RECORD OF LABORATORY TRAINING FOR THE IBMS SPECIALIST DIPLOMA CLINICAL BIOCHEMISTRY

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Personal Details
Name:
IBMS Membership Number:
IBMS Membership Grade:
HCPC Registration Number:
Date of HCPC Registration:
Employment Address:
Telephone Number:
Date Specialist Training Commenced:
Name of Training Officer:

Confirmation of Completed Training		
Date Training Completed	Training Officer's Signature	Candidate's Signature

Recommendation for Award of Specialist Diploma		
Date of External Examination	External Examiner's Signature	External Examiner's Name

Training Review

A training review should occur on a monthly basis between the trainee and training officer. These will provide an opportunity for feedback, set targets, agreed deadlines and monitor progress.

Reviewed by	Date	Comments

Contents

1. INTRODUCTION

1.1. In order for you to be awarded an Institute Specialist Diploma you must be a current member of the Institute since the time you were issued with the portfolio. You must have held corporate membership for at least one year and be a current member at the time of the examination.

1.2. The Institute of Biomedical Science (Institute/IBMS) Specialist Portfolio provides the opportunity for you to gain recognition that you have finished a programme of structured, standardised post-registration training. This requires you to complete the IBMS Record of Training for the Specialist Diploma (Specialist Portfolio), submit a portfolio of evidence for assessment and undertake an oral examination of your specialist knowledge and understanding in your chosen field, in order to be awarded the Institute's Specialist Diploma.

1.3. Holding a Specialist Diploma demonstrates that you have been assessed against a benchmark standard for a specialist practitioner in your chosen discipline. It can be used by your employer to demonstrate specialist knowledge and skills linked to career and pay progression.

1.4. The Specialist Portfolio is considered to be the property of the individual as it represents a commitment by the employer to professional development specific to them. It is not 'owned' by the laboratory. If you are re-employed by another laboratory and you wish to continue with a partially completed portfolio it is at the discretion of your new employer whether or not they wish to continue with the same portfolio or restart the process. If they opt to continue with the existing portfolio, the new employer is responsible for reviewing the evidence in your portfolio and confirming your competence in line with the requirements of your position.

1.5. To support completion of this Specialist Portfolio a separate guidance document has been produced (*Institute of Biomedical Science Specialist Portfolio Guidance for Candidates, Training Officers and External Examiners).* This provides all of the information required to ensure the portfolio is completed and assessed in accordance with the Institute's requirements. Following the guidance in this document is essential to your success.

1.6. It is strongly recommended that you and your training officer/mentor read and understand this document. Failure to do so could jeopardise your chances of success. External examiners for the portfolio are required to read and understand it as part of their responsibility as a representative of the Institute.

1.7. A discipline specific portfolio reflects the range of analyses that are considered to be relevant to your specialty. All sections must be completed in order to express your ability to operate at the specialist level. Completion of the sections should follow the formal training

programme that is submitted by your laboratory to the IBMS as part of the laboratory training approval process.

1.8. The IBMS Specialist Portfolio can only be completed in laboratories which hold IBMS approval for post-registration training.

1.9. The following sections highlight some key points **but are not a substitute** for reading the information contained in the *Institute of Biomedical Science Specialist Portfolio Guidance for Candidates, Training Officers and External Examiners.*

2. TRAINING

2.1. As a requirement for IBMS approval of your laboratory for training you must have an indicative training programme which sets out the sections of the laboratory they will rotate through, the expected duration in each area, the module(s) that are covered and how training is assessed.

2.2. In-service training and assessment must demonstrate good scientific practice based on the knowledge and competence in the stated module in order to meet the requirements of the external examination process. Each module requires you to demonstrate knowledge and competence elements specific to an investigation or task. It is the responsibility of the trainer(s) to ensure that you meet the expected level defined by the following learning outcomes which have been subdivided into these areas.

Knowledge and understanding
As a successful candidate you will be able to:

a. Demonstrate knowledge and understanding of complex scientific and technical aspects of their specialist discipline including: correct procedures for handling specimens before, during and after analysis; maintenance of routine equipment; principles of in-house data management systems and quality control/assurance procedures.

b. Demonstrate knowledge and understanding of the scientific basis of the laboratory tests and the disease process under investigation.

c. Show an awareness of current issues and developments within healthcare and biomedical science.

These are evidenced by in-house assessments of training and examination of knowledge during the *viva voce* with the external examiner to assess the ability of the candidate to describe/discuss these aspects of their work.

Professional skills
As a successful candidate you will be able to:

a. Competently perform a range of laboratory tests without immediate supervision.

b. Demonstrate self-direction in solving problems and exercising personal autonomy in relation to scope of practice.

c. Demonstrate a systematic application of professional knowledge and understanding in the interpretation of laboratory data to determine action based on best practice.

These are evidenced by the in-house assessments of training and portfolio of evidence.

Transferable skills
As a successful candidate you will be able to:

a. Demonstrate communication skills within the laboratory environment and as part of the laboratory team. This is evidenced by the presentation.

b. Demonstrate the ability to critically reflect in order to inform best practice. This is evidenced by personal reflective statements.

2.3. Where you do not have access to a particular technique, knowledge must still be demonstrated together with an understanding of the key skills required to perform the test. There may also be other tests your laboratory includes within its basic in-house repertoire in which you are additionally required to be competent. These can be assessed and then recorded in the reflective practice statement at the end of each sub-section.

2.4. The Institute recommends that you have a regular review of your training (e.g. on a monthly basis) with your training officer in order to monitor your progress. These sessions will provide an opportunity for you to receive feedback on how your training and completion of your portfolio is progressing against the structured departmental training programme you will be following, which is a requirement for IBMS training laboratory approval). It is a time to take into consideration issues that have impacted on your training, and whether additional support is required or available. Targets to complete stages of your training can be set and deadlines for meeting them, agreed.

3. EVIDENCE

3.1. Evidence is generated through the internal assessment of your training and can be from a variety of sources (see section 5.11 in the guidance document for some examples). Many pieces of evidence will be generated and you will need to select those most suitable for the

Specialist Portfolio module. Your training officer should be asked to check these are appropriate and confirm meet the requirements of the standards for external examination.

3.2. Evidence must be filed in a single specialist portfolio of evidence.

3.3. In addition to evidence of answering questions set by the trainer only ONE other example of evidence is required for the **Evidence of Achievement** section. This is chosen by you as an example of evidence that demonstrates your knowledge and competence in performing a particular technique.

3.4. You are required to justify your choice of evidence in a reflective practice statement at the end of every module.

3.5. Evidence must be sufficient to enable an informed judgement by the visiting examiner on whether the standard in terms of knowledge and skills for the module has been met.

The amount of evidence must not exceed the requirement for evidence stipulated in the evidence of achievement section and should be presented in one A4 size lever arch folder.

3.6. Your portfolio of evidence will be externally assessed as part of examining your suitability for the award of an IBMS Specialist Diploma. It is very important that it is well organised and an index for the evidence is provided.

4. COMPLETING THE RECORD OF LABORATORY TRAINING

4.1. Once you have completed your training for a particular module it must be signed off by the trainer to confirm that the knowledge and competence requirements and the Evidence of Achievement sections have been met.

4.2. You are required to complete a reflective practice statement at the end of each module to justify your selection of evidence.

4.3. All sections of your record of training for the Specialist Portfolio must be completed and signed off by the trainer, and your portfolio of supporting evidence checked, to confirm your suitability for the specialist examination.

5. END-POINT ASSESSMENT

5.1. On completion of training and in accordance with the requirements of the Specialist Diploma, your employer should apply to the Institute for the appointment of a visiting external examiner.

5.2. Accompanying the portfolio should be a signed statement from the laboratory manager testifying to the range of laboratory investigations that you undertake in your own laboratory. This will be used by the external examiner to guide the areas for questioning during the laboratory tour. Please note the external examiner can ask questions on any of the modules in the record of training for the Specialist Portfolio and your portfolio of evidence.

5.3. The external examiner will determine your suitability for the award of the Specialist Diploma by assessing your knowledge and understanding of your specialty through the oral presentation; the evidence of training you have provided and questions asked during the laboratory tour.

5.4. Your presentations should not be overcomplicated and slides should be kept simple: they are really a prompt to give your talk a structure. You are talking about things you know: how you gained your experience, key aspects of your work, recent developments that may have occurred, or are planned and any particular interests you have. The external examiner may also wish to ask some questions related to the presentation or seek points of clarification.

5.5. Your portfolio of evidence will provide the examiner with an opportunity to assess the quality of your training (e.g. through the questions asked by the trainer) and your understanding of the techniques (e.g. annotated evidence, witness statements, reflective statements).

5.6. During the laboratory tour with *viva voce* the external examiner will not assess your practical competence; this was the responsibility of your trainer. However, they will expect you to be able to demonstrate knowledge and understanding of the practical aspects underpinning a technique and corrective action you might take if things go wrong.

It is reasonable for the examiner to ask questions on any aspect covered in the portfolio. A theoretical knowledge is required as a minimum on tests performed outside of the department. Questions may include references to equipment in use, samples that are being processed, investigative techniques being performed, quality control, results and health and safety.

5.7. After this you will be informed of the outcome (Pass or Fail) and verbal feedback will be provided by the examiner. If you have not been successful the examiner will provide more detailed written feedback explaining the reason(s) for this outcome and providing guidance on how to address them. This will be recorded in the examiner's report. A timeline will be agreed by the candidate, training officer and examiner to address any shortfalls. A subsequent full or partial examination will be required and this must be arranged through the IBMS.

6. COMPLETION OF REPORTS AND AWARD

6.1. Check with your trainer that they have submitted the feedback report form to the Institute. Both the external examiner and the laboratory trainer are required to submit reports, and delays in this part of the process will delay the award of your Specialist Diploma.

6.2. Once the reports have been received the Institute will issue your Specialist Diploma. If you are currently in the class of Licentiate you will be eligible to apply to upgrade your membership to become a Member. Upgrading to the next level of membership is not automatic and you are advised to make an application to the Institute as soon as possible in order to access the Institute's higher level qualifications to assist you in furthering your career.

Section 7:
Clinical Biochemistry

This section covers the range of procedures and diagnostic techniques that have been identified as being most relevant to practice as a specialist biomedical scientist in clinical biochemistry. Candidates completing these are expected to be able to demonstrate the application of knowledge and skills examined in section 2 of this portfolio.

It is accepted that some of these tests may not be performed in the candidate's own laboratory. Whilst practical skills may not be achievable (for example through secondment to another laboratory) to the level of someone performing them regularly, knowledge and understanding of its application is still required and may be examined.

There may be other tests, outside of those listed in this portfolio, that are part of the training laboratory's basic repertoire in which the individual is required to be competent. These can be recorded in the reflective statement at the end of each sub-section.

Section 7.1 Laboratory Quality

KNOWLEDGE

The candidate is expected to be able to demonstrate knowledge and understanding of the following:

1. Laboratory quality management systems, including clinical governance processes, laboratory accreditation, audit, the role of the quality manager and the management of errors, incidents and non-conformances.
2. The management of quality records and data.
3. The pre-analytical factors affecting clinical biochemistry tests, how they influence acceptance criteria, and how process failures are actioned.
4. The influence of specific pre-analytical factors on laboratory tests, e.g. sample age, temperature, preservatives, haemolysis, icterus, lipaemia, drugs.
5. Processes for establishing metrological traceability, and their influence on results.
6. Internal quality control processes, including the use of appropriate materials, establishing acceptance criteria, use of internal quality control rules, the detection of different types of error conditions and the actioning of failed internal quality control results.
7. Processes for periodic monitoring of internal quality control results and their use in the comparison of equipment and operators.
8. Use of laboratory data to calculate uncertainty of measurement for tests, and the potential uses of uncertainty of measurement data.
9. The laboratory's processes for identifying unusual and/or critical results.
10. The laboratory's processes for participation in inter-laboratory comparison schemes (External Quality Assessment or Proficiency Testing). The candidate must be aware of the methods of assessing performance, the criteria for determining acceptable performance, and demonstrate investigation of adverse performance.

COMPETENCE

Be able to:

a. Assess the suitability of clinical samples for analysis on the appropriate laboratory analyser and take appropriate action if not.
b. Apply quality control procedures to laboratory investigations.
c. Troubleshoot a poorly performing method and take steps to rectify it.
d. Investigate unusual results and take action for critical results in a timely fashion.
e. Complete all relevant documentation in accordance with quality control and audit requirements.

EVIDENCE OF ACHIEVEMENT

This section requires the trainer to sign that the candidate has successfully achieved fitness to practice as a biomedical scientist at the specialist level. The candidate is required to present the supporting evidence indicated below as a separate specialist portfolio of evidence.

Candidate has been assessed by the trainer to work in accordance with standard laboratory procedures. (No other evidence is required).

Date of completion:

Trainer's name:

Trainer's signature:

Candidate has answered questions set by the trainer on the knowledge and skill components required to complete this module. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

One other piece of evidence chosen by the candidate as an example of their competence in this area

Date of completion:

Trainer's name:

Trainer's signature:

This is to confirm that the knowledge and competence requirements for this section and the requirements in the Evidence of Achievement section have been met.

External Assessor's signature:

External Assessor's name:

Date:

Section 7.1 Reflective Practice

This section is used to demonstrate that you can relate knowledge from several areas, draw conclusions and reflect on your own performance with regard to current and future practice as an independent professional learner. It is therefore a useful source of information for your CPD profile should you be audited by the Health and Care Professions Council (HCPC).

The external examiner will review this reflective report which should cross reference to the evidence contained in the portfolio. This may lead to further discussion during the *viva voce*.

