

# RECORD OF LABORATORY TRAINING FOR THE IBMS SPECIALIST DIPLOMA CYTOPATHOLOGY



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

<b>Confirmation of Completed Training</b>		
Date Training Completed	Training Officer's Signature	Candidate's Signature

<b>Recommendation for Award of Specialist Diploma</b>		
Date of External Examination	External Examiner's Signature	External Examiner's Name



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## 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: This portfolio differs from other disciplines in that you must achieve the required depth and breadth of knowledge specified in a minimum of 2 out of the 3 modules in the relevant section of the portfolio (either A or B) in order to meet the requirements of the external examination process (e.g. 7A.1 & 7A.2 or 7A.1 & 7A.3).**

- 2.1. As a requirement for IBMS approval of your laboratory for training you must have an indicative training programme which sets out the sections of the laboratory they will rotate through, the expected duration in each area, the module(s) that are covered and how training is assessed.
- 2.2. In-service training and assessment must demonstrate good scientific practice based on the knowledge and competence in the stated modules in order to meet the requirements of the external examination process. Each module requires you to demonstrate knowledge and competence elements specific to an investigation or task. It is the responsibility of the trainer(s) to ensure that you meet the expected level defined by the following learning outcomes which have been subdivided into three areas.

### **Knowledge and understanding**

As a successful candidate you will be able to:

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

- b. Demonstrate knowledge and understanding of the scientific basis of the laboratory tests and the disease process under investigation.
- c. Show an awareness of current issues and developments within healthcare and biomedical science.

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

#### **Professional skills**

As a successful candidate you will be able to:

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

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

#### **Transferable skills**

As a successful candidate you will be able to:

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

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

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

### 3. EVIDENCE

- 3.1. Evidence is generated through the internal assessment of your training and can be from a variety of sources (see section 5.11 in the guidance document for some examples). Many pieces of evidence will be generated and you will need to select those most suitable for the Specialist Portfolio module. Your training officer should be asked to check these are appropriate and confirm meet the requirements of the standards for external examination.
- 3.2. Evidence must be filed in a single specialist portfolio of evidence.
- 3.3. In addition to evidence of answering questions set by the trainer only **ONE** other example of evidence is required for the **Evidence of Achievement** section. This is chosen by you as an example of evidence that demonstrates your knowledge and competence in performing a particular technique.
- 3.4. You are required to justify your choice of evidence in a reflective practice statement at the end of every module.
- 3.5. Evidence must be sufficient to enable an informed judgement by the external examiner on whether the standard in terms of knowledge and skills for the module has been met.

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

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

## **4. COMPLETING THE RECORD OF LABORATORY TRAINING**

- 4.1. Once you have completed your training for a particular module it must be signed off by the trainer to confirm that the knowledge and competence requirements and the Evidence of Achievement sections have been met.
- 4.2. You are required to complete a reflective practice statement at the end of each module to justify your selection of evidence.
- 4.3. All sections of your record of training for the Specialist Portfolio must be completed and signed off by the trainer, and your portfolio of supporting evidence checked, to confirm your suitability for the specialist examination.

## **5. END-POINT ASSESSMENT**

- 5.1. On completion of training and in accordance with the requirements of the Specialist Diploma, your employer should apply to the Institute for the appointment of a visiting external examiner.
- 5.2. Accompanying the portfolio should be a signed statement from the laboratory manager testifying to the range of laboratory investigations that you undertake in your own laboratory. This will be used by the external examiner to guide the areas for questioning during the laboratory tour. Please note the external examiner can ask questions on any of the modules in the record of training for the Specialist Portfolio and your portfolio of evidence.
- 5.3. The external examiner will determine your suitability for the award of the Specialist Diploma by assessing your knowledge and understanding of your specialty through: the oral presentation; the evidence of training you have provided and questions asked during the laboratory tour.
- 5.4. Your presentations should not be overcomplicated and slides should be kept simple: they are really a prompt to give your talk a structure. You are talking about things you know: how you gained your experience, key aspects of your work, recent developments that may have occurred, or are planned and any particular interests you have. The external examiner may also wish to ask some questions related to the presentation or seek points of clarification.

