RECORD OF LABORATORY TRAINING FOR THE IBMS SPECIALIST DIPLOMA CELLULAR PATHOLOGY

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

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

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

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

Contents

1. INTRODUCTION

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

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

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

1.4. The Specialist Portfolio is considered to be the property of the individual as it represents a commitment by the employer 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. All sections must be completed in order to express your ability to operate at the specialist level. Completion of the sections should follow the formal training programme that is submitted by your laboratory to the IBMS as part of the laboratory training approval process.

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

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

2. TRAINING

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

2.2. In-service training and assessment must demonstrate good scientific practice based on the knowledge and competence in the stated 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 trainee(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 actions based on best practice.

These are evidenced by the in-house assessments, 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 for 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 the 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

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 you a 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 report. A timeline will be agreed by the candidate, training officer and examiner to address any shortfalls. A subsequent full or partial examination will be required and this must be arranged through the IBMS.

6. COMPLETION OF REPORTS AND AWARD

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

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

Section 7:
Cellular Pathology

This section covers the range of proced nd diag stic tec iques that have been identified as being most relevant t practi as a sp ali biomedical scientist in Cellular
Pathology. Candidates com leting sec are expected to be able to demonstrate the applicati of knowle e and skill defined in section 2 of this portfolio.

It is accepted that ome of th tests m not be performed in the candidate's own laboratory. W st practical sk m not be achievable (for example through secondment to oth laborato to the level of someone performing them regularly nowledg nd understanding of its application is still required and may be exami ed.

There m e other tests, outside of those listed in this portfolio, that are part of the ining la ratory' basic repertoire in which the individual is required to be co petent. T an be recorded in the reflective statement at the end of each sub-se ion.

Section 7.1 Tissue Preparation Techniques

Subsection 7.1a Fixation

KNOWLEDGE

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

1. Changes that cells and tissue undergo when they are removed from the body.
2. Which samples require fixation and which do not.
3. Assessment of the risks of handling unfixed tissues.
4. Cross-linking and precipitating/denaturing mechanisms of fixation.
5. Mode of action of common fixatives.
6. Impact of poor fixation on diagnosis.
7. Practical impact of penetration rates of fixatives into tissues.
8. Fixation reaction time and its impact on specimen handling and processing.
9. Risks and hazards associated with the use and disposal of fixative solutions.
10. Properties of a perfect fixative and factors affecting optimal fixation.
11. Relative merits of fixatives used in cellular pathology.
12. Mechanism of fixation and relative merits and risks associated with:
    - Formalin
    - Glutaraldehyde
    - Bouin's fluid
    - Ethanol
    - Methanol
    - Acetone

COMPETENCE

You must be able to:

a. Select and use the appropriate fixative solution.
b. Ensure appropriate fixation of specimens.
c. Prepare fixative solutions following standard operating procedures and maintain appropriate records.
d. Apply appropriate safety practices to handling, using and disposal of fixative solutions.
e. Monitor environmental hazards associated with fixative solutions.
f. Troubleshoot problems which may arise, including root cause analysis, as appropriate.

EVIDENCE OF ACHIEVEMENT

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

Candidate has been assessed by 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 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 7.1 Tissue Preparation Techniques

Subsection 7.1b Tissue selection

KNOWLEDGE

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

1. Invasive and non-invasive surgical procedures and their relationship to the collection of histopathology and cytopathology specimens (e.g. resection, biopsy, fluids).
2. Key anatomical specimen sites.
3. Principles of tissue selection and the factors that need to be considered.
4. Need to log sample details and avoid sample mix up.
5. Need for further or alternate fixation methods.
6. Need to pin out specimens.
7. Principles of tumour grading and staging with respect to tissue sampling.
8. Rationale of tissue selection procedures in your own laboratory relative to your scope of practice.

COMPETENCE

You must be able to:

a. Apply appropriate criteria for tissue selection within the cellular pathology laboratory.
b. Assist with consultant-led specimen dissection and maintenance of appropriate specimen records.
c. Take dictation during specimen dissection.
d. Assist with the pinning out of specimens, as appropriate.
e. Label cassettes accurately in order to maintain the link between sample and request.
f. Transfer category A specimens from pot to cassette.
g. Troubleshoot problems which may arise, including root cause analysis, as appropriate.

EVIDENCE OF ACHIEVEMENT

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

Candidate has been assessed by 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 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 7.1 Tissue Preparation Techniques

Subsection 7.1c Decalcification

KNOWLEDGE

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

1. Homeostatic regulation of calcium levels.
2. Principles and practice of decalcification.
3. Different decalcifying solutions and their uses.
4. Risks and hazards associated with the use and disposal of decalcifying agents.
5. When and when not to use decalcifying agents.
6. Pathological significance of calcification in tissue.
7. How decalcification may affect use of subsequent methods of analysis.
8. Relative merits of decalcifying agents used in cellular pathology.

COMPETENCE

You must be able to:

a. Prepare and monitor specimens for decalcification, keeping audit trails as appropriate.
b. Select an appropriate decalcifying agent for a range of samples.
c. Perform decalcification procedures on a variety of calcified tissues.
d. Test for the completion of decalcification.
e. Prepare decalcified samples for processing, maintaining records as appropriate.
f. Troubleshoot problems which may arise, including root cause analysis, as appropriate.

EVIDENCE OF ACHIEVEMENT

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

Candidate has been assessed by 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 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 7.1 Tissue Preparation Techniques

Subsection 7.1d Tissue processing and embedding

KNOWLEDGE

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

1. Principles and practice of paraffin wax tissue processing for a range of tissues.
2. Influence of processing schedules on the quality of sample preservation and subsequent analysis.
3. Relative merits of different processing reagents and schedules.
4. Effects of heat, pressure and vacuum on tissue processing times and tissue morphology.
5. Principles and practice of resin processing.
6. Principles and practice of a range of tissue embedding techniques and potential errors that may arise.
7. Correct orientation for embedding a range of tissues.
8. Risks and hazards associated with the use and disposal of processing reagents.
9. Risks and hazards associated with the use and disposal of embedding media.

COMPETENCE

You must be able to:

a. Prepare tissues prior to processing.
b. Evaluate, select and use the appropriate processing protocol for a range of samples, maintaining audit trail records as appropriate.
c. Select and use the appropriate processing reagents.
d. Perform processing and embedding procedures on a range of tissues.
e. Select and use the appropriate embedding medium.
f. Use a range of automated tissue processors.
g. Correctly orientate a range of tissues when embedding.
h. Perform basic maintenance and troubleshooting of tissue processing and embedding equipment.
   Troubleshoot problems which may arise, including root cause analysis, as appropriate.

