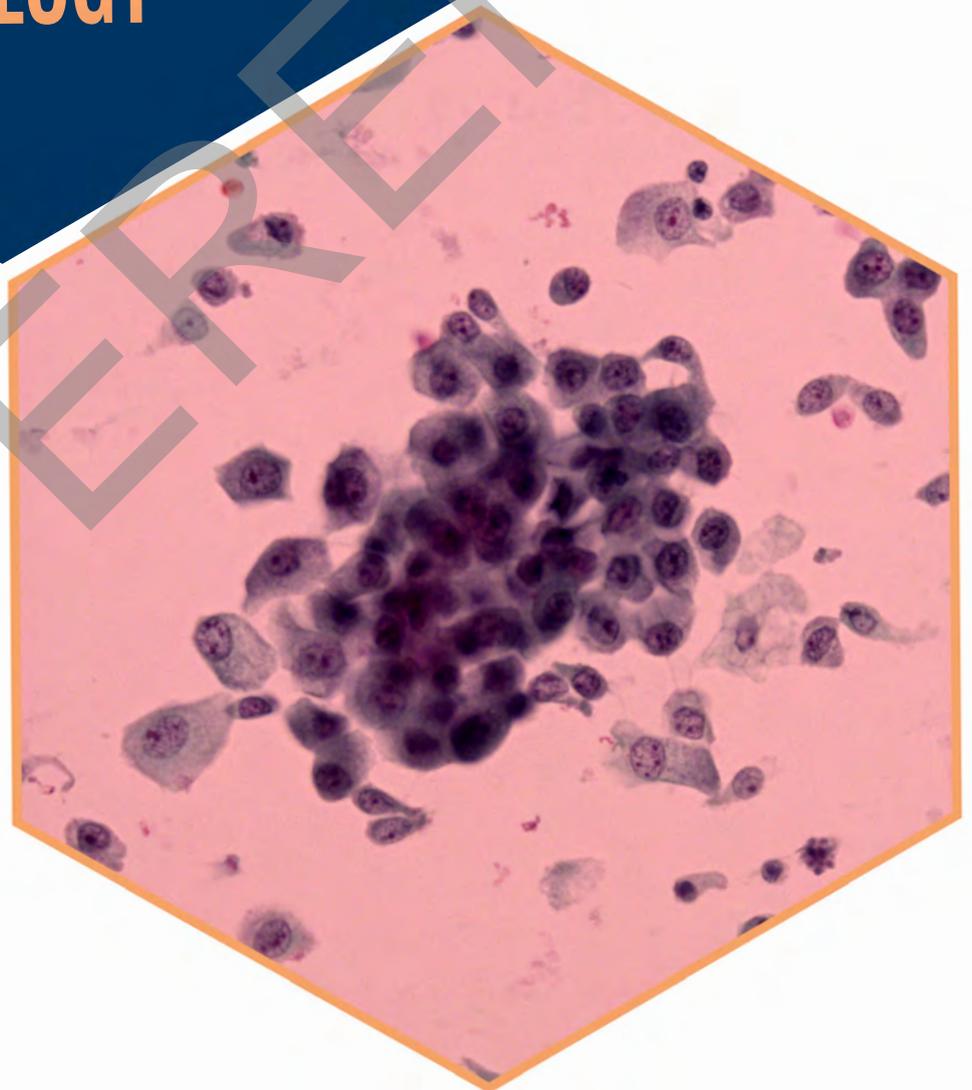


RECORD OF LABORATORY
TRAINING FOR THE
IBMS SPECIALIST DIPLOMA
**DIAGNOSTIC
CYTOPATHOLOGY**



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FOREWORD

The purpose of the Institute's Specialist Portfolios is to provide a training programme and qualification that are directly relevant to biomedical scientist post-registration discipline specific practice.

In light of the increasing specialised biomedical scientist roles focusing mainly on either cervical or diagnostic fields of cytology the IBMS Cytology Advisory Panel made the decision to totally review and relaunch the cytology Specialist Portfolios to better reflect the more focussed services now provided by laboratories. The changes also reflect the increasing role molecular based techniques are playing across pathology as a whole and increasingly so within cytology.