Candidate's Reflective Practice Statement Part 1.

Summarise your role within the laboratory in the context of this section.

Section 7.1 Candidate's Reflective Practice Statement Part 2.

The ethos of undertaking reflective practice should be the recognition that it is a naturally occurring characteristic of those wishing to develop. How you complete this section is personal to your own circumstances. It should be approached by recognising you have a responsibility to demonstrate self-awareness when analysing gaps in your knowledge. This is therefore an opportunity to reflect on aspects of training, the application of new knowledge and skills, and how goals have been achieved.

Personal reflection on your training and examples of evidence for this section.

Section 7.2 Laboratory Automation

KNOWLEDGE

The candidate is expected to be able to demonstrate knowledge and understanding of the following:

1. Scientific principles and application of the analytical techniques employed in clinical chemistry laboratories both broadly in terms of applied technique and specifically in the employing laboratory.
2. Key automated steps within the analyser.
3. Name, location and function of the key mechanical components of automated analysers and how they contribute to the analytical process. To include batch, random-access analyser and open or closed systems.
4. General principles of calibration of automated analysis methods.
5. Pre- and post-analytical laboratory processes that can be automated either as stand-alone automation or integrated with the analysers, for example with tracking systems.
6. Range of samples that may be analysed on general chemistry and immunoassay analysers.
7. Understand the structure of the instrument software user interface including the role of "middleware" and application of automated verification.
8. Function and design of the basic instrument and chemistry parameters.
9. Factors affecting sample integrity and appropriate corrective action.
10. Health and safety risks associated with the analyser's general and specific reagents including COSHH, risk assessments and decontamination protocols.
11. Maintenance procedures undertaken on a daily, weekly, fortnightly or less frequent interval on general chemistry and immunoassay analysers.

COMPETENCE

Be able to:

a. Undertake standard maintenance of automated analysers.
b. Calibrate and quality control a standard repertoire of tests on automated instruments, including the interpretation of calibration and quality control data.
c. Assess the suitability of clinical samples for analysis on the appropriate laboratory analyser and take appropriate action if not suitable.
d. Troubleshoot a poorly performing method and take steps to rectify it.
e. Investigate an unexpected result and take appropriate action if required.
f. Complete all relevant documentation in accordance with quality control and audit requirements.

EVIDENCE OF ACHIEVEMENT

This section requires the trainer to sign candidate has successfully achieved fitness to practice as a biomedical scientist at the specialist level. The candidate is required to present the supporting evidence indicated below as a separate specialist portfolio of evidence.

Candidate has been assessed by the trainer to work in accordance with standard laboratory procedures. (No other evidence is required).

Date of completion:

Trainer's name:

Trainer's signature:

Candidate has answered questions set by the trainer on the knowledge and skill components required to complete this module. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

One other piece of evidence chosen by the candidate as an example of their competence in this area

Date of completion:

Trainer's name:

Trainer's signature:

This is to confirm that the knowledge and competence requirements for this section and the requirements in the Evidence of Achievement section have been met.

External Assessor's signature:

Internal Assessor's name:

Date:

Section 7.2 Reflective Practice

This section is used to demonstrate that you can relate knowledge from several areas, draw conclusions and reflect on your own performance with regard to current and future practice as an independent professional learner. It is therefore a useful source of information for your CPD profile should you be audited by the Health and Care Professions Council (HCPC).

The external examiner will review this reflective report which should cross reference to the evidence contained in the portfolio. This may lead to further discussion during the *viva voce.*

Candidate's Reflective Practice Statement Part 1.

Summarise your role within the laboratory in the context of this section.

Section 7.2 Candidate's Reflective Practice Statement Part 2.

The ethos of undertaking reflective practice should be the recognition that it is a naturally occurring characteristic of those wishing to develop. How you complete this section is personal to your own circumstances. It should be approached by recognising you have a responsibility to demonstrate self-awareness when analysing gaps in your knowledge. This is therefore an opportunity to reflect on aspects of training, the application of new knowledge and skills, and how goals have been achieved.

Personal reflection on training and examples of evidence for this section

Section 7.3 Fluid and Electrolyte Disorders

KNOWLEDGE

The candidate is expected to be able to demonstrate knowledge and understanding of the following:

1. Basic physiology of water and electrolyte control with specific reference to:
   - role of anti-diuretic hormone
   - the renin-angiotensin-aldosterone system
   - associated regulatory mechanisms
2. Analytical parameters undertaken in the assessment of water and electrolyte metabolism, including sodium and potassium in plasma/serum and urine.
3. Principles and practice of methods commonly utilised for analysis of sodium and potassium in biological fluids, including the difference between direct and indirect ion selective electrodes and their application with a range of analysers (i.e. POCT systems and larger laboratory based systems).
4. Relationship between osmolality, osmolarity and plasma constituents and how to calculate a plasma osmolarity.
5. Principles and practice of the methods available to measure osmolality.
6. Significance of the water deprivation test.
7. Common causes of electrolyte disturbance and how persistent abnormalities may be investigated further with additional biochemical testing.
8. Artefactual effects on electrolyte analysis, particularly sample collection.

COMPETENCE

Be able to

a. Assess the suitability of clinical samples for analysis of electrolytes including appropriate selection of tests and analysers, and take appropriate action if samples are not suitable.

b. Perform analysis of samples in accordance with standard laboratory procedure including quality control and audit requirements.
   Monitor results, consider possible interference, and take appropriate action.
   Identify abnormal results and likely significance to clinical detail.

EVIDENCE OF ACHIEVEMENT

This section requires the trainer to sign candidate has successfully achieved fitness to practice as a biomedical scientist at the specialist level. The candidate is required to present the supporting evidence indicated below as a separate specialist portfolio of evidence.

Candidate has been assessed by the trainer to work in accordance with standard laboratory procedures. (No other evidence is required).

Date of completion:

Trainer's name:

Trainer's signature:

Candidate has answered questions set by the trainer on the knowledge and skill components required to complete this module. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

One other piece of evidence chosen by the candidate as an example of their competence in this area

Date of completion:

Trainer's name:

Trainer's signature:

This is to confirm that the knowledge and competence requirements for this section and the requirements in the Evidence of Achievement section have been met.

External Assessor's signature:

Internal Assessor's name:

Date:

Section 7.3 Reflective Practice

This section is used to demonstrate that you can relate knowledge from several areas, draw conclusions and reflect on your own performance with regard to current and future practice as an independent professional learner. It is therefore a useful source of information for your CPD profile should you be audited by the Health and Care Professions Council (HCPC).

The external examiner will review this reflective report which should cross reference to the evidence contained in the portfolio. This may lead to further discussion during the *viva voce.*

Candidate's Reflective Practice Statement Part 1.

Summarise your role within the laboratory in the context of this section.

Section 7.3 Candidate's Reflective Practice Statement Part 2.

The ethos of undertaking reflective practice should be the recognition that it is a naturally occurring characteristic of those wishing to develop. How you complete this section is personal to your own circumstances. It should be approached by recognising you have a responsibility to demonstrate self-awareness when analysing gaps in your knowledge. This is therefore an opportunity to reflect on aspects of training, the application of new knowledge and skills, and how goals have been achieved.

Personal reflection on training and examples of evidence for this section

Section 7.4 Acid-Base Disorders

Core analytes: hydrogen ion [pH], bicarbonate, pO_2, pCO_2, lactate

KNOWLEDGE

The candidate is expected to be able to demonstrate knowledge and understanding of the following:

1. Homeostasis and physiological significance of buffer systems.
2. Normal acid-base balance including bicarbonate reabsorption and hydrogen ion excretion, including the transport of carbon dioxide and oxygen.
3. Disturbances of hydrogen ion homeostasis and the link to other disease states.
4. Acid-base disturbances, including anion gap. To include examples of:
   - non respiratory (metabolic) acidosis
   - respiratory acidosis
   - respiratory alkalosis
   - metabolic alkalosis
   - mixed disorder
5. Principles and limitations of pH, pO_2, pCO_2 and lactate electrodes.
6. Principles and limitations of the analytical methods employed for bicarbonate.
7. Sample requirements for blood gas analysis.
8. Secondary functions of the blood gas analyser (e.g. Hb, measurement of Hb derivatives, other ISE electrodes).
9. Factors affecting sample integrity and appropriate corrective action.
10. Relevant internal and external quality assurance procedures.

COMPETENCE

Be able to:

a. Assess suitability of sample for analysis and take appropriate action if not suitable.
b. Perform or observe the analysis and validation of blood gases (including pH, pO_2 and pCO_2) in accordance with standard laboratory procedure.
c. Perform or observe the preparation of equipment for the analysis of blood gas samples.
d. Monitor results, consider possible interference, and take appropriate action.
e. Identify abnormal results and likely significance to clinical detail.
f. Complete all relevant documentation in accordance with quality control and audit requirements.

EVIDENCE OF ACHIEVEMENT

This section requires the trainer to sign candidate has successfully achieved fitness to practice as a biomedical scientist at the specialist level. The candidate is required to present the supporting evidence indicated below as a separate specialist portfolio of evidence.

Candidate has been assessed by the trainer to work in accordance with standard laboratory procedures. (No other evidence is required).

Date of completion:

Trainer's name:

Trainer's signature:

Candidate has answered questions set by the trainer on the knowledge and skill components required to complete this module. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

One other piece of evidence chosen by the candidate as an example of their competence in this area

Date of completion:

Trainer's name:

Trainer's signature:

This is to confirm that the knowledge and competence requirements for this section and the requirements in the Evidence of Achievement section have been met.

External Assessor's signature:

Internal Assessor's name:

Date:

Section 7.4 Reflective Practice

This section is used to demonstrate that you can relate knowledge from several areas, draw conclusions and reflect on your own performance with regard to current and future practice as an independent professional learner. It is therefore a useful source of information for your CPD profile should you be audited by the Health and Care Professions Council (HCPC).

The external examiner will review this reflective report which should cross reference to the evidence contained in the portfolio. This may lead to further discussion during the *viva voce*.

Candidate's Reflective Practice Statement Part 1.

Summarise your role within the laboratory in the context of this section.

Section 7.4 Candidate's Reflective Practice Statement Part 2.

The ethos of undertaking reflective practice should be the recognition that it is a naturally occurring characteristic of those wishing to develop. How you complete this section is personal to your own circumstances. It should be approached by recognising you have a responsibility to demonstrate self-awareness when analysing gaps in your knowledge. This is therefore an opportunity to reflect on aspects of training, the application of new knowledge and skills, and how goals have been achieved.

Personal reflection on training and examples of evidence for this section

Section 7.5 Kidney Disease

KNOWLEDGE

The candidate is expected to be able to demonstrate knowledge and understanding of the following:

1. Basic anatomy and physiology of normal kidney function and common pathologies that may arise including the differences between acute kidney injury (AKI) and chronic kidney disease (CKD).
2. Investigations that are indicators of glomerular filtration rate (GFR), specifically plasma or serum creatinine, urea and cystatin C, and their analytical and clinical limitations.
3. Deriving a calculated/estimated GFR, including creatinine clearance, the CKD-epi equation and other equations that may be adopted locally, including those appropriate to children.
4. Additional analyses, measures and variables that are required in the calculation of GFR, for example urine creatinine, timed urine volume, subject age, gender, ethnicity, height and weight depending on the GFR calculation applied.
5. Reference GFR procedures that use exogenous markers (e.g. chromium EDTA or iohexol clearance).
6. Methods available to measure urinary protein (including urine test strip methods) and their relative merits.
7. How urinary albumin can be used in monitoring kidney disease and its specific application for the assessment of diabetic nephropathy.
8. Analyses in urine that may be used to assess renal tubular function including urine phosphate, glucose, pH and specific proteins.
9. Effects of renal disease on a range of biochemical analyses other than those specifically listed above, for example plasma potassium, PTH, vitamin D and haematinic investigations.
10. Categorisation of chronic kidney disease stages based on clinical findings and GFR value.
11. Calculation and clinical utility of the Acute Kidney Algorithm
12. Role of the laboratory in implementing clinical practice guidelines for the management of AKI and CKD (e.g. NICE*, KDIGO*).

*National Institute for Health and Care Excellence
*Kidney Disease Improving Global Outcomes

COMPETENCE

Be able to:

a. Assess the suitability of clinical samples for analysis of markers of renal disease including appropriate selection of tests and analysers, and take appropriate action if not suitable.
b. Analyse markers of renal disease (e.g. sodium, potassium, urea, urinary albumin and creatinine) in plasma/serum and urine with standard automated methods.
c. Accurately calculate eGFR using a formula based method such as ckd-epi.
d. Perform analysis of samples in accordance with standard laboratory procedure.
e. Monitor results, consider possible interference, and take appropriate action.
f. Identify abnormal results and likely significance to clinical detail.
g. Complete all relevant documentation in accordance with quality control and audit requirements.

EVIDENCE OF ACHIEVEMENT

This section requires the trainer to sign candidate has successfully achieved fitness to practice as a biomedical scientist at the specialist level. The candidate is required to present the supporting evidence indicated below as a separate specialist portfolio of evidence.

Candidate has been assessed by the trainer to work in accordance with standard laboratory procedures. (No other evidence is required).

Date of completion:

Trainer's name:

Trainer's signature:

Candidate has answered questions set by the trainer on the knowledge and skill components required to complete this module. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

One other piece of evidence chosen by the candidate as an example of their competence in this area

Date of completion:

Trainer's name:

Trainer's signature:

This is to confirm that the knowledge and competence requirements for this section and the requirements in the Evidence of Achievement section have been met.

