of laboratory methodology, the clinical and statistical evaluation thereof and appropriate management of a clinical laboratory, including:
 - Laboratory management
 - Technical skills on testing platforms and quality assurance programmes
 - Cost-effective service
 - Statistical interpretation and evaluation
- To develop skills for the integration of knowledge of laboratory medicine into the health care system (eg Infection control, antibiotic stewardship, evidence based selection of tests and effectiveness of testing algorithms)
- To develop leadership and management skills
- To promote and apply basic, clinical and translational research into laboratory decision making and consultation

1.2 Training should prepare a registrar to:

- Function independently within the scope of a regional hospital laboratory
- Share duties with fellow clinical pathologists or mono-specialist pathologists at regional and/or tertiary hospital laboratories
- Act as a clinical pathologist in one or more departments at academic or tertiary hospital laboratories, depending on level of competence, expertise and additional training
- Pursue independent research

The expectation that clinical pathologists should be trained and exposed to the full curriculum content of individual mono-specialist pathology disciplines is misguided.

The clinical pathologist should be capable of diagnosing and advising on conditions that are considered common and/or serious in the context of the South African population and be familiar with the testing repertoire and laboratory structure that defines a secondary/regional laboratory.

Knowledge of conditions diagnosed at reference/tertiary laboratories requires only basic understanding of pathophysiology, methodology and result interpretation, but registrars should have comprehensive knowledge of specimen sampling and referral protocols pertaining to the diagnosis of such conditions.

1.3 Personal characteristics needed

A clinical pathologist should exhibit the following traits:

- An interest in the basic sciences of medicine, laboratory technology and laboratory management
- Good observation, interpretative, analytical and report writing skills
- An ability to combine test data from all investigations to appropriately assist in the correct diagnosis and management of patients
- Able to work as part of a team of medical, nursing and laboratory staff
- A commitment to continuous learning to maintain knowledge of current practices in the field in clinical pathology
- Good interpersonal and communication skills

1.4 Level of Knowledge

A three-tiered level approach to acquisition of knowledge in Clinical Pathology is advised:

- **Basic competence [B]:**
A registrar should have a basic understanding of the principles and laboratory practices relating to the specific topic.
- **Advanced competence [A]:**
A registrar should have comprehensive knowledge of the principles and laboratory practices relating to the specific topic, be able to understand the relation between various concepts and ability to integrate them. These would pertain to the more common and serious conditions encountered at a regional laboratory.
- **Expert [E]:**
In-depth knowledge of the topic and understanding of the principles and laboratory practices should be on par with that of mono-specialty pathologist, and registrars should demonstrate same level of clinical skills and management of these topics as would be expected from a mono-specialty pathologist.

Unless indicated by [B] or [E] in this curriculum, level of knowledge should be at advanced level of competence.

APPENDIX B

1.0 CHEMICAL PATHOLOGY

1.1 Technical – Analytical Techniques and Instrumentation

Registrars should aim to understand the basic principles of the following methodologies and their application in clinical medicine:

- Optical techniques
- Electrochemistry and chemical sensors
- Electrophoresis
- Freezing point depression
- Chromatography
- Mass Spectrometry
- Enzymology
- Immunochemical techniques
- Point-of-care
- Molecular diagnostic techniques

Registrars should be thoroughly experienced at the end of training with the techniques for measurement of commonly requested analytes, including general understanding of the methods of measurement, interferences and limitations of each assay as well as clinical utility of each analyte individually and in combination and pre-analytical variations in the interpretation of results of these analytes:

- Electrolytes (sodium, potassium, chloride, calcium, magnesium, phosphate)
- Urea
- Creatinine
- Blood gases
- Proteins and albumin
- Bilirubin
- Transaminases (AST and ALT)
- GGT
- Alkaline phosphatase
- LDH
- Creatine Kinase
- Troponins
- Cholesterol and Triglycerides - Lipogram
- Glucose
- Ketones
- HbA1c
- Ammonia
- Lactate
- Uric acid
- Amylase
- Lipase
- Cortisol
- Insulin
- Growth Hormone, IGF-1
- Prolactin
- FSH, LH
- hCG
- Estrogens
- Testosterone

- Progesterone.../

- Progesterone
- 17-OH-progesterone
- DHEAS
- Prostate-specific antigen
- Sex hormone binding globulin
- Aldosterone
- Renin
- TSH and thyroid hormones (including anti-thyroid and anti-TSH antibodies)
- Parathyroid hormone
- C-reactive protein and pro-calcitonin
- Iron profile (ferritin, transferrin, iron,TS),
- vitamin B12, serum and red cell folate, homocysteine
- Tumor markers

1.2 **Statistical elements – Refer also to Laboratory Management**

- Method validation/Method comparison
- Establishment and use of reference values
- Pre-analytical variables
- Biological variation
- Reference change values
- Sensitivity, specificity, predictive value, relative risk ratios, odd ratios
- Quality control – internal and external
- Inter-laboratory correlation
- Uncertainty of measurement

1.3 **Management – Refer also to Laboratory Management**

- Pre-analytical process
 - Sample requirement, collection and handling
 - Specimen reception and identification
 - Specimen quality-indices in serum and plasma
- Laboratory automation
- Clinical Laboratory Informatics
- Quality Management

1.4 **Information technology [B]**

- Requirements of a laboratory IT system
- Preparation of Powerpoint® presentations and use of Excel®
- Web based literature search

1.5 **Physiological biochemistry [B]**

A basic understanding of metabolic pathways is essential to understand disease processes.