EVIDENCE OF ACHIEVEMENT

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

Candidate has been assessed by 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 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 7.1 Tissue Preparation Techniques

Subsection 7.1e Microtomy

KNOWLEDGE

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

1. Principles and practice of microtomy.
2. Action of a range of microtomes for the production of tissue sections.
3. Hazards associated with microtomes.
4. Principles and practice of section mounting.
5. Requirement for good quality sections.
6. Rationale underpinning the examination of deeper sections.
7. Section adhesives and the practical importance of their use.
8. The clinical significance and impact for patients of sections that are either too shallow or too deep.
9. The maintenance of clinical material for supplementary diagnostic and therapeutic testing.

COMPETENCE

You must be able to:

a. Set up and use a microtome safely and correctly cut wax, and where relevant, resin sections.
b. Adjust your personal workstation in an ergonomic manner.
c. Correctly orientate tissues for sectioning.
d. Cut a range of tissue sections to the required standard, maintaining appropriate audit trail records.
e. Follow standard operating procedures for levels, serials, section coils/curls, and step sections appropriately.
f. Perform basic maintenance and troubleshooting of microtomy equipment.
g. Evaluate microtomes and blades for routine use.
h. Troubleshoot problems which may arise, including root cause analysis, as appropriate.

EVIDENCE OF ACHIEVEMENT

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

Candidate has been assessed by 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 trainer on the knowledge and skill components required to complete this module. (Evidence in support 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 7.1 Tissue Preparation Techniques

Subsection 7.1f Cryotomy

KNOWLEDGE

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

1. Principles of cryotomy.
2. Application of frozen sections in cellular pathology.
3. Workings of a cryostat.
4. Principles of rapid freezing of tissues and how this relates to ice crystal artefact.
5. Diagnoses that may be made on frozen sections.
6. Preparation of cryostat sections.
7. Risks and hazards associated with the use and decontamination of cryostats.

COMPETENCE

You must be able to:

a. Orientate and freeze tissues appropriately.
b. Cut frozen sections to the required standard, maintaining audit trails, as appropriate.
c. Rapidly prepare frozen sections in a timely manner for 'intra-operative' diagnosis.
d. Decontaminate cryostats appropriately.
e. Perform basic maintenance and troubleshooting of cryotomy equipment.
f. Evaluate cryostats and blades for routine use.
g. Troubleshoot problems that may arise, including root cause analysis, as appropriate.

EVIDENCE OF ACHIEVEMENT

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

Candidate has been assessed by 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 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 7.1 Tissue Preparation Techniques

Subsection 7.1g Immunochemistry

KNOWLEDGE

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

Pre-analytical

1. Specific types of common fixatives and their characteristics, and their compatibility with subsequent immunocytochemical staining procedures (cross reference to 7.1a).
2. Specific types of common decalcifying agents and their characteristics, and their suitability and compatibility with subsequent immunocytochemical staining procedures (cross reference to 7.1c).
3. Effects on subsequent procedures with particular regard to immunocytochemical staining and the appearance of artefacts produced by processing.
4. Practice and problems associated with the production of samples suitable for immunocytochemical staining from cytological specimens, to include direct smears, cytocentrifuge and liquid-based preparations, fine-needle aspirates (FNAs), clots and cell blocks.
5. Potential problems associated with prolonged section storage and loss of tissue antigenicity (cross reference to 7.1e).
6. Challenges associated with the use of immunocytochemistry on resin sections.

Analytical

1. Familiarity with appropriate antigen retrieval, methodologies, including proteolytic enzyme digestion, heat mediated methods, and their mechanisms, as far as they are known.
2. Different proteolytic enzyme digestion methodologies (including working knowledge), awareness of the importance of optimal digestion, assessment of this in stained preparations.
3. Experience of different heat-mediated antigen retrieval methodologies (including working knowledge), various heat delivery systems, to include on instrument retrieval and heated baths, and various antigen retrieval solutions.
4. Methods for validation and verification of primary antibodies before introduction into diagnostic procedure and the requirement for assessment of batch-to-batch variation when in use.

KNOWLEDGE

Analytical (continued)

5. Concepts of sensitivity, specificity, avidity and affinity, and their significance to the quality of immunocytochemical staining.
6. Appropriate dilution of primary antibody reagents, and the effects on subsequent immunocytochemical staining results.
7. Problems of non-specific and inappropriate staining, their causes and methods for their reduction or elimination.
8. Necessity of including appropriate run controls and maintaining audit trails.

Post-analytical

1. Patterns and localisation in normal and abnormal cells and tissue types (Cross reference to relevant demonstration methods) in order to interpret immunocytochemistry preparations for routine diagnostic use.

COMPETENCE

You must be able to:

Pre-analytical

a. Pre-treat slides for immunocytochemistry following local standard operating procedures.

Analytical

a. Stain slides for immunocytochemistry using manual/automated methods following local standard operating procedures.
b. Optimise antibody titres, maintaining audit trails.

Post-analytical

a. Recognise staining patterns for core repertoire antibodies on normal tissues.
b. Determine the suitability of a completed immunocytochemistry run for further analysis based on included controls.
   Analyse the causes of suboptimal immunostaining.

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 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 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 7.1 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 laboratory role in the context of the previous sections:

Section 7.1 Candidate's Reflective Practice Statement Part 2.

The ethos of undertaking reflective practice should be the recognition that it is a naturally occurring characteristic of those wishing to improve. 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:

Section 7.2 Demonstration Methods

Subsection 7.2a Haematoxylin staining with and without eosin staining

Indicative repertoire: Haematoxylin and eosin, PTAH, Weigert's haematoxylin

KNOWLEDGE

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

1. Different types of haematoxylin formulae.
2. Haematoxylin to haematin oxidation process and its control.
3. Advantages, disadvantages and use of haematoxylins made with the following mordants:
   - Alum
   - Iron
   - Lead
4. Staining mechanism of alum haematoxylin.
5. Principles of haematoxylin and eosin staining and the value of it as the primary diagnostic stain in cellular pathology.
6. Reviewing cases and material microscopically for internal and external quality control.
7. Use of automated staining machines.
8. Monitoring the quality of haematoxylin and eosin staining.
9. Risks and hazards associated with the preparation and disposal of reagents used in haematoxylin and eosin staining.

COMPETENCE

You must be able to:

a. Follow demonstration methods accurately.

b. Select and use the correct haematoxylin and eosin solution, maintaining appropriate records.

c. Select and use the appropriate control materials, maintaining audit trails, as appropriate.

d. Use appropriate microscopy techniques to visualise methods.

e. Assess stained sections for quality.

f. Resolve any problems associated with the staining method, including root cause analysis, as appropriate.

g. Dispose of waste reagents safely.

h. Perform basic maintenance on automated staining machines and slide coverslippers.

