

RECORD OF LABORATORY TRAINING FOR THE IBMS SPECIALIST DIPLOMA **BLOOD SCIENCES**



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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

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REFERENCE

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 for professional development specific to them. It is not 'owned' by the laboratory. If you are re-employed in 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. The Specialist Portfolio in Blood Sciences is compiled of sections that contain modules in Clinical Biochemistry, Haematology and Transfusion Science. The award is achieved by completing two or three sections in the following combinations:
 - Clinical Biochemistry and Haematology
 - Clinical Biochemistry and Hospital Transfusion Practice
 - Clinical Biochemistry, Haematology and Hospital Transfusion Practice

Please note: A combination of only Haematology and Hospital Transfusion Practice together is not an option. 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 modules 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 three 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 healthcare 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 external 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 techniques 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.



7A

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 defined 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 7A.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 of tests and its 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 and/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.

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7A.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 7A.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.

REFERENCE

Section 7A.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 or random-access analyser and open or closed systems.
4. General principles of calibration of automated analyser 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.

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7A.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 7A.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.

REFERENCE

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 devices (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 disturbances 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.
- c. Monitor results, consider possible interference, and take appropriate action.
- d. 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.

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7A.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 7A.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.

REFERENCE

Section 7A.4 Acid-Base Disorders

Core analytes: hydrogen ion [pH], bicarbonate, pO₂, pCO₂, 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, pO₂, pCO₂ 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, pO₂ and pCO₂ 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.

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7A.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 7A.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.

REFERENCE

Section 7A.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 applied locally, including those appropriate to children.
4. Additional analyses, measures and variables that are required in the calculation of GFR, (e.g 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, (e.g. plasma potassium, PTH, vitamin D and haematinic investigations).
10. Categorisation of chronic kidney disease stages based on clinical findings and GFR values.
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.

Internal 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 7A.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.

REFERENCE

Section 7A.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 use 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
 - α 1-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 or 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.
- d. 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).

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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.

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7A.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 7A.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.

REFERENCE

Section 7A.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 variants 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 & GPs.
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

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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.

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7A.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 7A.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.

REFERENCE

Section 7A.8 Lipids, Lipoproteins and Cardiovascular Disease
Subsection 7A.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 implication 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

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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:

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Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7A.8 Lipids, Lipoproteins and Cardiovascular Disease

Subsection 7A.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.

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7A.8 Lipids, Lipoproteins and Cardiovascular Disease
Subsection 7A.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.
- 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:

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.

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7A.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 7A.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.

REFERENCE

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.

REFERENCE

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.

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7A.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 7A.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.

REFERENCE

Section 7A.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.

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7A.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 7A.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.

REFERENCE

Section 7A.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 type 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 increase 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

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Trainer's signature:

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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.

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7A.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 7A.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.

REFERENCE

Section 7A.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 automated method.
- c. Validate the results taking note of analytical and clinical error messages.
- d. Monitor results, consider possible interference, 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.

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7A.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 7A.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.

REFERENCE

Section 7A.13 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 7.13a, and exposure to the measurement of the drugs in section 7.13b.

Subsection 7A.13a 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.
9. 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.

REFERENCE

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.

Internal Assessor's signature:

Internal Assessor's name:

Date:

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 drugs, including:
 - immunoassay
 - high performance liquid chromatography
 - ion selective electrodes
4. The significance of results outside the therapeutic range.
5. Factors affecting sample integrity and appropriate corrective action.
6. Specific risks associated with the reagents or method.
7. Relevant internal and external quality assurance procedures.

COMPETENCE

Be able to:

- a. Confirm that the sample was collected at the optimum time since last dose.
- b. Perform the timely analysis of antimicrobial drug in plasma/serum.
- c. Validate the results.
- d. Monitor results, consider possible interference, and take appropriate action.
- e. Report results appropriately 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.

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7A.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 7A.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.

REFERENCE

Section 7A.14 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 the 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 gaps.
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 effect posed 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.

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7A.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 7A.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.

REFERENCE

Section 7A.15 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 diagnoses.
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:

1. Assess suitability of samples for analysis on the appropriate laboratory analyser and take appropriate action if not suitable.
2. Perform the timely analysis of plasma/serum: T4 total or free, T3 total or free (depending on local repertoire), TSH. Be aware of the methods available for TPO analysis.
3. Validate the results.
4. Monitor results, consider possible interference, and take appropriate action.
5. Report results appropriate to the significance of the result.
6. 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.

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7A.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 7A.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.

REFERENCE

Section 7A.16 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 method 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.
- f. 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.

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7A.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 7A.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.

REFERENCE

Section 7A.17 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 method employed and sample requirements.
8. Dynamic function tests requiring estimation 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 where 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 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.

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7A.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 7A.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.