- 5.5. Your portfolio of evidence will provide the examiner with an opportunity to assess the quality of your training (e.g. through the questions asked by the trainer) and your understanding of the techniques (e.g. annotated evidence, witness statements, reflective statements).
- 5.6. During the laboratory tour with *viva voce* the external examiner will not assess your practical competence; this was the responsibility of your trainer. However, they will expect you to be able to demonstrate knowledge and understanding of the practical aspects underpinning a techniques and corrective action you might take if things go wrong.

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

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

## **6. COMPLETION OF REPORTS AND AWARD**

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

# Section 7: Cytopathology

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

Candidates have the option to complete either Section 7A or Section 7B and a **minimum** of 2 out of the 3 modules within that section (e.g. 7A.1 Cervical Cytopathology & 7A.2 Non-Cervical Cytopathology or 7A.1 & 7A.3 HPV Molecular).

If completing Section 7A candidates must have successfully completed the NHS Cervical Screening Programme (NHSCSP) training logbook. If completing Section 7B candidates must have successfully completed the City and Guilds or NHSCSP training in Cervical Cytology portfolio and been awarded the Diploma in Cervical Cytology Screening

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 7A

Candidates must have successfully completed the NHS Cervical Screening Programme training logbook.

### Section 7A.1 Cervical Cytopathology Subsection 7A.1a Female genital tract

#### KNOWLEDGE

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

1. Anatomy of the female genital tract.
2. Physiology of the female genital tract.
3. Histology of the female genital tract.
4. Process of squamous metaplasia and the development of the transformation zone.

#### COMPETENCE

##### Be able to:

- a. Describe the various stages of the menstrual cycle, the hormonal variations and the effects on the epithelia of the female genital tract.
- b. Recognise the cytological and histological features of squamous metaplasia.
- c. Recognise histological images from the female genital tract.

**EVIDENCE OF ACHIEVEMENT**

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

**Section 7A.1      Cervical Cytopathology**  
**Subsection 7A.1b      Cervical screening programmes**

**KNOWLEDGE**

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

1. Theory and practice of screening programmes.
2. Multidisciplinary nature of a cancer/cervical screening programme.
3. Purpose, aims and organisation of the cancer/cervical screening programme (e.g. NHS Cervical Screening Programme (NHSCSP) appropriate to your country of work).
4. Cervical screening programmes of the other UK countries.
5. Roles cytology and human papillomavirus (HPV) testing play in national screening programmes (current & future).

**COMPETENCE**

**Be able to:**

- a. Access and interpret information relating to a cervical cancer screening programme (KC 53, KC61, KC65 data or equivalent).
- b. Locate relevant documentation pertaining to the cancer screening programme in the laboratory (NHSCSP guidelines or equivalent).

**EVIDENCE OF ACHIEVEMENT**

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

**Section 7A.1****Cervical Cytopathology****Subsection 7A.1c****Aetiology and epidemiology of cervical cancer****KNOWLEDGE**

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

1. Incidence, prevalence and worldwide variation of cervical cancer.
2. Risk factors for cervical cancer.
3. Relationship between human papillomavirus (HPV) and cervical neoplasia.

**COMPETENCE****Be able to:**

- a. Analyse data on incidence and mortality from national statistics.
- b. Relate risk factors to the development of cervical cancer.

**EVIDENCE OF ACHIEVEMENT**

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

**Section 7A.1      Cervical Cytopathology**  
**Subsection 7A.1d      Call and recall systems**

**KNOWLEDGE**

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

1. Systematic nature of cervical screening.
2. Operation of call and recall systems.
3. Rationales for the age range and intervals for cervical screening.

**COMPETENCE**

**Be able to:**

- a. Assess the appropriateness of a sample received based on call and recall history.
- b. Resolve issues relating to inappropriate recall period.