The outcome of the review is two new cytology portfolios in cervical and diagnostic cytology that have evolved from the previous combined version. Additional elements have been added to both fields to reflect the expansion of expected knowledge now required. This can be seen most noticeably within the diagnostic cytology version.

Individuals successfully completing one of the new cytology portfolios will be awarded a Specialist Diploma in either Cervical or Diagnostic Cytology. For the small number of individuals that continue to work in laboratories that provide both cervical and diagnostic services there is the option to complete both portfolios at the same time or separately and then to receive two separate Specialist Diploma awards if they are assessed to have met the required standards within each portfolio. A separate assessment will be required for each version.

There may be elements within each portfolio that are not part of a laboratory's repertoire; in these instances, the candidate must ensure the knowledge elements are fully evidenced. Training officers and managers are encouraged to provide candidates with practical experience to support the required knowledge elements that may involve a visit to another laboratory to experience the practical application of elements not handled in their own department.

It is hoped that these new portfolios will better support the training and development of our biomedical scientist workforce as we operate in new and different ways.

Kirstie Rice

Chair Cytopathology Advisory Panel

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

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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

Please note: You must achieve the required depth and breadth of knowledge specified in Section 7. All units in this section must be completed.

- 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 you will rotate through, the expected duration in each area, the unit(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 units in order to meet the requirements of the external examination process. Each unit requires you to demonstrate knowledge and competence elements specific to an investigation or task. It is the responsibility of the trainer(s) to ensure that you meet the expected level defined by the following learning outcomes which have been subdivided into three areas.

Knowledge and understanding

As a successful candidate you will be able to:

- a. Demonstrate knowledge and understanding of complex scientific and technical aspects of your 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 your ability to describe/discuss these aspects of your work.

Professional skills

As a successful candidate you will be able to:

- a. Competently perform a range of laboratory tests without immediate supervision.
- b. Demonstrate self-direction in solving problems and exercising personal autonomy in relation to scope of practice.
- c. Demonstrate a systematic application of professional knowledge and understanding in the interpretation of laboratory data to determine action based on best practice.

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

Transferable skills

As a successful candidate you will be able to:

- a. Demonstrate communication skills within the healthcare environment and as part of the laboratory team. This is evidenced by the presentation.
- b. Demonstrate the ability to critically reflect in order to inform best practice. This is evidenced by personal reflective statements.

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

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

3. EVIDENCE

- 3.1. Evidence is generated through the internal assessment of your training and can be from a variety of sources (see section 5.11 in the guidance document for some examples). Many pieces of evidence will be generated and you will need to select those most suitable for the Specialist Portfolio unit. Your training officer should be asked to check these are appropriate and confirm they 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 unit.
- 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 unit has been met.

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

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

4. COMPLETING THE RECORD OF LABORATORY TRAINING

- 4.1. Once you have completed your training for a particular unit 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 to justify your selection of evidence. These are usually at the end of the section 7 or may be at the end of a set of common units within section 7.
- 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 an 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 units in the record of training for the Specialist Portfolio and your portfolio of evidence.
- 5.3. The external examiner will determine your suitability for the award of the Specialist Diploma by assessing your knowledge and understanding of your specialty through: the oral presentation; the evidence of training you have provided and questions asked during the laboratory tour.
- 5.4. Your presentations should not be overcomplicated and slides should be kept simple: they are really a prompt to give your talk a structure. You are talking about things you know: how you gained your experience, key aspects of your work, recent developments that may have occurred, or are planned and any particular interests you have. The external examiner may also wish to ask some questions related to the presentation or seek points of clarification.
- 5.5. Your portfolio of evidence will provide the examiner with an opportunity to assess the quality of your training (e.g. through the questions asked by the trainer) and your

understanding of the techniques (e.g. annotated evidence, witness statements, reflective statements).

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

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

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

6. COMPLETION OF REPORTS AND AWARD

- 6.1. Check with your trainer that they have submitted the feedback report form to the Institute. Both the external examiner and the laboratory trainer are required to submit reports and delays in this part of the process will delay the award of your Specialist Diploma.
- 6.2. Once the reports have been received the Institute will issue your Specialist Diploma. If you are currently in the class of Licentiate, you will be eligible to apply to upgrade your membership to become a Member. Upgrading to the next level of membership is not automatic and you are advised to make an application to the Institute as soon as possible in order to access the Institute's higher-level qualifications to assist you in furthering your career.