REFERENCE

7B

Haematology

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 working in haematology. If part of the service there is an option in hospital transfusion practice. Candidates completing these are expected to be able to demonstrate the application of knowledge and skills defined 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 7B.1 Primary Investigations of Blood and its Components
Subsection 7.1a Cell counting and haemoglobin concentration measurement

KNOWLEDGE

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

1. Principles and practice of the automated cell counting/concentration methods for:
 - Leucocytes
 - Erythrocytes (RBCs)
 - Platelets
 - Reticulocytes
 - Nucleated RBCs
 - White cell differentials
 - RBC parameters
 - Haemoglobin
2. The use of calibration and control materials and how to deal with out of limit values.
3. Correct preparation of samples for testing and pre-analytical factors that could affect accuracy of the results.
4. Effects of haemolysis, lipaemia, icterus, microthrombi, pre-analytical variables and storage conditions on laboratory results.
5. The use of reference values and the significance of abnormal results.
6. Limitations of tests and further investigations that may be required.
7. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

- a. Check the suitability of sample quality for analysis.
- b. Match samples to patient unique identification and confirm urgency of analysis.
- c. Prepare and operate named automated analysers for routine use.
- d. Perform analysis in accordance with standard laboratory procedure.
- e. Critically evaluate results and understand the process of auto-validation, delta checks, reference ranges and conditional ranges.
- f. Complete all relevant documentation in accordance with quality assurance 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.

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7B.1 Primary Investigations of Blood and its Components
Subsection 7B.1b Erythrocyte sedimentation rate (ESR)/plasma viscosity

KNOWLEDGE

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

1. Principles and purpose of ESR measurement and environmental effects on the accuracy of results.
2. Principles and purpose of measurement of plasma viscosity.
3. Relevance of these measurements in the diagnosis and monitoring of disease.
4. Urgent scenarios in which ESR measurement is important.
5. Principles of instrumentation used for ESR and plasma viscosity measurement.
6. Reference values and the significance of abnormal results.
7. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

- a. Prepare and operate named automated analysers for routine use.
- b. Prepare samples for manual ESR technique if method is used locally.
- c. Perform named tests in accordance with standard laboratory procedure.
- d. Identify abnormal results and likely significance to clinical detail.
- e. Complete 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.

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7B.1
Subsection 7B.1c

Primary Investigations of Blood and its Components
Identification and enumeration of peripheral blood cells by microscopy

KNOWLEDGE

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

1. Principles and application of light microscopy.
2. Principles and practice of staining blood cells by Romanowsky staining.
3. Use of slidemaker/strainers.
4. Pre-analytical variables that will affect the appearance of blood cells.
5. Mechanisms of normal haemopoiesis.
6. Recognition of normal and abnormal red cell morphology, their relationships to red cell indices and clinical significance.
7. Normal morphological features of the myeloid and lymphoid series of white blood cells.
8. Significance of abnormal or immature white blood cells on the peripheral blood film and their significance.
9. Key features of blasts and signs of dysplasia.
10. Abnormal platelet morphology and numbers on the peripheral blood film and their significance.
11. Normal reference values and the significance of abnormal results.
12. Internal quality control and external quality assurance procedures, including digital or standard NEQAS schemes.

COMPETENCE

Be able to:

- a. Prepare and stain blood films of suitable quality for morphological analysis.
- b. Set up a microscope for viewing blood films.
- c. Accurately identify morphological features of normal and abnormal cells.
- d. Perform tests in accordance with standard laboratory procedures.
- e. Manually enumerate WBC differential counts.
- f. Estimate the platelet count from the blood film and confirm accuracy of automated count.
- g. Assess platelet clumping and adhesion to neutrophils.
- h. Identify possible abnormalities and likely significance to clinical details.
- i. Refer samples for further testing according to abnormalities.
- j. Complete documentation in accordance with quality assurance 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.

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7B.1 Primary Investigations of Blood and its Components
Subsection 7B.1d Infectious mononucleosis

KNOWLEDGE

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

1. The principles and practice of the screening test for infectious mononucleosis (IM).
2. Blood count, serological and morphological features of infectious mononucleosis.
3. Limitations of IM screening tests.
4. Differential diagnosis if a patient presents with signs of IM but screening gives a negative result.
5. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

- a. Perform tests in accordance with standard laboratory procedure.
- b. Clearly distinguish between positive, negative and equivocal results.
- c. Complete 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.

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7A.1 Primary Investigations of Blood and its Components
Subsection 7A.1e Screening test for sickle cell haemoglobin (HbS)

KNOWLEDGE

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

1. Principles and practice of the screening test for sickle cell haemoglobin (HbS).
2. Limitations of HbS screening tests.
3. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

- a. Prepare samples and perform tests in accordance with standard laboratory procedure.
- b. Clearly distinguish between positive, negative and equivocal results.
- c. Complete documentation in accordance with quality control and audit requirements.
- d. Describe local clinical procedures to follow up positive or negative results.