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 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 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 7.2 Demonstration Methods

Subsection 7.2b Extracellular proteins and connective tissues

Indicative repertoire: Masson Trichrome, Haematoxylin Van Gieson, Congo Red, Sirius Red, Elastic Van Gieson, Reticulin, Collagen IV

KNOWLEDGE

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

1. Role of fibrin in tissues and the pathophysiology of fibrin formation.
2. Pathophysiology of amyloid formation and the different types of amyloid.
3. Principles and practice of routine staining methods for the demonstration of extracellular proteins.
4. Immunocytochemical methods available for the demonstration of amyloid.
5. Use of potassium permanganate pre-treatment prior to Congo red staining to differentiate between AL and AA amyloid.
6. Polarised light examination of Congo red-stained preparations.
7. Quality control materials and procedures used in extracellular protein demonstration.
8. Reviewing cases and material microscopically for internal quality control and external quality assessment.
9. Key clinical conditions where these demonstration methods may be of diagnostic value.

COMPETENCE

You must be able to:

a. Follow demonstration method protocols accurately and safely.
b. Select and use the correct staining method to demonstrate amyloid and fibrin.
c. Select and use the appropriate control materials.
d. Use appropriate microscopy techniques to visualise methods.
Identify stained extracellular protein.
f. Assess stained sections for quality, maintaining appropriate audit trail records.
g. Resolve any problems associated with the staining methods, including root cause analysis, as appropriate.
h. Dispose of waste reagents safely.

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.

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Date of completion:

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Trainer's signature:

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Date of completion:

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Internal Assessor's signature:

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Date:

Section 7.2 Demonstration Methods

Subsection 7.2c Carbohydrates, glycoproteins and mucins

Indicative repertoire: PAS, Alcian Blue, AB/DPAS, Toluidine Blue, Jones Methenamine Silver, GCDFP-15, CEA

KNOWLEDGE

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

1. Application and principles of carbohydrate demonstration.
2. Principles of the pathophysiology of carbohydrate formation and the pathological significance of variations of expression of carbohydrate.
3. Types of carbohydrate present in different tissues.
4. Principles and practice of routine staining and impregnation methods for the demonstration of carbohydrate.
5. Reviewing cases and material microscopically for internal and external quality control.
6. Key clinical conditions where these demonstration methods may be of diagnostic value.
7. Risks and hazards associated with carbohydrate demonstration methods.

COMPETENCE

You must be able to:

a. Follow demonstration method protocols accurately and safely.
b. Select and use the correct staining or impregnation method to demonstrate carbohydrate present in different tissues.
c. Select and use the appropriate control materials, maintaining appropriate audit trail records.
d. Use appropriate microscopy techniques to visualise methods.
e. Identify stained carbohydrate present in different tissues.
f. Assess stained sections for quality.
g. Resolve any problems associated with the staining methods, including root cause analysis as appropriate.
h. Dispose of waste reagents safely.

EVIDENCE OF ACHIEVEMENT

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Date of completion:

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Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7.2 Demonstration Methods

Subsection 7.2d Lipids

Indicative repertoire: Sudan Black, Oil Red O

KNOWLEDGE

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

1. Types of lipid stored in tissue.
2. Principles of the pathophysiology of lipid formation and the significance of variations in its expression.
3. Principles and practice of routine staining and histochemical methods for the demonstration of different lipids.
4. Reviewing cases and material microscopically for internal quality control and external quality assessment.
5. Key clinical conditions where these demonstration methods may be of diagnostic value.
6. Risks and hazards associated with lipid demonstration methods.

COMPETENCE

You must be able to:

a. Discuss the application of lipid demonstration techniques.
b. Follow demonstration methods protocols accurately and safely.
c. Select and use the correct histochemical method to demonstrate lipids present in different tissues.
d. Select and use the appropriate control materials, maintaining audit trail records as appropriate.
e. Use appropriate microscopy techniques to visualise methods.
f. Identify stained lipids present in different tissues.
g. Assess stained sections for quality.
h. Resolve any problems associated with the staining methods, including root cause analysis, as appropriate.
i. Dispose of waste reagents safely.

EVIDENCE OF ACHIEVEMENT

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Date of completion:

Trainer's name:

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:

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Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7.2 Demonstration Methods

Subsection 7.2e Infective agents

Indicative repertoire: PAS, Gram, ZN, Orcein, HPV, EBV, CMV, Grocott, Warthin & Starry, Wade Fite, Giemsa

KNOWLEDGE

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

1. Types of infective agents most commonly seen and the pathological significance of infective agent demonstration.
2. Cytopathic effects of common infective agents.
3. Principles and practice of routine staining and impregnation methods for the demonstration of infective agents.
4. Reviewing cases and material microscopically for internal quality control and external quality assessment.
5. Key clinical conditions where these demonstration methods may be of diagnostic value.
6. Risks and hazards associated with infective agent demonstration methods.
7. Clinical application of infective agent demonstration methods.

COMPETENCE

You must be able to:

a. Follow demonstration method protocols accurately and safely.
b. Select and use the correct staining or impregnation method to demonstrate infectious agents present in different tissues.
c. Select and use the appropriate control materials, maintaining appropriate audit trail records.
d. Use appropriate microscopy techniques to visualise methods.
e. Identify stained infectious agents present in different tissues.
f. Assess stained sections for quality.
g. Resolve any problems associated with the staining or impregnation methods, including root cause analysis, as appropriate.
Dispose of waste reagents safely.

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 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 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 7.2 Demonstration Methods

Subsection 7.2f Pigments and minerals

Indicative repertoire: Perls, Masson Fontana, Orcein, Von Kossa

KNOWLEDGE

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

1. Principles of pigment and mineral demonstration.
2. Principles of the pathophysiology of pigment and mineral formation and the types of pigments and mineral normally deposited in tissue.
3. Principles and practice of routine staining and impregnation methods for the demonstration and identification of the pigments and minerals.
4. Pathological significance of variations of expression of pigments.
5. Reviewing cases and material microscopically for internal quality control and external quality assessment.
6. Key clinical conditions where these demonstration methods may be of diagnostic value.
7. Risks and hazards associated with the demonstration of pigments and minerals.

COMPETENCE

You must be able to:

a. Follow demonstration methods protocols accurately and safely.
b. Select and use the correct staining or impregnation method to identify pigments and minerals present in different tissues.
c. Select and use the appropriate control materials, maintaining audit trail records.
d. Use appropriate microscopy techniques to visualise methods.
e. Identify stained pigments and minerals present in different tissues.
f. Assess stained sections for quality.
g. Resolve any associated problems with the visualisation, staining or impregnation methods including root cause analysis, as appropriate.
h. Dispose of waste reagents safely.