Section 7: Diagnostic Cytopathology

This section covers the range of procedures and diagnostic non-gynaecological cytology techniques that have been identified as being most relevant to practice as a specialist biomedical scientist working in cytopathology.

Candidates completing either of these sections are expected to be able to demonstrate the application of knowledge and skill defined in section 2 of this portfolio.

Some of these may not be performed in the candidate's own laboratory and whilst practical competence may not be achievable to the level of someone performing them regularly knowledge and understanding of its application is required.

There may be other tests that the training laboratory include in their basic repertoire and therefore requires the individual to be competent in. These can be recorded in the reflective log at the end of each sub-section.

Section 7 Diagnostic Cytopathology (non-gynaecological techniques)

Unit 7.1 General diagnostic cytology sample preparation

KNOWLEDGE

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

1. Different types of sampling methods available.
2. Importance of correct sampling.
3. Correct presentation and requirements for all types of diagnostic cytology samples.
4. Principles of the validation and verification of sample examination processes to UKAS standards.
5. Theory and practice of fixation.
6. Theory and practice of preparation techniques for all types of diagnostic cytology samples i.e. using various concentration methods, air drying or fixation as appropriate.
7. Theory and practice of routinely used demonstration techniques i.e. Papanicolaou stain and Giemsa/Diff Quik for all types of diagnostic cytology samples.
8. Theory and practice of special staining techniques used to demonstrate a variety of cellular and extracellular components and infective agents such as mucins, lipids, pigments and minerals, *Aspergillus*, *Pneumocystis*, *Tuberculosis*.
9. Importance of how processing affects the microscopical interpretation of the sample.
10. Risks and hazards associated with fixed and unfixed samples.
11. Ethical and safe use, storage and disposal of residual samples and stained preparations.

COMPETENCE

Be able to:

- a. Construct an accurate macroscopic description for all samples.
- b. Validate all consumables and reagents prior to use in accordance with quality assurance requirements.
- c. Optimally prepare all types of diagnostic cytology samples in accordance with standard operating procedures.
- d. Identify and rectify any problems encountered in specimen preparation.
- e. Stain diagnostic cytology preparations using routine stains and special stain methods.
- f. Evaluate and verify the stained preparations using appropriate control material.
- g. Complete all documentation in accordance with quality assurance and audit requirements.

EVIDENCE OF ACHIEVEMENT

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

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

Date of completion:

Trainer's name:

Trainer's signature:

Candidate has answered questions set by the trainer on the knowledge and skill components required to complete this unit. (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:

Unit 7.2 General principles and microscopy

KNOWLEDGE

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

1. Relationship between cell structure and function.
2. The mechanisms of tumour genesis and metastasis.
3. Benign processes affecting cellular morphology.
4. Normal cytological features of abraded, aspirated and exfoliated material from tissues or epithelia.
5. General cytological features of reactive and malignant cells.
6. How to correlate cytological features with histology.
7. Relevance of immediate diagnosis.
8. Current government recommendation on cancer waiting times.
9. General principles of diagnostic samples and the difference from screening programme specimens.
10. The role of diagnostic cytology in the diagnosis of neoplasia.
11. Nomenclature and classification systems for neoplastic conditions.
12. The role of cancer multidisciplinary teams.

COMPETENCE

Be able to:

- a. Set up and use a microscope.
- b. Recognise normal cells from various diagnostic cytology samples.
- c. Stain and assess immediately made cytology preparations, either in the laboratory or at a remote location.
- d. Complete all documentation in accordance with quality assurance and audit requirements.
- e. Discuss the general principles of diagnostic cytology.
- f. Discuss the role of diagnostic cytology in the diagnosis of neoplasia.
- g. Describe the nomenclature and classification systems for neoplastic conditions.
- h. Explain the role of cancer multidisciplinary teams in patient management.

