EFLM
European Syllabus

Post-graduate Training for Specialists in Laboratory Medicine

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This portfolio has been developed to enable the recognition of structured, standardized training and assessment of specialist in laboratory medicine. Successful completion of the portfolio will lead to the award of a European Specialist in Laboratory Medicine (EuSpLM).

This portfolio is comprised of core sections for each discipline. Based on the requirements of regulated countries the framework should have a training content including:

- General chemistry of at least 35%
- General chemistry plus haematology of at least 65%
- Flexibility as to the remaining 35%, including general chemistry, haematology, microbiology, and genetics and IVF in a proportion consistent with the requirements in the country of destination, consisting of work experience, accredited courses, relevant exams of the national training programs, traineeships.

The syllabus is divided into 4 main sections. Each section has modules which address a range of knowledge and skills appropriate to be achieved by the end of training. Each trainee must complete all modules and fulfil the evidence of achievement.

Section A: the generic knowledge, skills and competencies that need to be acquired during training.

Section B: the specialist knowledge (clinical and analytical) to be acquired within each discipline.

Section C: the skills and competencies required to carry out research, development and audit.

Section D: leadership skills and competencies

TEACHING AND LEARNING METHODS

Trainees will achieve the competencies described in the syllabus through a variety of learning methods. There will be a balance of different modes of learning from formal teaching programmes to experiential learning 'on the job'. Trainees will learn clinical and analytical skills appropriate to their level of training through work-based placement within the appropriate department.
To achieve full exposure to a variety of scientific and clinical experiences, as laboratory medicine specialists it may be necessary to receive training in more than one center. Educational supervisors may play a role in organising a rotational training plan that fulfils the training requirements. The training program aims to provide the trainee with both theoretical knowledge as well as scientific, clinical and managerial skills via range of activities such as:

- Participating in Laboratory reporting rota

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- Participating in multidisciplinary meetings at which biochemical and haematological results are presented and discussed in light of various clinical cases.
- Attending ward rounds and clinics at which patients are being investigated for disease of major organ function.
- Generating a portfolio of clinical cases involving each of the major areas of laboratory testing. The case discussion should include a sufficient amount of detail demonstrating the trainee's analytical and consultative skills. Appendix 1 gives an example of case presentation format.
- Case presentations in hospital, seminars and conferences
- Attending relevant clinical and scientific meetings and appropriate management training courses.

METHOD OF ASSESSMENT

Example tools that can be used for academic, professional and workplace-based assessments include:

- Internal/external formal examination – components may include essays, short answer and/or multiple choice questions, laboratory-based practical, oral examination, critical scenario appraisals, written dissertations.
- Direct observation – capturing the supervisor's and others' perception in internal and external environments of the trainee's understanding of the specialty, his/her skills acquisition, his/her personal and professional presentation and development
- Multi-source feedback – capturing others' perception of the trainee's knowledge, skills, competence, attitude, behaviour, learning need and potential.
- Case-based discussion – through capturing the trainee's perspective on a range of topics – clinical, scientific, professional – a picture builds of strengths, weaknesses, personal qualities, his/her understanding of roles and contributions.
- Use of log books/personal portfolios that record expectations of the education programme against achievements and progression milestones, and which may invite supervisor input
- Evaluation of written output – examples include (peer reviewed) publications, audits, policy and procedure documents
- Internal and external appraisal

DEVELOPMENT OF COMPETENCIES

The supervisor should put in place a programme that:

- Provides evidence of satisfactory acquisition of the knowledge, skills and competence commensurate with a specialist
- Provides evidence of the capability, professionalism and potential of the trainee.

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- Enables the trainee to demonstrate readiness to progress
- Generates feedback to inform progression and learning needs;
- Helps to identify a trainee who may be in difficulty and who may need additional support

Expected competency development over 4/5 years of training is given below:

Stage 1

Trainees should demonstrate:

- **basic knowledge of laboratory techniques that underpin laboratory medicine practice**
- **basic knowledge of laboratory practice including health and safety and quality assurance**
- **basic knowledge of the presentation, differential diagnosis of the common laboratory medicine disorders**
- **Sufficient understanding of clinical and analytical practice to offer basic advice on the interpretation of laboratory data.**

Stage 2

- **Trainees should develop the knowledge listed at stage 1 to provide a firm foundation for practice of understanding of most principles and practice under direct supervision.**
- **The trainee should be able to deal with most of the day to day issues in a laboratory medicine**

Stage 3

At an advanced stage of the training. The trainee should demonstrate an in-depth knowledge and understanding of the principles and practice in all sections of laboratory medicine and its clinical application. The trainee should be competent to perform the task/procedure and demonstrate a level of clinical and professional judgement commensurate with independent practitioner.

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DIARY LOG SHEET OF PRACTICAL EXPERIENCES

This log sheet is for trainees to record all practical experience completed throughout the training.

Dates	Section/Placement details

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Name: Base Hospital:

DIARY LOG SHEET OF CLINICAL EXPERIENCES

This log sheet is for trainees to record all clinical experience completed throughout the training.

Dates	Section/Placement details

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Name: Base Hospital:

DIARY LOG SHEET OF TRAINING EXPERIENCES

This log sheet is for trainees to record all training experience completed throughout the training.

Dates	Section/Placement details

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A. GENERIC KNOWLEDGE

Training Objectives: by the end of training, a specialist in laboratory medicine should be able to assess, plan, deliver, interpret, effectively communicate with clinicians' and evaluate high quality clinical services that are targeted to meet the needs of individuals and groups of patients.

Structure 5

1. Basic knowledge requirements
2. Indications for laboratory medicine
3. Influence of collection and storage of specimens
4. Analytical principles and techniques
5. Reference methodology
6. Evaluation and assessment
7. Case related medical evaluation of laboratory tests

GENERIC KNOWLEDGE	Competence Achieved / date Assessor's signature		
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A1 BASIC KNOWLEDGE REQUIREMENTS			
Knowledge of the structure and function of the prokaryotic and eukaryotic cells, as well as of viruses			
Understanding of the chemical, cellular and tissue level of organisation of the body.			
Understanding of normal anatomy, physiology and pathology of the body across the integumentary, skeletal, nervous, cardiovascular (including blood, blood vessels and lymphatic system), respiratory, endocrine, renal, gastro-intestinal (including nutrition), urinary system and reproductive system.			

SECTION A. GENERIC KNOWLEDGE

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Knowledge of the process by which embryonic development occurs from conception to birth.			
Knowledge of the principles of inheritance, DNA and genetics including carrier status, genetic crosses/pedigree/punnet squares/cross diagrams.			
Knowledge of the cellular, tissue and system responses to disease including cell death, inflammation, neoplasia, hypertrophy, hyperplasia and tissue responses to injury and repair.			
Describe the pathophysiology of disease development in common diseases across the body systems.			
In addition to the knowledge requirements of laboratory medicine disciplines described here, an understanding of the basic principles of histology including microscopy and staining techniques.			
Understand the basic principles of pharmacology and toxicology including pharmacokinetic, pharmacodynamic, pharmacogenomic, toxicokinetic, toxicodynamic toxicogenomic and nutrigenomics.			
Understand the basic principles of epidemiology.			