External Assessor's signature:

Internal Assessor's name:

Date:

Section 7.5 Reflective Practice

This section is used to demonstrate that you can relate knowledge from several areas, draw conclusions and reflect on your own performance with regard to current and future practice as an independent professional learner. It is therefore a useful source of information for your CPD profile should you be audited by the Health and Care Professions Council (HCPC).

The external examiner will review this reflective report which should cross reference to the evidence contained in the portfolio. This may lead to further discussion during the *viva voce.*

Candidate's Reflective Practice Statement Part 1.

Summarise your role within the laboratory in the context of this section.

Section 7.5 Candidate's Reflective Practice Statement Part 2.

The ethos of undertaking reflective practice should be the recognition that it is a naturally occurring characteristic of those wishing to develop. How you complete this section is personal to your own circumstances. It should be approached by recognising you have a responsibility to demonstrate self-awareness when analysing gaps in your knowledge. This is therefore an opportunity to reflect on aspects of training, the application of new knowledge and skills, and how goals have been achieved.

Personal reflection on training and examples of evidence for this section

Section 7.6 Liver Function and Associated Disease States

KNOWLEDGE

The candidate is expected to be able to demonstrate knowledge and understanding of the following:

1. The role of the liver in: carbohydrate, fat, protein and hormone metabolism; storage; the metabolism and excretion of bilirubin; detoxification of drugs and foreign compounds.
2. Common disease processes affecting the liver and their management including: cholestasis; hepatitis; cirrhosis; malignancy.
3. Causes of pancreatitis, and the importance of the laboratory in providing differential diagnosis and ongoing support for the patient.
4. Epidemiology of liver disease according to race, age and sex and the role of liver disease in pregnancy.
5. Metabolism and breakdown of haemoglobin; the excretion and physiological importance of total and direct bilirubin.
6. Major causes of jaundice, including pre-hepatic, post hepatic and hepatic.
7. Inherited abnormalities of bilirubin metabolism, including Gilbert's syndrome.
8. The significance of abnormal bilirubin in plasma/serum/urine.
9. Albumin synthesis in the liver and its role to indicate functional capacity of the organ.
10. Link between measurement of total protein, albumin and secondary globulin estimation, including the significance of abnormalities of globulin fraction
11. The link between bile acid measurement and cholestasis in pregnancy.
12. Metabolic function of the enzymes listed and the principles and limitations of diagnostic enzymology.
13. The role and significance of alkaline phosphatase isoenzymes.
14. Investigations to measure the following core analytes:
    - total bilirubin
    - conjugated (direct) bilirubin
    - total protein and albumin
    - bile acids
    - AST, ALT, GGT, ALP, amylase.

KNOWLEDGE (continued)

15. Investigations to measure the following associated analytes:
    - autoantibodies
    - ALP Isoenzymes
    - urine bilirubin and urine urobilinogen
    - γ-gamma globulins
    - α-fetoprotein
    - α1-antitrypsin
    - copper and ceruloplasmin
16. Principles and limitations of the analytical methods employed and sample requirements.
17. Factors affecting sample integrity and specific risks associated with the reagents / method of investigation.
18. Reference ranges for stated analytes and understand the significance of abnormal results individually and as part of a multi-analyte profile.

COMPETENCE

Be able to:

a. Assess suitability of samples for analysis on the appropriate laboratory analyser and take action if not suitable.
b. Perform and validate the following in accordance with standard laboratory procedure, including quality control and audit:
    - total bilirubin in serum/plasma/urine
    - conjugated (direct)
    - urine urobilinogen
    - albumin, total protein and bile acids
    - stated enzymes in serum/plasma
    - alkaline phosphatase isoenzymes
c. Monitor results, consider possible interference, and take appropriate action. Identify abnormal results and likely significance to clinical detail.

EVIDENCE OF ACHIEVEMENT

This section requires the trainer to sign candidate has successfully achieved fitness to practice as a biomedical scientist at the specialist level. The candidate is required to present the supporting evidence indicated below as a separate specialist portfolio of evidence.

Candidate has been assessed by the trainer to work in accordance with standard laboratory procedures. (No other evidence is required).

Date of completion:

Trainer's name:

Trainer's signature:

Candidate has answered questions set by the trainer on the knowledge and skill components required to complete this module. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

One other piece of evidence chosen by the candidate as an example of their competence in this area

Date of completion:

Trainer's name:

Trainer's signature:

This is to confirm that the knowledge and competence requirements for this section and the requirements in the Evidence of Achievement section have been met.

External Assessor's signature:

External Assessor's name:

Date:

Section 7.6 Reflective Practice

This section is used to demonstrate that you can relate knowledge from several areas, draw conclusions and reflect on your own performance with regard to current and future practice as an independent professional learner. It is therefore a useful source of information for your CPD profile should you be audited by the Health and Care Professions Council (HCPC).

The external examiner will review this reflective report which should cross reference to the evidence contained in the portfolio. This may lead to further discussion during the *viva voce.*

Candidate's Reflective Practice Statement Part 1.

Summarise your role within the laboratory in the context of this section.

Section 7.6 Candidate's Reflective Practice Statement Part 2.

The ethos of undertaking reflective practice should be the recognition that it is a naturally occurring characteristic of those wishing to develop. How you complete this section is personal to your own circumstances. It should be approached by recognising you have a responsibility to demonstrate self-awareness when analysing gaps in your knowledge. This is therefore an opportunity to reflect on aspects of training, the application of new knowledge and skills, and how goals have been achieved.

Personal reflection on training and examples of evidence for this section

Section 7.7 Investigation of Diabetes Mellitus and Hypoglycaemia

KNOWLEDGE

The candidate is expected to be able to demonstrate knowledge and understanding of the following:

1. Aetiology, pathophysiology and lifestyle factors increasing the risk of diabetes including the difference between Type 1, Type 2 and secondary diabetes.
2. Pathways of gluconeogenesis, glycogen synthesis and glycogen breakdown.
3. Metabolic effects of insulin and pathogenesis of diabetes-associated complications.
4. WHO diagnostic criteria for diabetes and impaired glucose regulation as endorsed by Diabetes UK.
5. Local policy on the investigation of individuals with suspected diabetes and the sample requirements for glucose, HbA1c, insulin, C-peptide and lipid analyses.
6. The differences between diabetes impaired fasting glucose and impaired glucose tolerance.
7. Self-induced/maliciously induced hypoglycaemia and its investigation.
8. Local procedure for performing an oral glucose tolerance test and interpretation with respect to the WHO criteria.
9. Methodologies available for the estimation of glucose and the limitations of using glucose levels in the monitoring of diabetes.
10. Differences found by using different sample types (e.g. whole blood, plasma/serum, capillary).
11. Implications of the NICE guidelines on the monitoring of diabetes and the need for monitoring lipids in diabetes.
12. Different methodologies for measuring glycated haemoglobin (HbA1c) and the effect of Hb variation on these assays.
13. The purpose and limitations of measuring glycated protein (fructosamine).
14. The role of urinary microalbumin and methods available for measurement.
15. The mechanisms by which the following can be used to monitor and manage glucose levels: diet; different classes of drugs; blood glucose self-monitor devices; slow-release drug preparations; fast/slow acting insulin.

KNOWLEDGE (continued)

16. Situations that require closer monitoring than is usual, for example pregnancy, and assays for this. Common causes, and the investigation of, fasting hypoglycaemia and reactive hypoglycaemia.
17. The role of insulin and C-peptide assays in the investigation of hypoglycaemia.
18. Metabolic deficiencies that cause hypoglycaemia in neonates/infants and the laboratory investigations used to identify them.
19. Methods available for urinary sugar analysis and the role of urinary sugar chromatography in neonates.
20. Reference ranges for all parameters measured by your laboratory when investigating diabetes mellitus and hypoglycaemia, and what levels are designated as good control, adequate control and poor control.
21. Role of the laboratory in the selection, user training and performance monitoring of POCT glucometers within the Trust.
22. Local protocol for the communication of abnormal glucose results to wards.
23. Role of other healthcare services in the management of diabetes (e.g. podiatry, retinal screening, dieticians).
24. Protocols followed and the laboratory support given in the treatment of diabetic coma.

COMPETENCE

Be able to:

a. Demonstrate a clear understanding of the local guidelines and sample requirements for the investigation of suspected cases of diabetes and subsequent control.
b. Explain the role of the laboratory in the diagnosis, treatment and monitoring of diabetes mellitus and hypoglycaemia in adults and neonates.
c. Measure glucose, HbA1c, lipids and other analytes used by your laboratory to investigate diabetes mellitus and hypoglycaemia (e.g. insulin, C-Peptide and describe the methodological techniques used).
d. Use POCT devices to monitor diabetes mellitus and hypoglycaemia and understand the methodological techniques used.
e. Describe methodological techniques used to measure sugars in urine and fructosamine.
f. Explain why different values are obtained for glucose using different sample types.
g. Describe the effect of Hb variants on the laboratory HbA1c assay.
h. Describe the local protocol for the investigation of a neonate that "fails to thrive".

EVIDENCE OF ACHIEVEMENT

This section requires the trainer to sign candidate has successfully achieved fitness to practice as a biomedical scientist at the specialist level. The candidate is required to present the supporting evidence indicated below as a separate specialist portfolio of evidence.

Candidate has been assessed by the trainer to work in accordance with standard laboratory procedures. (No other evidence is required).

Date of completion:

Trainer's name:

Trainer's signature:

Candidate has answered questions set by the trainer on the knowledge and skill components required to complete this module. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

One other piece of evidence chosen by the candidate as an example of their competence in this area

Date of completion:

Trainer's name:

Trainer's signature:

This is to confirm that the knowledge and competence requirements for this section and the requirements in the Evidence of Achievement section have been met.

External Assessor's signature:

Internal Assessor's name:

Date:

Section 7.7 Reflective Practice

This section is used to demonstrate that you can relate knowledge from several areas, draw conclusions and reflect on your own performance with regard to current and future practice as an independent professional learner. It is therefore a useful source of information for your CPD profile should you be audited by the Health and Care Professions Council (HCPC).

The external examiner will review this reflective report which should cross reference to the evidence contained in the portfolio. This may lead to further discussion during the *viva voce*.

Candidate's Reflective Practice Statement Part 1.

Summarise your role within the laboratory in the context of this section.

Section 7.7 Candidate's Reflective Practice Statement Part 2.

The ethos of undertaking reflective practice should be the recognition that it is a naturally occurring characteristic of those wishing to develop. How you complete this section is personal to your own circumstances. It should be approached by recognising you have a responsibility to demonstrate self-awareness when analysing gaps in your knowledge. This is therefore an opportunity to reflect on aspects of training, the application of new knowledge and skills, and how goals have been achieved.

Personal reflection on training and examples of evidence for this section

Section 7.8 Lipids, Lipoproteins and Cardiovascular Disease

Subsection 7.8a Major lipids in atherosclerosis and cardiovascular disease

KNOWLEDGE

The candidate is expected to be able to demonstrate knowledge and understanding of the following:

1. The role and transport of the major lipids in the blood to include: fatty acids; triglycerides; cholesterol; phospholipids.
2. Classification of lipoproteins, their composition, metabolism and principle function.
3. Epidemiology of cardiovascular disease according to all associated risk factors.
4. Rationale of treatment of hyperlipidaemia in relationship to cardiovascular disease with reference to the relevant NICE guidelines.
5. Definition, diagnosis and treatment of patients presenting with Acute Coronary Syndrome (ACS).
6. Definition, diagnosis, treatment and prognosis of patients presenting with Chronic Heart Failure (CHF).

COMPETENCE

Be able to:

a. Describe the implications that treating cardiovascular disease has on the NHS and the overall economic effect.
b. Demonstrate an understanding of hypercholesterolemia (when due to LDL) as an important risk factor in coronary heart disease.
c. Demonstrate an understanding of the implication of treating Chronic Heart Failure for the NHS with reference to the NICE guidelines.

EVIDENCE OF ACHIEVEMENT

This section requires the trainer to sign candidate has successfully achieved fitness to practice as a biomedical scientist at the specialist level. The candidate is required to present the supporting evidence indicated below as a separate specialist portfolio of evidence.

Candidate has been assessed by the trainer to work in accordance with standard laboratory procedures. (No other evidence is required).

Date of completion:

Trainer's name:

Trainer's signature:

Candidate has answered questions set by the trainer on the knowledge and skill components required to complete this module. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

One other piece of evidence chosen by the candidate as an example of their competence in this area

Date of completion:

Trainer's name:

Trainer's signature:

This is to confirm that the knowledge and competence requirements for this section and the requirements in the Evidence of Achievement section have been met.

External Assessor's signature:

Internal Assessor's name:

Date:

Section 7.8 Lipids, Lipoproteins and Cardiovascular Disease

Subsection 7.8b Diagnosis of cardiovascular disease

Core analytes: Cholesterol, Triglyceride, HDL-Cholesterol, Creatine Kinase, Troponin, B-type Natriuretic Peptide (BNP) or N-Terminal pro-B-type Natriuretic Peptide (NTproBNP)

Associated analytes: CK-MB, Myoglobin, hs-CRP

KNOWLEDGE

The candidate is expected to be able to demonstrate knowledge and understanding of the following:

1. National or international guidelines in determining risk in association with reference
2. Triglyceride measurements in chronic heart disease (CHD) and its association with other disease states particularly pancreatitis.
3. Influence of sex, age, exercise, obesity, alcohol and extraneous oestrogens on lipoproteins.
4. Causes of secondary hyperlipidaemia.
5. Causes of primary hyperlipidaemia and treatment (NICE guidelines).
6. Principles and limitations of the analytical methods employed and sample requirements for:
   - cholesterol
   - triglyceride
   - HDL-cholesterol
7. Factors affecting sample integrity and appropriate corrective action.
8. How to calculate LDL cholesterol, and non-HDL cholesterol and recognise its limitations.
9. Other proposed markers of CHD.