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.

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7B.1 Primary Investigations of Blood and its Components
Subsection 7B.1f Malaria parasites

KNOWLEDGE

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

1. Geographical occurrence of malaria.
2. Risk assessment protocol for viral haemorrhagic fever (VHF) assessment prior to malaria request.
3. Techniques for detecting the presence of human malaria parasites, including:
 - Thick and thin blood films
 - Use of different stains
 - Immunochromatography
 - Awareness of other tests (e.g. PCR, QBC)
4. Presenting clinical symptoms of suspected cases and haematological changes.
5. Different types of malaria parasites.
6. The life cycle of malarial parasites and the stages found in the blood.
7. The effect of drug treatment on detection.
8. The limitations of techniques employed.
9. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

- a. Prepare samples and perform tests in accordance with standard laboratory procedure.
- b. Clearly distinguish between positive, negative and equivocal results.
- c. Complete documentation in accordance with quality assurance and audit requirements.
- d. Describe the local clinical procedures to follow up positive or negative results.
- e. Recognise malarial parasites on blood films.
- f. Estimate malaria parasitaemia, knowing when this should be undertaken, and its significance.

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.

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7B.1 Primary Investigations of Blood and its Components
Subsection 7B.1g Coagulation screening

KNOWLEDGE

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

1. Components of the *in vivo* and *in vitro* haemostatic pathways and their modes of action.
2. Principles and practice of techniques for measuring prothrombin (PT) and which clotting factors are involved.
3. Principles and practice of the techniques for measuring activated partial thromboplastin time (APTT) and which clotting factors are involved.
4. Principles of instrumentation used to assess haemostasis function.
5. Pre-analytical variables that can affect results.
6. Normal reference values and the significance of abnormal results.
7. The relationship between abnormal PT and APTT and other laboratory tests (e.g. full blood count and liver function tests).
8. Principles and practice of the techniques for measuring thrombin time (TT) and reptilase time (RT).
9. Effects of anticoagulant therapy on PT, APTT and TT measurement.
10. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

- a. Check the suitability of sample quality for analysis.
- b. Match samples to patient unique identification and confirm urgency of analysis.
- c. Measure prothrombin time (PT) and activated partial thromboplastin time (APTT) in accordance with standard laboratory procedure.
- d. Critically evaluate results.
- e. Identify samples that may require further investigations.
- f. Complete documentation in accordance with quality assurance 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.

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7B.1 Primary Investigations of Blood and its Components
Subsection 7B.1h Fibrinogen

KNOWLEDGE

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

1. Components of the *in vivo* and *in vitro* haemostatic pathways and their modes of action.
2. Laboratory investigation and clinical emergency of suspected disseminated intravascular coagulation (DIC).
3. Principles and practice of fibrinogen estimation.
4. How to distinguish between afibrinogenemia, hypofibrinogenemia and dysfibrinogenemia.
5. Principles of instrumentation used to estimate fibrinogen.
6. Pre-analytical variables that can affect results.
7. Normal reference values and the significance of abnormal results.
8. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

- a. Check the suitability of sample quality for analysis.
- b. Match samples to patient unique identification and confirm urgency of analysis.
- c. Prepare assay reagents and controls for use.
- d. Prepare and operate named automated analysers for use.
- e. Prepare and check controls are within acceptable limit.
- f. Perform analysis in accordance with standard laboratory procedures.
- g. Identify problems that may affect result and take remedial action.
- h. Identify samples that may require further investigations.
- i. Complete documentation in accordance with quality assurance 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.

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7B.1 Primary Investigations of Blood and its Components
Subsection 7B.1i Fibrin degradation products

KNOWLEDGE

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

1. Components of the *in vivo* and *in vitro* haemostatic pathways and their modes of action.
2. Principles and practice of D-dimer estimation.
3. Principles of the instrumentation and manual method used to detect fibrin degradation products.
4. Pre-analytical variables and interacting substances that can affect results.
5. Normal reference values and the significance of abnormal results.
6. Use of D-dimer for the investigation of suspected cases of venous thromboembolism.
7. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

- a. Check the suitability of sample quality for analysis.
- b. Match samples to patient unique identification and confirm urgency of analysis.
- c. Perform analysis in accordance with standard laboratory procedures.
- d. Identify problems that may affect result, and take remedial action.
- e. Identify samples that may require further investigations or action.
- f. Complete documentation in accordance with quality assurance 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.