SECTION A. GENERIC KNOWLEDGE

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GENERIC KNOWLEDGE	Competence Achieved / date Assessor's signature		
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Understanding personalisation of laboratory medicine based on "omics" advanced technologies (metabolomics, proteomics, transcriptomics, genomics).			
Competencies			
• Broad knowledge of all aspects of clinical laboratory sciences relevant to the discipline practiced. • Broad knowledge of, and insight into, biochemical, haematological and immunological processes in human health and disease on a general and patient-specific level. • Appreciation of developments in science and technology and in the understanding of disease in order to ensure the appropriate use of laboratory investigations.			
A2 INDICATIONS FOR LABORATORY MEDICINE			
In the early detection of disease or disease susceptibility, screening, and in epidemiology.			
In organ and disease related diagnosis.			
In monitoring vital functions and predicting disease outcome.			
In treatment targeting, predicting and monitoring the response to therapy.			

SECTION A. GENERIC KNOWLEDGE

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GENERIC KNOWLEDGE	Competence Achieved / date Assessor's signature		
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Indications for subsequent specialised examinations.			
Indications for functional tests.			
Prognostic assessment.			
Competencies			
• Appreciation of developments in science and technology and in the understanding of disease in order to ensure the appropriate use of laboratory investigations.			
A3 INFLUENCE OF COLLECTION AND STORAGE OF SPECIMENS			
Place and time of sample collection, preservation, influence of nutrition, drugs, posture, fasting state, etc.			
Choice and correct use of anticoagulants and transport media, order of draw, tourniquet effects.			
Care of the specimens, patient identification, transport, storage, stability of analytes, influence of temperature, freezing/thawing.			
Competencies			
• Recognition of pre-analytical factors that influence the validity of the analytical process; • Ability to deliver the pre-analytical requirements of a laboratory medicine service			
A4 ANALYTICAL PRINCIPLES AND TECHNIQUES			

SECTION A. GENERIC KNOWLEDGE

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Training objectives: a broad understanding of the principles of analytical techniques used in laboratory medicine			
Separation techniques • Chromatography – liquid, gas, thin layer, column, high pressure performance, affinity • Electrophoresis – gel, capillary zone, isoelectric focussing • Equilibrium Dialysis • Centrifugation – ultracentrifugation • Liquid-liquid extraction and solid phase extraction			
Standard analytical techniques • Titrimetry • Osmometry			
Spectrometric methods • Spectrophotometry – ultra violet, visible • Atomic absorption • Turbidimetry • Nephelometry • Fluorimetry • Flame emission • Reflectometry • Mass spectrometry, tandem mass spectrometry • Matrix Assisted Laser Desorption/Ionization – Time Of Flight (MALDI-ToF)			

SECTION A. GENERIC KNOWLEDGE

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GENERIC KNOWLEDGE	Competence Achieved / date Assessor's signature		
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• Nuclear magnetic resonance • Infrared			
Electrochemical techniques • Ion selective electrodes • Biosensor impedance (cell counting)			
Molecular genetic techniques • Extraction, preparation, and DNA/RNA separation techniques • Polymerase chain reaction (PCR), reverse transcription PCR, • Quantitative PCR techniques (real time PCR techniques, digital PCR techniques) • Techniques for detecting single nucleotide polymorphisms (SNPs) • Techniques for detecting more complex genetic variation, DNA sequencing methodologies • Microsatellite and array technology • Cytogenetic analysis • Fluorescence in situ hybridization (FISH) • Comparative genomic hybridisation			
Immunological techniques • Principles of Antigen-Antibody reactions, immunoassay design			

SECTION A. GENERIC KNOWLEDGE

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• Competitive immunoassay • Non-competitive immunoassay • Homogeneous and heterogeneous assays • Interferences • Signal detection systems – radioisotopes, colorimetric/fluorimetric labels • Immuno-precipitation – (immunofixation, immuno-turbidometry, immune-nephelometry) • Agglutination techniques			
Enzymes • Analytical techniques – reaction rate, end point analyses • Enzymes as reagents • Enzyme kinetics, inhibitors, allosteric behaviour			
Microscopy • Light brightfield, phase-contrast, polarising, interference contrast, darkfield, fluorescence microscopy			
Flow cytometry • Cell counting, cell markers detection and fluorochromes • Subsystems; fluidics, optics and electronics			

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Haematological cell staining techniques and preparation of smears, slides or films			
Cross-matching of blood for blood transfusion. Indirect antiglobulin test, direct antiglobulin test and Rhesus- and ABO-antagonism			
Rheology			
Culture and sensitivity; microbial culturing, selection of media, incubation conditions, organism identification techniques, antibiotic sensitivity testing			
Microbial cell staining techniques – microbe, virus, parasite and fungus identification (including principal differential characteristics)			
Diagnostic serology for infectious diseases			
Competencies			
• Knowledge of, and insight into, the use and limitations of technology and analytical techniques relevant to the field of specialisation. • An appreciation of technological developments with innovative and creative approaches to their implementation. • Specialist knowledge within chosen specialt(ies)			
A5 REFERENCE METHODOLOGY Training objective: an understanding of the principles of metrological traceability for			

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standardisation of measurements			
Metrological levels of traceability depending on the existence of definitive and reference measurement procedures.			
Metrological levels of traceability depending on certified reference materials.			
Regulations of the European Parliament and of the Council on in vitro diagnostic medical devices (repealing Directive 98/79/EC) as the legal background for metrological traceability and standardisation of measurements in laboratory medicine.			
The international concept for metrological traceability of measurements in laboratory medicine according to a set of international standards.			
Competencies			
• Ability to differentiate reasons for performance characteristics of definitive and reference measurements carried out in a routine diagnostic laboratory • Ability to recognise the advantages of standardised measurements for the development of definitive reference intervals and decision limits			
A6 EVALUATION AND ASSESSMENT Training objective: to acquire the skills and competence to evaluate methods, new diagnostic tests and their application			

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Analytical evaluation of laboratory methods • Binding standards on EU and/or on the national level (e.g. "Regulation of the European parliament and of the council on in vitro diagnostic medical devices") • Quality assurance: internal quality control and external quality assessment • Method performance: precision, accuracy, specificity and interference, laboratory statistics (e.g. ranges and limits), carry over			
Clinical evaluation of laboratory methods • Biological variability. Genetic influences, environmental influences, population, age, sex, nutrition, season and time of day, influence of therapeutic agents. • Laboratory statistics (e.g. diagnostic validity) of analytical methods. • Diagnostic strategies and analytical goals in the use of clinical chemistry tests.			
Laboratory statistics Basics • Descriptive statistics (e.g. mean, median, quantiles, SD, CV, correlation measures) • Inferential statistics (e.g. distributions, parameter estimation, confidence intervals)			

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• Design of experiments (e.g. power analysis, stratification, batch effects) • Basic features of machine learning techniques Biostatistics • Hypothesis testing o Comparison of two samples (e.g. t-, Wilcoxon-, F-test,) o Correlation testing (e.g. Pearson, Spearman, Fisher, chi-square) o Goodness of fit (e.g. Kolmogorov-Smirnov, Shapiro-Wilk) o Multiple testing (e.g. ANOVA, Kruskall-Wallis, Bonferroni) • Comparison and visualisation of methods o Robust linear regression (e.g. Deming, Passing-Bablock) o Visualisation methods (e.g. Youden and Bland-Altman Plot) • Ranges and limits o Analytical ranges (e.g. limits of detection/quantification and linearity, critical difference) o Reference intervals (direct and indirect methods) and laboratory data standardization o Other cut-off values (e.g. therapeutic ranges, risk			

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ranges) • Diagnostic validity o Diagnostic sensitivity and specificity, predictive values o AUROC analysis (incl. multiclass AUC) o Odds ratio • Diagnostic strategies o Exploratory data analysis (e.g. box plots, PCA, clustering) o Classification (e.g. logistic regression, decision trees) Bioinformatics • Omics technologies (genomics, transcriptomics, proteomics, metabolomics) • Data bases (e.g. ENSEMBLE, RefSeq, ClinVar, dbSNP, PDB, MASCOT, MetaboAnalyst) • Data formats and search algorithms (e.g. FASTA, BLAST) • Sequence analysis (variant calling, scoring matrices)			
Competencies			
• Ability to determine the essential parameters required to evaluate a laboratory method. • Ability to conduct an evaluation using appropriate statistical tools, spreadsheets and databases. • Ability to determine the clinical significance of the outcome of a laboratory method evaluation.			