- Carbohydrates
- Lipids
- Enzymes
- Amino acids and proteins
- Nucleic acid
- Electrolytes and the kidney
- Blood gases and pH
- Nutrition, trace elements and vitamins [B]
- Concept of malnutrition
- Obesity
- Concept of metabolic syndrome
- Pregnancy [B]

1.6 Pathophysiology

Sodium and Water Metabolism

- Osmolality and Osmolarity
- Technical:
 - Electrolyte Exclusion Effect
 - Sweat testing
- Disorders of serum sodium
 - Sodium homeostasis
 - Hypernatraemia
 - Hyponatraemia
 - Pseudohyponatraemia
- Disorders of renal water excretion
 - Water homeostasis
 - Polyuria
 - Oliguria

1.7 Potassium

- Homeostasis
- Hyperkalaemia
- Hypokalaemia

1.8 Acid-Base and Blood Gases

- Basic physiology
- Methodology in pH and blood gas measurement
- Classification and characteristics of acid-base disorders
- Conditions associated with abnormal acid-base status

1.9 Bone Metabolism – Calcium, Phosphate and Magnesium

- Integrated control of mineral metabolism
- Hormones regulating mineral metabolism
- Parathyroid Hormone
 - Biochemistry and physiology
 - Methodology and measurement
 - PTHrP
- Vitamin D
 - Biochemistry and physiology
 - Methodology and measurement
- Calcitonin
- Calcium
 - Biochemistry and physiology
 - Methodology and measurement
 - Hypocalcaemia
 - Hypercalcaemia
- Phosphate
 - Biochemistry and physiology
 - Methodology and measurement
 - Hypophosphataemia
 - Hyperphosphataemia
- Magnesium
 - Biochemistry and physiology
 - Methodology and measurement
 - Hypomagnesaemia
 - Hypermagnesaemia
- Biochemical markers of bone turnover [B]
- Metabolic Bone diseases [B]
 - Osteoporosis
 - Rickets
 - Paget's disease
 - Renal osteodystrophy

1.10 Renal Pathology

- Creatinine
 - Physiology and Biochemistry
 - Clinical significance
 - Analytical measurement and standardisation
- Urea
 - Physiology and Biochemistry
 - Clinical significance
 - Analytical measurement
- Proteinuria
 - Definition, classification and methodologies
 - Common causes and clinical significance
 - Urinary albumin and micro-albuminuria
- Classification of kidney disease and common causes
 - Estimated glomerular function and measurement
- Basic understanding of kidney diseases and laboratory assessment pertaining to each
 - Acute kidney injury
 - Chronic kidney disease
 - Uraemic syndrome
 - Glomerular disease
 - Tubular disease
 - Renal calculi
- Screening for kidney disease
 - Urinalysis and microscopic examination
- Assessment of kidney function: estimation of glomerular filtration rate [E]
- Renal replacement therapy – basic principles of laboratory assessment of hemo- and peritoneal adequacy [B]

1.11 Cardiac Markers

- Clinical diagnostic criteria
 - Acute myocardial infarct
- Cardiac biomarkers: physiology, analytical implications and clinical applications [E]
 - Troponins
 - Creatine Kinase and isoenzymes CKMB-mass
 - Myoglobin
 - Brain natriuretic peptide
- CRP and high-sensitive CRP in cardiovascular disease

1.12 Urate and Gout

- Uric Acid
 - Biochemistry and physiology
 - Clinical significance
 - Analytical methodology

1.13 Disease and disorders of gastro-intestinal tract

- Physiology and metabolism of analytes constituting a 'liver function panel'
 - Transaminases (AST and ALT), alkaline phosphatase, GGT, LDH, albumin
 - Basic knowledge of measurement methodology of these analytes, the limitations and interference
 - Common conditions associated with abnormal values of these analytes
 - Diagnostic strategy employing these analytes
- Clinical/Laboratory approach to, and common causes of:
 - Jaundice (including neonatal jaundice)
 - Prehepatic
 - Intrahepatic
 - Post-hepatic
 - Hepatocellular disease
 - Cholestatic disease
 - Cirrhosis
 - Disorders of GIT function
- Investigations indicated for complications associated with liver disease
- Basic concepts of chemical pathology relating to the gastro-intestinal tract
 - Gastric function testing [B]
 - Diagnostic testing for *H.pylori*
 - Celiac Disease
 - Pancreas
 - Acute pancreatitis
 - Chronic pancreatitis
 - Malabsorption [B]
 - Chronic diarrhea

1.14 Plasma lipids and Lipoproteins [E]

- Biochemistry and pathophysiology
- Clinical significance and diagnosis of
 - Primary hyperlipidemia – conditions commonly seen in South African population
 - Causes of secondary hyperlipidemia
- Analytical methodology and measurement

1.15 Endocrinology

- Hypothalamus and Pituitary Gland
 - Growth hormone
 - Physiological actions
 - Clinical significance and laboratory testing
 - Prolactin
 - Physiological actions
 - Clinical significance and laboratory testing
 - Macroprolactin
 - ACTH
 - Physiological actions
 - Clinical significance and laboratory testing
 - FSH and LH
 - Physiological actions
 - Clinical significance
 - ADH
 - Physiological actions
 - Clinical significance
 - ❖ Diabetes Insipidus
 - ❖ Syndrome of Inappropriate Antidiuretic Hormone Secretion

- Adrenal cortex
 - Adrenocortical steroids: biochemistry and metabolism
 - Functional testing of adrenal cortex
 - Disorders of Adrenal Cortex and their biochemical diagnosis
 - Hypofunction
 - ❖ Adrenal Insufficiency: Hypocortisolism, Addison's disease
 - Hyperfunction
 - Cushing's Syndrome
 - Hyperaldosteronism – Conn's Syndrome
 - Congenital adrenal hyperplasia
- Mineralocorticoids
 - Adrenal medulla: catecholamines synthesis and metabolism
 - Laboratory testing (Analytical methods)
 - Pheochromocytoma
- Thyroid Gland [E]
 - Biochemistry and metabolism
 - Laboratory testing (analytical methodology)
 - Thyroid dysfunction Disorders of the thyroid gland/ thyroid function
 - Hyperthyroidism
 - Hypothyroidism
 - Subclinical disease
 - Congenital thyroid disease
 - Non-thyroidal disease (Euthyroid Sick Syndrome)
 - Effects of drugs on thyroid function test
- Diabetes (Carbohydrates) [E]
 - Metabolism of carbohydrates
 - Classification and basic pathogenesis of diabetes mellitus
 - Diagnosis
 - Role of laboratory in diabetes mellitus (Laboratory testing)
 - Self blood glucose monitoring, Estimated Average Glucose
 - Clinical/laboratory approach to hypoglycaemia
 - Determination of glucose and ketone bodies in body fluids
 - Determination of lactate and pyruvate in body fluids
 - Glycated proteins
 - Biochemistry
 - Clinical significance
 - Analytical methodology
- Reproductive endocrinology
 - Clinical/Laboratory assessment of:
 - Infertility [B]
 - Amenorrhea
 - PCOS
 - Down syndrome screening [B]
 - Ambiguous genitalia [B]
 - Analytical methodology [B]
 - Testosterone
 - DHEAS
 - Sex-binding hormone globulin and free androgen-index
 - Estrogens and Progesterone
 - Effects of oral contraceptives on various analytes [B]
- Carcinoid tumours
 - Basic biochemistry and pathophysiology
 - Analytical methodology and measurement
 - Causes of secondary hypertension