COMPETENCE

Be able to:

a. Assess suitability of samples for analysis on the appropriate laboratory analyser and take appropriate action if not suitable.
b. Perform the timely analysis and validation of lipids in serum/plasma.
c. Validate the results.
d. Monitor results, consider possible interference, and take appropriate action.
e. Report results appropriate to the significance of the result.
f. Complete all relevant documentation in accordance with quality control and audit requirements.

EVIDENCE OF ACHIEVEMENT

This section requires the trainer to sign candidate has successfully achieved fitness to practice as a biomedical scientist at the specialist level. The candidate is required to present the supporting evidence indicated below as a separate specialist portfolio of evidence.

Candidate has been assessed by the trainer to work in accordance with standard laboratory procedures. (No other evidence is required).

Date of completion:

Trainer's name:

Trainer's signature:

Candidate has answered questions set by the trainer on the knowledge and skill components required to complete this module. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

One other piece of evidence chosen by the candidate as an example of their competence in this area

Date of completion:

Trainer's name:

Trainer's signature:

This is to confirm that the knowledge and competence requirements for this section and the requirements in the Evidence of Achievement section have been met.

External Assessor's signature:

Internal Assessor's name:

Date:

Section 7.8 Lipids, Lipoproteins and Cardiovascular Disease
Subsection 7.8c Diagnosis of acute coronary heart disease

KNOWLEDGE

The candidate is expected to be able to demonstrate knowledge and understanding of the following:

1. Rationale of using multiple analytes in the diagnosis of acute coronary syndrome (ACS).
2. Use of serial troponin measurements and different algorithms for rapid assessment of ACS.
3. The impact the laboratory result may have on treatment of patients presenting with ACS.
4. The structural and physiological role of the troponins.
5. The algorithm for diagnostic use and interpretation of:
   - troponins
   - high sensitive troponin (HST)
6. Principles and limitations of the analytical methods employed for troponins.
7. The meaning of clinical sensitivity and specificity.
8. Other markers of ACS and use of point of care testing (POCT).
9. Use of HST in the diagnosis of acute coronary injury.
10. The role of the laboratory in the diagnosis, treatment and prognosis of a patient presenting with chest pain, against current national guidelines.

COMPETENCE

Be able to:

a. Assess suitability of samples for analysis on the appropriate laboratory analyser and take appropriate action if not suitable.
b. Perform the timely analysis and validation of troponins.
   Monitor results, consider possible interference, and take appropriate action.
d. Report results appropriate to the significance of the result.
e. Complete all relevant documentation in accordance with quality control and audit requirements.

EVIDENCE OF ACHIEVEMENT

This section requires the trainer to sign candidate has successfully achieved fitness to practice as a biomedical scientist at the specialist level. The candidate is required to present the supporting evidence indicated below as a separate specialist portfolio of evidence.

Candidate has been assessed by the trainer to work in accordance with standard laboratory procedures. (No other evidence is required).

Date of completion:

Trainer's name:

Trainer's signature:

Candidate has answered questions set by the trainer on the knowledge and skill components required to complete this module. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

One other piece of evidence chosen by the candidate as an example of their competence in this area

Date of completion:

Trainer's name:

Trainer's signature:

This is to confirm that the knowledge and competence requirements for this section and the requirements in the Evidence of Achievement section have been met.

External Assessor's signature:

External Assessor's name:

Date:

Section 7.8 Lipids, Lipoproteins and Cardiovascular Disease
Subsection 7.8d Diagnosis of chronic heart failure

KNOWLEDGE

The candidate is expected to be able to demonstrate knowledge and understanding of the following:

1. Causes of heart failure which may result in a medical emergency or asymptomatic presentation.
2. Impact the laboratory result may have on patients presenting with heart failure.
3. Structural and physiological role of B-type natriuretic peptide (BNP) or N-terminal pro-B-type natriuretic peptide (NT-proBNP).
4. Normal reference ranges for BNP or NT-proBNP.
5. Clinical pathway for interpretation of BNP or NT-proBNP.
6. Principles and limitations of the analytical methods employed and sample requirements.
7. Factors affecting sample integrity and appropriate corrective action.

COMPETENCE

Be able to:

a. Assess suitability of sample for analysis on the appropriate laboratory analyser and take appropriate action if not.
b. Perform the timely analysis and validation of BNP.
c. Monitor results, consider possible interference, and take appropriate action.
d. Report results appropriate to the significance of the result.
e. Complete all relevant documentation in accordance with quality control and audit requirements.

EVIDENCE OF ACHIEVEMENT

This section requires the trainer to sign candidate has successfully achieved fitness to practice as a biomedical scientist at the specialist level. The candidate is required to present the supporting evidence indicated below as a separate specialist portfolio of evidence.

Candidate has been assessed by the trainer to work in accordance with standard laboratory procedures. (No other evidence is required).

Date of completion:

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Trainer's signature:

Candidate has answered questions set by the trainer on the knowledge and skill components required to complete this module. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

One other piece of evidence chosen by the candidate as an example of their competence in this area

Date of completion:

Trainer's name:

Trainer's signature:

This is to confirm that the knowledge and competence requirements for this section and the requirements in the Evidence of Achievement section have been met.

External Assessor's signature:

Internal Assessor's name:

Date:

Section 7.8 Reflective Practice

This section is used to demonstrate that you can relate knowledge from several areas, draw conclusions and reflect on your own performance with regard to current and future practice as an independent professional learner. It is therefore a useful source of information for your CPD profile should you be audited by the Health and Care Professions Council (HCPC).

The external examiner will review this reflective report which should cross reference to the evidence contained in the portfolio. This may lead to further discussion during the *viva voce.*

Candidate's Reflective Practice Statement Part 1.

Summarise your role within the laboratory in the context of this section.

Section 7.8 Candidate's Reflective Practice Statement Part 2.

The ethos of undertaking reflective practice should be the recognition that it is a naturally occurring characteristic of those wishing to develop. How you complete this section is personal to your own circumstances. It should be approached by recognising you have a responsibility to demonstrate self-awareness when analysing gaps in your knowledge. This is therefore an opportunity to reflect on aspects of training, the application of new knowledge and skills, and how goals have been achieved.

Personal reflection on training and examples of evidence for this section

Section 7.9 Investigations for Disorders of Calcium, Phosphate and Magnesium Homeostasis

KNOWLEDGE

The candidate is expected to be able to demonstrate knowledge and understanding of the following:

1. Mechanisms of calcium, magnesium and phosphate homeostasis and their inter-relationship.
2. The role of these minerals in bone formation and resorption in bone disorders and the consequences of treatment.
3. The role of calcium, phosphate and magnesium in various disease states.
4. Principles and practice of techniques for the measurement of calcium, phosphate and magnesium.
5. Relationships between and roles of PTH, PTHrp, vitamin D and calcitonin in calcium regulation, and when and how these hormones may be measured.
6. Principles and limitations of methods used to measure calcium, magnesium and phosphate.
7. The relationship and physiological significance of ionised and total calcium and the calculations used to correct calcium results.
8. The role of PTH, vitamin D in regulating levels of calcium in the body.
9. Principles and techniques used for the measurement of PTH and the limitations of the assays.
10. Principles and techniques used in measurement of vitamin D.
11. Implications and causes of
    - hypercalcaemia and hypocalcaemia
    - hypermagnesaemia and hypomagnesaemia
    - hypophosphataemia and hyperphosphataemia
12. The role of the kidneys in regulation of calcium levels in blood.
13. Biochemical testing for and implications of bone disease, including markers of bone turnover.
14. Principles and practice of techniques used to measure calcium, phosphate and magnesium.

COMPETENCE

Be able to:

a. Explain the physiological significance of calcium, phosphate and magnesium.
b. Give examples of calcium and magnesium disorders and the consequences for biochemical test results.
c. Locate information for sample requirements for PTH, vitamin D, calcitonin and markers of bone turnover.
d. Analyse and validate calcium, magnesium and phosphate understanding the sample requirements and limitations of analysis.

EVIDENCE OF ACHIEVEMENT

This section requires the trainer to sign candidate has successfully achieved fitness to practice as a biomedical scientist at the specialist level. The candidate is required to present the supporting evidence indicated below as a separate specialist portfolio of evidence.

Candidate has been assessed by the trainer to work in accordance with standard laboratory procedures. (No other evidence is required).

Date of completion:

Trainer's name:

Trainer's signature:

Candidate has answered questions set by the trainer on the knowledge and skill components required to complete this module. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

One other piece of evidence chosen by the candidate as an example of their competence in this area

Date of completion:

Trainer's name:

Trainer's signature:

This is to confirm that the knowledge and competence requirements for this section and the requirements in the Evidence of Achievement section have been met.

External Assessor's signature:

Internal Assessor's name:

Date:

Section 7.9 Reflective Practice

This section is used to demonstrate that you can relate knowledge from several areas, draw conclusions and reflect on your own performance with regard to current and future practice as an independent professional learner. It is therefore a useful source of information for your CPD profile should you be audited by the Health and Care Professions Council (HCPC).

The external examiner will review this reflective report which should cross reference to the evidence contained in the portfolio. This may lead to further discussion during the *viva voce*.

Candidate's Reflective Practice Statement Part 1.

Summarise your role within the laboratory in the context of this section.

Section 7.9 Candidate's Reflective Practice Statement Part 2.

The ethos of undertaking reflective practice should be the recognition that it is a naturally occurring characteristic of those wishing to develop. How you complete this section is personal to your own circumstances. It should be approached by recognising you have a responsibility to demonstrate self-awareness when analysing gaps in your knowledge. This is therefore an opportunity to reflect on aspects of training, the application of new knowledge and skills, and how goals have been achieved.

Personal reflection on training and examples of evidence for this section

Section 7.10 Cancer Biochemistry and Tumour Markers

Core analytes: PSA, AFP, CEA, HCG, faecal haemoglobin and HIAA.

KNOWLEDGE

The candidate is expected to be able to demonstrate knowledge and understanding of the following:

1. Different types of tumour and the disorders in biochemistry they can cause.
2. Staging of tumour growth and the implications for the patient biochemically.
3. Tumour markers for screening, diagnosis and monitoring of malignant disease.
4. Criteria for the ideal tumour marker.
5. Clinical sensitivity and specificity of methods; problems with cross reactivity and prozone effects.
6. Possible biochemical consequences of tumour growth (e.g. ectopic hormone production).
7. The roles of faecal occult blood, PSA, CEA, CA125, CA15-3, CA19-9, AFP, HCG, HIAA, catecholamines and metadrenalines and how these assays may be performed.
8. Sample requirements for tumour marker measurement and possible interferences or cross reactions.

COMPETENCE

Be able to:

a. Explain the physiological significance of tumour marker measurements.
b. Give examples of routinely used tumour markers and how they are used appropriately.
c. Locate information regarding sample requirements for tumour marker tests and be able to give advice to clinicians regarding sample types.
d. Explain the methodological techniques used to measure tumour markers and how different methods and standards used may alter results obtained.

EVIDENCE OF ACHIEVEMENT

This section requires the trainer to sign candidate has successfully achieved fitness to practice as a biomedical scientist at the specialist level. The candidate is required to present the supporting evidence indicated below as a separate specialist portfolio of evidence.

Candidate has been assessed by the trainer to work in accordance with standard laboratory procedures. (No other evidence is required).

Date of completion:

Trainer's name:

Trainer's signature:

Candidate has answered questions set by the trainer on the knowledge and skill components required to complete this module. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

One other piece of evidence chosen by the candidate as an example of their competence in this area

Date of completion:

Trainer's name:

Trainer's signature:

This is to confirm that the knowledge and competence requirements for this section and the requirements in the Evidence of Achievement section have been met.

External Assessor's signature:

External Assessor's name:

Date:

Section 7.10 Reflective Practice

This section is used to demonstrate that you can relate knowledge from several areas, draw conclusions and reflect on your own performance with regard to current and future practice as an independent professional learner. It is therefore a useful source of information for your CPD profile should you be audited by the Health and Care Professions Council (HCPC).

The external examiner will review this reflective report which should cross reference to the evidence contained in the portfolio. This may lead to further discussion during the *viva voce*.

Candidate's Reflective Practice Statement Part 1.

Summarise your role within the laboratory in the context of this section.

Section 7.10 Candidate's Reflective Practice Statement Part 2.

The ethos of undertaking reflective practice should be the recognition that it is a naturally occurring characteristic of those wishing to develop. How you complete this section is personal to your own circumstances. It should be approached by recognising you have a responsibility to demonstrate self-awareness when analysing gaps in your knowledge. This is therefore an opportunity to reflect on aspects of training, the application of new knowledge and skills, and how goals have been achieved.

Personal reflection on training and examples of evidence for this section

Section 7.11 Specific Protein Markers

KNOWLEDGE

The candidate is expected to be able to demonstrate knowledge and understanding of the following:

1. Basic chemical and physical properties of protein molecules.
2. The relationship between serum, plasma, urine, CSF and other fluid types of proteins.
3. Principles, limitations and roles of the following techniques:
   - gel electrophoresis
   - capillary electrophoresis
   - immunofixation/immunotyping
   - turbidimetry
   - nephelometry
   - cold agglutinins
4. Abnormalities on serum protein electrophoresis and identification of the 6 major groupings seen.
5. Patterns most likely to be seen in the following conditions:
   - acute-phase reaction
   - chronic infection
   - myeloma / MGUS
6. Immunoglobulin synthesis in the body, the roles of the five classes of Immunoglobulin (IgG, IgA, IgM, IgD, IgE) and the difference between "heavy" and "light" chains.
7. Identification and monitoring of monoclonal bands.
8. Laboratory protocol for the investigation of suspected myeloma.
9. Diagnostic criteria and prognostic factors for myeloma including the role of serum free light chains in diagnosis and prognosis in patients with monoclonal gammopathy.
10. The relevance of Hyperviscosity Syndrome.
11. The difference between myeloma and MGUS.