SECTION A. GENERIC KNOWLEDGE

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• Ability to obtain, explore, and employ knowledge in the application of laboratory medicine tests. • Ability to take responsibility for the data and information produced, including knowledge of the influence of variation (biological as well as analytical) on interpretation of data. • Ability to understand the principles and results of multivariate data analyses. • Basic understanding of established bioinformatics algorithms and tools.			
A7 CASE RELATED MEDICAL EVALUATION OF LABORATORY TESTS Training objective: To hold an evidence base evidence base for the choice of tests and interpretation of results.			
Evaluation of individual results (identifying extreme values, recognition of significance of previous results, recognition of combinations of findings typical of diseases).			
Use of reference values (influence of age, genetics, sex, lifestyle, interfering factors, effect of therapeutic agents, biological and analytical variation) and limits of decision.			
Longitudinal evaluation of critical differences during disease course, e.g., in long-term conditions, during therapeutic drug monitoring and as a result of treatment regimen changes.			
Recommended testing strategies in response to clinical demand for intervention and guidance.			
Independent initiation and/or recommendation of further investigations, reflective testing.			

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The laboratory report – provision of evaluation, guidance and interpretive comments.			
Competencies			
• Provision of interpretive, advisory and intervention guidance in the application of laboratory tests, as appropriate. • Ability to communicate the value of laboratory investigations to service users.			
A8 REFERENCE METHODOLOGY Training objective: an appreciation of the contribution of laboratory medicine to better health and best care.			
By the end of training, a specialist in laboratory medicine should be and evaluate high quality clinical services that are targeted to meet the needs of individuals and groups of patients. Training requires exposure to clinical environments where laboratory medicine impacts on patient care. Examples include acute and critical care, and application of point of care testing. Participation in ward rounds, provision of direct clinical care (as appropriate) as a member of the clinical team and other contact with the users of the laboratory is key to achieving clinical competency. Participating and leading seminars and case discussions also provide valuable experiences.			
Competencies			

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• Ability to communicate effectively with colleagues in the planning and delivery of clinical services • Understanding of his/her professional responsibility for the well-being and personal safety of patients, colleagues, and community and workplace environment. • Ability to provide direct clinical care, as appropriate. • Ability to advise appropriate laboratory tests for diagnosis of specific pathology and interpretation of obtained results. • Ability to prepare clinical reports interpreting the results of laboratory investigations.			

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B. SPECIALIST KNOWLEDGE

Training Objective: By the end of training the trainee specialist in Laboratory medicine will be able to synthesis, evaluate and apply knowledge and perform range of clinical and technical skills and procedure. The trainee will be able to demonstrate the attitude and behaviors necessary for professional practice.

SPECIALIST KNOWLEDGE	Competence level / date Assessor's signature		
	1	2	3
B1 CLINICAL CHEMISTRY/IMMUNOLOGY			
Serum fluid and protein and amino acid assessment: Understand the principles of protein measurement in body fluids. Know the principles of serum, urine, cerebrospinal fluid (CSF) and protein electrophoresis. Know the properties and function of the principle proteins such as albumin, protease inhibitors, transport proteins, caeruloplasmin, clotting factors and immunoglobulins. Understand the acute phase response and its effect on different biochemical measurements. Recognise key patterns of dysproteinemias and paraproteinemia, alpha-antitrypsin and immunoglobulin deficiencies.			

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Lipid Assessment: understand the chemical structures, biosynthesis, classification, function, and metabolism of lipids and lipoproteins. Understand the metabolic basis of inherited and acquired hyper-and –hypo-lipoproteinemia. Understand and evaluate the biochemical basis for atheroma, coronary heart disease, associated risk factors and primary and secondary cardiovascular disease prevention. Know Fredrickson classification and Treatment of hypercholesterolemia in adults and the classification of hyperlipidemia. Know the principles of analytic techniques for laboratory investigations of lipids.			
Gastric, pancreatic, and intestinal function: By the end of the training period the trainee should understand the physiological and biochemistry of digestion. The endocrine function of the gut, the production and control of gastrointestinal hormones with examples of pathological conditions such as peptic ulcer disease, pancreatic tumours. Major pathological condition of the gut e.g. pyloric obstruction, malabsorption, pancreatitis, anaemia due to bowel disease, intestinal failure, malignant tumours including carcinoid syndrome and neuroendocrine tumours. Investigation of gut function, gut hormones, investigation of malabsorption and diarrhoea. The principles and practical			

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problem of faecal analysis.			
Glucose and evaluation of diabetes mellitus: Understand the metabolism of glucose and carbohydrates (insulin, C-peptide, and other regulatory hormones). Be familiar with the classification of diabetes, the diagnostic criteria for diabetes, impaired glucose tolerance and impaired fasting glucose. Understand the principles of glycated haemoglobin and its role in diagnosis of diabetes. Understand the pathophysiology of type 1 and type 2 diabetes mellitus, secondary diabetes and gestational diabetes. Know the acute complications of diabetes such as diabetic ketoacidosis and hyperosmolar hyperglycaemic state, as well as chronic complications such as microvascular and macrovascular diseases. Understand the principles of treatment of diabetes and monitoring including glucose monitoring, the use of insulin and dietary control and other pharmacological agents. Develop knowledge in laboratory investigations of diabetes including blood glucose, oral glucose tolerance test, haemoglobin A1c, and urinary microalbumin. Be familiar with metabolic syndrome and understand the diagnosis and investigations of hypoglycaemia.			

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Mineral and bone metabolism: Understand the biochemistry and physiology of bone metabolism including calcium, phosphate, magnesium, parathyroid hormone and vitamin D. Know the causes, investigation, diagnosis and monitoring of conditions such as hyper and hypoparathyroidism, hyper and hypocalcaemia, hyper and hypophosphatemia, hyper and hypomagnesemia. Be familiar with conditions such as osteoporosis including steroid therapy, osteomalacia, renal osteodystrophy, Paget's diseases and chronic malabsorption. Know the hormones that regulate mineral metabolism (parathyroid hormone (PTH), calcitonin, and vitamin D) as well as parathyroid hormone-related protein (PTHrP). Understand the methodologies for measurement of PTH assays, calcium (total, ionised and adjusted) and vitamin D.			
Porphyrins: Understand the biochemistry and physiology of haemoglobin metabolism. The metabolic basis, diagnosis, investigation and monitoring of porphyrin conditions.			