1.16 Plasma and Fluids Proteins

- Principles of protein analysis
- Principles and interpretation of pleural fluid
- Principles and interpretation of CSF
- Albumin
- C-Reactive protein
- Haptoglobin
- Transferrin and β -2-transferrin
- Complement Proteins (C3 and C4)
- Immunoglobulins and β -2-microglobulin
- Procalcitonin

1.17 Iron (collate with Haematology) [E]

- Biochemistry and physiology
- Measurement and methodology
- Interpretation/clinical relevance and reporting of values
 - Iron deficiency
 - Iron overload
 - Anemia of chronic disease

1.18 Vitamin B12, Folate and homocysteine (collate with Haematology) [E]

- Biochemistry and physiology
- Measurement and methodology
- Interpretation/clinical relevance and reporting of values

1.19 Porphyrins [B]

- Biochemistry and pathophysiology
- Basic methodology and basics of laboratory diagnosis of porphyria
- Specimen requirement for acute presentation and screening

1.20 Tumor Markers [B]

- Basic principles and clinical utility, limitations, sensitivity and specificity
 - AFP
 - CEA
 - hCG
 - PSA [E]
 - M protein/ paraprotein
 - Carbohydrate markers and Blood group antigen-related cancer markers (CA15-3, CA19-9 etc)

1.21 Inborn-errors-of-metabolism [B]

- General approach only – referral to monospecialist
 - Hypoglycaemia
 - Metabolic acidosis
 - Hyperlactataemia
 - Hyperammonaemia

1.22 Immunology:**1.22.1 Allergic disease [B]**

- Pathogenesis of allergic reactions and commonly associated allergic disorders
- Principles of IgE measurement

1.22.2 Auto-immune diseases [B]

- Principle of auto-immunity
 - Immunological tolerance and anergy
- Clinical features, pathogenesis and diagnosis of multi-system auto-immune diseases:
 - Rheumatoid arthritis
 - Systemic Lupus Erythematosus
 - Auto-immune thyroid disease
 - Pernicious anemia
 - Type 1 diabetes mellitus
 - Celiac disease
 - Immune-mediated liver disease
- Basic concepts related to Multiple Sclerosis and interpretation of CSF
- Rheumatoid factor and antibodies to cyclic citrullinated peptide

1.23 Therapeutic drug monitoring and Toxicology [B]

- Drug monitoring and Overdose – diagnosis, including toxic syndromes, and management
 - Commonly prescribed anti-epileptics
 - Acetaminophen
 - Salicylates
 - Benzodiazepines and tricyclic antidepressants
 - Lithium
 - Digoxin
 - Organophosphates
 - Carbon monoxide
 - Alcohol
- Urine drug-of-abuse testing

1.24 Practical Skills**1.24.1 Laboratory Procedures**

- Apply the principles of operation, and where appropriate either perform the specific analysis or demonstrate ability to use the associated equipment:
- Automated general chemistry analysers
 - Perform calibration
 - Run Internal controls
 - Assess quality control
 - Methodology applied, eg ISE, spectrophotometry, enzyme assays, immunochemistry assays
 - Trouble-shooting
- Serum, urine and CSF protein electrophoresis (Agarose electrophoresis, immunofixation and Capillary zone electrophoresis)
 - Interpret and report on different electrophoretic patterns
 - Advise on further diagnostic assessment
- Serum and urine osmolality
- pH measurement on fluids
- Polymerase chain reaction and DNA extraction
- Blood gas analysis and co-oximetry
- Immunoassays
- POC devices

1.24.2 Dynamic testing

- As far as possible be able to perform, or advised clinical staff on protocols for performance of
 - Sweat test
 - Overnight dexamethasone suppression test
 - Oral glucose tolerance test
 - ACTH Short Synacthen test
- Be able to interpret results of these tests and advise further testing

1.25 Immunoglobulin quantitative and qualitative disorders

- Interpret protein electrophoresis patterns
- Interpret CSF oligoclonal banding patterns
- Interpret immunofixation test
- Recommend follow-up testing for abnormal or equivocal cases

1.26 Auto-immune diseases

- Understand methodology for measurement of rheumatoid factor and antibodies to cyclic citrullinated peptide and formulate interpretive comment
- Understand principles and interpretation of immunofluorescence tests for antibodies to nuclear antigens

1.27 Allergic disease

- Interpret and comment on IgE measurements

1.28 Identify and differentiate between urate and calcium pyrophosphate crystals utilising polarised light Perform and comment on Method Validation (collate with Laboratory Management)**1.28.1 Basic Laboratory Mathematics**

- Units and amounts and their conversions
- Dilutions and solutions
- Relative molecular mass and stoichiometry
- Acid, bases and buffers
- Basic concepts of statistical analysis
 - Mean
 - Median
 - Standard deviation
 - Co-efficient of variation
 - Normal (Gaussian) distribution
 - Tests for normality
 - Outliers
- 95% Confidence Intervals
 - Parametric
 - Non-parametric
- Half lives, decay and elimination

1.29 Laboratory Management

Knowledge and skills should be obtained and development through a candidates rotation of ALL the divisions and laboratory management can be assess in all four disciplines.