**EVIDENCE OF ACHIEVEMENT**

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

**Section 7A.1      Cervical Cytopathology**  
**Subsection 7A.1e      Liquid-based cytology**

**KNOWLEDGE**

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

1. Theory and practice of liquid-based cytology.
2. Theory and practice of human papillomavirus (HPV) testing.

**COMPETENCE**

**Be able to:**

- a. Prepare liquid-based cytology and human papillomavirus (HPV) samples in accordance with standard laboratory procedures.
- b. Examine liquid-based cytology and HPV preparations in accordance with standard laboratory procedures.
- c. Critically evaluate results.
- d. Complete all relevant documentation in accordance with laboratory 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 module. (Evidence to support this is required).**

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

**Section 7A.1      Cervical Cytopathology**  
**Subsection 7A.1f      Primary care**

**KNOWLEDGE**

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

1. Role of primary care staff in obtaining samples for cervical screening.
2. Principle of audit of sample takers.
3. How transformation zone sampling is assessed.

**COMPETENCE**

**Be able to:**

- a. Liaise with and advise primary care staff on issues related to sampling.
- b. Identify, refer or return mismatching or incomplete samples to smear takers.
- c. Audit samples taken within a primary care service.

**EVIDENCE OF ACHIEVEMENT**

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

**Section 7A.1****Cervical Cytopathology****Subsection 7A.1g****Processing cervical samples****KNOWLEDGE**

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

1. Theory and practice of processing cervical samples.
2. Importance of how processing affects the microscopical interpretation of the sample.
3. Theory and practice of fixation.
4. Theory and practice of Papanicolaou staining.
5. Theory and practice of human papillomavirus (HPV) testing.
6. Risk and hazards associated with sample processing.
7. Principles and application of light microscopy.

**COMPETENCE****Be able to:**

- a. Prepare samples in accordance with standard operating procedures.
- b. Identify factors that might influence effective preparation of samples.
- c. Identify risks and hazards when handling and preparing samples.
- d. Evaluate and verify the stained preparations.
- e. Complete all relevant documentation in accordance with laboratory quality assurance (IQC/ EQA) and audit requirements.

**EVIDENCE OF ACHIEVEMENT**

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

**Section 7A.1****Cervical Cytopathology****Subsection 7A.1h****Screening of cervical samples – normal cellular appearance****KNOWLEDGE**

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

1. What constitutes a satisfactory cervical sample and how this may be distinguished from an unsatisfactory sample.
2. Normal cellular appearance of cervical samples.
3. Variations in cellular appearance due to inflammation, infection, metaplasia and iatrogenesis.
4. Know the relevant internal and external quality assurance procedures.

**COMPETENCE****Be able to:**

- a. Identify unsatisfactory samples (both technical and cytological)
- b. Perform a match between prepared slide and request form – audit receipt and numbering of specimens.
- c. Microscopically examine prepared slides.
- d. Recognise the normal constituents of a cervical sample.
- e. Recognise cellular appearances associated with inflammation, infection, squamous metaplasia and iatrogenic changes.
- f. Complete all relevant 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 module. (Evidence to support this is required).**

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

**Section 7A.1****Cervical Cytopathology****Subsection 7A.1i****Screening of cervical samples - organisms****KNOWLEDGE**

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

1. The role organisms have in the development of vaginitis and cervicitis.
2. Commonly found organisms of the vagina that can be seen in cervical samples.
3. Awareness of other endogenous and exogenous flora of the vagina.
4. Relevant internal quality control and external quality assessment procedures.

**COMPETENCE****Be able to:**

- a. Perform a match between prepared slide and request form.
- b. Microscopically examine prepared slides.
- c. Recognise common organisms found in cervical samples.
- d. Recognise the cytopathic effects associated with the presence of organisms or infections.
- e. Complete all the relevant documentations (paper or electronic) 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 module. (Evidence to support this is required).**

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

**Section 7A.1**  
**Subsection 7A.1j**

**Cervical Cytopathology**  
**Screening of cervical samples – abnormalities**

**KNOWLEDGE**

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

1. Histopathological basis of cervical intraepithelial neoplasia (CIN) and squamous carcinoma.
2. Histopathological basis of cervical glandular intraepithelial neoplasia (CGIN) and adenocarcinoma.
3. Cytomorphology of CIN and squamous carcinoma.
4. Cytomorphology of CGIN and adenocarcinoma.
5. Grading criteria associated with dyskaryosis and CIN.
6. Relevance of borderline changes.
7. Histopathological basis of non-cervical adenocarcinoma.
8. Relevant internal and external quality assurance procedures.