EVIDENCE OF ACHIEVEMENT

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

KNOWLEDGE

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

1. Specific types of common fixatives, their characteristics and their compatibility with subsequent immunocytochemical staining procedures.
2. Effects on subsequent procedures with particular regard to immunocytochemical staining and the appearance of artefacts produced by poor processing.
3. 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.
4. Potential problems associated with prolonged storage and loss of tissue antigenicity.
5. Familiarity with appropriate antigen retrieval methodologies, including proteolytic enzyme digestion, heat mediated methods and their mechanisms, as far as they are known.
6. Different proteolytic enzyme digestion methodologies (including working knowledge), awareness of the importance of optimal digestion, assessment of this in stained preparations.
7. 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.
8. Methods for validation and verification of primary antibodies before introduction into a diagnostic procedure and the requirement for assessment of batch-to-batch variation when in use.
9. Concepts of sensitivity, specificity, avidity and affinity and their significance to the quality of immunocytochemical staining.
10. Appropriate dilution of primary antibody reagents and the effects on subsequent immunocytochemical staining results.

KNOWLEDGE (continued)

11. Problems of non-specific and inappropriate staining, their causes and methods for their reduction or elimination.
12. Necessity of including appropriate run controls and maintaining audit trails.
13. Patterns and localisation in normal and abnormal cells in order to interpret immunocytochemistry preparations for routine diagnostic use.

COMPETENCE

You must be able to:

- a. Pre-treat slides for immunocytochemistry following local standard operating procedures.
- b. Stain slides for immunocytochemistry using manual /automated methods following local standard operating procedures.
- c. Optimise antibody titres, maintaining audit trails.
- d. Recognise staining patterns for core repertoire antibodies on tissues and cells.
- e. Determine the suitability of a completed immunocytochemistry run for further analysis based on included controls.
- f. 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 unit. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

KNOWLEDGE

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

1. Anatomy, physiology and histology of the respiratory tract.
2. Disease processes affecting the respiratory tract.
3. Investigative methods used in respiratory tract disease.
4. Variety of sampling methods available.
5. Relevance and importance of optimising preparatory techniques in samples from respiratory tract cytology.
6. Criteria for accessing the adequacy of samples.
7. Normal cytological features of sputum, bronchial washings, brushings and lavages.
8. Cytological features of contaminants and artefacts including those related to treatment of disease.
9. Cytological features and cytopathic effects of respiratory tract infections including:
 - *Aspergillus*
 - *Candida*
 - Cytomegalovirus
 - *Pneumocystis jirovecii*
10. Role of cytology in non-neoplastic pulmonary disease.
11. Principles of differential cell counts in interstitial lung disease.
12. Cytological features and cytopathic effects of malignancy.
13. Cytological appearances of the following tumours:
 - Squamous carcinoma
 - Small cell carcinoma
 - Adenocarcinoma

KNOWLEDGE (continued)

14. Diagnostic cytology pitfalls.
15. Role of ancillary techniques including: immunocytochemistry, molecular testing, personalised medicine for targeted therapies.
16. Commonly used special stains in respiratory samples and the expected staining pattern for positive versus negative cellular components of preparations and control material.
17. Commonly used antibodies for immunocytochemistry in respiratory samples and the expected staining pattern for positive versus negative cellular components of preparations and control material.
18. Guidelines for the reporting and management of diseases of the respiratory tract.

COMPETENCE

Be able to:

- a. Work in accordance with standard operating procedures to optimise specimen preparation utilising the range of techniques available to prepare, stain and evaluate cytology samples from the respiratory tract.
- b. Recognise common artefacts, contaminants and infective agents.
- c. Recognise the difference between normal, reactive and malignant cells.
- d. Be able to assess and comment upon the value of additional preparations i.e. special stains and immunocytochemistry stains performed on specimens.
- e. Complete all documentation in accordance with quality assurance and audit requirements.