1.30 Organisational and Leadership [B]

- Basic concept of management structure and function
- Role of ethics in medical and managerial decision-making
- Laboratory organisation
 - Pre-analytical sample acquisition
 - Accessioning and processing
 - Structure of analytical units
 - Post-analytical sample resulting
 - Workflow analysis

1.31 Financial skills [B]

- Basic concepts of financial statement presentation and analysis
 - Be familiar with common terminology and reading of financial statements
- Budget process as applied in operational planning
 - Develop skills for drawing up a budget
 - Identify fixed, variable and discretionary costs
 - Participate in ongoing monitoring of laboratory budget
- Assessment for need of new instruments
- Utilisation monitoring and management

1.32 Regulatory skills [B]

- Be familiar with regulatory bodies relevant to the practice of pathology in South Africa
- Understand the regulatory requirements for data/results storage and storage of samples
- Be familiar with the Occupational Health and Safety Act
- Standard Operating Procedures (SOP):
 - Development, authorship and review of SOP
 - Application of SOP in the clinical laboratory

1.33 Resource management/Demand management [B]

- Assess cost-effectiveness of laboratory procedures and understand test cost determination
- Test utilisation (including Electronic Gate Keeping)
- Minimal Retest Intervals
- Auto-reviewing

1.34 Selection Methodology

- Select appropriate test methods (and instruments) – with consideration of various factors, including:
 - Performance characteristics
 - Quality control
 - Calibration
 - Reagent usage
 - Waste disposal
 - Cost and remuneration
 - Service and maintenance
 - Test usage and clinical utility

1.35 Quality Management

- Recognise, report and analyse issues relating to quality control in the laboratory
 - Apply pre-analytical quality control procedures to sample handling
 - Apply internal quality control procedures, including:
 - Reference ranges and application
 - Basic statistics as applied to quality control
 - Measure of uncertainty
 - Apply external quality assurance procedures
 - Laboratory accreditation
 - Adverse event reporting
 - Audits and quality improvement
- Understand the use of calibrators and controls in laboratory assays
- Understand assay interference, including methods for detection and minimisation
- Interpret quality assurance reports, and investigate sources of variation in results from different laboratories

1.36 Audits

- Be familiar with the principles and process of, and with active participation in, laboratory audits

1.37 Laboratory Safety

- Explain concepts of risk management in the laboratory
- Explain laboratory safety principles
 - Universal precautions
 - Specific aspects of a safe working environment
 - Basic understanding of the aspects of ergonomics in the workplace
- Be familiar with the use of equipment for biological, chemical and fire safety, first aid and resuscitation
- Be familiar with laboratory safety documents and incident report forms
- Be familiar with the Occupational Health and Safety Act

1.38 Patient Safety

- Be familiar with the practice of laboratory medicine as applied to the protection of patient rights
- Promote appropriate use of laboratory investigations
- Application of risk management principles to minimise errors
- Promote and advise on relevant epidemiology and public health issues

1.39 Application of statistics to diagnostic testing

- Define and explain terminology used in assay assessment and QC, including
 - Precision
 - Accuracy
 - Inter-assay and intra-assay variability
 - Selectivity and 'matrix effect' in immunoassays
- Understand tools used in assay performance assessment
 - Levy-Jennings
- Interpret internal quality assurance reports
 - List, explain and apply Westgard Rules
- Understand tools used to compare performance of different assays
- Linear regression
- Bland-Altman plots
- Kappa statistic
- Chi-squared analysis
- Understand assay validity, including measurement of
 - Selectivity
 - Precision
 - Accuracy
 - Recovery
 - Lower limit of quantification
 - Stability of reagents
 - Interfering substances
- Discuss process of new test method selection
- Reference Ranges
 - Define and explain
 - Mean
 - Median
 - Standard deviation
 - Co-efficient of variation
 - Normal (Gaussian) distribution
 - Tests for normality
 - Outliers
 - 95% Confidence Intervals
 - Parametric
 - Non-parametric
 - Explain process of establishing a reference range
- Measurement of Uncertainty (MOU)
 - Explain the principles and clinical relevance of MOU

- Diagnostic application of assay results
 - Define and explain
 - Sensitivity, specificity, positive predictive value and negative predictive value
 - Define and explain concept of odds ratio
 - Explain principles of receiver Operating Characteristics (ROC) curves and their applications to assay cut-offs
 - Area under the ROC curve analysis
 - Explain Bayes theorem: Pre-test and post-test probability and Likelihood ratios

APPENDIX C

1.0 HAEMATOLOGY

1.1 Methodology as applied in the haematology laboratory

- Blood film preparation (including indication and interpretation of stains, eg Romanowsky, Supravital, Perl's Prussian blue)
- Performing a blood count
- Principles of cell counter instruments (eg Sysmex, Coulter, Bayer)
 - Method: Electrical impedance and light scattering
 - Detecting erroneous/spurious blood counts
 - Appropriate course of action
 - Issues relating to automated haematology:
 - 'Absolute values' and 'Relative values'
 - WBC correction for nucleated red blood cells
 - Absolute neutrophil count
 - Clinical utility
 - Clinical utility of band cell counts
 - Understand QC procedures (Rumke limits and Bull analysis)
- Automated and manual differential counts
- Reticulocyte count: automated and manual
- Flow Cytometry [B]
 - Principles of flow cytometry
 - Understand diagnostic and prognostic information generated by flow cytometric analysis
 - Understand, interpret and comment on flow cytometry panels used for the evaluation of lymphoma, leukemia and PNH
 - Principles, interpretation and limitations of CD4 testing by panleuco-gating including troubleshooting common problems
 - Understand commonly used antigens to define
 - T-lymphocytes subsets
 - B lymphocytes
 - Lymphoma panel
 - Acute leukemia panel
- Coagulation testing:
 - General principles of testing and instrumentation
 - Prothrombin time
 - Activated partial thromboplastin time
 - Fibrinogen
 - D-dimer
 - Thrombin time
 - Factor Assays
 - Quality control (internal and external)
- Thrombophilia testing: tests available, indications and interpretation [B]
 - Lupus Anticoagulant and the Antiphospholipid Syndrome
- Mechanisms of action and principles of anti-thrombotic therapy
 - Monitoring of anti-coagulation therapy
 - Principles of INR monitoring
 - Point-of-care testing for INR
- Haemolytic tests:
 - Coombs test: indication, principles and interpretation
 - Osmotic fragility: principles [B]
 - Sickling test: principles [B]
 - HPLC and Hb electrophoresis: principles and interpretation [B]