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7B.1 Primary Investigations of Blood and its Components
Subsection 7B.1j Anticoagulant therapy

KNOWLEDGE

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

1. Principles of heparin and vitamin K antagonist (VKA) therapy.
2. Principles and practice of monitoring anticoagulant therapy with unfractionated heparin (UFH), low molecular weight heparin and related anticoagulants (e.g. danaparoid, fondaparinux).
3. Principles and practice of the international normalised ratio (INR) system for monitoring VKA therapy.
4. Principles of instrumentation used to determine INR.
5. Pre-analytical variables that can affect results.
6. Therapeutic ranges and significance of out of range results.
7. Principles, practice and limitations of assessing direct thrombin inhibitor (DTI) and direct factor Xa inhibitor (DFXaI) therapy with routine coagulation screening tests and specific assays for DTI and DFXaI.
8. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

- a. Check the suitability of sample quality for analysis.
- b. Match samples to patient unique identification and confirm urgency of analysis.
- c. Prepare test reagents and controls for use.
- d. Prepare and perform INR in accordance with standard laboratory procedures.
- e. Prepare and perform APTT in accordance with standard laboratory procedures.
- f. Prepare and perform anti-Xa assays for LMWH and related anticoagulants, UFH and DFXaIs in accordance with standard laboratory procedure.
- g. Prepare and check controls are within acceptable limit.
- h. Identify problems that may affect results and take corrective action.
- i. Identify samples that may require further investigations or action.
- j. Complete documentation in accordance with quality assurance 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.

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7B.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 7B.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.

REFERENCE

Section 7B.2 Iron Deficiency Anaemia and Iron Overload

KNOWLEDGE

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

1. Normal erythropoiesis and production of haemoglobin.
2. Normal iron metabolism and storage.
3. The effect of iron deficiency on red cell indices, including reticulocyte parameters and red cell morphology.
4. The effect of iron overload on red cell indices.
5. Clinical causes of iron deficiency, functional iron deficiency and iron overload.
6. Laboratory tests available to assess iron status (e.g. serum ferritin, serum transferrin, serum iron, zinc protoporphyrin).
7. Pre-analytical variables that can affect results.
8. Normal reference values and the significance of abnormal results.
9. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

- a. Check the suitability of sample quality for analysis.
- b. Match samples to patient unique identification and confirm urgency of analysis.
- c. Perform named techniques in accordance with standard laboratory procedures.
- d. Identify problems that may affect result and take corrective action.
- e. Identify samples that may require further investigations or action.
- f. Complete documentation in accordance with quality assurance 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.

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7B.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 7B.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 your training and examples of evidence for this section.

REFERENCE

KNOWLEDGE

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

1. Metabolism of vitamin B12 and folate, and their role in haemopoiesis.
2. Causes of vitamin B12 and folate deficiency.
3. Changes in blood cell indices and morphological features associated with vitamin B12 and folate deficiency.
4. Differences between, and causes of, megaloblastic and other types of macrocytic anaemia.
5. Red cell morphology and indices.
6. Folate cycle and role in cell production.
7. Neural tube defects.
8. Principles and practice of relevant techniques for the measurement of vitamin B12 and folate.
9. Limitations of tests and further investigations that may be required.
10. Reference values and the significance of abnormal results.
11. Internal quality control and external quality assessment procedures.

COMPETENCE**Be able to:**

- a. Check the suitability of sample quality for analysis.
- b. Match samples to patient unique identification and confirm urgency of analysis.
- c. Perform named techniques to measure vitamin B12 and folate status in accordance with standard laboratory procedures.
- d. Identify problems that may affect the result and take corrective action.
- e. Identify samples that may require further investigation or action.
- f. Complete documentation in accordance with quality assurance 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.

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7B.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 7B.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 your training and examples of evidence for this section.

REFERENCE

7C

Hospital Transfusion Practice

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 working in haematology with an option in hospital transfusion practice. Candidates completing these sections are expected to be able to demonstrate the application of knowledge and skills defined 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

KNOWLEDGE

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

1. The basis of the major blood group systems (e.g. genes, antigens and antibodies) and their clinical significance in transfusion medicine.
2. Principles of the indirect antiglobulin test (IAT), and of commonly used technologies available for detection of clinically significant antibodies.
3. Factors affecting antigen-antibody reactions *in vitro*.
4. Principles of serological tests used in manual and automated blood grouping and antibody screening, their appropriate use and potential sources of error.
5. Increased security afforded by the electronic transfer of ABO/D and antibody screening results from automation to the LIMS.
6. Specifications of reagents for patient blood grouping and antibody screening, the rationale behind their selection, and controls required depending on the testing system and methods used.
7. The use of potentiators in routine reagents and the potential difficulties in result interpretation.
8. Validation of reagents prior to use and actions to take in any cases where validation fails.
9. Minimum specifications for blood grouping in emergency situations, and before the issue of group compatible blood.
10. The relevance of erroneous and anomalous results of patient testing.
11. Internal quality control and external quality assessment procedures.
12. Local policies and procedures and national guidelines covering all of the above.