EVIDENCE OF ACHIEVEMENT

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

KNOWLEDGE

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

1. Anatomy, histology and pathophysiology of the urinary tract.
2. Investigative methods used in diagnosing urinary tract disease.
3. Methods of sample collection and the effects on sample presentation.
4. Relevance and importance of optimising preparatory techniques in samples from urinary tract cytology.
5. Appearance of contaminants and artefacts.
6. Normal cytological features of urine samples.
7. Appearance and significance of the presence of crystals and casts in urine.
8. Appearance and/or cytopathic effects of urinary tract infections.
9. Iatrogenic changes in the urinary tract.
10. Cytomorphological features of neoplastic disease and malignancy.
11. Grading criteria of papillary carcinoma.
12. Paris classification of reporting guidelines for reporting and management of malignancies of the urinary tract.
13. Diagnostic cytology pitfalls.
14. Role of ancillary techniques.

COMPETENCE

Be able to:

- a. Work in accordance with standard operating procedures to optimise specimen preparation to prepare, stain and evaluate cytology samples from the urinary tract.
- b. Recognise common artefacts, contaminants and infective agents.
- c. Recognise the difference between normal, reactive and malignant cells.
- d. Be able to assess and comment upon the value of additional preparations i.e. special stains and immunocytochemistry stains performed on specimens.
- e. Complete all documentation in accordance with quality assurance and audit requirements.

EVIDENCE OF ACHIEVEMENT

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

KNOWLEDGE

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

1. Anatomy, histology and pathophysiology of body cavities.
2. Methods for collection and preparation of serous effusions.
3. Relevance and importance of optimising preparatory techniques in samples from serous cavities.
4. Process and significance of serous effusion formation and associated clinical conditions.
5. Range of normal cells that may be seen in effusion specimens.
6. Recognise the cytological features associated with reactive changes in serous effusions.
7. Cytomorphological features of malignancy.
8. Recognise the cytological features of metastatic disease in serous effusions.
9. Recognise the significant features associated with malignant mesothelioma and methods of confirmation.
10. Differential diagnoses and potential diagnostic cytology pitfalls.
11. Role of ancillary techniques including the use of immunocytochemistry panels.
12. Commonly used special stains in serous effusion samples and the expected staining pattern for positive versus negative cellular components of preparations and control material.
13. Commonly used antibodies for immunocytochemistry in serous effusion samples and the expected staining pattern for positive versus negative cellular components of preparations and control material.
14. The rationale for the collection and assessment of peritoneal washing samples and the common cytological features seen in these specimens.

COMPETENCE

Be able to:

- a. Work in accordance with standard operating procedures to optimise specimen preparation to prepare, stain and evaluate serous fluids, peritoneal washings and cytology samples from serous cavities.
- b. Recognise the difference between normal, reactive and malignant cells.
- c. Be able to assess and comment upon the value of additional preparations i.e. special stains and immunocytochemistry stains performed on specimens.
- d. Complete all documentation in accordance with quality assurance and audit requirements.

EVIDENCE OF ACHIEVEMENT

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

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

Date of completion:

Trainer's name:

Trainer's signature:

Candidate has answered questions set by the trainer on the knowledge and skill components required to complete this unit. (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:

Unit 7.7 Synovial Fluids

Indicative repertoire: Polarising microscopy, gout, pseudogout, septic arthritis

KNOWLEDGE

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

1. Anatomy and physiology of synovial joints.
2. Clinical presentations of synovial fluid and arthrocentesis.
3. Preparatory techniques for wet and stained preparations.
4. Morphology of cell content.
5. Crystal analysis of gout and pseudogout.
6. Diagnostic significance of cell counts \pm crystals and microbiology correlation.
7. Reviewing cases and material microscopically for internal and external quality control.
8. Risks and hazards associated with the preparation and disposal of reagents used in synovial fluid preparation.

COMPETENCE

Be able to:

- a. Select and use control materials, maintaining appropriate audit trails.
- b. Use an appropriate microscopy technique to identify crystals and artefacts
- c. Perform a differential cell count if appropriate to routine laboratory practice.
- d. Set up and perform basic maintenance on equipment used in process
- e. Dispose of waste reagents safely and correctly.