**COMPETENCE**

**Be able to:**

- a. Microscopically examine prepared slides.
- b. Recognise and grade squamous abnormalities.
- c. Recognise and grade glandular abnormalities (cervical and non-cervical).
- d. Recognise cytological features of malignancy.
- e. Recognise borderline nuclear changes.
- f. Complete all the relevant 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).**

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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 module. (Evidence to support this is required).**

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Internal Assessor's signature:

Internal Assessor's name:

Date:

**Section 7A.1****Cervical Cytopathology****Subsection 7A.1k****Management of cytology reports and human papillomavirus (HPV) results****KNOWLEDGE**

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

1. Current terminology and guidelines in cervical screening.
2. Role of cytology and human papillomavirus (HPV) status in the management of cervical abnormalities and post-treatment.
3. Role colposcopy has in diagnosis, assessment and follow-up of cervical abnormalities.
4. Role of the gynaecologist in diagnosis and follow-up of non-cervical abnormalities.
5. Relevant internal and external quality assurance procedures.

**COMPETENCE****Be able to:**

- a. Make the correct management recommendations for unsatisfactory or normal cervical cytology reports.
- b. Describe and record the correct management recommendations for abnormal cervical cytology reports.
- c. Identify where it is appropriate to perform cytology or HPV testing according to clinical history.
- d. Complete all the relevant 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:

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

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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. Audit cycle.
2. Principle of multidisciplinary audit.
3. Quality assurance structure for the NHS Cervical Screening Programme (NHSCSP) or equivalent.
4. Importance of internal quality control as part of good laboratory practice.
5. Importance of external quality assessment as part of good laboratory practice.
6. How quality assurance data are used to help monitor the effectiveness of the NHSCSP or equivalent.

**COMPETENCE**

**Be able to:**

- a. Interpret quality assurance data to analyse personal and laboratory performance.
- b. Identify performance outside national performance indicators.
- c. Interpret quality assurance data to analyse the laboratory's performance.

**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).**

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Trainer's name:

Trainer's signature:

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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:

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Trainer's signature:

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Internal Assessor's signature:

Internal Assessor's name:

Date:

**Section 7A.1      Cervical Cytopathology**  
**Subsection 7A.1m      Colposcopy and gynaecology**

**KNOWLEDGE**

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

1. Role of colposcopy in the diagnosis, treatment and management of cervical disease.
2. Role of the gynaecologist in the diagnosis, treatment and management of non-cervical disease.
3. Role of multidisciplinary team meetings in the management of cervical disease.

**COMPETENCE**

**Be able to:**

- a. Describe the role of colposcopy in the diagnosis, treatment and management of cervical disease.
- b. Discuss the selection of appropriate cases for MDT meetings.
- c. Attend appropriate MDT meetings.

**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 module. (Evidence to support this is required).**

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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Internal Assessor's signature:

Internal Assessor's name:

Date:

**Section 7A.1      Cervical Cytopathology**  
**Subsection 7A.1n      Failsafe**

**KNOWLEDGE**

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

1. Role of failsafe in the screening programme.
2. Requirements for laboratory involvement in failsafe programme.

**COMPETENCE**

**Be able to:**

- a. Describe the failsafe system within the laboratory.
- b. Monitor the referral process resulting from abnormal reports.

**EVIDENCE OF ACHIEVEMENT**

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

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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 7A.1****Cervical Cytopathology****Subsection 7A.1o****New technologies and ancillary techniques in screening****KNOWLEDGE**

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

1. Use of semi-automated and automated scanning devices and digital pathology.
2. Technology and use of molecular pathology techniques (e.g. polymerase chain reaction [PCR], hybrid capture).
3. Potential impact of human papillomavirus (HPV) vaccination on the screening programme.
4. Use of biomarker tests.
5. Theory and rationale for HPV testing for triage/test of cure (TOC) and as a primary screening tool.

**COMPETENCE****Be able to:**

- a. Describe the potential use of new technologies and how these may be introduced into the NHS Cervical Screening Programme (NHSCSP) or equivalent.
- b. Understand the use of ancillary testing in cervical cytology and the impact of new technologies in the NHSCSP.