COMPETENCE

Be able to:

- a. Apply sample acceptance criteria and demonstrate understanding of the risks associated with inadequately labelled samples in transfusion.
- b. Perform indirect antiglobulin tests (IAT) and demonstrate an understanding of possible sources of error dependent on the technology used and the patient's clinical condition.
- c. Perform blood grouping and antibody screening tests using manual and automated methods.
- d. Complete documentation accurately and in accordance with quality control and audit requirements, use IT and follow procedures to minimize the risk of transcription error.
- e. Select and apply appropriate controls, recognise control failures and identify further actions required.
- f. Interpret patient blood grouping and antibody screening results, recognise anomalies and identify further actions required.
- g. Provide safe blood components for patients, where clinically necessary, before a confirmed ABO/D result can be established.

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.

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7C.1 Patient and Donor ABO/D Typing and Antibody Screening
Subsection 7C.1b Investigation of ABO and RhD anomalies

KNOWLEDGE

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

1. Clinical and laboratory factors that may affect results of ABO/D typing.
2. Clinical and laboratory factors that may lead to anomalous results of ABO/D typing.
3. Principle and practice of investigating blood group anomalies in specific patient groups (e.g. paediatric, elderly and immunosuppressed patients).
4. Principles and practice of investigating blood group anomalies in various clinical and technical scenarios, including:
 - Haemopoietic stem cell transplantation
 - Presence of cold agglutinins
 - Transfusion reactions
 - Potential 'wrong blood in tube
5. The scientific basis and significance of ABO subgroups and weak/partial D types in patients.
6. Limitations of testing when using rare antisera.
7. How to interpret anomalous grouping results in clinical and laboratory circumstances and selection of safe and appropriate components for the patient.
8. Criteria and trigger factors for further testing or referral before a blood group can be assigned.
9. Local policies and procedures and national guidelines covering all of the above.

COMPETENCE

Be able to:

- a. Prepare samples and select reagents and controls.
- b. Select appropriate tests to investigate ABO/D anomalies and perform them in accordance with standard laboratory procedures.
- c. Interpret results of tests and controls and distinguish between normal, erroneous and anomalous results.
- d. Assign appropriate blood groups to patients to ensure safe transfusion practice.
- e. Identify samples requiring additional testing and possible referral.
- f. Complete documentation in accordance with quality assurance 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.

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7C.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 7C.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.

REFERENCE

Section 7C.2 Antibody Identification

KNOWLEDGE

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

1. The basis of the major blood group systems, characteristics of red cell antigens within each system and clinical significance of corresponding antibodies in pre-transfusion and antenatal scenarios.
2. Mechanisms of antigen:antibody reactions and their role in *in vivo* red cell destruction.
3. Principles, practice and application of the range of tests available to aid antibody identification.
4. How to positively identify antibody specificities using British Committee for Standards in Haematology (BCSH) guidance on inclusion.
5. How to systematically exclude antibody specificities as part of the antibody identification process.
6. Relevance of red cell phenotyping in antibody identification.
7. How to interpret results, recognise and deal with samples requiring further investigations.
8. Internal and external quality assurance procedures.
9. Local policies and procedures and national guidelines covering all of the above.

COMPETENCE

Be able to:

- a. Prepare samples, select reagents and controls.
- b. Perform routine red cell antibody identification tests in accordance with standard laboratory procedures.
- c. Interpret the result of antibody identification, and recognise cases requiring additional tests and/or clinical advice.
- d. Recognise the likely clinical significance of the antibody specificities identified and select safe blood components for transfusion.
- e. Complete documentation in accordance with quality assurance 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.

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7C.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 7C.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 your training and examples of evidence for this section.

REFERENCE

Section 7C.3 Red Cell Phenotyping

KNOWLEDGE

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

1. Relevance of red cell phenotyping in pre-transfusion and antenatal testing.
2. Rationale for extended red cell phenotyping for patients on long-term transfusion support, and know which groups of patients may require blood matched for antigens other than ABO and D.
3. Situations in which red cell phenotyping cannot be performed and genotyping is required.
4. Selection of reagents and controls for red cell phenotypes.
5. Requirements for validation of reagents prior to use.
6. Relevance of antithetical groups when performing red cell phenotypes.
7. Internal quality control and external quality assessment procedures.
8. Local policies and procedures and national guidelines covering all of the above.

COMPETENCE

Be able to:

- a. Recognise situations where phenotyping will not give a reliable result.
- b. Prepare samples and select reagents and controls.
- c. Perform extended red cell phenotyping in accordance with standard laboratory procedures.
- d. Identify appropriate antithetical and familial antigen groups required for a complete phenotype.
- e. Interpret results and distinguish between normal, unusual, erroneous and abnormal results.
- f. Complete documentation in accordance with quality control and audit requirements.
- g. Identify samples requiring referral for additional testing.

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.