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 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 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 7.2 Demonstration Methods

Subsection 7.2g Epithelial markers

Indicative repertoire: CK5/6, CK7, CK20, Pan-cytokeratin, CDX-2, CEA, Ber-EP4, P40, P63

KNOWLEDGE

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

1. Role of cytokeratins within epithelial cells.
2. Role of other common epithelial markers within cells.
3. Principles and practice of cytokeratin demonstration.
4. Relevant antibody validation and verification procedures.
5. Reviewing cases and materials microscopically for internal quality control and external quality assessment.
6. Key clinical conditions where these demonstration methods have diagnostic value as individual markers and as components of diagnostic panels.
7. Application and principles of epithelial marker demonstration

COMPETENCE

You must be able to:

a. Follow demonstration method protocols accurately and safely.
b. Validate epithelial marker methods.
c. Select and use the appropriate control material, maintaining appropriate audit trails.
d. Identify stained epithelial cells present in different tissues.
e. Assess stained sections for quality
f. Resolve any associated problems with the staining methods including root cause analysis, as appropriate.
g. Dispose of waste reagents safely.

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.

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Date of completion:

Trainer's name:

Trainer's signature:

Candidate has answered questions set by 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 7.2 Demonstration Methods

Subsection 7.2h Muscle filament markers

Indicative repertoire: Desmin, smooth muscle actin, smooth muscle myosin

KNOWLEDGE

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

1. Role of muscle filament markers.
2. Principles and practice of muscle filament marker demonstration.
3. Relevant validation and verification procedures.
4. Reviewing cases and materials microscopically for internal quality control and external quality assessment.
5. Key clinical conditions where these demonstration methods may be of diagnostic value.

COMPETENCE

You must be able to:

a. Follow demonstration method protocols accurately and safely.
b. Select and use the appropriate control material, maintaining audit trail records.
c. Identify stained muscle filament markers present in different tissues.
d. Assess stained sections for quality.
e. Resolve any associated problems with the staining methods including root cause analysis, as appropriate.
f. Dispose of waste reagents safely.

EVIDENCE OF ACHIEVEMENT

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Candidate has been assessed by 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 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 7.2 Demonstration Methods

Subsection 7.2i Lymphoid markers

Indicative repertoire: CD3, CD5, CD10, CD15, CD20, CD21, CD23, CD30, CD45, CD79a

KNOWLEDGE

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

1. Role of lymphoid markers for the differentiation of lymphoid cell populations in health and disease.
2. Principles and practice of lymphoid marker demonstration.
3. Relevant antibody validation and verification procedures.
4. Reviewing cases and materials microscopically for internal quality control and external quality assessment.
5. Key clinical conditions where these demonstration methods may be of diagnostic value.
6. Application and principles of lymphoid marker demonstration as single entities or as panels.

COMPETENCE

You must be able to:

a. Review slides singly or as panels.
b. Follow demonstration methods protocols accurately and safely.
c. Select and use the appropriate control material, maintaining audit trail records.
d. Assess stained sections for quality.
e. Resolve any associated problems with the staining methods including root cause analysis, as appropriate.
f. Dispose of waste reagents safely.

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.

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Date of completion:

Trainer's name:

Trainer's signature:

Candidate has answered questions set by 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 7.2 Demonstration Methods

Subsection 7.2j Cell cycle markers

Indicative repertoire: Ki-67, Cyclin D1

KNOWLEDGE

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

1. Role of cell cycle markers in diagnostic cellular pathology.
2. Principles and practice of cell cycling marker demonstration.
3. Relevant antibody validation and verification procedures.
4. Reviewing cases and materials microscopically for internal quality control and external quality assessment.

COMPETENCE

You must be able to:

a. Follow demonstration method protocols accurately and safely.
b. Able to validate cell cycle marker methods.
c. Select and use the appropriate control material, maintaining appropriate audit trails.
d. Identify stained cell cycling present in different tissues.
e. Resolve any associated problems with the staining methods including root cause analysis, as appropriate.
f. Dispose of waste reagents safely.
g. Use semi-quantative scoring, including H-score and Quickscore.

EVIDENCE OF ACHIEVEMENT

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Candidate has been assessed by 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 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 7.2 Demonstration Methods

Subsection 7.2k Melanocyte markers

Indicative repertoire: Melan A, HMB45, S100, SOX 10

KNOWLEDGE

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

1. Role of melanin in normal human physiology and the role of melanocyte markers in cellular pathology.
2. Principles and practice of melanoma marker demonstration.
3. Relevant antibody validation and verification procedures.
4. Review cases and materials microscopically for internal quality control and external quality assessment.
5. Key clinical conditions where these demonstration methods have diagnostic value.

COMPETENCE

You must be able to:

a. Follow demonstration method protocols accurately and safely.
b. Select and use the appropriate control material, maintaining appropriate audit trails.
c. Identify stained melanoma markers present in different tissues.
d. Assess stained sections for quality.
e. Resolve any associated problems with the staining methods including root cause analysis, as appropriate.
f. Dispose of waste reagents safely.

EVIDENCE OF ACHIEVEMENT

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Date:

Section 7.2 Demonstration Methods

Subsection 7.2l Neuroendocrine markers

Indicative repertoire: Grimelius, chromogranin, neuron-specific enolase, hormone-specific antibodies

KNOWLEDGE

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

1. Role of neuroendocrine cells and the clinical value of neuroendocrine markers in diagnostic cellular pathology.
2. Principles and practice of neuroendocrine marker demonstration.
3. Relevant antibody validation and verification procedures.
4. Reviewing cases and materials microscopically for internal control.
5. Key clinical conditions where these demonstration methods may be of diagnostic value.

COMPETENCE

You must be able to:

a. Follow demonstration method protocols accurately and safely.
b. Select and use the appropriate control materials, maintaining appropriate audit trails.
c. Identify stained neuroendocrine cells present in different tissues.
d. Assess stained sections for quality.
e. Resolve any associated problems with the staining methods including root cause analysis, as appropriate.
f. Dispose of waste reagents safely.

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

Date of completion:

Trainer's name:

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Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7.2 Demonstration Methods

Subsection 7.2m Immunoglobulins

Indicative repertoire: Kappa, lambda, IgG, IgA, IgM, C3c

KNOWLEDGE

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

1. Role of immunoglobulins in immune and inflammatory responses.
2. Key clinical conditions where immunoglobulin demonstration methods may contribute to diagnosis of B-cell proliferations and autoimmune disease.
3. Principles and practice of immunoglobulin demonstration.
4. Relevant antibody validation and verification procedures.
5. Reviewing cases and material microscopically for internal quality control and external quality assessment.