**EVIDENCE OF ACHIEVEMENT**

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

## **Section 7A.1 Reflective Practice**

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 Part 1.**

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

## **Section 7.A1 Candidate's Reflective Practice Statement Part 2.**

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

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

REFERENCE

**KNOWLEDGE**

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

1. Different types of sampling methods available.
2. Importance of correct sampling.
3. Correct presentation and requirements for all types of non-cervical samples.
4. How to prepare all types of non-cervical samples using various concentration methods, air drying or fixation as appropriate.
5. How to prepare all types of non-cervical samples using routine staining methods, special staining methods, and ancillary methods.
6. Risks and hazards associated with fixed and unfixed samples.
7. 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. Optimally prepare all types of non-cervical samples in accordance with standard operating procedures.
- c. Identify and rectify any problems encountered in specimen preparation.
- d. Stain non-cervical preparations using routine stains, special stains or immunological methods.
- e. Complete all the relevant 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 module. (Evidence to support this is required).**

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

**KNOWLEDGE**

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

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

## **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. Complete all the relevant documentation in accordance with quality assurance and audit requirements.

REFERENCE

**EVIDENCE OF ACHIEVEMENT**

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

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

Date of completion:

Trainer's name:

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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:

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. Principles behind industrial screening.
4. Methods of sample collection.
5. Relevance and importance of optimising preparatory techniques in samples from urinary tract cytology.
6. Appearance of contaminants and artefacts.
7. Normal cytological features of urine samples.
8. Appearance and significance of the presence of crystals and casts in urine.
9. Appearance and/or cytopathic effects of urinary tract infections.
10. Iatrogenic changes in the urinary tract.
11. Cytomorphological features of neoplastic disease and malignancy.
12. Grading criteria of papillary carcinoma.
13. Diagnostic 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. Complete all the relevant 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.

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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. Normal cytological features of effusions.
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 pitfalls.
11. 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 serous fluids, peritoneal washings and cytology samples from serous cavities.
- b. Recognise the difference between normal, reactive and malignant cells.
- c. Complete all the relevant 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).**

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

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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:

**KNOWLEDGE**

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

1. Theory of fine-needle aspiration techniques in superficial sites and utilising imaging techniques.
2. Procedures available to optimise sample preparation.

**COMPETENCE**

Be able to:

- a. Optimise specimen preparation.
- b. Stain slides in accordance with standard operating procedures and critically evaluate results.
- c. Complete all the relevant 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).**

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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. Relationship between cell structure and function.
2. Normal cytological features of abraded, aspirated and exfoliated material from tissues or epithelia.
3. General cytological features of reactive and malignant cells.
4. How to correlate cytological features with histology.
5. Relevance of immediate diagnosis.
6. Current government recommendation on cancer waiting times.

**COMPETENCE**

**Be able to:**

- a. Set up and use a microscope.
- b. Recognise normal cells from various non-cervical samples.
- c. Stain and assess immediately made cytology preparations, either in the laboratory or at a remote location.
- d. Complete all the relevant 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).**

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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:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

## **Section 7A.2 Reflective Practice**

This section is used to demonstrate that 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 Part 1.**

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

## **Section 7A.2 Candidate's Reflective Practice Statement Part 2.**

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

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

REFERENCE

**Section 7A.3 Human Papillomavirus (HPV) Molecular**  
**Subsection 7A.3a Human papillomavirus**

**KNOWLEDGE**

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

1. Different types of human papillomavirus (HPV).
2. Role of HPV in cervical cancer.
3. Nature and molecular structure of HPV.
4. Mode of transmission of HPV.
5. Molecular techniques for detecting HPV.
6. Relevance of HPV subtypes.

**COMPETENCE**

**Be able to:**

- a. Describe the structure of HPV, its genome and corresponding viral proteins.
- b. Describe the role of HPV in oncogenesis.
- c. Describe the use of molecular techniques in the detection of HPV.