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7C.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 7C.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 your training and examples of evidence for this section.

REFERENCE

Section 7C.4 Selection of Red Cells and Components

KNOWLEDGE

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

1. Criteria for the selection of donors and the mandatory tests performed on all donations.
2. Extended and additional testing performed on donations for specific patient categories (e.g. neonates).
3. Principles of blood component preparation, and the range of blood components available.
4. How to interpret tests and their results from other areas/disciplines of pathology (e.g. haematology and coagulation) in clinical context to determine transfusion requirements.
5. Alternatives to allogeneic blood transfusion.
6. Importance of communication with all staff groups involved in effective provision of transfusion support in routine and emergency situations.
7. Criteria for selection of red cells and components for patients with clinical conditions giving rise to special requirements (e.g. HSCT, IUT, neonates, AIHA, solid organ transplants, red cell antibodies).
8. Rationale for selection of red cells and components with additional specifications (e.g. irradiated, CMV negative, HbS negative, K- for females of child-bearing potential, phenotyped).
9. Relevant internal quality control and external quality assessment procedures.
10. Main requirements of national guidelines relating to the above.
11. Local policies and procedures and national guidelines covering all of the above.

COMPETENCE

Be able to:

- a. Determine what tests are required before issuing blood or components.
- b. Select the appropriate blood component to meet the patient's special requirements.
- c. Provide safe and effective blood and components for emergency use.
- d. Provide transfusion support in cases of major haemorrhage, demonstrating the ability to communicate effectively with all parties involved.
- e. Recognise the potential need for specialist products (e.g. cryoprecipitate, PCC).
- f. Complete documentation in accordance with quality control and audit requirements.
- g. Identify cases requiring specialist components, products or clinical advice.

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.

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7C.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 7C.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 your training and examples of evidence for this section.

REFERENCE

Section 7C.5 Pre-Transfusion Testing Procedures

KNOWLEDGE

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

1. Importance of pre-transfusion testing in establishing compatibility.
2. Value of a historical record in pre-transfusion procedures.
3. The role of IT and automation in improving security in pre-transfusion testing.
4. Criteria for suitability of samples for serological crossmatching/electronic issue, depending on the patient's recent transfusion and obstetric history.
5. Principles and practice of serological compatibility testing.
6. Principles and practice of 'electronic' and remote issue of blood and components and the criteria for use.
7. How to investigate an incompatible serological crossmatch.
8. Internal quality control and external quality assessment procedures.
9. Local policies and procedures and national guidelines covering all of the above.

COMPETENCE

Be able to:

- a. Determine what tests are required before issuing blood or components.
- b. Determine whether or not patients are suitable for electronic issue.
- c. Perform necessary compatibility tests in accordance with standard laboratory procedures.
- d. Clearly distinguish between normal and abnormal results.
- e. Evaluate requests for further blood components to decide whether additional samples/tests are required before issue.
- f. Complete documentation in accordance with quality control and audit requirements.
- g. Identify cases where additional testing or clinical advice is required.

Section 7C.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 7C.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 your training and examples of evidence for this section.

REFERENCE

Section 7C.6 Issuing of Blood Components and Products

KNOWLEDGE

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

1. Correct procedures for the labelling and issue of blood components and products by the transfusion laboratory for patient use.
2. Subsequent storage requirements and expiry times of thawed plasma products.
3. Relevant storage and transport criteria for issued blood components/products.
4. Procedures for traceability, recall, restocking and disposal of blood components and products.
5. Local policies and procedures and national guidelines covering all of the above.

COMPETENCE

Be able to:

- a. Prepare fresh frozen plasma (FFP) and cryoprecipitate for issue.
- b. Visually inspect blood components to ensure they are fit for use.
- c. Label and issue blood components/products via IT systems to ensure complete traceability.
- d. Manage requests for further red cells, components or products.
- e. Manage return of unused blood components/products.
- f. Complete 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.

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7C.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 7C.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 your training and examples of evidence for this section.

REFERENCE

Section 7C.7 Blood Stocks Management

KNOWLEDGE

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

1. Risks associated with inappropriate care and handling of blood components and products.
2. Principles of appropriate use of blood and blood components.
3. The requirement for traceability from donor to patient and vice versa.
4. The role of stock management in the efficient use of blood.
5. The role of the Blood Stocks Management Scheme (BSMS).
6. Local policies and procedures and national guidelines covering all of the above, including emergency blood management where national stock levels are 'critical'.

COMPETENCE

Be able to:

- a. Check stocks and place routine orders with blood services in accordance with standard laboratory procedures.
- b. Order blood and blood components in routine and non-routine situations.
- c. Sort and rotate stock to ensure the most efficient use of stock is achieved.
- d. Collect data for the BSMS and act on feedback to minimise wastage.

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.

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7C.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 7C.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 your training and examples of evidence for this section.