1.2 Physiology and pathophysiology of red blood cell

- Erythropoiesis [E]
 - General aspects of and approach to anaemia
 - Hypochromic microcytic anaemias
 - Iron overload
 - Normochromic/Normocytic anaemias
 - Megaloblastic anaemias
 - Other macrocytic anaemias
 - Haemolytic anaemias
 - Congenital
 - Acquired
 - Laboratory features of intravascular and extravascular haemolysis
 - Aplastic anaemias and bone marrow failure syndromes
- Haemoglobin and haem-synthesis
 - Haemoglobin synthesis and degradation
 - Genetic disorders of haemoglobin (haemoglobinopathies)
 - Clinical and laboratory features
 - Principles of haemoglobin screening by HPLC and electrophoresis at acid and alkaline pH
 - Screening tests for Hemoglobin S
 - Detection methods for fetal haemoglobin
 - Polycythaemia
- Metabolism and abnormalities of red blood cell
 - Glucose-6-phosphate dehydrogenase deficiency
- Cell membrane and defects [B]
 - Hereditary spherocytosis
 - Hereditary elliptocytosis
 - Ovalocytosis
 - Stomatocytosis

1.3 Physiology and pathophysiology of granulocytes

- Granulopoiesis [E]
 - Granulocyte functions
 - Monocytes, dendritic cells and macrophages
 - Causes of quantitative changes (benign disorders/reactive changes)
- Lymphopoiesis [E]
 - Immunoglobulin production
 - B-lymphocyte development
 - T-lymphocyte development
 - Complement system
 - Causes of quantitative changes (benign disorders/reactive changes)
- Haematological malignancies
 - Understand the clinical features, morphologic, immunophenotypic, cytochemical and cytogenetic/molecular features of the commonly occurring haematological malignancies in adults and children
 - Acute leukaemias
 - Chronic myeloid leukaemia
 - Chronic lymphoid leukaemias
 - Myelodysplastic Syndromes
 - Myeloproliferative disorders
 - MDS/MPN disorders: JMML, CMML
 - Lymphoproliferative disorders (especially Burkitts lymphoma, DLBCL and CLL)
 - Multiple myeloma and related disorders

1.4 Physiology and pathophysiology of platelets

- Megakaryopoiesis [E]
 - Approach to thrombocytopenia
 - Reactive and malignant
 - Heparin-induced thrombocytopenia
 - Approach to thrombocytosis
 - Reactive and malignant
 - Pathophysiology, diagnosis and management of:
 - Immune thrombocytopenia
 - Thrombotic thrombocytopenic purpura
 - Platelet structure and function
 - Abnormalities and basic principles of platelet function testing
- Coagulation cascade and regulation of coagulation
- Clotting Factors: Pathophysiology and diagnosis of deficiencies
 - Factor VIII and Factor IX
 - Von Willebrand Factor
- Pathophysiology of arterial and venous thrombosis
 - Advise on diagnostic work-up [E]
 - Molecular analysis
 - Factor V Leiden
 - Prothrombin G20210A
 - Methylenetetrahydrofolate reductase (MTHFR)
- Vitamin K and pathophysiology of Vitamin K deficiency
- Fibrinogen, Factor XIII and Fibrinolysis
- Laboratory approach to DIC [E]

1.5 Haematological changes in systemic disease

- Renal disease
- Liver disease
- Blood abnormalities associated with infection
 - Bacterial and viral infections, including mycobacterial infection
 - Malaria
 - HIV

1.6 Important aspects of haematology in:

- Pregnancy
 - Anaemia
 - Thrombocytopenia
 - Haemostasis and thrombosis
- Neonatal Haematology
 - Anaemia
 - Thrombocytopenia
 - Haemolytic disease of newborn

1.7 Blood transfusion [B]

- Red cell antigens and blood group antibodies
- Techniques in blood group serology
- Cross-matching and pre-transfusion tests
- Complications, management and workup of blood transfusion (especially massive blood transfusion reaction)
- Blood products

1.8 Body fluid analysis [B]

- Clinical indications for body fluid analysis
- Understand cytopinsample preparation
- Morphological interpretation of cytopsin

1.9 Immune system

- Innate and adaptive immunity
- Cells comprising the immune system
 - Normal function and physiology
 - Principles of lymphocyte development
 - Principles of structural and functional evaluation of
 - B lymphocytes
 - T lymphocytes
 - Natural Killer cells
 - Phagocytic cells
- Immunoglobulin
 - Structure
 - Function and binding sites
 - Generation of immunoglobulin diversity, heavy chain class switching
 - Antibody development in response to acute and chronic infections, and after immunisation
- Complement system
 - Causes for inherited and acquired deficiencies
 - Methodology of complement measurement
- Causes of, and basic approach to, primary immune deficiencies
 - Advise on diagnostic approach to primary immune deficiencies
- Pathogenic principles of acquired immunodeficiency disorders
- Human major histocompatibility complex [B]
 - Basic function, structure and cell expression of HLA class I and class II
 - Role in HLA typing in organ and bone marrow/stem cell transplantation

1.10 Auto-immune diseases [B]

- Antiphospholipid syndrome
- Pernicious anaemia

1.11 Practical Skills**1.12 Peripheral smear analysis [E]**

- Recognise normal RBC, WBC and platelet morphology
 - Perform manual differential WBC count
- Review abnormal FBC results and correlate result with
 - Peripheral smear
 - Other laboratory findings
 - Clinical presentation
- Recognise abnormal morphology and advise on appropriate further laboratory testing
- Formulate a differential diagnosis
- Recognise commontechnical artifacts
- Recognise infectious disorders that can be detected on peripheral smear
 - Malaria
 - Understand methodology available for detection
 - Perform a parasite count and principles of species identification
- Correlate peripheral smear morphology with bone marrow pathology

1.13 Manual methods

- POC haemoglobin measurement and their limitations
- Principles of erythrocyte sedimentation rate
- Cytochemistry: Iron/Prussian Blue Stain, Myeloperoxidase and Sudan Black

1.14 Body-fluid analysis

- Identify blood and body fluid cell morphology
- Recognise malignant cells and recommend appropriate further laboratory investigations
- Correlate body fluid cell morphology with other relevant laboratory results, including chemistry and microbiology reports

1.15 Bone Marrow

- Technical aspects of performing, processing and reporting bone marrow aspirates and biopsies
 - Formulate differential diagnosis and integrate with peripheral smear analysis
 - Acute and chronic leukemia
 - Lymphoproliferative disorders
 - Myeloproliferative neoplasms
 - Myelodysplastic syndromes
 - Infectious pathology (viral, fungal and bacterial)
 - Non-infectious systemic disease (collagen vascular disease, non-haematological malignancies and haematinic deficiencies)
 - Advise on further laboratory testing