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Neoplasia (tumour markers): Be familiar with the range of tumour markers undertaken by medical laboratories and their relationship to specific types of cancer including prostate, lung, breast, ovarian, thyroid, pituitary, adrenal, liver, skin, testicular cancers and those of the gastro-intestinal tract. Know the principles and limitations of laboratory methods of various tumour markers, the pathological process that lead to production of tumour markers and the criteria for an ideal tumour marker. Understand the value of tumour markers in diagnosis, screening, prognosis, monitoring. Neoplasia (liquid biopsy): be familiar with clonal heterogeneity and major genetic aberrations in human cancer. Know the most important molecular methods for the sensitive detection of mutant tumour genes in plasma.			

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Cardiac biomarkers and the assessment of cardiovascular system: Know the definition of myocardial infarction and understand the interaction of diagnostic modalities in its definition. Understand the current methods of calculating risk, their limitation and use of biochemical markers for risk stratification in acute coronary syndromes. Know the pathophysiology and evaluation of congestive heart failure. Understand the markers of congestive heart failure and their biological and technical limitations. Understand the utility of inflammatory markers in the evaluation of cardiac risk (e.g. homocysteine and high sensitivity C-reactive protein). Know the biochemical investigation and management of hypertension.			
Endocrinology (Thyroid gland): Understand the structure, biosynthesis, secretion, and metabolism of thyroid hormones. Know thyroid physiology and common causes of thyroid diseases including congenital hypothyroidism and screening programme, hypo- and hyperthyroidism, autoimmune disease, autoantibodies, tumours including adenoma and/carcinoma and medullary thyroid cancer. Know the laboratory tests for the investigation of thyroid disorders and be able to interpret these analytes in their clinical context with an appreciation for the euthyroid sick			

SPECIALIST KNOWLEDGE	Competence level / date Assessor's signature		
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state. Be familiar with current analytical methodologies for thyroid testing and their limitations. Endocrinology (Pituitary gland): Understand the feedback loops in endocrinology and how they are exploited in diagnostic testing. Understand the physiological action, biochemistry, and regulation of anterior and posterior pituitary hormones. Understand the principles of various endocrine dynamic function tests. Understand the pathophysiology of disorders of the pituitary such as acromegaly, dwarfism, prolactinoma, diabetes insipidus, pan- hypopituitarism and isolated hormone deficiency. Understand the endocrine effects of cancer including ectopic hormones, multiples endocrine neoplasia and neuroendocrine tumours. Endocrinology (Adrenal gland): Understand the physiological of adrenal cortex function and its disorders including excess steroid production and deficiencies. Be familiar with the biochemistry, biosynthesis, chemical structure, and metabolism of glucocorticoids and mineralocorticoids. Know how to assess adrenal reserve and how to investigate Cushing's syndrome, Conn's disease, congenital adrenal hyperplasia. Understand the pathophysiology of adrenal medulla including catecholamine metabolism and metabolites,			

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pheochromocytoma, and neuroblastoma. Be familiar with the measurement of biochemical markers for the assessment of adrenal medulla. Understand the principles of suppression and stimulation testing of the adrenal gland. Understand regulation of the renin-angiotensin-aldosterone system. Understand the synthesis and metabolism of biogenic amines, including catecholamines and serotonin, as well laboratory tests for their evaluation.			
Reproductive function and pregnancy: understand the endocrinology of the gonads, including pituitary-gonadal axis, sexual dysfunction, precocious and delayed puberty, the ovarian cycle, metabolism of testosterone, ovarian failure and menopause and poly cystic ovarian syndrome. Be familiar with the biochemical assessment of hirsutism and virilisation. Understand the principles for hormone replacement therapy and oral contraceptives. Understand the physiology and clinical biochemistry of pregnancy, and prenatal testing. Know the causes, investigations, monitoring and management of the complications of pregnancy such as hydatidiform mole and choriocarcinoma.			

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Paediatric biochemistry and in-born errors of metabolism: Understand the physiology and biochemistry of the neonatal development. The fluid balance of neonate and the biochemical disturbances associated with over hydration and dehydration. The causes, investigation, monitoring and management of conditions such as jaundice, hypoglycaemia, liver disease, hypomagnesemia, hyperammonemia, disturbances of calcium and phosphate homeostasis, disease of prematurity such as metabolic bone disease. Understand the differences and unique aspects of paediatric and neonatal chemistry including reference intervals. The investigation of failure to thrive. Know the causes, investigation, diagnosis, monitoring and management of conditions such as hypoglycaemia, inherited and acquired calcium and phosphate disturbances, hyper-ammonaemia, lactic acidosis and renal disorders including Fanconi's syndrome and tubular defect.			
Know the key principles and criteria for establishing effective screening programmes. Understand the role of ante-natal screening for disorders such as fetal anomalies (serum biomarker and fetal DNA analysis programmes) ; neonatal programmes such as those for phenylketonuria, congenital hypothyroidism; cancer screening programmes			

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such as hose for prostate (risk management), breast and colorectal cancer.			
Inherited metabolic disorders: Understand the pathophysiology and biochemistry, clinical presentation and management of inherited metabolic diseases. Understand the principles of enzyme blocks in metabolic pathways and consequential clinical and pathology signs in common inherited metabolic diseases. Know the methods for investigation, diagnosis and monitoring of cystic fibrosis, disorders of amino acids metabolism, glycogen storage disease, carbohydrate metabolism, cerebral lipidosis, fatty acid oxidation defects, disorder of metal metabolism, mitochondrial disorders, mucopolysaccharidoses, organic acid disorders, peroxisomal disorders, primary and secondary purine and pyrimidine disorders, transports defects and urea cycle disorders. Know the prenatal investigation of inherited metabolic diseases of the fetus. Understand the causes and investigation and monitoring of encephalopathy and hyperammonemia. Understand the analysis of amino acids, organic acids, carnitine, acyl carnitines, enzyme assays, mucopolysaccharidoses, tissue culture and DNA investigation.			

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Urogenital Tract: By the end of training the trainee should understand composition of urine, mechanism of stone formation, renal tubular function and defects and the features of renal tubular defect. Understand the diagnosis and assessment of prostatic disease and renal, bladder and prostate cancer.			
Liver and biliary tract: Understand the function of the liver, mechanism of liver enzymes and the clinical utility of measuring hepatic enzymes. Understand bilirubin metabolism and formation, enterohepatic circulation, bile salt and the causes of jaundice. Understand the unique aspects of neonatal bilirubin and genetic defects that effect bilirubin metabolism. Know the disease of liver such as viral, autoimmune hepatitis, cirrhosis, alcohol/drug hepatotoxicity, non-alcoholic fatty liver disease, cholestasis, biliary obstruction and inherited disease such as hemochromatosis and Wilson's disease. Know the feature of hepatic failure and encephalopathy clinically and biochemically and the assessment of hepatic function.			