REFERENCE

Section 7C.8 Adverse Reactions and Events in Transfusion

KNOWLEDGE

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

1. Classification and characteristics of adverse reactions to transfusion.
2. Laboratory-based procedures for investigating suspected adverse reactions according to clinical presentation.
3. The process for internal and external recall.
4. The role of internal and external incident reporting (e.g. Serious Adverse Blood Reactions & Events [SABRE] / Serious Hazards of Transfusion [SHOT]) in reducing errors in blood transfusion.
5. Principles and application of root cause analysis.

COMPETENCE

Be able to:

- a. Respond to reports of suspected adverse reactions/events in accordance with standard laboratory procedures.
- b. Identify the probable 'type' of adverse reaction/event.
- c. Identify the samples required and refer for appropriate testing.
- d. Complete an internal and/or external recall in accordance with local laboratory procedures.
- e. Perform repeat testing on pre- and post-transfusion samples in cases of suspected haemolytic transfusion reactions.
- f. Interpret results in clinical context.
- g. Recognise when referral for additional testing is required.
- h. Complete documentation in accordance with quality control and audit requirement including relevant internal and external incident reporting.
- i. Inform the clinical and transfusion specialist staff of the outcome of laboratory investigation.
- j. Assess the need to report to SHOT and/or SABRE, and for internal SAE reporting.
- k. Take part in root cause analysis if required.

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.

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7C.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 7C.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 your training and examples of evidence for this section.

REFERENCE

Section 7C.9 Antenatal Testing and Procedures

KNOWLEDGE

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

1. Requirements for routine antenatal testing.
2. How to perform and interpret results of antenatal screening for red cell antibodies.
3. How identify samples requiring further investigation.
4. Clinical significance of red cell antibodies in the context of haemolytic disease of the fetus and newborn (HDFN).
5. Requirements for antenatal and post-natal follow up testing where clinically significant antibodies are detected.
6. Importance of communication in successful management of pregnancies in women with red cell antibodies.
7. Principles and application of routine anti-D prophylaxis (RAADP).
8. Principles of acid-elution/staining and flow cytometric methods for measuring fetal maternal haemorrhage (FMH).
9. How to interpret FMH results and instigate appropriate follow-up testing.
10. How to determine the dose of anti-D immunoglobulin required.
11. Local policies and procedures and national guidelines covering all of the above.

COMPETENCE

Be able to:

- a. Perform routine antenatal and post-natal testing.
- b. Identify cases where further investigation or action is required.
- c. Provide appropriate antenatal anti-D prophylaxis as RAADP, and to cover potentially sensitising events.
- d. Provide appropriate post-natal anti-D prophylaxis as a standard dose and to cover any identified FMH.
- e. Perform routine FMH testing by acid elution.
- f. Decide when samples require referral for additional or specialist testing.
- g. Communicate with all staff groups involved to ensure delivery of anti-D prophylaxis and appropriate laboratory follow up of pregnancies where red cell antibodies are identified.
- h. Complete documentation in accordance with quality assurance 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.

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7C.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 7C.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 your training and examples of evidence for this section.

REFERENCE

Section 7C.10 Haemolytic Disease of the Fetus and Newborn

KNOWLEDGE

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

1. Aetiology of haemolytic disease of the fetus and newborn (HDFN).
2. Significance of red cell antibodies in HDFN.
3. Criteria and methods for quantification of antibodies in pregnancy.
4. The need to differentiate between immune and prophylactic anti-D.
5. The role of paternal testing and fetal genotyping in monitoring HDFN.
6. Routine testing required on neonates and additional testing required when the mother has red cell antibodies.
7. Transfusion requirements for the treatment of HDFN.
8. Criteria for the selection of blood for intrauterine transfusion (IUT), exchange and top-up transfusions.

COMPETENCE

Be able to:

- a. Prepare samples, and select correct reagents and controls for all testing.
- b. Undertake compatibility testing and provide appropriate blood components for the fetus/neonate as IUT, exchange or top-up transfusion, in cases of HDFN due to red cell antibodies.
- c. Perform a direct antiglobulin test (DAT) on cord blood sample and comment on the significance of the results.
- d. Complete documentation in accordance with quality assurance 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.

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7C.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 7C.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 your training and examples of evidence for this section.

REFERENCE

Section 7C.11 Investigation of Red Cell Autoantibodies

KNOWLEDGE

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

1. The main reasons for *in vivo* sensitisation of red cells with immunoglobulins and/or complement in autoimmune haemolytic anaemias and post-transplantation.
2. The mechanism of *in vivo* red cell destruction.
3. Principles and practice of direct antiglobulin techniques (DAT) using poly- and monospecific antiglobulin reagents.
4. How a positive DAT may influence results of pre-transfusion testing.
5. How to provide blood for patients with autoantibodies.
6. Internal quality control and external quality assessment procedures.
7. How to interpret results and deal with samples requiring further investigations.