KNOWLEDGE (continued)

12. Specific proteins that are commonly measured and their roles including:
    - Beta-2 microglobulin
    - CRP
    - alpha-1-antitrypsin
    - ceruloplasmin
    - IgE
    - complement
    - cryoglobulins
    - carbohydrate deficient transferrin
    - serum free light chains
13. The value of measuring urinary total protein and carrying out urinary protein electrophoresis in relation to:
    - local methodology and alternative methods
    - identification of the major components seen on urinary protein electrophoresis
    - significance of the presence of free light chains in the urine
    - the role of urinary protein measurement in the diagnosis and monitoring of renal disease (protein/creatinine ratio)
    - identification and typing a monoclonal component seen in urine
    - the relationship between serum and urine protein
14. Investigations carried out on CSF and other bodily fluids in relation to:
    - origins of and the role of immunoglobulins in CSF
    - methods used to measure CSF Total Protein and CSF Immunoglobulins
    - causes of increased CSF Total Protein concentration
    - the role of CSF electrophoresis in the diagnosis of conditions such as multiple sclerosis
    - the difference between a fluid that is a transudate as opposed to an exudate

COMPETENCE

Be able to:

a. Assess suitability of samples for analysis.
b. Select the appropriate method for the specific protein under investigation and perform analysis and measurement of proteins.
c. Identify specific proteins and validate results.
d. Consider possible interference, and take appropriate action.
e. Report results appropriate to the significance of the result.
f. Complete all relevant documentation in accordance with quality control and audit requirements.

EVIDENCE OF ACHIEVEMENT

This section requires the trainer to sign candidate has successfully achieved fitness to practice as a biomedical scientist at the specialist level. The candidate is required to present the supporting evidence indicated below as a separate specialist portfolio of evidence.

Candidate has been assessed by the trainer to work in accordance with standard laboratory procedures. (No other evidence is required).

Date of completion:

Trainer's name:

Trainer's signature:

Candidate has answered questions set by the trainer on the knowledge and skill components required to complete this module. (Evidence to support this required).

Date of completion:

Trainer's name:

Trainer's signature:

One other piece of evidence chosen by the candidate as an example of their competence in this area.

Date of completion:

Trainer's name:

Trainer's signature:

This is to confirm that the knowledge and competence requirements for this section and the requirements in the Evidence of Achievement section have been met.

External Assessor's signature:

Internal Assessor's name:

Date:

Section 7.11 Reflective Practice

This section is used to demonstrate that you can relate knowledge from several areas, draw conclusions and reflect on your own performance with regard to current and future practice as an independent professional learner. It is therefore a useful source of information for your CPD profile should you be audited by the Health and Care Professions Council (HCPC).

The external examiner will review this reflective report which should cross reference to the evidence contained in the portfolio. This may lead to further discussion during the *viva voce*.

Candidate's Reflective Practice Statement Part 1.

Summarise your role within the laboratory in the context of this section.

Section 7.11 Candidate's Reflective Practice Statement Part 2.

The ethos of undertaking reflective practice should be the recognition that it is a naturally occurring characteristic of those wishing to develop. How you complete this section is personal to your own circumstances. It should be approached by recognising you have a responsibility to demonstrate self-awareness when analysing gaps in your knowledge. This is therefore an opportunity to reflect on aspects of training, the application of new knowledge and skills, and how goals have been achieved.

Personal reflection on training and examples of evidence for this section

Section 7.12 Hyperuricaemia and Gout

KNOWLEDGE

The candidate is expected to be able to demonstrate knowledge and understanding of the following:

1. Basic biochemistry of purine synthesis and degradation.
2. Common methods available for the analysis of uric acid.
3. Clinical conditions in which uric acid analyses may be of value including: gout, renal disease, pregnancy and malignancy.
4. The relationship between uric acid and other purines in the context of inborn errors of metabolism, (e.g. xanthinuria).

COMPETENCE

Be able to:

a. Assess the suitability of clinical samples for analysis of uric acid and take appropriate action if not suitable.
b. Analyse uric acid with a standard accredited method.
c. Validate the results taking note of analytical and clinical error messages.
d. Monitor results, consider possible interferences and take appropriate action.
e. Report results appropriate to the significance of the result.
f. Complete laboratory records as required.

EVIDENCE OF ACHIEVEMENT

This section requires the trainer to sign candidate has successfully achieved fitness to practice as a biomedical scientist at the specialist level. The candidate is required to present the supporting evidence indicated below as a separate specialist portfolio of evidence.

Candidate has been assessed by the trainer to work in accordance with standard laboratory procedures. (No other evidence is required).

Date of completion:

Trainer's name:

Trainer's signature:

Candidate has answered questions set by the trainer on the knowledge and skill components required to complete this module. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

One other piece of evidence chosen by the candidate as an example of their competence in this area

Date of completion:

Trainer's name:

Trainer's signature:

This is to confirm that the knowledge and competence requirements for this section and the requirements in the Evidence of Achievement section have been met.

External Assessor's signature:

Internal Assessor's name:

Date:

Section 7.12 Reflective Practice

This section is used to demonstrate that you can relate knowledge from several areas, draw conclusions and reflect on your own performance with regard to current and future practice as an independent professional learner. It is therefore a useful source of information for your CPD profile should you be audited by the Health and Care Professions Council (HCPC).

The external examiner will review this reflective report which should cross reference to the evidence contained in the portfolio. This may lead to further discussion during the *viva voce*.

Candidate's Reflective Practice Statement Part 1.

Summarise your role within the laboratory in the context of this section.

Section 7.12 Candidate's Reflective Practice Statement Part 2.

The ethos of undertaking reflective practice should be the recognition that it is a naturally occurring characteristic of those wishing to develop. How you complete this section is personal to your own circumstances. It should be approached by recognising you have a responsibility to demonstrate self-awareness when analysing gaps in your knowledge. This is therefore an opportunity to reflect on aspects of training, the application of new knowledge and skills, and how goals have been achieved.

Personal reflection on training and examples of evidence for this section

Section 7.13 Investigation of Micronutrients
Subsection 7.13a Vitamins

KNOWLEDGE

The candidate is expected to be able to demonstrate knowledge and understanding of the following:

1. Biological requirement for the different vitamins and vitamers in the human bo
2. Clinical effect of deficiency or excess of the different vitamins.
3. Biological requirement for B12 and folate in the human body and th effect of deficiency.
4. Effects of B12 and folate on haematological parameters.
5. Principles, techniques and limitations of different sample types ed in th measurement of vitamins such as:
   - spectrophotometry
   - immunoassay
   - high performance liquid chromatograp
   - gas chromatography
6. Specific risks associated with the re ts or m od.
7. Relevant internal and external quality assurance pr es.

COMPETENCE

Be able to:

a. Locate infor ation for sam e requi ments for vitamins not performed in your departme
b. Provi advic ample requirements and collection for vitamin and haematinics e nation.
c. nalyse o process sa ple for transport to referral laboratory.
d. Cor y enter results and any comment to laboratory computer system.
e. Validat nd re ort results appropriately to the significance of the result.
f. Complete relevant documentation in accordance with quality control and audit re ments.

EVIDENCE OF ACHIEVEMENT

This section requires the trainer to sign candidate has successfully achieved fitness to practice as a biomedical scientist at the specialist level. The candidate is required to present the supporting evidence indicated below as a separate specialist portfolio of evidence.

Candidate has been assessed by the trainer to work in accordance with standard laboratory procedures. (No other evidence is required).

Date of completion:

Trainer's name:

Trainer's signature:

Candidate has answered questions set by the trainer on the knowledge and skill components required to complete this module. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

One other piece of evidence chosen by the candidate as an example of their competence in this area

Date of completion:

Trainer's name:

Trainer's signature:

This is to confirm that the knowledge and competence requirements for this section and the requirements in the Evidence of Achievement section have been met.

External Assessor's signature:

Internal Assessor's name:

Date:

Section 7.13 Investigation of Micronutrients
Subsection 7.13b Trace elements

KNOWLEDGE

The candidate is expected to be able to demonstrate knowledge and understanding of the following:

1. Biological requirement for the different trace elements in the human body.
2. Clinical and biochemical features of lead poisoning.
3. Biological requirement for copper, magnesium and zinc in the human body and the effect of deficiency and excess.
4. National guidelines for the monitoring of aluminium in patients on renal dialysis.
5. The requirements for the monitoring of industrial workers using lead and other heavy metals.
6. The relationship between magnesium and calcium homeostasis.
7. Inherited defects affecting the transport and metabolism of copper.
8. Ceruloplasmin estimation.
9. Importance of iron measurements and the treatment techniques for patients admitted with an iron overdose.
10. Principles, techniques and limitations used in the measurement of trace elements including:
    - spectrophotometry
    - flame photometry (atomic emission spectrometry)
    - atomic absorption spectrophotometry
    - mass spectrometry (inductively coupled plasma)
11. Comparative benefits of using ICP-MS and atomic absorption spectrophotometry for the estimation of trace metals.
12. The difference between flame photometry and atomic absorption spectrophotometry and the use of a furnace for estimation of heavy metals.
13. Specific risks associated with the reagents or method.
14. Relevant internal and external quality assurance procedures.

COMPETENCE

You must be able to:

a. Explain the different sample types and specimen collection bottles required for trace element analysis and any special precautions when undertaking the assays.
b. Locate information for sample requirements for trace elements not performed in your department.
c. Provide advice on the correct procedure for sample collection.
d. Analyse or process sample for transport to referral laboratory.
e. Correctly enter results and any comment into laboratory computer system.
f. Validate and report results appropriately to the significance of the result.
g. Complete all relevant documentation in accordance with quality control and audit requirements.

EVIDENCE OF ACHIEVEMENT

This section requires the trainer to sign candidate has successfully achieved fitness to practice as a biomedical scientist at the specialist level. The candidate is required to present the supporting evidence indicated below as a separate specialist portfolio of evidence.

Candidate has been assessed by the trainer to work in accordance with standard laboratory procedures. (No other evidence is required).

Date of completion:

Trainer's name:

Trainer's signature:

Candidate has answered questions set by the trainer on the knowledge and skill components required to complete this module. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

One other piece of evidence chosen by the candidate as an example of their competence in this area

Date of completion:

Trainer's name:

Trainer's signature:

This is to confirm that the knowledge and competence requirements for this section and the requirements in the Evidence of Achievement section have been met.

External Assessor's signature:

Internal Assessor's name:

Date:

Section 7.13 Reflective Practice

This section is used to demonstrate that you can relate knowledge from several areas, draw conclusions and reflect on your own performance with regard to current and future practice as an independent professional learner. It is therefore a useful source of information for your CPD profile should you be audited by the Health and Care Professions Council (HCPC).

The external examiner will review this reflective report which should cross reference to the evidence contained in the portfolio. This may lead to further discussion during the *viva voce*.

Candidate's Reflective Practice Statement Part 1.

Summarise your role within the laboratory in the context of this section.

Section 7.13 Candidate's Reflective Practice Statement Part 2.

The ethos of undertaking reflective practice should be the recognition that it is a naturally occurring characteristic of those wishing to develop. How you complete this section is personal to your own circumstances. It should be approached by recognising you have a responsibility to demonstrate self-awareness when analysing gaps in your knowledge. This is therefore an opportunity to reflect on aspects of training, the application of new knowledge and skills, and how goals have been achieved.

Personal reflection on training and examples of evidence for this section

Section 7.14 Gastrointestinal Disorders and Malabsorption

KNOWLEDGE

The candidate is expected to be able to demonstrate knowledge and understanding of the following:

1. Functions of the major regions of the gastrointestinal tract and associated organs, the principal digestive secretions and their role in respect to nutritional status:
   - oral cavity
   - oesophagus
   - stomach
   - duodenum, proximal jejunum
   - liver and biliary system
   - exocrine pancreas
   - distal small intestine
   - large Intestine
   - rectum
2. Processes involved in the digestion and absorption of the following nutrient classes:
   - proteins
   - carbohydrates
   - fats
   - nucleic acids
   - water and mine
   - trace elem ts
   - vitamin
3. Main cause of mal sorption uding:
   - stric surg with bypass or gastric banding
   - thyrotoxicosis
   - anc atic insuffic ency
   - b salt insuff iency
   - muc l d orders

KNOWLEDGE (continued)

4. Clinical features associated with malabsorption and possible causes of:
    - diarrhoea, steatorrhoea, borborygmi
    - weight loss and growth failure
    - abdominal distension
    - anaemia
    - metabolic bone disease
    - easy bruising
5. Physical investigations used to assess nutrition status including Body Mass Index (BMI), skinfold thickness and MUST (Malnutrition Universal Screening Tool).
6. Principles and practice of the analytical investigations used in your laboratory to assess and monitor nutritional status. These should include:
    - urea, albumin, calcium, phosphate, alkaline phosphatase, magnesium, C-reactive protein
    - thyroid function tests, copper, zinc, selenium, iron & ferritin, glucose, vitamin D, folate
    - vitamin B12
    - faecal elastase
    - faecal calprotectin

COMPETENCE

Be able to:

a. Explain the functions of the major regions of the GIT and associated organs.
b. Give examples of tests routinely used in your laboratory to assess GI disorders and malabsorption.
c. Locate information for sample requirements for tests and be able to give advice to clinicians regarding sample types.
d. Explain the methodological techniques used to measure the assays listed in the 'Knowledge' section and how different methods and standards used may alter results obtained.