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Assessment of renal function: The trainee by end of the training period should know the renal physiology and how it can be assessed, including glomerular and tubular function; salt and water homeostasis, hydrogen ion homeostasis and renal production of hormones e.g. renin, erythropoietin and vitamin D. Understand the physiology of renal function and distinguish between pre-renal, intrinsic, and post-renal disease, acute versus chronic renal failure and uremic syndrome. Know the laboratory analytical methods for the measurement of creatinine, urea nitrogen and proteinuria. Understand how renal function may be assessed including measurement and estimation of glomerular filtration rate, markers of renal function, tubular function tests protein/creatinine ratio and drug interference in urine analysis.			

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SPECIALIST KNOWLEDGE	Competence level / date Assessor's signature		
	1	2	3
Water and electrolytes: Understand the distribution of water and electrolytes, renal handling of electrolytes and key metabolites and the interpretation of urinary electrolyte measurements. Understand the definition of osmolality, and calculation of osmotic gap Understand the common pitfalls and sources of error during estimation of the osmotic gap (e.g. hyperproteinemia, hyperlipidemia, hypermagnesemia). Understand the differential diagnosis of an unexplained, increased osmotic gap, including alcohol or glycol ingestion, alcoholic or diabetic ketosis or ketoacidosis, and osmotherapy (e.g., mannitol or glycerol administration), among others. Understand the principles of fluid balance, regulation of extracellular fluid, the role of antidiuretic hormone, renin-angiotensin-aldosterone and natriuretic peptides. Understand conditions in which water depletion and excess may occur and principles of intravenous fluid therapy.			
Assessment of pulmonary function, blood gases and oxygen saturation, acid-base status, and relevant electrolytes disorders: Understand the physiology of normal respiration, O2, CO2, transport and buffers. Understand the principles of the alveolar-arterial O2 gradient and anion gap. Understand the causes and assessment of acid-base			

SECTION B: SPECIALIST KNOWLEDGE

Name: Base Hospital:

SPECIALIST KNOWLEDGE	Competence level / date Assessor's signature		
	1	2	3
disturbances and understand the principles of H+, pCO2 and pO2 measurements. Know the pathophysiology of ketoacidosis and lactic acidosis. Be able to describe the haemoglobin-oxygen dissociation curve and factors that affect the curve. Understand the principles of integrated blood gas, electrolyte, and CO-oximetry systems.			
Enzymes: Understand the mechanism of induction of enzymes, enzymes stability and the differences between first- and zero-order kinetics of drug metabolism and clearance. Understand structural basis and quantifications of isoenzymes. The enzymes assays such as amylase, lipase, alkaline phosphatase, aminotransferase, gamma-glutamyl transferase, angiotensin converting enzymes, creatinine kinase and lactate dehydrogenase, cholinesterase and variants.			
Trace element: Understand the biochemistry, physiology, and metabolism of trace elements (iron, magnesium, zinc, copper, selenium, cobalt, and fluoride). Know the biochemistry and clinical significance of metal-binding proteins. Know the clinical assessments of trace elements such as serum iron, iron-binding capacity, transferrin, transferrin saturation, serum ferritin, zinc, protoporphyrin, and serum caeruloplasmin.			

SECTION B: SPECIALIST KNOWLEDGE

Name: Base Hospital:

SPECIALIST KNOWLEDGE	Competence level / date Assessor's signature		
	1	2	3
Therapeutic drug monitoring (TDM), drug of abuse and toxicology: Understand the principles of pharmacokinetics: absorption, distribution, metabolism and excretion. Understand the differences between pharmacokinetics and toxicokinetics. To be able to explain in the context of TDM the impact that diseases of the GI tract, liver, kidney may have on the drug metabolism. Understand the differences between first- and zero-order kinetics of drug metabolism. Understand the principles of pharmacogenomics in the interpretation of drug levels. Be able to calculate steady-state, peak or trough drug levels throughout a dosing cycle. Understand the principles of toxicodynamics of major drugs and poisons. Understand the pathophysiological basis and be able to recognise the five major toxicological syndromes (cholinergic, anticholinergic, sympathomimetic, opiate, and sedative-hypnotic). Understand laboratory evaluation and management of overdosed or poisoned patients. Understand the important differences between urine and blood for monitoring and detection of drugs. Understand the limitations of drug "screening" protocols. Understand the metabolic effect and toxicological profiles of specific agents. Be familiar with the major drugs of abuse and their clinical manifestations. Know the common methods for adulteration of urine and the techniques available in the			

SECTION B: SPECIALIST KNOWLEDGE

Name: Base Hospital:

SPECIALIST KNOWLEDGE	Competence level / date Assessor's signature		
	1	2	3
laboratory to detect them. Understand the general measures used in the treatment of drug addiction including compliance testing for methadone and the testing compliance of commonly abused drugs such as ethanol, opiates, amphetamines, methylenedioxy-methamphetamine (MDMA), benzodiazepines, and cocaine. Understand the laboratory role in investigation of the unconscious patient in cases of suspected intoxication. Know the advantage and limitations of different analytical techniques for the analysis of both therapeutic and abused drugs and the common causes of false positives due to cross-reactivity. Understand the legal framework for screening for drugs, including pre-employment screening, industrial health screening and drug of abuse screening. Understand the principles and legal implications of specimen collection, chain of custody, release of results and employer responsibilities related to drugs of abuse screening and forensic science. Understand the requirement associated with storage and security of drugs and how to investigate post-mortem toxicology cases.			

SECTION B: SPECIALIST KNOWLEDGE

Name: Base Hospital:

SPECIALIST KNOWLEDGE	Competence level / date Assessor's signature		
	1	2	3
Vitamins: Know the definition and classification of vitamins, fat-soluble vitamins (A, D, E, and K) and water-soluble vitamins (B1, B2, B6, B12 (cobalamin), C, niacin, nicotinamide, folic acid, biotin, and pantothenic acid). Understand the clinical disorders associated with the deficiency as well as toxicity of vitamins.			
Immune system: Understand the role of the immune system in defence against infection, in cancer and malignancy; functions of the humoral and cellular immune systems and their regulation; specific and non-specific immune response, role of cytokines. Understand the application of tests for investigating the immune system; complement factors and hereditary and acquired disorders. Be familiar with primary and secondary causes of immunoglobulin deficiency, the role of cellular and humoral components in immune deficiency. Overproduction, monoclonal and polyclonal immunopathies. Understand the presentation, investigation and treatment of systemic autoimmune rheumatic disease and systemic vasculitides including Rheumatoid arthritis, Systemic lupus erythematosus, Sjogren's syndrome, Giant cell arteritis, Haemolytic uraemic syndrome and Glomerulonephritis. Understand the factor involved in development of atopic disease (allergy and			

SECTION B: SPECIALIST KNOWLEDGE

Name: Base Hospital:

SPECIALIST KNOWLEDGE	Competence level / date Assessor's signature		
	1	2	3
hypersensitivity). Production and role of IgE, mast cell degranulation. Principles of investigation of allergy (including coeliac disease). Understand the principles of anaphylaxis and anaphylactoid reactions			
Body Fluid Analysis: Understand clinical indications for body fluid analysis. The principles and methodologies for analysis of fluids such as cerebrospinal, ascetic, pleural, and synovial fluid. Understand how to distinguish between exudate and transudate fluids.			
Nutrition: Understand the normal physiology of human nutrition. Know the causes, investigation, diagnosis and monitoring and management of protein-energy malnutrition, markers of nutritional status, effects and effects of vitamin deficiency or excess, trace element deficiency of excess. Be familiar with nutrition related conditions such as refeeding syndrome, metabolic syndrome and obesity. Know the investigations, classifications, risk factors and complications of obesity. Understand the biochemistry of starvation. Understand the nutritional management of diseases such as inflammatory bowel disease, coeliac disease, short bowel syndrome, cancer, gall bladder disease, post major abdominal surgery, oesophagostomy and malabsorption.			