COMPETENCE

Be able to:

- a. Perform a DAT using poly- and monospecific reagents.
- b. Interpret results of tests and controls, and distinguish between normal, erroneous and anomalous results.
- c. Identify samples requiring further or additional testing.
- d. Complete documentation accurately 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.

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7C.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 7C.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 your training and examples of evidence for this section.

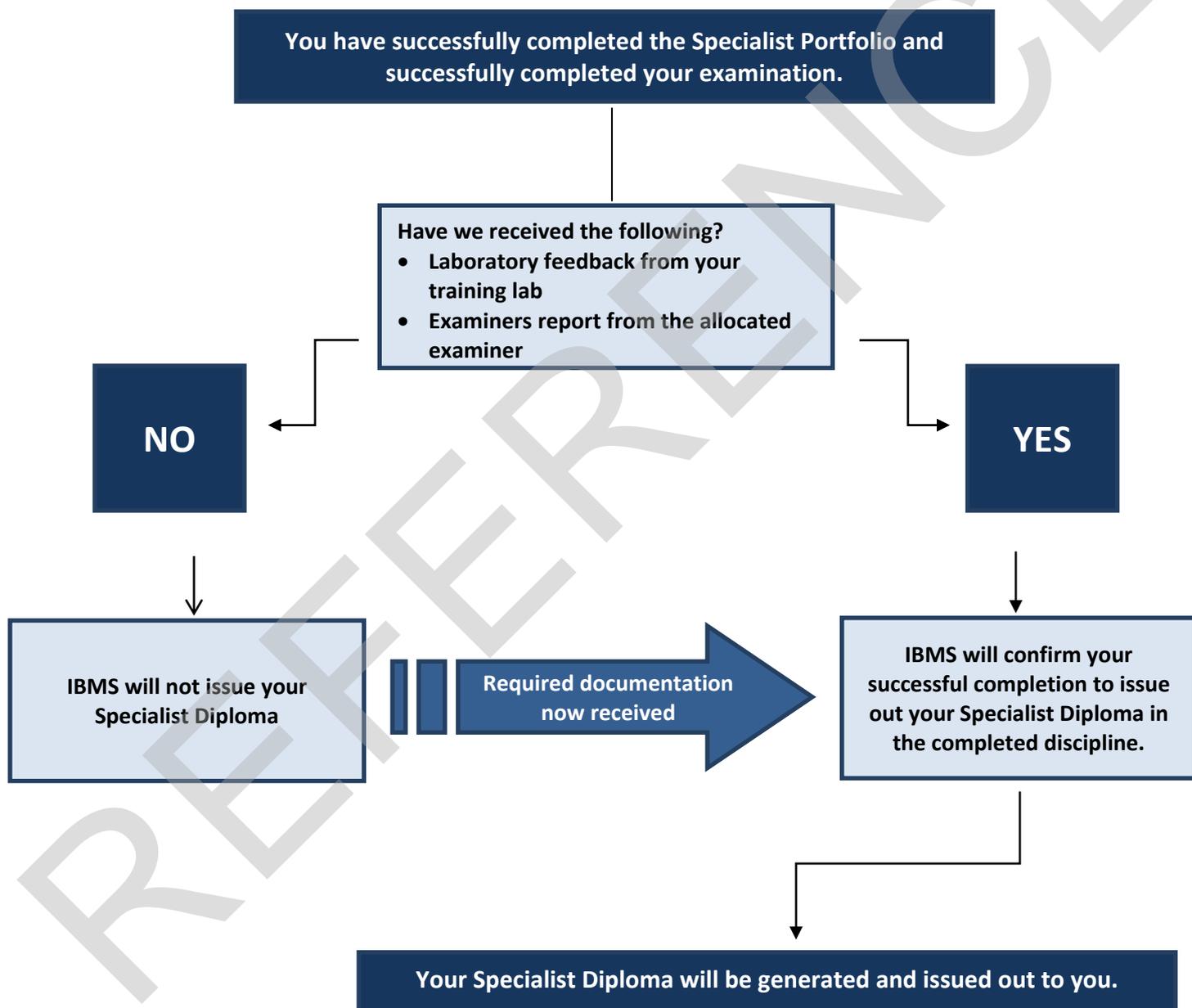
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Steps to IBMS Specialist Diploma

What is next: Your Specialist Diploma

Upon successful completion of the Specialist Portfolio, successful candidates are awarded the Specialist Diploma in the discipline(s) completed which will be issued out and sent to your provided address.

Note: The IBMS will also issue your award to your provided address.





About this document

Document title: Record of Laboratory Training for the Specialist Diploma in Blood Sciences

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Version: Version 4.2

Active date: July 2019

Review date: April 2021

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