1.16 Coagulation

- Interpret and report on coagulation screening tests
 - Prothrombin time
 - Activated partial thromboplastin time
 - Fibrinogen
 - Thrombin time
 - D-dimer
- Interpret results of lupus anticoagulant and anti-phospholipid antibody testing

1.17 Flow cytometry [B]

- Understand, interpret and comment on general flow cytometry, including panels used for the evaluation of lymphoma and leukemia

1.18 Immune deficiency disorders

- Recommend appropriate tests for evaluation of undiagnosed immune deficiency
- Understand principles and interpret neutrophil and phagocyte function assays

2.0 MOLECULAR DIAGNOSTICS AND GENETICS [B]**2.1 DNA structure and replication**

- Prokaryotic DNA synthesis
- Eukaryotic DNA synthesis
 - Organisation: Histones and nucleosomes

2.2 DNA repair**2.3 RNA structure and synthesis**

- Transcription of prokaryotic genes
- Transcription of eukaryotic genes
- Post-transcriptional modification of DNA

2.4 Protein synthesis

- Genetic code and translation
- Posttranslational modification

2.5 The cell cycle

- Phases of cell cycle
- Cell cycle checkpoints
- Regulation
- Mitosis and Meiosis
- Cell differentiation

2.6 Cell signaling

- G-protein coupled receptor pathway
- Receptor tyrosine kinase pathway
- JAK-STAT pathway
- WNT pathway

2.7 Adhesion molecules**2.8 Apoptosis**

- Necrosis
- Apoptosis

2.9 Epigenetics

- Basic concepts
- Therapeutic options

2.10 Oncogenes and Tumour Suppression Genes

- Retinoblastoma protein (RB1)
- p53
- BRCA1 and BRCA2
- PTEN

2.11 Biotechnology

- Nucleic acid methods
- Principle of nucleic acid hybridisation
- Polymerase chain reaction (PCR)
- Analysis of PCR products
- DNA sequencing
- Protein analysis
- Electrophoresis
- Mass spectrometry
- Solid-phase immunoassays
- Western Blot
- ELISA
- Cellular Phenotyping and Flow Cytometry
- Molecular Cytogenetics
- FISH
- Gene expression analysis
- mRNA: Microarrays
- Proteins: ELISA

2.12 Gene therapy

- Basic concepts

2.13 Practical Skills

Registrars are expected to observe the following procedures and be able to provide interpretation. Demonstrate knowledge of the principles to enable trouble-shooting of equivocal or false positive results.

- Nucleic acid extraction
- Manual and automated
- Determination of primer concentration
- Preparation of master mixes
- Thermal cyclers
- Nested PCR
- Real-time PCR
- Multiplex PCR
- Preparation of sample for sequencing
- Sequence analysis

APPENDIX D

1.0 MEDICAL MICROBIOLOGY

1.1 General microbiology

- Bacterial structure, growth and metabolism
- Bacterial genetics

1.2 Bacterial Pathogens

Registrars should understand the basic description, pathogenesis, clinical features, diagnosis, treatment and control and epidemiology, for the following organisms:

- Gram Positive Cocci
 - Staphylococcus aureus
 - Coagulase-negative Staphylococci
 - Streptococcus
 - Streptococcus pneumoniae, pyogenes, agalactiae
 - Viridans streptococci
 - Enterococcus
- Gram Positive Bacilli
 - Coryneform bacteria
 - Listeria monocytogenes
 - Bacillus anthracis and cereus
- Gram Negative Cocci
 - Neisseria meningitidis and Neisseria gonorrhoeae
 - Moraxella
- Gram Negative Bacilli
 - Enterobacteriaceae(in general, plus detail of following organisms)
 - Escherichia
 - Klebsiella
 - Proteus
 - Enterobacter
 - Morganella
 - Salmonella species
 - Shigella
 - Pseudomonas aeruginosa
 - Acinetobacter and other non-fermenters [B]
 - Vibrio cholerae
 - Campylobacter and helicobacter
 - Haemophilus
 - Brucella species
 - Legionella
 - Chlamydia
 - Rickettsia, Orienta, Ehrlichia and Coxiella
- Spirochetes
 - Treponema pallidum
- Anaerobic bacteria
 - General concepts of anaerobic infections
 - Clostridium
 - Non-sporing anaerobes
- Mycobacterial disease [E]
 - Mycobacterium tuberculosis
 - Pathology and pathogenesis
 - Co-pathogenesis of tuberculosis and HIV
 - ❖ Clinical aspects
 - ❖ Management
 - ❖ Drug interactions

- Microbiological testing

- Microbiological testing
- Immune-based tests
- Nucleic acid amplification tests
- New diagnostics
- Management (adults and children)
- Multidrug-resistant tuberculosis
- Antituberculosis drugs – including drug reactions/side effects
- Nontuberculous Mycobacteria
 - Mycobacterium avium Complex [A]
 - Other non-tuberculous mycobacteria [B]
 - Diagnosis and management
- Higher bacterial disease [B]
 - Nocardia
 - Actinomyces

1.3 Fungal Pathogens (Mycoses)

- General concepts of mycoses
- Candida
- Aspergillus
- Cryptococcus neoformans
- Histoplasma capsulatum [B]
- Pneumocystis species

1.4 Parasitic Pathogens [B]

- Protozoal Disease
 - General concepts of Protozoal disease
 - Entamoeba histolytica
 - Plasmodium species [E]
 - Trypanosoma brucei
 - Toxoplasma gondii
 - Giardia lamblia
 - Trichomonas vaginalis
 - Cryptosporidiosis
- Helminths [B]
 - General concepts of Helminth infections
 - Intestinal nematodes (roundworms)
 - Trematodes (Schistosomes)
 - Cestodes (Tapeworms)
 - Hydatid disease
- Ectoparasitic disease [B]
 - Pediculosis (Lice)
 - Scabies
 - Arthropod-borne disease
 - Ticks