SECTION B: SPECIALIST KNOWLEDGE

Name: Base Hospital:

SPECIALIST KNOWLEDGE	Competence level / date Assessor's signature		
	1	2	3
Neuromuscular system: Understand the normal physiology of muscles. Understand the biochemistry of psychiatric disease and the biochemical disturbances associated with neuromuscular disorders. Know the causes, investigation, monitoring and management of neuromuscular disorders such as multiple sclerosis, muscular dystrophy, Parkinson's disease and muscle disease. Understand the pathophysiology, formation and composition of cerebrospinal fluid and its role in the investigation and diagnosis of neurological disorders such as meningitis and suspected sub-arachnoid haemorrhage.			
B2 HAEMATOLOGY AND BLOOD TRANSFUSION			
Haematology Understand the theoretical and clinical background of: • Haematopoiesis in health and disease. • Morphology and kinetics of blood cells. • Enzymology of blood cells. • Haemoglobin synthesis and degradation; iron status. • Pathophysiology and investigations of haemolysis. • Classification, clinical indicators and laboratory markers of erythrocyte, granulocyte and lymphocyte disorders. • Hereditary and acquired, non-oncological			

SECTION B: SPECIALIST KNOWLEDGE

Name: Base Hospital:

SPECIALIST KNOWLEDGE	Competence level / date Assessor's signature		
	1	2	3
haematopoiesis abnormalities, including haemoglobinopathies and thalassemia. • Symptoms, pathogenesis and laboratory investigation of anaemia (including erythrocytes membrane and enzyme abnormalities and status of iron, vitamin B12, folate, metabolite etc.). • Symptoms, pathogenesis and laboratory investigation of haemato-oncological abnormalities (including leukaemias, myeloproliferative disorders, lymphomas, multiple myelomas, myelodysplastic syndrome etc.). • Haematological, immunological, microscopic, cytogenetic and molecular methods used in the diagnostics of haematological disorders, along with interpretation of obtained results. • The role and strategy of the laboratory diagnostics in haematological diseases diagnosing, differentiating, monitoring and evaluating the effects of treatment. • Acquire the theoretical and practical knowledge related to diagnostic procedures in haematology: • Complete blood count (CBC): WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, HDW, PLT, P-LCR, L-PLT, Reticulocyte, CBC with differential; knowledge of haematological parameters.			

SECTION B: SPECIALIST KNOWLEDGE

Name: Base Hospital:

SPECIALIST KNOWLEDGE	Competence level / date Assessor's signature		
	1	2	3
• Determination of erythrocyte sedimentation rate. • Preparation and staining of blood and bone marrow smears, along with microscopical evaluation. • Cytochemical staining including detection of MPO, FAG, PAS, Sudan black, acid phosphatase, esterase, iron. • Detection and measurement of variant and minor (HbA2 and HbF) haemoglobins. • Detection of abnormal haemoglobin derivatives: spectrophotometric analysis. • Haemoglobin electrophoresis on cellulose acetate, in agarose gel. • Foetal haemoglobin testing (Kleihauer, flow cytometric HbF determination). • Molecular diagnostic approaches. • Investigation of cellular characteristics and abnormalities by flow cytometry. • Flow cytometry and leukocyte sub-grouping. • Flow cytometric immunophenotyping of hematopoietic malignancies.			
Haemostasis Understand the theory and principles of:			

SECTION B: SPECIALIST KNOWLEDGE

Name: Base Hospital:

SPECIALIST KNOWLEDGE	Competence level / date Assessor's signature		
	1	2	3
• Haemostasis physiology including the role of blood vessels, platelets, coagulation factors, fibrinolytic system and inhibitors of coagulation. • Haemostatic risk factors for atherosclerosis and cardiovascular disease. • Inherited and acquired coagulation abnormalities leading to bleeding and/or thrombotic disorders (including platelet and fibrinogen abnormality, vWD, haemophilia, DIC, TTP, HELLP, HIT, thrombophilia, etc.). • Haemostatic dysfunction related to various diseases and clinical stages. • Clinical approach to investigation of haemostasis. • Interpretation of test results relating to haemostasis and its components. • Markers of coagulation activation. • Monitoring of therapy in bleeding disorders. • Anticoagulant treatment in clinical and outpatient conditions. • Anticoagulant and antiplatelet therapy. Acquire the theoretical and practical knowledge for diagnostic procedures related to haemostasis: • PT, APTT, TT, reptilase/ancrod time, concentration and/or activity of fibrinogen and other coagulation			

SECTION B: SPECIALIST KNOWLEDGE

Name: Base Hospital:

SPECIALIST KNOWLEDGE	Competence level / date Assessor's signature		
	1	2	3
factors, correction tests, ELT, plasminogen, PAI, circulating anticoagulant, etc). • Thrombin and plasmin activation: TAT, prothrombin fragments F1+2, D-dimer, PAP, • Platelet function (clot retraction, aggregation, PFA-100, thromboelastography, flow cytometry), • Laboratory diagnostics of VWF abnormalities (eg. vWAg, vWR:Cof, RIPA, multimers, ADAMTS13), • Thrombophilia testing (including A-PCR, FV Leiden, FII, AT, PC, PS, APA, etc.). • INR, APTT-R, anti-Xa.			
Blood transfusion Principles of patient identifications and pre-transfusion testing: • Blood group antigens and other antigen systems as considered in blood transfusion (including genetics). • Selection criteria of donors for blood transfusion. • Several types of transfusion reactions, foetal maternal bleeding. • Medical applications, clinical relevance and indications for the administration of blood and blood components. • Preparation and application of blood components. • Organisation of blood banking.			

SECTION B: SPECIALIST KNOWLEDGE

Name: Base Hospital:

SPECIALIST KNOWLEDGE	Competence level / date Assessor's signature		
	1	2	3
• Platelet antibodies. • Typing of leucocytes and tissue antigens. • Recognition of cell markers using monoclonal antibodies.The application of plasmapheresis both in donors and in patients. Acquire the theoretical and practical knowledge related to diagnostic procedures in blood transfusion: • Typing of irregular (auto) antibodies; determination of antibody titre. • Extended blood group typing. • Investigation of transfusion reactions. • Typing of B and T lymphocytes.			
B3 MICROBIOLOGY			
Clinical bacteriology • Bacterial cells structures and associated functions • Bacterial classification and phylogeny • Bacterial physiology (metabolism, growth curve) • Bacterial genetics: role of mobile genetic elements (plasmids, insertion sequences, integrons, transposons et.) in transfer of resistance and virulence genes, mechanisms of transfer (conjugation, transformation, transduction etc)			

SECTION B: SPECIALIST KNOWLEDGE

Name: Base Hospital:

SPECIALIST KNOWLEDGE	Competence level / date Assessor's signature		
	1	2	3
• Normal microbiota: definition, composition, roles • Bacterial pathogenicity and virulence factors • Microbial biofilms: definition, biofilm associated infections, resistance to antimicrobials • Colonisation versus infection • Commonly encountered bacteria and related infections (morphological, colony and cultural, biochemical, antigenic and pathogenic features) • Aetiology, pathophysiology and presentation, including sources and routes of transmission of infectious diseases in the community and hospital-acquired infection (HAI) • Emerging and changing patterns of bacterial infections			
Clinical Virology • Animal viruses classification • Viral replication and modes of transmission • Commonly encountered viruses and related human infections • Emerging and changing patterns of viral infections • Microbiology health and safety legislation and its application within the laboratory			
Sexually transmitted infections • The aetiology, pathophysiology and clinical presentation			

SECTION B: SPECIALIST KNOWLEDGE

Name: Base Hospital:

SPECIALIST KNOWLEDGE	Competence level / date Assessor's signature		
	1	2	3
of the more common sexually transmitted infections (STI) • Congenital STI and associated risks • Investigation and management of common infection problems in the intensive care unit (ICU) • Infections specific to pregnancy (e.g. septic abortion, chorioamnionitis, endometritis) • Infections that may compromise pregnancy (e.g. STI, fungal infection, parasitic disease) • Pathophysiology of infectious disease in children (e.g. neonatal meningitis, group B sepsis, intraventricular shunt infections) • Treatment of childhood infections, including the selective use of antimicrobials			
Mycology and clinical parasitology • Fungal replication and modes of transmission • Parasitic life cycles and modes of transmission • Pathogenesis, epidemiology, clinical investigation and management of fungal and parasitic infection • Commonly encountered fungal and parasitic infections • Emerging fungal and parasitic diseases • Principles and practice of treatment of fungal and parasitic infection			

SECTION B: SPECIALIST KNOWLEDGE

Name: Base Hospital:

SPECIALIST KNOWLEDGE	Competence level / date Assessor's signature		
	1	2	3
• Role of specialised microbiology laboratories in mycology and parasitology			
Principles of Antimicrobial therapy • Structure, classification and mechanism of action of commonly prescribed antimicrobial agents • Antimicrobial resistance: definition, mechanisms, surveillance, assessment and risk to human health • Natural versus acquired resistance • Natural resistance phenotypes of the most clinically relevant microorganisms • Current guidelines relating to antimicrobial susceptibility testing and their use in clinical practice • Methods for antimicrobial susceptibility testing - disk diffusion, agar diffusion, broth microdilution, E-Test etc. • Emerging antimicrobial agents, e.g. revived and novel antimicrobials, bacteriophages, iRNA, vaccines, serotherapy, anti-pathogenic strategies (e.g., quorum sensing inhibitors), physical antimicrobial strategies based on physical agents (cold plasma, phtotodynamic therapy etc.) • Value of antimicrobial stewardship			
Epidemiology and health protection • Communicable disease surveillance and reporting,			

SECTION B: SPECIALIST KNOWLEDGE

Name: Base Hospital:

SPECIALIST KNOWLEDGE	Competence level / date Assessor's signature		
	1	2	3
• Role of laboratory services and techniques to support epidemiological investigation • The principles of outbreak prevention, investigation, and management • Standards and guidelines in relation to occupational exposure to infectious agents • Epidemiological consequences of hospital-acquired and community disease control with reference to tuberculosis, viral hepatitis, HIV and genitourinary disease • Management of needlestick injuries in the clinical setting • Decontamination, disinfection and sterilisation in the hospital, laboratory and primary care setting • Principles of screening for certain organisms, eg MRSA, multi-resistant Gram-negatives, including CPE, vancomycin-resistant enterococci • Water safety within the healthcare setting, Legionella, Pseudomonas, M. chimera • Investigation protocols and patient pathways relevant to hospital-acquired and community infection • Environmental outbreaks, e.g. Legionella, Norovirus • The role of health protection and surveillance agencies			

SECTION B: SPECIALIST KNOWLEDGE

Name: Base Hospital:

SPECIALIST KNOWLEDGE	Competence level / date Assessor's signature		
	1	2	3
Public Health Worldwide: Implications for Clinical Microbiology • Pathogens involved in food- and water-borne infections • Common causes of infection in returning travellers (e.g. malaria, viral haemorrhagic fever) • Epidemiology, distribution and investigation of common tropical infections (e.g. malaria, tuberculosis, enteric fever, cholera, dysentery, schistosomiasis, onchocerciasis, trypanosomiasis, gastrointestinal GIT parasites, dengue, yellow fever) • Epidemiology, distribution, investigation and management of pandemic influenza and other global infectious diseases. The role of the WHO, governments and health providers • Bioterrorism and measures to reduce risk			
B4 GENETICS, GENOMICS AND CYTOGENETICS			
• Nucleic acid structure and function • Chromosome structure, function and abnormalities (e.g. Down's syndrome, sex chromosome abnormalities, translocations) • Nomenclature used to describe the human genome • DNA replication, transcription and translation • Meiosis, mitosis, and Mendelian inheritance			

SECTION B: SPECIALIST KNOWLEDGE

Name: Base Hospital:

SPECIALIST KNOWLEDGE	Competence level / date Assessor's signature		
	1	2	3
• Patterns of inheritance (autosomal, X-linked, non-Mendelian) • Use of genome analysis tools, the role of bioinformatics in the investigation and management of genetic and genomic disorders • Common genetic and genomic disorders and their impact on patient and their families • Scientific basis of inherited and sporadic cancers • Principles and practice of genetic counselling			
B5 IN VITRO FERTILISATION			
• A basic knowledge of sperm count, sperm vitality and mortality and sperm morphology • A basic knowledge of fresh and frozen sperm preparation • An understanding of the factors affecting oocyte quality. • An understanding of the contribution of laboratory medicine investigations in assessment of fertility, assessment of opportunities for in vitro fertilisation, and the monitoring of progression of pregnancy. • Cryopreservation of gametes (sperm and oocyte) and embryos, and theoretical and practical aspect of slow cooling and verification.			

Name: Base Hospital:

C. RESEARCH, DEVELOPMENT AND AUDIT

Training objective: by the end of the training, a specialist in laboratory medicine should be able to plan, conduct, supervise, clinically evaluate, interpret and report research, development and audit findings. Examples include original research, translation of research, and adoption and diffusion of innovations into clinical practice. As laboratory medicine is continually and rapidly evolving involvement in research, development and audit is indispensable. Special attention must be paid to the following:

RESEARCH, DEVELOPMENT AND AUDIT	Competence level / date Assessor's signature		
	1	2	3
C RESEARCH, DEVELOPMENT AND AUDIT			
Development and improvement in technologies, techniques and methodologies; with special emphasis on new developments in areas such as molecular biology, proteomics, mass spectrometry.			
Procedures to test and evaluate the steps of a method and the components of an instrument.			
Initiation, conduct and evaluation of laboratory-based and clinical research and development based on best evidence of practice.			
Initiation, conduct and evaluation of clinical and laboratory audit to ensure quality, governance and patients' needs continue to be met.			
Generating outcomes of research and development, audit and service improvement programmes using recognised scientific and statistical techniques.			
Competencies			
• Ability to conduct research, either basic or applied, in order to further knowledge in the field of laboratory medicine.			