COMPETENCE

You must be able to:

a. Follow demonstration method protocols accurately and safely.
b. Select and use the appropriate control material, maintaining appropriate audit trails.
c. Identify stained immunoglobulins present in different tissues.
d. Assess stained sections for quality.
e. Resolve any associated problems with the staining methods, including root cause analysis, as appropriate.
f. Dispose of waste reagents safely.

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Date of completion:

Trainer's name:

Trainer's signature:

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Date of completion:

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Date:

Section 7.2 Demonstration Methods

Subsection 7.2n Companion diagnostics

Indicative repertoire: Oestrogen receptor, progesterone receptor, HER2, PD-1/PD-L1, Alk, Ros-1, BRAF V600E

KNOWLEDGE

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

1. Pathophysiology of oestrogen, progesterone, and HER2 receptors.
2. Role of prognostic markers in disease management in breast and, additionally, for HER2 in gastric cancer.
3. Principles and practice of predictive and prognostic marker demonstration.
4. Reviewing cases and material microscopically for internal quality control and external quality assessment.
5. Principles of quality control and assurance, relating to false positive and false negative rates.

COMPETENCE

You must be able to:

a. Follow demonstration method protocols accurately and safely.
b. Select and use the appropriate control material, maintaining appropriate audit trail records.
c. Identify stained companion diagnostics markers in different tissues.
d. Assess stained sections for quality.
e. Resolve any associated problems with the staining methods, including root cause analysis, as appropriate.
f. Dispose of waste reagents safely.
g. Monitor ongoing consistency of staining of companion diagnostic markers.
h. Use semi-quantitative scoring (H-score and Quickscore) and methods for scoring HER2 staining in accordance with current best practice guidelines.

EVIDENCE OF ACHIEVEMENT

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

Candidate has been assessed by 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 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 7.2 Reflective Practice

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

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

Candidate's Reflective Practice Statement Part 1.

Summarise your laboratory role in the context of the previous sections:

Section 7.2 Candidate's Reflective Practice Statement Part 2.

The ethos of undertaking reflective practice should be the recognition that it is a naturally occurring characteristic of those wishing to improve. 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:

Section 7.3 Specialist Tissues

Subsection 7.3a Muscle biopsies

Indicative repertoire: ATPase pH9.4, ATPase pH4.2, ATPase pH4.6, NADH transferase, Gomori, NADH, COX, Acid Phosphatase, Lipid, PAS, Succinic dehydrogenase.

KNOWLEDGE

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

1. Principles of muscle biopsy and clinical application of demonstration techniques used in the diagnosis of muscle disease.
2. Principles and practice of preparation of fresh, frozen, fixed and electron microscopy muscle samples.
3. Principles and practice of routine staining and histochemical methods for muscle including identification of stained elements, quality assessment and resolution of associated problems.
4. Ancillary methods used with muscle samples.
5. Risks and hazards associated with muscle samples.

COMPETENCE

You must be able to:

a. Discuss the clinical application of demonstration techniques used in the diagnosis of muscle disease.
b. Prepare fresh muscle biopsy tissue for frozen, fixed and electron microscopy analysis.
c. Correctly select and use staining or histochemical methods to identify elements within muscle biopsies.
d. Select and use the appropriate control material.
e. Use appropriate microscopy techniques to visualise methods.
f. Assess stained sections for quality.
g. Identify demonstrated structural, histochemical and cellular elements within muscle biopsies.
h. Resolve any associated problems with the staining or histochemical methods, including root cause analysis, as appropriate.
i. Dispose of waste reagents and residual material safely.

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 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 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 7.3 Specialist Tissues

Subsection 7.3b Nerve biopsies

Indicative repertoire: Haematoxylin and eosin, Luxol fast blue, Gomori trichrome, Glial fibres, Myelin, Neurofibrillary tangles, Senile Plaques, Nissl substance.

KNOWLEDGE

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

1. Principles of nerve biopsy sampling.
2. Principles and practice of direct visualisation, routine staining and histochemical and impregnation methods for nerve tissue.
3. Principles and practice of handling fresh, frozen and fixed nerve samples.
4. Ancillary methods used with nerve samples.
5. Risks and hazards associated with nerve samples.
6. Diagnostic relevance of nerve biopsy.

COMPETENCE

You must be able to:

a. Discuss the application of nerve biopsy demonstration techniques.
b. Select and use correct visualisation, staining, histochemical or impregnation methods to identify elements within nerve biopsies.
c. Select and use control materials, maintaining audit trails.
d. Use microscopy techniques to visualise methods, as appropriate.
e. Identify stained elements within nerve biopsies.
f. Assess stained sections for quality.
g. Resolve any problems associated with the visualisation, staining, histochemical or impregnation methods.
h. Dispose of waste reagents and residual material safely.

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 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 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 7.3 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 laboratory role in the context of the previous sections:

Section 7.3 Candidate's Reflective Practice Statement Part 2.

The ethos of undertaking reflective practice should be the recognition that it is a naturally occurring characteristic of those wishing to improve. 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:

Section 7.4 Molecular Testing

Subsection 7.4a *In situ* hybridisation

Indicative repertoire: HER2, HPV, EML4-Alk fusions, EBV, immunoglobulin mRNA.

KNOWLEDGE

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

1. Principles of *in situ* hybridisation techniques, including the use of fluorescence and chromogenic methodologies.
2. Role of the clinical application of *in situ* hybridisation in diagnostic pathology.

COMPETENCE

You must be able to:

a. Prepare cell and formalin-fixed, paraffin wax-embedded (FFPE) samples for DNA and RNA analysis.
b. Stain tissue sections using *in situ* hybridisation.
c. Select control material, maintaining appropriate audit trails.
d. Use appropriate microscopy techniques to visualise stained material.
e. Assess quality in prepared sections.
f. Clearly distinguish between positive, negative and equivocal results.
g. Resolve problems associated with the demonstration methods, including root cause analysis, as appropriate.
h. Dispose of waste reagents and residual material safely.

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 trainer to work in accordance with standard laboratory procedures. (No other evidence is required).

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Trainer's name:

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 7.4 Molecular Testing

Subsection 7.4b Molecular analysis of sample homgenates

Indicative repertoire: Braf V600e, KRAS, EGFR, ROS-1, T-cell gene rearrangement studies.

KNOWLEDGE

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

1. Principles of molecular biology methodology.
2. Clinical value and application of molecular biology techniques in diagnostic cellular pathology.
3. Role of molecular methods using sample homogenates in the diagnosis/prognosis/therapeutic implications of key named pathologies.