1.5 Antimicrobial therapy

- Principles of antibiotic therapy
- Pharmacokinetics and pharmacodynamics of antibiotic therapy
- Principles of in vitro susceptibility testing
 - Different methods
 - Broth dilution
 - Disk diffusion
 - Agar dilution
 - E-test
 - Achievable serum drug concentration
 - Minimum inhibitory concentration (MIC)
 - Minimum bacterial concentration (MBC)
 - Establishment of breakpoints
 - Quality control
- Antibiotic: mechanism of action, indications and contraindications
 - Penicillins
 - Cephalosporins
 - Other β -lactam antibiotics
 - Fusidic acid
 - Aminoglycosides
 - Tetracyclines and chloramphenicol
 - Rifamycins
 - Metronidasole
 - Macrolides, Clindamycin and Ketolides
 - Glycopeptides, Streptogramins and lipopeptides
 - Polymyxins
 - Oxasolidinones (Linesolid)
 - Sulfonamides and Trimethoprim
 - Quinolones
 - Nitrofurantion
 - Antimycobacterial drugs
 - Antifungals
- Mechanisms of antibiotic resistance, and molecular detection where appropriate
 - Detection methods for phenotypes:
 - Methicillin-resistant staphylococci
 - Vancomycin-resistant staphylococci
 - Penicillin resistant *S. pneumoniae*
 - Vancomycin resistant enterococci
 - Extended-spectrum β -lactam resistance
 - Inducible AmpC resistance
 - Carbapenem resistance
 - Inducible clindamycin resistance

1.6 Immunology: Infectious disease serology

- Typical course of serum antigens and antibodies used in diagnosis of common infectious diseases:
 - Bacterial infections: Streptococcus group A
 - Fungal disease
 - Protozoa: Toxoplasma, Scistosoma
 - Spirochetes: Syphilis serology [E]
 - Antibody response to immunisation

1.7 Major Clinical Syndrome

Recognise the basic clinical features, common and serious associated causative pathogens, diagnosis, treatment and prevention of:

- Fever
 - Fever of unknown origin
 - Fever and rash in the acutely ill
- Sepsis [E]
 - Community associated
 - Hospital associated (Nosocomial infections)
- Upper respiratory tract infections
 - Pharyngitis and laryngitis
 - Acute laryngotracheobronchitis
 - Otitis externa and otitis media
- Pleuropulmonary and bronchial infections
 - Chronic obstructive pulmonary disease
 - Acute pneumonia, including [E]
 - Ventilator-associated
 - Community acquired
 - Chronic pneumonia
 - Pleural effusion and empyema
 - Lung abscess
 - Cystic fibrosis
- Urinary tract infections [E]
- Intra-abdominal infections
 - Peritonitis and intra-peritoneal abscesses
 - Appendicitis
- Cardiovascular infections
 - Infective endocarditis
- Central nervous system infections
 - General approach
 - Encephalitis
 - Meningitis
 - Acute [E]
 - Chronic
- Skin and soft tissues infections
 - Cellulitis and subcutaneous tissue infections
- Gastrointestinal infections and food poisoning
 - Principles and syndromes of enteric infections
 - Acute and chronic diarrhea
 - Antibiotic-associated colitis
 - Food poisoning
- Bone and joint infections
 - Infectious arthritis
 - Osteomyelitis
 - Prosthetic infections
- Diseases of reproductive organs and sexually transmitted disease
 - Urethritis
 - Vulvovaginitis and cervicitis
 - Pelvic inflammatory disease
 - Prostatitis, epididymitis and orchitis
 - Genital ulcer disease
- Eye infections
 - Conjunctivitis

1.8 Infection Prevention and Control (IPC)

- Organisation for infection control
 - Requirements for IPC programs
 - Healthcare facility IPC programs
 - Community-based IPC programs
- Isolation
- Disinfection, sterilisation and control of hospital waste
 - Reprocessing of medical devices
- Risk management in IPC
- Disease surveillance
- Outbreak investigation and management

1.9 Basic principles of epidemiology**1.10 Practical Skills****1.11 Microbiological tests**

- Prepare, apply and interpret stains appropriately
 - Gram's stain
 - Acid-fast stain
 - India ink
 - Toluidine Blue
 - Fluorescent antibody stains
- Appropriate sample collection, media selection and inoculation
 - Preparation of culture media and agar plates
 - Plating of clinical specimens
 - Processing anaerobic cultures and obtaining pure cultures
- Demonstrate skills and understanding of techniques for organism identification
 - Manual methods, eg catalase test, oxidase test
 - Semi-automated and automated methods
- Apply quality control measurements across the analytical process

1.12 Antimicrobial therapy

- Interpretation of antibiotic susceptibility test, including recognition of resistance patterns
- Provide appropriate advice on selection and use of antimicrobial agents
- Implement, support and develop antimicrobial control policies

1.13 Immunology: Infectious disease serology

- Interpretation on infectious disease serology and advise further management
- Limitations of serology testing (IgM Assays)
- Interpretation of immunisation status studies
- Concept of prozone phenomenon

1.14 Laboratory maintenance

- Use and maintain laboratory equipment, including but not limited to:
 - Incubators
 - Centrifuges
 - Safety cabinets
 - Refrigerators

1.15 Infection Prevention and Control and Public Health

- Provide appropriate advice on infection control measures
- Implement, support and develop infection control policies
- Provide appropriate advice regarding detection, surveillance and intervention with respect to infectious diseases of public health importance
- Formulate strategies to investigate and manage outbreaks of infectious disease
- Apply notification requirements

APPENDIX E

1.0 VIROLOGY

1.1 Principles of Basic Virology

Basic knowledge and understanding of medically important viruses with more extensive knowledge of viruses of relative importance in the South African context

- This should include:
 - Basic pathogenesis, including modes of transmission
 - Clinical features of infection
 - Laboratory diagnosis
 - Treatment, prevention and control
- The medically important viruses:
 - Adenovirus
 - Herpesvirus [E]
 - Herpes Simplex
 - Varicella-Zoster
 - Cytomegalovirus
 - Epstein-Barr Virus
 - Kaposi's Sarcoma-associated Herpesvirus
 - HHV6 and HHV7
 - Poxviruses
 - Papillomaviruses
 - Hepatitis A, B, C, D and E [E]
 - Parvovirus
 - Mumps, Measles and Rubella
 - Picornaviruses (including enteroviruses)
 - Respiratory viruses (influenza, RSV, human metapneumovirus and para-influenza viral infections)
 - HIV [E]
 - Rabies
 - Arboviruses
- Prevention and treatment of viral infections
 - Mechanism of action of antiviral drugs, indications, contra-indications, drug dosages, route of administration and duration of treatment
 - Viral vaccines: Different vaccine approaches, concepts of herd immunity and vaccine coverage rates
 - Prophylaxis for travel-related infections
 - Use of human immunoglobulins [B]