SECTION C: RESEARCH, DEVELOPMENT AND AUDIT

Name: Base Hospital:

RESEARCH, DEVELOPMENT AND AUDIT	Competence level / date Assessor's signature		
	1	2	3
• Ability to undertake literature/systematic reviews and design quantitative and qualitative programmes for research, development, audit and service improvement based on best evidence. • Ability to appraise the need and set priorities for research, development, audit and service improvement programmes. • Understanding of research governance, ethical and legal frameworks, funding streams, the influence of regulatory and healthcare-related organisations in local settings. • Ability to design and conduct the required experiments to ensure objectives are met. • The application of statistical and biostatistical procedures to evaluate quantitative and qualitative information and data. • Ability to appraise and translate outcomes to enhance activities, as appropriate. • Ability to communicate orally and in writing, including the production of clear, cogent reports and publications in international scientific journals.			

Name: Base Hospital:

D1. LEADERSHIP SKILLS

Training objective: To operate as a clinical leader supporting and transforming health and health care services. Depending on the working environment the specialist in laboratory medicine should be familiar with some or all aspects of the responsibilities listed below.

LEADERSHIP SKILLS	Competence level / date Assessor's signature		
	1	2	3
D1.1 LABORATORY DIRECTION AND LEADERSHIP			
Specifying service requirements.			
Setting strategy and establishing policy.			
Formulating laboratory plans.			
Assessing resource requirements – staff, space, equipment.			
Analysing costing (efficiency) and cost-benefits (effectiveness).			
D1.2 LABORATORY ORGANISATION			
Design and utilisation of space and facilities.			
Selection of methodologies and equipment.			
Selection of information management and technology systems.			
Recruiting and managing a staff/skill mix appropriate for the service.			
Establishing pre-analytical, analytical and post-analytical processes.			
Preparing protocols, procedures and guidelines.			
Preparing business and strategic plans and service level agreements.			

SECTION D: LEADERSHIP SKILLS

Name: Base Hospital:

LEADERSHIP SKILLS	Competence level / date Assessor's signature		
	1	2	3
Budgetary responsibilities (contracting, performance management, financial controls).			
Design of request and report forms.			
D1.3 QUALITY			
The criteria and process of laboratory accreditation			
Medical laboratory and point of care testing.			
Risk management and procedures designed to minimise risks			
Requirements for a quality management system – quality assurance, governance, monitoring of planned actions, audit, incident reporting.			
Managing internal quality control and external quality assessment performance.			
Data, information and knowledge management: use of medical informatics, data processing, spread sheets/databases, electronic/telecommunications.			
D1.4 EDUCATION/TRAINING/CONTINUOUS PROFESSIONAL DEVELOPMENT			
Demonstrate good communication, mentoring, supervising and assessing skills.			
To be able plan and prepare teaching material using evidence based information and data.			
Participate in range of teaching and assessment methods			
Build a good knowledge of the clinical context before teaching or training others			

SECTION D: LEADERSHIP SKILLS

Name: Base Hospital:

LEADERSHIP SKILLS	Competence level / date Assessor's signature		
	1	2	3
Understand the range of different mentoring styles from perspective of the learner and the teacher.			
Ensuring skills, competencies and motivation of staff meet service requirements.			
Ensuring staff access education and training programmes appropriate for service needs.			
Participation, as appropriate, in staff education, training and appraisal.			
Ensuring staff remain up to date by participation in continuous professional development (CPD).			
Ensuring own training, education, appraisal and CPD needs are maintained.			
D1.6 LABORATORY HEALTH AND SAFETY			
Handling of potentially infectious samples (e.g. HIV and hepatitis), handling of noxious chemicals and isotopes, mechanical and electrical safety, fire precautions, dealing with an accident, accident prevention and hygiene regulations, occupational diseases.			
Aware of all the legal rules and regulation of health care service that have to be met to ensure compliance with safe practice and maintaining attainment of accreditation status			
Alert systems, incident reporting.			
D1.7 LEGAL, ETHICAL AND GOVERNANCE CONSIDERATIONS			
Laws, regulations, guidelines and recommendations on work in clinical laboratories: in particular requirements for accreditation of services, education and training, health and			

SECTION D: LEADERSHIP SKILLS

Name: Base Hospital:

LEADERSHIP SKILLS	Competence level / date Assessor's signature		
	1	2	3
safety, infection control, buildings, employment law, regulation and registration of staff.			
Ethical aspects and conventions on production, interpretation, reporting and use of medical laboratory data.			
Confidentiality, data protection and security.			
Clinical and research governance expectations of government, health care-related organisations and employers for high quality, evidence-based care.			

Competencies

- Ability to safeguard and protect the public against misuse of medical laboratory investigations.
- Knowledge of the principles of management leading to satisfactory direction, supervision, and organisation of a laboratory department in a public or private hospital or in any other healthcare environment resulting in the provision of a competent service as laid down in a laboratory quality manual, based on good laboratory services as defined in EN-ISO document 15189 11.
- Ability to determine the optimum distribution of resources across central laboratories, peripheral sites and near patient testing settings.
- Ability to assess conflicting and various technical, financial, and human considerations (e.g., care, quality, safety, cost, and time scales) both in the short- and long-term, and to find the optimal solution in relation to patient care.
- Ability to apply current techniques in human resource management.
- • Execution of judgment and leadership.

Name: Base Hospital:

D2 PROFESSIONAL PRACTICE AND SOFT SKILLS

Training objective: to demonstrate adequate knowledge and skills and appropriate attitudes to work largely autonomously and taking the initiative in complex situations and performing complex clinical and scientific by the end of 5 years training period.

The specialist in laboratory medicine develops sufficient skills to communicate fluently with patients, medical and other colleagues and develops skills to write meaningful reports. Finally, specialist in Laboratory medicine should be able to critically appraise the literature and communicate outcome in writing or verbally with colleagues.

New specialists in laboratory medicine will:

PROFESSIONAL SKILLS	Competence level / date Assessor's signature		
	1	2	3
D2 PROFESSIONAL SKILLS			
Have the breadth of knowledge and skills to take responsibility for safe clinical decisions.			
Have the self-awareness to acknowledge where the limits of their competence lie and when it is appropriate to refer to other senior colleagues for advice for advice.			
Critically apply their understanding of the role and importance of continuing professional development to ensure that professional knowledge and skills are being kept up to date.			
Act at all times in a manner that demonstrates probity in all aspects of professional practice and code of conduct.			
Display a professional commitment to ethical practice consistently operating within national and local ethical, legal and governance requirements.			

APPENDIX 1

Name: Base Hospital:

Workplace Based Assessment Form
Case Based Discussion

Trainee's name:		**Stage of training:** Year: 1 2 3 4 5 (Please circle)
Brief outline of procedure, indicating focus for assessment		
Tick category of case or indicate if other;	☐ Biochemistry ☐ Haematology ☐ Immunology ☐ Genetics ☐ Microbiology Other (please specify):	

Please ensure patient is not identifiable

Grade the following area using the scale provided	**1**	**2**	**3**	**4**
1. Understanding of the theory of case				
2. Additional investigations (appropriateness, safety, cost effective)				
3. Consideration of laboratory issues				
4. Action and follow up				
5. Advice to clinical users				
6. Overall clinical judgment				
7. Overall professionalism				

1- Below expectation 2- Borderline 3-Meets expectation 4- Above expectation

If score 1 or 2 only, suggest development work:	
Signature of Assessor	
Signature of Trainee	
Date of assessment	