EVIDENCE OF ACHIEVEMENT

This section requires the trainer to sign candidate has successfully achieved fitness to practice as a biomedical scientist at the specialist level. The candidate is required to present the supporting evidence indicated below as a separate specialist portfolio of evidence.

Candidate has been assessed by the trainer to work in accordance with standard laboratory procedures. (No other evidence is required).

Date of completion:

Trainer's name:

Trainer's signature:

Candidate has answered questions set by the trainer on the knowledge and skill components required to complete this module. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

One other piece of evidence chosen by the candidate as an example of their competence in this area

Date of completion:

Trainer's name:

Trainer's signature:

This is to confirm that the knowledge and competence requirements for this section and the requirements in the Evidence of Achievement section have been met.

External Assessor's signature:

Internal Assessor's name:

Date:

Section 7.14 Reflective Practice

This section is used to demonstrate that you can relate knowledge from several areas, draw conclusions and reflect on your own performance with regard to current and future practice as an independent professional learner. It is therefore a useful source of information for your CPD profile should you be audited by the Health and Care Professions Council (HCPC).

The external examiner will review this reflective report which should cross reference to the evidence contained in the portfolio. This may lead to further discussion during the *viva voce*.

Candidate's Reflective Practice Statement Part 1.

Summarise your role within the laboratory in the context of this section.

Section 7.14 Candidate's Reflective Practice Statement Part 2.

The ethos of undertaking reflective practice should be the recognition that it is a naturally occurring characteristic of those wishing to develop. How you complete this section is personal to your own circumstances. It should be approached by recognising you have a responsibility to demonstrate self-awareness when analysing gaps in your knowledge. This is therefore an opportunity to reflect on aspects of training, the application of new knowledge and skills, and how goals have been achieved.

Personal reflection on training and examples of evidence for this section

Section 7.15 Therapeutic Drug Monitoring

There are a large number of drugs which require therapeutic monitoring but many of these are only measured in specialised services attached to specific clinical units.

It is expected that the specialist trainee will have a thorough theoretical grounding in the contents of section 7.15a, exposure to the measurement of the drugs in section 7.15b; and be aware of the need for monitoring of the drugs in section 7.15c.

Subsection 7.15a Essential requirements of Therapeutic Drug Monitoring (TDM

KNOWLEDGE

The candidate is expected to be able to demonstrate knowledge and understanding of the following:

1. The purpose of therapeutic drug monitoring (TDM).
2. Principles, limitations and increasing application of pharmacokinetics and pharmacogenetics.
3. Definitions of half-life, dosing interval, trough level, minimum effective dose, maximum therapeutic dose and importance of sampling time.
4. Principles and techniques used in measurement of drugs, including:
   - colourimetry
   - flame photometry (atomic emission spectrometry)
   - immunoassay
   - high performance liquid chromatography
   - gas chromatography
   - mass spectrometry
5. Principles and limitations of the analytical method employed and sample requirements.
6. Significance of results outside the therapeutic range.
7. Factors affecting sample integrity and appropriate corrective action.
8. Specific risks associated with the reagents or method.
   Relevant internal and external quality assurance procedures.

COMPETENCE

Be able to:

a. Explain the need for sample and last dose time to a variety of professional groups (phlebotomist, nursing staff, including community based staff), hospital clinicians and general practitioners).
b. Explain the reasons for the difference in measured concentration using different assay technologies.
c. Locate information for sample requirements for TDM not performed in your department.
d. Explain the methodological techniques used in TDM.

EVIDENCE OF ACHIEVEMENT

This section requires the trainer to sign candidate has successfully achieved fitness to practice as a biomedical scientist at the specialist level. The candidate is required to present the supporting evidence indicated below as a separate specialist portfolio of evidence.

Candidate has been assessed by the trainer to work in accordance with standard laboratory procedures. (No other evidence is required).

Date of completion:

Trainer's name:

Trainer's signature:

Candidate has answered questions set by the trainer on the knowledge and skill components required to complete this module. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

One other piece of evidence chosen by the candidate as an example of their competence in this area

Date of completion:

Trainer's name:

Trainer's signature:

This is to confirm that the knowledge and competence requirements for this section and the requirements in the Evidence of Achievement section have been met.

External Assessor's signature:

Internal Assessor's name:

Date:

Section 7.15 Therapeutic Drug Monitoring

Subsection 7.15b Core drugs

KNOWLEDGE

The candidate is expected to be able to demonstrate knowledge and understanding of the following:

1. The purpose of therapeutic drug monitoring for each agent.
2. Principles and limitations of drug assays to measure:
   - lithium, digoxin, phenytoin, carbamazepine (CBZ) and valproate
   - gentamicin (or other aminoglycoside antibiotic)
   - theophylline
   - vancomycin
3. Principles and techniques used in measurement of d[illegible]including:
   - immunoassay
   - high performance liquid chromatography
   - ion selective electrodes
4. The significance of results outside the therap[illegible]tic range.
5. Factors affecting sample integrity a[illegible]propria[illegible]correcti[illegible]action.
6. Specific risks associated with th[illegible]eagen[illegible]or methe[illegible]
7. Relevant internal and external q[illegible]lity a[illegible]ce procedures.

COMPETENCE

Be able to:

a. Confirm tha[illegible]e sa[illegible]ple was co[illegible]ected at the optimum time since last dose.
b. Perf[illegible]m the tim[illegible] analysis of antimicrobial drug in plasma/serum.
c. [illegible]idate the result[illegible]
d. M[illegible]itor[illegible]esults, consider possible interference, and take appropriate action.
e. Repo[illegible]esults ap[illegible]opriately to the significance of the result.
f. Complet[illegible]ll r[illegible]evant documentation in accordance with quality control and audit requirements.

EVIDENCE OF ACHIEVEMENT

This section requires the trainer to sign candidate has successfully achieved fitness to practice as a biomedical scientist at the specialist level. The candidate is required to present the supporting evidence indicated below as a separate specialist portfolio of evidence.

Candidate has been assessed by the trainer to work in accordance with standard laboratory procedures. (No other evidence is required).

Date of completion:

Trainer's name:

Trainer's signature:

Candidate has answered questions set by the trainer on the knowledge and skill components required to complete this module. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

One other piece of evidence chosen by the candidate as an example of their competence in this area

Date of completion:

Trainer's name:

Trainer's signature:

This is to confirm that the knowledge and competence requirements for this section and the requirements in the Evidence of Achievement section have been met.

External Assessor's signature:

Internal Assessor's name:

Date:

Section 7.15 Therapeutic Drug Monitoring

Subsection 7.15c Drug monitoring investigations

KNOWLEDGE

The candidate is expected to be able to demonstrate knowledge and understanding of the following:

1. How to monitoring the following classes of drugs and the reasons for this. (The drug names are given as examples only and not exhaustive as there are clearly other members of each class of drug). Knowledge of all the drug assays either referred from or analysed in their laboratory is expected:
   - anti-epileptics – lamotrigine
   - anti-psychotics – clozapine
   - anti-tumour – methotrexate
   - cardiac drugs – amiodarone
   - anti-retroviral drugs – constituents of HAART
   - immunosuppressives – cyclosporine, azathioprine (TPMT phenotyping or genotyping)
2. How to access information to advise clinicians on sample requirements for all these classes of drugs.
3. Principles and techniques used in the measurement of drugs, including:
   - spectrophotometry
   - colorimetry
   - immunoassay
   - high performance liquid chromatography
   - mass spectrometry
4. General principles and limitations of the analytical method employed and sample requirements.
5. Significance of results outside the therapeutic range.
6. Factors affecting sample integrity and appropriate corrective action.

COMPETENCE

Be able to:

a. Provide advice on the correct procedure for sample collection.
b. Either analyse or process sample for transport to referral laboratory.
c. Correctly enter results and any comment to laboratory computer system.
d. Report results appropriately to the significance of the result.
e. Complete all relevant documentation in accordance with quality control and au
requirements.

EVIDENCE OF ACHIEVEMENT

This section requires the trainer to sign candidate has successfully achieved fitness to practice as a biomedical scientist at the specialist level. The candidate is required to present the supporting evidence indicated below as a separate specialist portfolio of evidence.

Candidate has been assessed by the trainer to work in accordance with standard laboratory procedures. (No other evidence is required).

Date of completion:

Trainer's name:

Trainer's signature:

Candidate has answered questions set by the trainer on the knowledge and skill components required to complete this module. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

One other piece of evidence chosen by the candidate as an example of their competence in this area

Date of completion:

Trainer's name:

Trainer's signature:

This is to confirm that the knowledge and competence requirements for this section and the requirements in the Evidence of Achievement section have been met.

External Assessor's signature:

Internal Assessor's name:

Date:

Section 7.15 Reflective Practice

This section is used to demonstrate that you can relate knowledge from several areas, draw conclusions and reflect on your own performance with regard to current and future practice as an independent professional learner. It is therefore a useful source of information for your CPD profile should you be audited by the Health and Care Professions Council (HCPC).

The external examiner will review this reflective report which should cross reference to the evidence contained in the portfolio. This may lead to further discussion during the *viva voce*.

Candidate's Reflective Practice Statement Part 1.

Summarise your role within the laboratory in the context of this section.

Section 7.15 Candidate's Reflective Practice Statement Part 2.

The ethos of undertaking reflective practice should be the recognition that it is a naturally occurring characteristic of those wishing to develop. How you complete this section is personal to your own circumstances. It should be approached by recognising you have a responsibility to demonstrate self-awareness when analysing gaps in your knowledge. This is therefore an opportunity to reflect on aspects of training, the application of new knowledge and skills, and how goals have been achieved.

Personal reflection on training and examples of evidence for this section

Section 7.16 Chemical Toxicology

Subsection 7.16a Chemical poisons

Core analytes: paracetamol, salicylate, ethanol, ethylene glycol and carbon monoxide.

KNOWLEDGE

The candidate is expected to be able to demonstrate knowledge and understanding of the following:

1. The role of the laboratory in the estimation of paracetamol, salicylate, ethanol, ethylene glycol and carbon monoxide in a range of sample types.
2. The role of the laboratory in the diagnosis, treatment and support of patients poisoned by heavy metals.
3. Routine toxicology analysis available in most laboratories and those only available in specialist centres.
4. Principles of diagnosis and treatment of poisoning including use of Toxbase and the National Poisons Information Service (NPIS).
5. Metabolism of toxic substances at therapeutic and overdose levels e.g. salicylate and paracetamol.
6. Other laboratory investigations used to support the poisoned patient including calculation of anion and osmolality gap.
7. Principles and limitations of the analytical method employed and sample requirements, (e.g. spectrometry, chromatography). Factors affecting sample integrity appropriate corrective action and the risks associated with the reagents or method.
8. The metabolism of ethanol.
9. Acute and chronic abuse of ethanol and other alcohols including methanol and ethylene glycol.
10. The significance of ethanol, methanol and ethylene glycol levels in acute poisoning, chronic alcohol abuse and legal/forensic cases.
11. Other analyses which may be measured to reflect alcohol use over differing time periods and how to interpret the results.
12. The toxic effects caused by carbon monoxide.
13. Use of hyperbaric treatment and the availability of such treatment.

KNOWLEDGE (continued)

14. Point of Care Testing (POCT) as well as laboratory testing.
15. The guidelines for the timing of collection, type of sample and timing of analysis for use in investigation of the poisoned patient.
16. Analyses used to monitor chronic substance abuse.
17. Occupational and environmental toxicology.
18. Relevant internal and external quality assurance procedures.
19. The difference between qualitative and quantitative analysis.

COMPETENCE

Be able to:

a. Confirm the presence of paracetamol, salicylate, iron, ethanol, ethylene glycol and carbon monoxide in a range of sample types.
b. Deal with requests for ethylene glycol according to local procedures.
c. Deal with requests for heavy metals according to local procedures.
d. Confirm the time between exposure and sample collection and analysis.
e. Perform the timely analysis of plasma/serum and other body fluids.
f. Validate the results.
g. Monitor results, consider possible interference, and take appropriate action.
h. Report results appropriately to the significance of the result.
i. Complete all relevant documentation in accordance with quality control and audit requirements.

EVIDENCE OF ACHIEVEMENT

This section requires the trainer to sign candidate has successfully achieved fitness to practice as a biomedical scientist at the specialist level. The candidate is required to present the supporting evidence indicated below as a separate specialist portfolio of evidence.

Candidate has been assessed by the trainer to work in accordance with standard laboratory procedures. (No other evidence is required).

Date of completion:

Trainer's name:

Trainer's signature:

Candidate has answered questions set by the trainer on the knowledge and skill components required to complete this module. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

One other piece of evidence chosen by the candidate as an example of their competence in this area

Date of completion:

Trainer's name:

Trainer's signature:

This is to confirm that the knowledge and competence requirements for this section and the requirements in the Evidence of Achievement section have been met.

External Assessor's signature:

Internal Assessor's name:

Date:

Section 7.16 Chemical Toxicology
Subsection 7.16b Drugs of abuse

Core analytes: amphetamines, barbiturates, benzodiazepines, cannabinoids, cocaine and metabolites, LSD and opiates.