EVIDENCE OF ACHIEVEMENT

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

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

Date of completion:

Trainer's name:

Trainer's signature:

Candidate has answered questions set by the trainer on the knowledge and skill components required to complete this unit. (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:

Unit 7.8 Fine needle aspiration collection and preparation

KNOWLEDGE

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

1. Theory of fine-needle aspiration (FNA) techniques in superficial sites and utilising imaging techniques.
2. Procedures available to optimise sample preparation.
3. Range of sites most commonly sampled.
4. Advantages and disadvantages of rapid on-site evaluation (ROSE).
5. Use of PPE as required within a clinic setting.

COMPETENCE

Be able to:

- a. Optimise specimen preparation.
- b. Stain slides in accordance with standard operating procedures and critically evaluate results.
- c. Complete all documentation in accordance with quality assurance and audit requirements.

EVIDENCE OF ACHIEVEMENT

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

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

Date of completion:

Trainer's name:

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

Date of completion:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

KNOWLEDGE

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

1. Principles and practice of EUS (endoscopic ultrasound-guided) fine needle aspiration (FNA).
2. Anatomy, histology and histopathology of the gastro-intestinal tract.
3. Body sites from which EUS FNA samples are taken.
4. The different sample preparation techniques.
5. Additional ancillary techniques that may be performed on residual material such as molecular testing & flow cytometry.

COMPETENCE

Be able to:

- a. Optimise specimen preparation.
- b. Stain slides in accordance with standard operating procedures.
- c. Undertake accurate assessment of sample adequacy.
- d. Identify cell content present and assess relevance to sample site.
- e. Select suitable transport media for residual specimen with reference to any additional clinical requirements for subsequent investigations where appropriate.
- f. Complete all documentation in accordance with quality assurance and audit requirements.

EVIDENCE OF ACHIEVEMENT

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

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Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

KNOWLEDGE

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

1. Principles and practice of EBUS (endobronchial ultrasound-guided) fine needle aspiration (FNA).
2. Anatomy, histology and histopathology of the respiratory tract.
3. Body sites from which EBUS FNA samples are taken.
4. The different sample preparation techniques.
5. Additional ancillary techniques that may be performed on residual material such as molecular testing & flow cytometry.

COMPETENCE

Be able to:

- a. Optimise specimen preparation.
- b. Stain slides in accordance with standard operating procedures.
- c. Undertake accurate assessment of sample adequacy.
- d. Identify cell content present and assess relevance to sample site.
- e. Select suitable transport media for residual specimen with reference to any additional clinical requirements for subsequent investigations where appropriate.
- f. Complete all documentation in accordance with quality assurance and audit requirements.

EVIDENCE OF ACHIEVEMENT

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

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

Date of completion:

Trainer's name:

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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:

Unit 7.11 Head and neck fine needle aspiration collection, assessment and preparation

KNOWLEDGE

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

1. Principles and practice of head and neck fine needle aspiration (FNA).
2. Anatomy, histology and histopathology of the head and neck appropriate to sample site collection including thyroid, salivary glands and lymph nodes.
3. Body sites from which head and neck FNA samples are taken.
4. The different sample preparation techniques.
5. Additional ancillary techniques that may be performed on residual material such as molecular testing & flow cytometry.

COMPETENCE

Be able to:

- a. Optimise specimen preparation.
- b. Stain slides in accordance with standard operating procedures.
- c. Undertake accurate assessment of sample adequacy.
- d. Identify cell content present and assess relevance to sample site.
- e. Select suitable transport media for residual specimen with reference to any additional clinical requirements for subsequent investigations where appropriate.
- f. Complete all documentation in accordance with quality assurance and audit requirements.

EVIDENCE OF ACHIEVEMENT

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

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

Date of completion:

Trainer's name:

Trainer's signature:

Candidate has answered questions set by the trainer on the knowledge and skill components required to complete this unit. (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. Units 7.1 – 7.11 Reflective Practice Part 1

This section is used to demonstrate that as a candidate for the award 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

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

Section 7. Units 7.1 – 7.11 Reflective Practice Part 2

The ethos of undertaking reflective practice should be the recognition that it is a naturally occurring characteristic of those wishing to develop. As a candidate for the award 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.

Candidate's Reflective Practice Statement

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

Unit 7.12 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. Somatic versus germline mutations in cancer development.
6. Molecular processes involved in cancer development, growth and metastasis.
7. How genomic information may be integrated into cancer pathways.