COMPETENCE

You must be able to:

a. Prepare sample homogenates from cell samples for DNA and RNA analysis.
b. Select and use control material, maintaining appropriate audit trails.
c. Assess preparations for nucleic acid integrity and purity.
d. Undertake (q)PCR analysis for identification of specific gene sequences.
e. Resolve problems associated with demonstration methods, including root cause analysis, as appropriate.
f. Dispose of waste reagents and residual materials safely.

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 trainer to work in accordance with standard laboratory procedures. (No other evidence is required).

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Trainer's name:

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Date of completion:

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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 7.4 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 laboratory role in the context of the previous sections:

Section 7.4 Candidate's Reflective Practice Statement Part 2.

The ethos of undertaking reflective practice should be the recognition that it is a naturally occurring characteristic of those wishing to improve. 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:

Section 7.5 Microscopy and image capture
Subsection 7.5a Light microscopy

KNOWLEDGE

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

1. Principles and application of light microscopy in clinical diagnostic procedures.
2. Microscopic recognition of normal histological tissue and some key features of pathological tissues.

COMPETENCE

You must be able to:

a. Set up a light microscope for Kohler illumination.
b. Identify normal tissue/cellular appearances under the microscope and be able to recognise commonly occurring pathological features.
c. Recognise special stains on normal tissue types/controls.
d. Recognise common staining patterns of normal tissues using immunocytochemistry.

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 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 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 Microscopy
Subsection 7.5b Electron microscopy

KNOWLEDGE

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

1. Principles of electron microscopy.
2. Clinical applications of transmission electron microscopy in diagnostic techniques.
3. Applications of scanning electron microscopy in diagnostic techniques.
4. Principles and application of associated techniques.

COMPETENCE

You must be able to:

a. Prepare semi-thin and ultra-thin sections for electron microscopy.
b. Prepare electron microscopy images from prepared samples.

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 trainer to work in accordance with standard laboratory procedures. (No other evidence is required).

Date of completion:

Trainer's name:

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 7.5 Microscopy
Subsection 7.5c Digital pathology, image capture and analysis

KNOWLEDGE

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

1. Principles of digital pathology systems, z-stacking, scanning, storage and syst access and security.
2. The use of macroscopic and microscopic images in professional practi e (e.g. teaching, MDT, referral etc).
3. Principles of recording cellular pathology images.
4. Need for accurate storage of images under the terms of appr riate D Protecti legislation.
5. Know the process for image back-up via IT network

COMPETENCE

You must be able to:

a. Scan slides for digital pathology stem assessing ali of scanned images.
b. Describe the use of cameras fo acros pic and mic scopic imaging of cellular pathology specimens.

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 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 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 laboratory role in the context of the previous sections:

Section 7.5 Candidate's Reflective Practice Statement Part 2.

The ethos of undertaking reflective practice should be the recognition that it is a naturally occurring characteristic of those wishing to improve. 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:

Section 7.6 Principles of Pathology
Subsection 7.6a Normal and pathological tissues

KNOWLEDGE

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

1. Biology of normal and abnormal growth.
2. Macroscopic and microscopic features of normal tissue for the main organ syste
3. Use of algorithms to aid the diagnosis of malignant diseases.
4. Reasons for tissue preparation for microscopy examination.
5. Value of accurate specimen site identification for the reporting o pecimens (e.g Barrett's oesophagus).
6. Classification of diseases using pathology nomenclature.
7. Nuclear and cytoplasmic changes of reversible cell i .
8. Most important causes of cell injury.
9. Metaplastic process in a variety of organs.
10. Atrophy, and can give examples of this fo of adapt tion.
11. Causes of hypertrophy and hyperplasia, and e appropriate examples of each.
12. Various forms of necrosis, and can ppropr examp s of each.
13. Programmed cell death (apopt s).
14. Autophagy and its role in home asis a ease.

COMPETENCE

You must be able t

a. Recognise croscop and m scopic differences in normal and abnormal tissues from l majo n types.
b. R ognise micros ically different types of epithelia and their location in the body.
c. ognis he follow conditions:
   - H trophy
   - Hype asia
   - Parakera is
   - hy
   - Necrosis
   - Metaplasia
   - Apoptosis
   - Autophagy
d. Discuss the role of supplementary tests in the evaluation of pathological tissues.

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 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 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 7.6 Principles of Pathology

Subsection 7.6b Inflammation, fibrosis and malignancy

KNOWLEDGE

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

1. Acute inflammation and the related terms: calor (heat); rubor (redness); tumour (swelling); dolor (pain) and functio laesa (loss of function).
2. Cell types involved in acute and chronic inflammatory processes.
3. Neoplasia and the related terms: tumour, cancer and oncology.
4. Classification of tumours on the basis of their clinical behaviour and histopathological features.
5. Typical features of benign and malignant tumours.
6. Metastasis and its pathogenesis.
7. Genetic basis of cancer and underlying molecular events in pathogenesis and progression.
8. Common forms of carcinoma and sarcoma, tissues of origin, and benign equivalents.
9. Various approaches to studying the aetiology and pathogenesis of cancer.
10. Environmental carcinogens that commonly affect humans.
11. Significance and the clinical value of tumour-associated antigens.
12. Link between classification of diagnosis and therapy.
13. Application of cellular pathological techniques in the identification of inflammation and fibrosis.
14. Principles of screening for malignant disease and the role of cellular pathology in diagnosis.

COMPETENCE

You must be able to:

a. State the histological appearance of malignant cells, using appropriate terminology.
b. List the common types of cancer and their location.
c. Describe the current state of knowledge about the molecular basis of cancer.
d. Describe the multi-stage nature of cancer and be able to discuss factors that influence this process.
e. Distinguish among the known genetic mechanisms leading to cancer and discuss methods of prevention in genetically susceptible people.
f. Recognise the histological appearance of inflamed tissues.
g. List the causes of inflammation.

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 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 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 7.6 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 laboratory role in the context of the previous sections:

Section 7.6 Candidate's Reflective Practice Statement Part 2.

The ethos of undertaking reflective practice should be the recognition that it is a naturally occurring characteristic of those wishing to improve. 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:

Section 8:
MOLECULAR PATHOLOGY (OPTIONAL)

This section covers the range of molecular pathology procedures and diagnostic techniques that have been identified as being most relevant to practice as a specialist biomedical scientist in cellular pathology. Candidates completing these are expected to be able to demonstrate the application of knowledge and skill 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.