KNOWLEDGE

The candidate is expected to be able to demonstrate knowledge and understanding of the following:

1. The role of your laboratory in support of the poisoned patient including the estimation and confirmation of the presence of common drugs of abuse (e.g. amphetamines, barbiturates, benzodiazepines, cannabinoids, cocaine and metabolites, LSD and opiates) and those used in the treatment of chronic abusers (e.g. Buprenorphine and metabolites; Methadone and metabolites).
2. Legislation relating to the use and abuse of drugs.
3. Regulations relating to the storage and security of drugs.
4. Principles and limitations of screening and confirmation analysis for tests associated with drugs of abuse in your own laboratory.
5. The need to use different analytical principles for screening and confirmation testing.
6. Sample types used in the detection and estimation of abused drugs, including:
   - urine
   - blood/serum/plasma
   - hair
   - gastric contents
   - saliva/ oral fluid
   - tissue samples
7. Understand the requirements for 'Chain of Custody' as appropriate to sample handling.
8. Difference between qualitative and quantitative analysis.
9. Principles, techniques and sample requirements used in the measurement of drugs, including:
   - spectrophotometry;
   - immunoassay;
   - high performance liquid chromatography;
   - gas chromatography;
   - mass spectrometry;
   - ion-specific electrodes;
   - flame emission spectrophotometry

KNOWLEDGE (continued)

10. Principles and limitations of pharmacokinetics.
11. Factors affecting sample integrity and appropriate corrective action.
12. Problems associated with post mortem samples and drug redistribution.
13. Specific risks associated with the reagents or method.
14. Relevant internal and external quality assurance procedures.

COMPETENCE

Be able to:

a. Maintain 'Chain of Custody' handling and completion of documentation according to standard operating procedure.
b. Describe the principles and practice of screening procedures and confirmation of positive screening results (and quantitative analysis, if appropriate).

EVIDENCE OF ACHIEVEMENT

This section requires the trainer to sign candidate has successfully achieved fitness to practice as a biomedical scientist at the specialist level. The candidate is required to present the supporting evidence indicated below as a separate specialist portfolio of evidence.

Candidate has been assessed by the trainer to work in accordance with standard laboratory procedures. (No other evidence is required).

Date of completion:

Trainer's name:

Trainer's signature:

Candidate has answered questions set by the trainer on the knowledge and skill components required to complete this module. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

One other piece of evidence chosen by the candidate as an example of their competence in this area

Date of completion:

Trainer's name:

Trainer's signature:

This is to confirm that the knowledge and competence requirements for this section and the requirements in the Evidence of Achievement section have been met.

External Assessor's signature:

Internal Assessor's name:

Date:

Section 7.16 Reflective Practice

This section is used to demonstrate that you can relate knowledge from several areas, draw conclusions and reflect on your own performance with regard to current and future practice as an independent professional learner. It is therefore a useful source of information for your CPD profile should you be audited by the Health and Care Professions Council (HCPC).

The external examiner will review this reflective report which should cross reference to the evidence contained in the portfolio. This may lead to further discussion during the *viva voce*.

Candidate's Reflective Practice Statement Part 1.

Summarise your role within the laboratory in the context of this section.

Section 7.16 Candidate's Reflective Practice Statement Part 2.

The ethos of undertaking reflective practice should be the recognition that it is a naturally occurring characteristic of those wishing to develop. How you complete this section is personal to your own circumstances. It should be approached by recognising you have a responsibility to demonstrate self-awareness when analysing gaps in your knowledge. This is therefore an opportunity to reflect on aspects of training, the application of new knowledge and skills, and how goals have been achieved.

Personal reflection on training and examples of evidence for this section

Section 7.17 Gastrointestinal Inherited Metabolic Disorders and Newborn Screen: Prenatal Screening for Predicting Down's Syndrome

INTRODUCTION

The candidate is expected to be able to demonstrate a working knowledge of the overall scope and prevalence of diseases within the populations that are served and the tests offered within and outside the candidate's own laboratory.

There are a large number of disorders that can be investigated. Many are only measured in specialised laboratories, others as services attached to specific clinical units. Therefore, it is expected that the trainee will not necessarily have much exposure to all of the analytical processes described but they should be exposed to the 'first line' testing such as detection of reducing substances in urine.

The disorders that may warrant consideration will include the following types with examples given in brackets:

- carbohydrate metabolism (glycogen storage disease)
- amino acid metabolism (phenylketonuria, maple syrup urine disease, glutaric acidemia type 1)
- organic acid metabolism (organic aciduria - alcaptonuria)
- fatty acid oxidation and mitochondrial metabolism (medium chain acyl dehydrogenase deficiency, glutaric acidemia type 2)
- P metabolism (acute intermittent porphyria)
- P or pyrimidine metabolism (Lesch-Nyhan syndrome)
- steroid metabolism (congenital adrenal hyperplasia)
- M function (Kearns-Savre syndrome)
- P function (Zellweger syndrome)
- lysosomal storage disorders (Gaucher's disease)

KNOWLEDGE

Subsection 7.17a. Major categories of inherited metabolic diseases:

The candidate is expected to be able to demonstrate knowledge and understanding of the following:

1. Principles of metabolic disorders and screening programmes.
2. Procedures used to screen within their own laboratory.
3. Tests used within specialized centres.
4. Need for ongoing monitoring in certain conditions.

Subsection 7.17b The case to screen for disease

1. Genetic basis of inherited disease.
2. Metabolic significance and classification of:
   - organic acids
   - carbohydrate intolerance
3. Inborn errors of metabolism presenting w[illegible] organic[illegible]ciduria.
4. Principles and limitations of screening tests f[illegible]anic acidurias and carbohydrates.
5. Inborn errors of amino acid metab[illegible]
6. Underlying metabolic disorder[illegible]using c[illegible]tic fibrosis
7. Porphyrin biosynthetic pathway[illegible]d cl[illegible]ion of the porphyrias.
8. Screening programmes[illegible] inherited[illegible]d congenital disorders.
9. Purpose, principles [illegible]d limitations of s[illegible]ening.
10. Importance of sampli[illegible]tim[illegible] in terms of integrity of sample and in terms of timely therapy.
11. The follow[illegible]g terms in the [illegible]t of screening for differences: predictive value, sensitivity, sp[illegible]fic[illegible]y, selectivity, prevalence, false negative, false positive.
12. Sp[illegible]men needs, [illegible]ests offered and limitations of the Newborn Screening Services [illegible]cluding:
    - [illegible]K Newborn Screening Programme Centre and Blood Spot Forms
    - tes[illegible]offered
13. Factors t[illegible]may affect suitability of samples including Blood Transfusion and [illegible]aturity.
14. Patients' rights and ethical issues.
15. Genetic basis of Down's syndrome.
16. United Kingdom (UK) Screening programmes for inherited and congenital disorders.
17. Non-laboratory techniques used in the pre-natal screening for Down's syndrome.

Subsection 7.17c. Analytical Techniques

1. Purpose of common analyses and the principles and limitations of the analytical method employed and sample requirements.
2. Factors affecting sample integrity and appropriate corrective action.
3. Principles and techniques used in measurement, including:
   - colorimetry
   - immunoassay
   - high performance liquid chromatography
   - gas chromatography
   - mass spectrometry
   - thin layer chromatography
4. Where molecular genetics and other analyses should be use
5. Principles and limitations of sweat collection methods.
6. Principles and limitations of methods for the estimation o odium chloride, osmolality, and electrical conductivity of sweat samp
7. Principles and limitations of the AFP, HCG, inhi n-A and estriol methods used in the prenatal screening for neural tube defects d Down's syndr me.
8. Principle behind the calculation of Down's ndro e risk using he Triple/Quadruple test.
9. Further investigations by speciali unit including T a molecular techniques).
10. Principles of Prenatal Diagnos including Chorionic illus Sampling and ethical and medical risks associated.
11. Specific risks associate with the rea ts or method.
12. Other tests initiated a resul of detect abnormal amino acid patterns.
13. Relevant intern and e al quality assurance procedures.
14. Significance results outs the re erence range.

COMPETENCE

Be able to:

a. Explain the clinical manifestation of at least one inherited metabolic disease resulting from:
   - decreased synthesis of a normal metabolite
   - increased synthesis of a normal metabolite
   - compromised trans-membrane transport
   - decreased receptor synthesis
   - altered binding of a coenzyme to an enzyme
b. Confirm times when the samples should be collected.
c. Explain the methods available and the associated advantages and disadvantages for markers of the most common inborn metabolic disorders.
d. Analyse results, consider possible interference, and take appropriate action.
e. Report results appropriately to the significance of the
f. Complete all relevant documentation in accordance with quality and audit requirements.

EVIDENCE OF ACHIEVEMENT

This section requires the trainer to sign candidate has successfully achieved fitness to practice as a biomedical scientist at the specialist level. The candidate is required to present the supporting evidence indicated below as a separate specialist portfolio of evidence.

Candidate has been assessed by the trainer to work in accordance with standard laboratory procedures. (No other evidence is required).

Date of completion:

Trainer's name:

Trainer's signature:

Candidate has answered questions set by the trainer on the knowledge and skill components required to complete this module. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

One other piece of evidence chosen by the candidate as an example of their competence in this area

Date of completion:

Trainer's name:

Trainer's signature:

This is to confirm that the knowledge and competence requirements for this section and the requirements in the Evidence of Achievement section have been met.

External Assessor's signature:

Internal Assessor's name:

Date:

Section 7.17 Reflective Practice

This section is used to demonstrate that you can relate knowledge from several areas, draw conclusions and reflect on your own performance with regard to current and future practice as an independent professional learner. It is therefore a useful source of information for your CPD profile should you be audited by the Health and Care Professions Council (HCPC).

The external examiner will review this reflective report which should cross reference to the evidence contained in the portfolio. This may lead to further discussion during the *viva voce.*

Candidate's Reflective Practice Statement Part 1.

Summarise your role within the laboratory in the context of this section.

Section 7.17 Candidate's Reflective Practice Statement Part 2.

The ethos of undertaking reflective practice should be the recognition that it is a naturally occurring characteristic of those wishing to develop. How you complete this section is personal to your own circumstances. It should be approached by recognising you have a responsibility to demonstrate self-awareness when analysing gaps in your knowledge. This is therefore an opportunity to reflect on aspects of training, the application of new knowledge and skills, and how goals have been achieved.

Personal reflection on training and examples of evidence for this section

Section 7.18 Investigation of Thyroid Disease

Core analytes: Thyroid Stimulating Hormone (TSH), Thyroxine (T4), Free T4 (fT4), Tri-iodothyronine (T3) and/or Free T3 (fT3) and anti-Thyroid Peroxidase Antibodies (TPO).

KNOWLEDGE

The candidate is expected to be able to demonstrate knowledge and understanding of the following:

1. Mechanisms of hormone control and action on target organs.
2. Synthesis, control and function of hormones in the hypothalamic-pituitary-thyroid axis.
3. Biochemistry and physiology of the thyroid gland.
4. Measurement of T3, T4 and TSH.
5. The clinical significance of free hormones compared to total hormone levels.
6. Dynamic function tests requiring estimation of thyroid hormones.
7. Principles and limitations of total and free hormone assays in general.
8. Effect of auto-antibodies in the pathogenesis of thyroid disease and evaluate their use as biomarkers in differential diagnosis.
9. Principles and limitations of the analytical method employed and sample requirements.
10. Significance of abnormal results.
11. Factors affecting sample integrity and appropriate corrective action.
12. Specific risks associated with the reagents or method.
13. Relevant internal and external quality assurance procedures.

COMPETENCE

Be able to:

a. Assess suitability of samples for analysis on the appropriate laboratory analyser and take appropriate action if not suitable.
b. Perform the timely analysis of plasma/serum: T4 total or free, T3 total or free (dependent on local repertoire), TSH. Be aware of the methods available for TPO analysis.
c. Validate the results.
d. Monitor results, consider possible interference, and take appropriate action.
e. Report results appropriate to the significance of the result.
f. Complete all relevant documentation in accordance with quality control and audit requirements.

EVIDENCE OF ACHIEVEMENT

This section requires the trainer to sign candidate has successfully achieved fitness to practice as a biomedical scientist at the specialist level. The candidate is required to present the supporting evidence indicated below as a separate specialist portfolio of evidence.

Candidate has been assessed by the trainer to work in accordance with standard laboratory procedures. (No other evidence is required).

Date of completion:

Trainer's name:

Trainer's signature:

Candidate has answered questions set by the trainer on the knowledge and skill components required to complete this module. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

One other piece of evidence chosen by the candidate as an example of their competence in this area

Date of completion:

Trainer's name:

Trainer's signature:

This is to confirm that the knowledge and competence requirements for this section and the requirements in the Evidence of Achievement section have been met.

External Assessor's signature:

Internal Assessor's name:

Date:

Section 7.18 Reflective Practice

This section is used to demonstrate that you can relate knowledge from several areas, draw conclusions and reflect on your own performance with regard to current and future practice as an independent professional learner. It is therefore a useful source of information for your CPD profile should you be audited by the Health and Care Professions Council (HCPC).

The external examiner will review this reflective report which should cross reference to the evidence contained in the portfolio. This may lead to further discussion during the *viva voce*.

Candidate's Reflective Practice Statement Part 1.

Summarise your role within the laboratory in the context of this section.

Section 7.18 Candidate's Reflective Practice Statement Part 2.

The ethos of undertaking reflective practice should be the recognition that it is a naturally occurring characteristic of those wishing to develop. How you complete this section is personal to your own circumstances. It should be approached by recognising you have a responsibility to demonstrate self-awareness when analysing gaps in your knowledge. This is therefore an opportunity to reflect on aspects of training, the application of new knowledge and skills, and how goals have been achieved.

Personal reflection on training and examples of evidence for this section

Section 7.19 Abnormal Pituitary Function

Core analytes: growth hormone, prolactin, adrencorticotrophic hormone (ACTH), thyroid stimulating hormone (TSH), luteinising hormone (LH) and follicle stimulating hormone (FSH).