COMPETENCE

You must be able to:

- a. Discuss the role of molecular pathology and its relationship to diagnostic cytopathology.
- b. Giving examples of the specific molecules and genes involved, describe the process of invasion and metastasis.
- c. Explain the rationale behind stratified medicine.

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 unit. (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:

Unit 7.13 Introduction to gene sequencing

KNOWLEDGE

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

1. Relationship between genetics and cancer.
2. Understand the principles and types of sequencing with their applications to cellular pathology.
3. Role played by the Human Genome Project and the potential contribution of the 100,000 genomes project.
4. How the developing state of knowledge impacts on the value of the sequencing data.

COMPETENCE

You must be able to:

- a. Explain the difference between proteomics and genomics – highlighting the value of each.
- b. Demonstrate an understanding of how genomics affects cancer diagnosis and treatment.
- c. Demonstrate an application of the above knowledge to an area of your 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.

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

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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:

Unit 7.14 Sample considerations

KNOWLEDGE

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

1. Understand the impact of different fixatives in use in cellular pathology.
2. Advantages and disadvantages of fixed versus unfixed samples.
3. The need to assess the risk of handling unfixed samples.
4. Requirements for transport of samples to the laboratory and the impact of cold ischaemic time on samples.
5. Requirements for sample handling in the laboratory.
6. Requirements for traditional diagnostics and when this should not be compromised by molecular studies.
7. Importance of tumour volume / load and the effect of necrosis and other benign elements on total neoplastic content.

COMPETENCE

You must be able to:

- a. Discuss why fixation is important in molecular studies.
- b. Discuss the factors affecting fresh specimens which will impact on molecular studies.
- c. Perform an assessment of tumour cellularity on cytology slides.

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:

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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:

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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:

Unit 7.15 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 extraction quality/quantity.
2. Significant differences in processing and outcomes for DNA vs RNA extraction from different sample types.
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 nucleic acid integrity are a key determiner of extraction yields.
- b. Explain the theory behind and give technical background to various methodologies (to include but not limited to...):
 - "Crude" lysis methods
 - Spin column-based
 - Magnetic (bead) isolation techniques
 - Sonication
- c. Discuss how the particularities of these methods render them more or less suitable for certain samples.
- d. Explain basic advantages and limitations of automation.
- e. Compare and contrast the requirements placed upon extraction methods by example downstream methods (i.e. real-time PCR vs WGS, additional examples encouraged).

EVIDENCE OF ACHIEVEMENT

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Date of completion:

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Internal Assessor's signature:

Internal Assessor's name:

Date:

Unit 7.16 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 sample's use for genomic studies.
5. Importance of EQA schemes for molecular pathology.
6. Discuss sensitivity, specificity and accuracy with regard to UKAS requirements.

COMPETENCE

You must be able to:

- a. Identify and describe UKAS requirements and quality assurance schemes relevant to molecular studies in your scope of practice.

EVIDENCE OF ACHIEVEMENT

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Date of completion:

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Internal Assessor's signature:

Internal Assessor's name:

Date:

Unit 7.17 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 cytopathology.
3. Key diagnostic and prognostic information supported by ISH techniques.
4. Selection, interpretation and troubleshooting of *in-situ* hybridisation methodologies as an adjunct to cytopathological analysis.
5. Indicative demonstration methods: *Her2*, HPV, *EML4-Alk* fusions, EBV, immunoglobulin mRNA.

COMPETENCE

You must be able to:

- a. Prepare cytological samples for DNA and RNA analysis.
- b. Stain cytological preparations 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.

EVIDENCE OF ACHIEVEMENT

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Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7. Units 7.12 – 7.17 Reflective Practice Part 1

This section is used to demonstrate that as a candidate for the award 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

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

Section 7. Units 7.12 – 7.17 Reflective Practice Part 2

The ethos of undertaking reflective practice should be the recognition that it is a naturally occurring characteristic of those wishing to develop. As a candidate for the award 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.

Candidate's Reflective Practice Statement

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



About this document

Document title: Record of Laboratory Training for the Specialist Diploma in Diagnostic Cytopathology

Produced by: Education and Professional Standards Committee

Contact: Education Department

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