IMPORTANT INFORMATION: END-POINT ASSESSMENT

1. The molecular pathology module will be examined in a second and separate assessment in an external location, not your employing laboratory. This will usually be the Institute's London office but may be an alternative location that is more convenient to both candidate and examiners.

2. The end-point assessment differs from the end-point assessment for Specialist Portfolios in that it does not include a presentation or laboratory tour.

3. The end-point assessment will be in two parts:

   Part One: a review of the record of laboratory training to check all components have been signed off and to verify appropriate training has been undertaken through a review of the portfolio of evidence.

   Part Two: a *viva voce* (30 mins) to examine the candidate's knowledge and understanding of the module.

4. The process begins once the applicant's training officer submits a completed request for the appointment of an external examiner. This should be accompanied by **one paper copy** of their record of laboratory training and **one paper copy** of the portfolio of evidence, together with **electronic versions** of both.

5. This will trigger the appointment within 4 weeks of the external examiner with expertise in molecular pathology in the context of cellular pathology. The external examiner will be sent a copy of the record of laboratory training and portfolio of evidence for review within 4 weeks. The candidate's training officer will receive confirmation that this stage has been completed.

6. The following outcomes apply to Part One:

   - Outcome 1: Candidate has met all of the requirements for the record of laboratory training and portfolio of evidence and may proceed to Part Two;
   - Outcome 2: Candidate has partially met the requirements record of laboratory training and portfolio of evidence and is required to submit further evidence to address specific standards of proficiency before they proceed to Part Two;

     They will be advised on the possible sources of evidence specific for the module that would be suitable to demonstrate the standard has been met. Candidates will be allowed a maximum of 1 month to submit further evidence. Only the standards requiring additional evidence will be reassessed.

- Outcome 3: Candidate has failed to meet the requirements for record of laboratory training and portfolio of evidence and a period of further training is required. Advice will be given on the nature of this. Candidates will need to resubmit their portfolio of evidence for full assessment. A fee will apply for re-assessment of the portfolio.

7. Once the external examiner has informed the IBMS they have reviewed the portfolio the candidate's training officer will be contacted by the IBMS education team to inform them of the outcome.

8. If the candidate is able to proceed to part two a date and venue for the *viva voce* will be agreed with the candidate and external examiner.

9. The candidate and external examiner will be expected to attend the *viva voce* as arranged.

10. The external examiner will complete a report form to confirm the areas covered in the oral examination with example questions and outcomes of the examination process.

11. The external examiner will communicate the outcome (Pass or Fail) to the candidate on the day of the *viva voce*.

12. If the candidate has passed feedback may be provided at the discretion of the examiner.

13. If the candidate fails, the examiner will provide detailed feedback as to the issues and guidance as to 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 shortcomings. A subsequent *viva voce* will be required and this must be arranged through the IBMS.

14. Feedback should be concise, constructive and based on the Institute's guidance in relation to specialist portfolio training and completion. Personal opinions or advice may be offered in the context of examples of good practice, but it should be clear they are personal and **NOT** a specific requirement of the Institute.

Section 8.1 Introduction to Cancer and Stratified Medicine – a Molecular Perspective

KNOWLEDGE

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

1. Normal processes involved in regulating cell growth and regulation.
2. Hallmarks of cancer.
3. Classification of different types of cancer.
4. How the family history of a cancer relates to its molecular biology.
5. How damage to cellular components can result in precancerous and cancerous changes.
6. Molecular processes involved in cancer development, growth and metastasis.
7. How genomic information may be integrated into cancer screening programme.

COMPETENCE

You must be able to:

a. Discuss the role of molecular pathology and its relationship to cellular pathology.
b. Name and explain the significance of the hallmarks of cancer.
c. Giving examples of the specific molecules and genes involved, describe the process of invasion and metastasis.
d. Explain the rationale behind the change in the structure of the NHS Cervical Screening Programme from one based on cellular morphology, to a primary screen of high-risk HPV infection.

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 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 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 8.1 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 laboratory role in the context of the previous sections:

Section 8.1 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 improve. 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:

Section 8.2 Introduction to Gene Sequencing for Cellular Pathology Specimens

KNOWLEDGE

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

1. Relationship between genetics and cancer.
2. Difference between whole genome, whole exome and targeted sequencing with the reasons for using each.
3. Role of proteomics.
4. Process of Next Generation Sequencing, and how genomic data can be used with diagnosis.
5. Role played by the Human Genome Project and the potential contribution of the 100,000 genomes project.
6. Significance of identifying Single Nucleotide Pleomorphisms in prostate cancer.
7. How the developing state of knowledge impacts on the value of the sequencing data.

COMPETENCE

You must be able to:

1. Explain the difference between proteomics and genomics – highlighting the value of each.
2. Demonstrate an understanding of how molecular pathology can provide stratification in cancer, by discussing SNPs in prostate cancer and relating this to the biological behaviour of the disease and subsequent prognosis.
3. Discuss how the evolving picture of genomics and proteomics results in an uncertain characterisation in some disease states.

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 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 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 8.2 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 laboratory role in the context of the previous sections:

Section 8.2 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 improve. 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:

Section 8.3 Sample Handling

Subsection 8.3a Pre-analytical considerations

KNOWLEDGE

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

1. Which samples require fixation and which do not.
2. Importance of fixation in molecular studies.
3. The need to assess the risk of handling unfixed tissues.
4. Requirements for transport of samples to the laboratory.
5. Impact of cold ischaemic time on a sample.
6. Requirements for sample handling in the laboratory.
7. Requirements for traditional diagnostics and when this should not be compromised by molecular studies.

COMPETENCE

You must be able to:

a. Discuss why fixation is important in molecular studies.
b. Discuss the factors affecting fresh tissue that will impact on molecular studies.
c. Discuss why transport of samples may impact on molecular studies.

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 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 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 8.3 Sample Handling

Subsection 8.3b Tissue selection for molecular studies

KNOWLEDGE

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

1. Principles of tissue selection and the factors that need to be considered.
2. The need to log sample details.
3. Principles of tumour grading and staging with respect to tissue sampling.
4. Principles of mirror-block sampling.
5. Requirements for dissection with regard to molecular testing.

COMPETENCE

You must be able to:

a. Discuss the rationale of tissue selection procedures for molecular testing.
b. Be able to select and dissect appropriate tissue for molecular testing.
c. Ensure tissue for molecular testing is handled appropriately.

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 trainer to work in accordance with standard laboratory procedures. (No other evidence is required).