1.2 Diagnostic Techniques in Virology

- Viral Isolation [B]
 - General concepts and practice including specimen collection and transport
- Viral Serology
 - Principles of ELISA methods:
 - Conjugate
 - Substrate
 - Optical density (cut-off values and ratios)
 - Assay format
 - ❖ Direct
 - ❖ Indirect
 - ❖ Competitive
 - ❖ Capture
 - Advantages and limitations of each type
 - Concepts and limitations of IgM and IgG assays
 - Assay validation – sensitivity, specificity and predictive value
 - Selecting appropriate serological test for samples and directing supplementary test based on initial results
 - Trouble-shooting assay problems

- Molecular Virology
 - Principles of nucleic acid-based virus detection techniques –qualitative and quantitative
 - Trouble-shooting commercial nucleic acid-based assays
 - PCR laboratory design and minimising amplicon contamination

1.3 Specific Viral Diseases

Knowledge and understanding of the following viral diseases, including clinical features, laboratory investigation, management and epidemiology

- HIV/AIDS [E]
- Sexually transmitted infections
- Viral Hepatitis [E]
- Viral infections of the gastro-intestinal system (gastroenteritis)
- Viral Hemorrhagic Fevers
- Viral infections of central nervous system
- Viral infections of the cardiovascular system
- Viral infections of respiratory tracts
- Childhood viral infections
- Viral infections in pregnancy, the fetus and neonate
- Aspects of viral infections related to transfusion medicine [B]
- Viral infections in the immune-compromised patient

1.4 Aspects of Infection Prevention and Control (IPC) and Public Health

(Knowledge should be integrated with Microbiology)

- Outbreak Investigation
- Viral disease surveillance: measles, polio and influenza
- Infection control of medically important viruses
- Management of patients with suspected viral hemorrhagic fever
- Management of needle-stick injuries
- Emerging and re-emerging viral infections: Basic concepts only

1.5 Practical Skills

Cell culture: [*Registrars should observe the procedures and understand the principles. It will not be expected of registrars to perform or interpret any of these tests*]

- Cell maintenance
- Trypsinisation and re-seeding of cells
- Cell count
- Cell storage
- Cell retrieval from storage
- Preparation of cell culture media
- Sterility testing

1.6 Virus Isolation: [*Registrars should observe the procedures and understand the principles. It will not be expected of registrars to perform or interpret any of these tests*]

- Preparation of samples for virus isolation
- Tube culture
 - Processing
 - Interpretation
- Shell Vial culture
 - Processing
 - Interpretation
- Haemadsorption
- Virus identification by cytopathic effect
- Virus identification by IFA

- Virus identification.../

- Virus identification/typing by neutralisation
 - Basic principles and interpretation of results
- Antibody detection by neutralisation
 - Basic principles and interpretation of results
- Virus titration
 - Basic principles and interpretation of results
- Rapid virus detection by IFA

1.7 **Viral Serology [E]**

- Manual ELISA IgM
- Manual ELISA IgG
- Automated ELISA (including antibody and antigen ELISA)
- IgG Avidity assays
- Rapid tests:
 - Immunochromatographic
 - Particle agglutination
- Principle of Western Blot

1.8 **Molecular Virology [E]**

- HIV DNA PCR
- HIV Viral Load
- Real-time and Multiplex PCR
- Methodology of CD4 count estimation

APPENDIX F

1.0 RECOMMENDED READING

Selective reading from the following resources is recommended with guidance from training supervisors. Emphasis should be on a subject-driven approach with selective reading.

2.0 ESSENTIAL TEXTBOOKS

- Carl A Burtis, Edward R Ashwood, David E Burns. Tiets – Fundamentals of Clinical Chemistry
- Marshall, Bangert and Lapsley. Clinical Chemistry
- ESC Koay, Noel Walmsley. A Primer of Chemical Pathology
- Dacie and Lewis. Practical Haematology
- Hoffbrand et al. Postgraduate Haematology
- Swerdlow et al. WHO Classification of Tumours of Haematopoietic and Lymphoid Tissues
- S Anderson, K Poulsen. Anderson's Atlas of Hematology
- GL Wood. Koneman's Color Atlas and Textbook of Diagnostic Microbiology
- David N Gilbert et al. The Sanford guide to antimicrobial therapy
- DD Richman. Clinical Virology

Selective reading from the following additional textbooks recommended for topics not sufficiently covered in essential textbooks

- D Gardner and D Shoback. Greenspan's Basic and Clinical Endocrinology
- Lawrence A. Kaplan et al. Clinical Chemistry
- AHB Wu. Tiets – Clinical Guide to Laboratory Tests
- A Deacon et al. Calculations in Laboratory Science
- PC Champe et al. Lippincott's Illustrated Reviews: Biochemistry
- Bain BJ. Bone Marrow Pathology
- Bain BJ. Blood Cells: A practical guide
- Lyonell G. Israels, Esther D. Israels. Mechanisms in Hematology
- P Murray et al. Manual of Clinical Microbiology
- Gerald L. Mandell et al. Principles and Practice of Infectious Diseases
- Betty A Forbes, et al. Bailey and Scott's Diagnostic Microbiology.
- HS Schaaf, AI Sumla. Tuberculosis – a comprehensive clinical reference
- WA Strohl et al. Lippincott's Illustrated Reviews: Microbiology
- AJ Suckerman. Principles and Practice of Clinical Virology
- S Mehtar. Understanding Infection Prevention and Control
- S Plotkin et al. Vaccines
- I Roit. Essential Immunology
- L Sompayrac. How the immune system works
- B Mendelow et al. Molecular Medicine for Clinicians

Journals

Registrars should read selectively from various journals, with the focus on review articles, and should be guided by training supervisors.

- Clinical Chemistry
- Annals of Clinical Biochemistry
- The Clinical Biochemist Reviews
- ClinicaChimicaActa
- Clinical Chemistry and Laboratory Medicine
- Clinics in Laboratory Medicine
- Blood Reviews
- British Journal of Haematology
- Antimicrobial Agents and Chemotherapy
- Clinical Infectious Diseases
- Clinical Microbiology Newsletter
- Clinical Microbiology Reviews
- Journal of Hospital Infection