KNOWLEDGE

The candidate is expected to be able to demonstrate knowledge and understanding of the following:

1. Mechanism of hormone control and action on target organ.
2. Synthesis, control and function of Growth Hormone, Prolactin, ACTH, TSH, LH and FSH in health and disease.
3. Biochemistry and physiology of the hypothalamic pituitary axis.
4. Principles and limitations of peptide hormone assays in general.
5. Principles and limitations of the analytical method employed and sample requirements.
6. Dynamic function tests requiring estimation of pituitary hormones.
7. Significance of abnormal results.
8. Factors affecting sample integrity and appropriate corrective action.
9. Specific risks associated with the reagents or method.
10. Relevant internal and external quality assurance procedures.

COMPETENCE

Be able to:

a. Assess suitability of sample for analysis (e.g. use of preservatives, storage conditions, timing) taking appropriate action if not suitable.
b. Select the appropriate method of analysis and prepare equipment for analysis.
c. Perform in a timely manner, the investigations undertaken by your laboratory where adrenal disease is suspected (e.g. growth hormone, prolactin, TSH, LH and FSH in serum, ACTH in plasma).
d. Validate the results.
e. Monitor results, consider possible interference, and take appropriate action.
f. Report results appropriate to the significance.
g. Complete all relevant documentation in accordance with quality control and audit requirements.

EVIDENCE OF ACHIEVEMENT

This section requires the trainer to sign candidate has successfully achieved fitness to practice as a biomedical scientist at the specialist level. The candidate is required to present the supporting evidence indicated below as a separate specialist portfolio of evidence.

Candidate has been assessed by the trainer to work in accordance with standard laboratory procedures. (No other evidence is required).

Date of completion:

Trainer's name:

Trainer's signature:

Candidate has answered questions set by the trainer on the knowledge and skill components required to complete this module. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

One other piece of evidence chosen by the candidate as an example of their competence in this area

Date of completion:

Trainer's name:

Trainer's signature:

This is to confirm that the knowledge and competence requirements for this section and the requirements in the Evidence of Achievement section have been met.

External Assessor's signature:

Internal Assessor's name:

Date:

Section 7.19 Reflective Practice

This section is used to demonstrate that you can relate knowledge from several areas, draw conclusions and reflect on your own performance with regard to current and future practice as an independent professional learner. It is therefore a useful source of information for your CPD profile should you be audited by the Health and Care Professions Council (HCPC).

The external examiner will review this reflective report which should cross reference to the evidence contained in the portfolio. This may lead to further discussion during the *viva voce*.

Candidate's Reflective Practice Statement Part 1.

Summarise your role within the laboratory in the context of this section.

Section 7.19 Candidate's Reflective Practice Statement Part 2.

The ethos of undertaking reflective practice should be the recognition that it is a naturally occurring characteristic of those wishing to develop. How you complete this section is personal to your own circumstances. It should be approached by recognising you have a responsibility to demonstrate self-awareness when analysing gaps in your knowledge. This is therefore an opportunity to reflect on aspects of training, the application of new knowledge and skills, and how goals have been achieved.

Personal reflection on training and examples of evidence for this section

Section 7.20 Reproductive Endocrinology

Core analytes: follicle stimulating hormone (FSH), luteinising hormone (LH), prolactin (PRL), oestradiol (E2), progesterone (PRG), testosterone (TES) and sex hormone binding globulin (SHBG), human chorionic gonadotrophin (HCG) and anti-Mullerian hormone (AMH).

KNOWLEDGE

The candidate is expected to be able to demonstrate knowledge and understanding of the following:

1. Mechanisms of hormone control and action on target organ.
2. Synthesis, control and function of hypothalamic/pituitary hormones.
3. Biochemistry and physiology of the female menstrual cycle.
4. Biochemistry and physiology of pregnancy.
5. The biochemical investigation of infertility.
6. The role of dynamic function testing and the assays involved.
7. Principles and limitations of hormone assays in general.
8. Principles and limitations of the analytical methods employed and sample requirements.
9. The significance of abnormal results.
10. Factors affecting sample integrity and appropriate corrective action.
11. Specific risks associated with the reagents or methods.
12. Relevant internal and external quality assurance procedures.

COMPETENCE

Be able to:

a. Determine the day of the menstrual cycle (for females) from the information given on the request form.
b. Assess suitability of samples for analysis on the appropriate laboratory analyser and take appropriate action if not suitable.
c. Perform in a timely manner, the investigations undertaken by your laboratory where pregnancy or disorders of the reproductive system are suspected.
d. Perform the timely analysis of sex hormones in serum, plasma or urine.
e. Validate the results.
   Monitor results, consider possible interference, and take appropriate action.
g. Report results appropriate to the significance of the result.
h. Complete all relevant documentation in accordance with quality control and audit requirements.

EVIDENCE OF ACHIEVEMENT

This section requires the trainer to sign candidate has successfully achieved fitness to practice as a biomedical scientist at the specialist level. The candidate is required to present the supporting evidence indicated below as a separate specialist portfolio of evidence.

Candidate has been assessed by the trainer to work in accordance with standard laboratory procedures. (No other evidence is required)

Date of completion:

Trainer's name:

Trainer's signature:

Candidate has answered questions set by the trainer on the knowledge and skill components required to complete this module. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

One other piece of evidence chosen by the candidate as an example of their competence in this area

Date of completion:

Trainer's name:

Trainer's signature:

This is to confirm that the knowledge and competence requirements for this section and the requirements in the Evidence of Achievement section have been met.

External Assessor's signature:

External Assessor's name:

Date:

Section 7.20 Reflective Practice

This section is used to demonstrate that you can relate knowledge from several areas, draw conclusions and reflect on your own performance with regard to current and future practice as an independent professional learner. It is therefore a useful source of information for your CPD profile should you be audited by the Health and Care Professions Council (HCPC).

The external examiner will review this reflective report which should cross reference to the evidence contained in the portfolio. This may lead to further discussion during the *viva voce*.

Candidate's Reflective Practice Statement Part 1.

Summarise your role within the laboratory in the context of this section.

Section 7.20 Candidate's Reflective Practice Statement Part 2.

The ethos of undertaking reflective practice should be the recognition that it is a naturally occurring characteristic of those wishing to develop. How you complete this section is personal to your own circumstances. It should be approached by recognising you have a responsibility to demonstrate self-awareness when analysing gaps in your knowledge. This is therefore an opportunity to reflect on aspects of training, the application of new knowledge and skills, and how goals have been achieved.

Personal reflection on training and examples of evidence for this section

Section 7.21 Investigation of Adrenal Disease

Core analytes: aldosterone, cortisol, adrenocorticotrophic hormone (ACTH) and catecholamines.

KNOWLEDGE

The candidate is expected to be able to demonstrate knowledge and understanding of the following:

1. Mechanism of hormone control and action on target organ.
2. Synthesis, control and function of aldosterone, cortisol, ACTH and catecholamines in health and disease with particular reference to Cushing's Syndrome, Conn's Syndrome and Addison's Disease.
3. Biochemistry and physiology of the adrenal cortex and medulla.
4. The role of neurotransmitters in the autonomic nervous system and causes of abnormal secretion.
5. The biochemistry of Conns and Addison's diseases and their effects on the electrolyte balance.
6. Principles and limitations of peptide and steroid hormone assays in general.
7. Principles and limitations of the analytical methods employed and sample requirements.
8. Dynamic function tests requiring stimulation of adrenal hormones.
9. The significance of abnormal results.
10. Factors affecting sample integrity and appropriate corrective action.
11. Specific risks associated with the reagents or method.
12. Relevant internal and external quality assurance procedures.

COMPETENCE

Be able to:

a. Assess suitability of samples for analysis (use of preservatives, storage conditions, timing) taking appropriate action if not suitable.
b. Select the appropriate method of analysis which may or may not be available in your local laboratory.
c. Prepare equipment for analysis.
d. Perform in a timely manner, the investigations undertaken by your laboratory when adrenal disease is suspected, (e.g. cortisol in serum and urine, ACTH in plasma, catecholamines in plasma and urine).
e. Validate the results.
f. Monitor results, consider possible interference, and take appropriate action.
g. Report results appropriate to the significance.
h. Complete all relevant documentation in accordance with quality metrics and audit requirements.

EVIDENCE OF ACHIEVEMENT

This section requires the trainer to sign candidate has successfully achieved fitness to practice as a biomedical scientist at the specialist level. The candidate is required to present the supporting evidence indicated below as a separate specialist portfolio of evidence.

Candidate has been assessed by the trainer to work in accordance with standard laboratory procedures. (No other evidence is required)

Date of completion:

Trainer's name:

Trainer's signature:

Candidate has answered questions set by the trainer on the knowledge and skill components required to complete this module. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

One other piece of evidence chosen by the candidate as an example of their competence in this area

Date of completion:

Trainer's name:

Trainer's signature:

This is to confirm that the knowledge and competence requirements for this section and the requirements in the Evidence of Achievement section have been met.

External Assessor's signature:

Internal Assessor's name:

Date:

Section 7.21 Reflective Practice

This section is used to demonstrate that you can relate knowledge from several areas, draw conclusions and reflect on your own performance with regard to current and future practice as an independent professional learner. It is therefore a useful source of information for your CPD profile should you be audited by the Health and Care Professions Council (HCPC).

The external examiner will review this reflective report which should cross reference to the evidence contained in the portfolio. This may lead to further discussion during the *viva voce*.

Candidate's Reflective Practice Statement Part 1.

Summarise your role within the laboratory in the context of this section.

Section 7.21 Candidate's Reflective Practice Statement Part 2.

The ethos of undertaking reflective practice should be the recognition that it is a naturally occurring characteristic of those wishing to develop. How you complete this section is personal to your own circumstances. It should be approached by recognising you have a responsibility to demonstrate self-awareness when analysing gaps in your knowledge. This is therefore an opportunity to reflect on aspects of training, the application of new knowledge and skills, and how goals have been achieved.

Personal reflection on training and examples of evidence for this section

Section 7.22 Point of Care Testing (POCT)

KNOWLEDGE

The candidate is expected to be able to demonstrate knowledge and understanding of the following:

1. Common POCT systems used in your hospital and the role of the laboratory in providing support for them. These may include blood gases and electrolytes, glucose, pregnancy testing, lactic acid, drugs of abuse screening, urine screening, HbA1c, cardiac markers.
2. Guidelines and policies and accreditation associated with point of care testing including role of POCT in patient focused care.
3. Advantages and disadvantages of point of care.
4. Areas or settings point of care testing is carried out.
5. Developments in point of care testing and changes to the way healthcare services are delivered.
6. Importance of correct pre and post analytical patient preparation, sample collection and analysis.
7. Factors affecting sample integrity and the implications of producing incorrect results.
8. Principles and techniques used in modern point of care equipment.
9. Principles and limitations of the analytical methods utilized in point of care testing equipment including:
   - amperometry
   - absorbance
   - spectroscopic analysis
   - reflectance
   - fluorescence
   - conductimetry
   - potentiometry
   - radio wave spectroscopy
   - dry reagent biosensors
   - microchip technology
   - immunoassay
   - non-invasive assays
10. Importance of regular training of clinical staff and competency testing.
11. Importance of correct data handling and storage.
12. Importance of staff using individual passwords on all POCT devices.
13. Relevant internal and external quality assurance procedures.

COMPETENCE

Be able to:

a. Define what is meant by point of care testing.
b. List the advantages and disadvantages of POCT.
c. Define where point of care testing is used in your own laboratory environment.
d. Describe the role of your laboratory in supporting POCT.
e. Provide advice on the correct sample type and/or collection device for sample collection.
f. Perform in a timely manner, analyses as required.
g. Validate results.
h. Monitor results, consider possible interference, and take appropriate action.
i. Report results appropriate to the significance.
j. Complete all relevant documentation in accordance with quality control and audit requirements.

EVIDENCE OF ACHIEVEMENT

This section requires the trainer to sign candidate has successfully achieved fitness to practice as a biomedical scientist at the specialist level. The candidate is required to present the supporting evidence indicated below as a separate specialist portfolio of evidence.

Candidate has been assessed by the trainer to work in accordance with standard laboratory procedures. (No other evidence is required).

Date of completion:

Trainer's name:

Trainer's signature:

Candidate has answered questions set by the trainer on the knowledge and skill components required to complete this module. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

One other piece of evidence chosen by the candidate as an example of their competence in this area

Date of completion:

Trainer's name:

Trainer's signature:

This is to confirm that the knowledge and competence requirements for this section and the requirements in the Evidence of Achievement section have been met.

External Assessor's signature:

Internal Assessor's name:

Date:

Section 7.22 Reflective Practice

This section is used to demonstrate that you can relate knowledge from several areas, draw conclusions and reflect on your own performance with regard to current and future practice as an independent professional learner. It is therefore a useful source of information for your CPD profile should you be audited by the Health and Care Professions Council (HCPC).

The external examiner will review this reflective report which should cross reference to the evidence contained in the portfolio. This may lead to further discussion during the *viva voce.*

Candidate's Reflective Practice Statement Part 1.

Summarise your role within the laboratory in the context of this section.

Section 7.22 Candidate's Reflective Practice Statement Part 2.

The ethos of undertaking reflective practice should be the recognition that it is a naturally occurring characteristic of those wishing to develop. How you complete this section is personal to your own circumstances. It should be approached by recognising you have a responsibility to demonstrate self-awareness when analysing gaps in your knowledge. This is therefore an opportunity to reflect on aspects of training, the application of new knowledge and skills, and how goals have been achieved.

Personal reflection on training and examples of evidence for this section

About this document

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Clinical Biochemistry

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