Date of completion:

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Date of completion:

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Date of completion:

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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 8.3 Sample Handling
Subsection 8.3.c Cryotomy

KNOWLEDGE

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

1. Principles of cryotomy and the use of a cryostat.
2. Principles of rapid freezing of tissues for molecular studies.
3. Risks and hazards associated with the use and decontamination of cryostats.
4. Principles of storage of frozen tissue, including the associated risks and hazards.
5. Principles of transport of frozen tissue, including the associated risks and hazards.

COMPETENCE

You must be able to:

a. Orientate and freeze tissues appropriately.
b. Cut frozen sections to the required standard.
c. Store frozen tissue appropriately.
d. Package frozen tissue for transport appropriately.
e. Decontaminate cryostats appropriately.
f. Perform basic maintenance and troubleshooting of cryotomy equipment.

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 trainer to work in accordance with standard laboratory procedures. (No other evidence is required).

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Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 8.3 Sample Handling

Subsection 8.3d Tissue Processing, embedding and microtomy

KNOWLEDGE

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

1. Effects of FFPE on molecular samples.
2. Requirements for processing, orientating mirror-blocks and producing sections.

COMPETENCE

You must be able to:

a. Prepare a FFPE tissue block for molecular studies.
b. Prepare sections for molecular studies.

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.

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Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 8.3 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 refere[illegible]e to the evidence contained in the portfolio. This may lead to further discussion during the *viva voc*

Candidate's Reflective Practice Statement Part 1.

Summarise your laboratory role in the context of the previous sections

Section 8.3 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 improve. 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:

Section 8.4 Assessment of Cellularity

KNOWLEDGE

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

1. Importance of tumour volume and be aware of necrosis and other benign elements which may affect total neoplastic content.
2. Local policies and procedures undertaken and required by the nearest Genomic Medicine Centre, regarding assessment of cellularity for the 100,000 genome project.
3. Percentage yields for successful and unsuccessful whole genome sequencing required by 100,000 genome project.
4. Different tissue types which require extra consideration for adequate neoplastic cellularity during tumour assessment and dissection.
5. Importance of EQA schemes for molecular pathology and assessment of cellularity.
6. Advantages and disadvantages of assessment of cellularity in core biopsies and resection specimens.

COMPETENCE

You must be able to:

a. Perform an assessment of tumour cellularity as part of slide reviews.
b. Define the difference between tumour volume and tumour surface area with respect to slide assessment.
c. Explain factors which could cause low neoplastic cellularity and DNA yield.
d. Describe extra considerations and requirements for adequate neoplastic cellularity when sampling tumour from the following tissue types:
   - Breast
   - Colorectal
   - Lung
   - Bladder
   - Pancreatobiliary
   - Hepatic
e. Discuss the role and importance of EQA schemes available to molecular pathology, in particular the assessment of cellularity.
f. Describe techniques which can be used to ensure maximum tumour cellularity is achieved for small or suboptimal tumour samples.
g. Demonstrate knowledge of techniques available to ensure adequate neoplastic content is achieved in suboptimal tissue samples.

EVIDENCE OF ACHIEVEMENT

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Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 8.4 Reflective Practice

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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 laboratory role in the context of the previous sections:

Section 8.4 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 improve. 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:

Section 8.5 Extraction Techniques in Molecular Pathology

KNOWLEDGE

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

1. Action and impact of pre-analytical factors upon Nucleic Acid (NA) extraction quality/quantity, blood vs tissue vs FFPE tissue.
2. Significant differences in processing and outcomes for DNA vs RNA extraction from human tissue.
3. Approaches to enhance/enrich for a given population.
4. Key methodologies for nucleic acid extraction.
5. Use of automation in nucleic acid extraction.
6. Factors in downstream processing that may dictate the requirements of a given extraction process.
7. Methodologies by which the quantity and quality/integrity of extracted nucleic acids may be assessed.
8. The need to optimise protocols dependent on which fixative has been used.

COMPETENCE

You must be able to:

a. Explain how pre-analytical factors affecting NA integrity are a key determiner of extraction yields.
b. Discuss macro- and micro-dissection, and explain some approaches/uses of both.
c. Explain the theory behind, and give a technical background to, various methodologies (to include but not limited to…):
   - "Crude" lysis methods
   - Spin column-based
   - Magnetic (bead) isolation techniques
   - Sonication
d. Discuss how the particularities of these methods render them more or less suitable for certain samples.
   Explain basic advantages and limitations of automation.
f. Compare and contrast the requirements places upon extraction methods by example downstream methods (i.e. real-time PCR vs WGS, additional examples encouraged).

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.

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Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 8.5 Reflective Practice

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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 laboratory role in the context of the previous sections:

Section 8.5 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 improve. 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:

Section 8.6 Quality Considerations in Molecular Pathology

KNOWLEDGE

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

1. Importance of triage and patient management with regard to whole genome sequencing.
2. Requirements for consent, use and storage of human tissue marked for genomic studies.
3. Local policies and procedures when providing specimens for molecular pathology testing.
4. Range of drawbacks which could impede a samples use for genomic studies
5. Importance of EQA schemes for molecular pathology

COMPETENCE

You must be able to:

a. Describe the factors which are taken into account before tissue is sampled for the 100,000 genome project.
b. List the advantages and disadvantages of fresh frozen tissue and formalin fixed paraffin embedded tissue with respect to quality of DNA yield for whole genome sequencing.
c. Identify and describe quality assurance schemes relevant to molecular studies in your scope of practice.

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.

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Date of completion:

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Internal Assessor's signature:

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Date:

Section 8.6 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 laboratory role in the context of the previous sections:

Section 8.6 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 improve. 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:

Section 8.7 *In Situ* Hybridisation

KNOWLEDGE

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

1. Principles of *in situ* hybridisation techniques, including the use of fluorescence and chromogenic methodologies.
2. Role of the clinical application of in-situ hybridisation in diagnostic pathology.

The following are in addition to module 7.4a

3. Key diagnostic and prognostic information supported by ISH techniques
4. Selection, interpretation and troubleshooting of in-situ hybridisation methodologies as an adjunct to histopathological analysis.
5. Indicative demonstration methods: *Her2*, HPV, *EML4* [illegible] EBV, immunoglobulin mRNA.

COMPETENCE

You must be able to:

a. Prepare cell and formalin-fixed, paraffin wax embedded (FFPE) samples for DNA and RNA analysis.
b. Stain tissue sections using *in situ* hybridisation.
c. Select appropriate control material.
d. Use appropriate microscopy techniques to visualise stained material.
e. Assess quality in prepared sections.
f. Clearly distinguish between positive, negative and equivocal results.
g. Resolve problems associated with the demonstration methods.
h. Dispose of waste reagents and residual material safely.

EVIDENCE OF ACHIEVEMENT

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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 laboratory role in the context of the previous sections:

Section 8.7 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 improve. 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:

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