**EVIDENCE OF ACHIEVEMENT**

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

**Section 7A.3 Human Papillomavirus (HPV) Molecular**  
**Subsection 7A.3b Molecular assays for HPV testing of cervical samples**

**KNOWLEDGE**

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

1. Various HPV testing systems available for use in the UK Cervical Screening programmes.
2. Theory and practice of human papillomavirus (HPV) testing assays.
3. Principles and limitations of the different molecular techniques.
4. Know what factors affect sample integrity relevant to HPV testing techniques.
5. Risks and hazards associated with sample processing.

**COMPETENCE**

**Be able to:**

- a. Apply knowledge to critically evaluate molecular assays for HPV testing.
- b. Evaluate the advantages and disadvantages of the different HPV testing assays available.
- c. Understand the principles of the assay(s) used within their laboratory, interpret data, evaluate results and anomalies.

**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 module. (Evidence to support this is required).**

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

**Section 7A.3 Human Papillomavirus (HPV) Molecular**  
**Subsection 7A.3c Use of molecular systems in HPV testing of cervical samples**

**KNOWLEDGE**

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

1. Various human papillomavirus (HPV) testing systems available for use in the UK Cervical Screening programmes.
2. Theory and practice of HPV testing.
3. Principles of the different molecular techniques.
4. What factors affect sample integrity relevant to HPV testing techniques.
5. Risks and hazards associated with sample processing.

**COMPETENCE**

**Be able to:**

- a. Identify suitable HPV testing systems for cervical samples.
- b. Apply knowledge to critically evaluate molecular systems for HPV testing.
- c. Evaluate the advantages and disadvantages of the different HPV testing systems available.
- d. Understand the workflow of samples ensuring efficiency while allowing for down time.

**EVIDENCE OF ACHIEVEMENT**

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

**Section 7A.3 Human Papillomavirus (HPV) Molecular**  
**Subsection 7A.3d Pre-analytical processing and integrity of HPV Samples**

**KNOWLEDGE**

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

1. Different pre-analytical automated systems available.
2. What factors affect sample integrity with relevance to human papillomavirus (HPV) testing techniques.
3. Risks and hazards associated with pre-analytical processing.

**COMPETENCE**

**Be able to:**

- a) Operate automated pre-analytical systems where appropriate for the technology in use.
- b) Undertake all relevant maintenance of equipment.
- c) Identify risks and hazards when preparing samples for HPV processing.
- d) Identify samples where integrity or suitability for HPV testing is compromised, and manage these appropriately.
- e) Undertake waste management and reagent replenishment, and monitor stock levels.
- f) Undertake cleaning schedules as appropriate to the technique in use.
- g) Complete all relevant documentation in accordance with laboratory quality assurance systems and audit requirements.

**EVIDENCE OF ACHIEVEMENT**

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

**Section 7A.3 Human Papillomavirus (HPV) Molecular**  
**Subsection 7A.3e Processing of samples for the detection of HPV**

**KNOWLEDGE**

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

1. Different automated systems available for the detection of human papillomavirus (HPV) in cervical screening samples.
2. What factors affect sample integrity with relevance to HPV testing techniques.
3. Risks and hazards associated with processing of samples for the detection of HPV.

**COMPETENCE**

**Be able to:**

- a. Ensure integrity of specimens for HPV testing methodology used.
- b. Undertake pre-analytical processing of specimens for HPV testing.
- c. Identify factors that might influence effective processing and analysis of samples.
- d. Undertake HPV molecular testing techniques.
- e. Operate processing systems.
- f. Undertake all relevant maintenance of equipment.
- g. Identify risks and hazards when preparing and processing samples.
- h. Undertake waste management and reagent replenishment, and monitor stock levels.
- i. Undertake cleaning schedules as appropriate to the technique in use.
- j. Complete all relevant documentation in accordance with laboratory quality assurance systems and audit requirements.

**EVIDENCE OF ACHIEVEMENT**

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

**KNOWLEDGE**

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

1. Importance of validation, quality control and quality assurance in human papillomavirus (HPV) testing.
2. Importance of external quality assurance and inter-laboratory schemes.
3. Relevant standards in relation to HPV testing and laboratory accreditation.
4. Principles of measurement of uncertainty.
5. Use of Levy-Jennings plots and CT values to monitor assay drift where appropriate.
6. Importance of calibration and servicing of equipment.

**COMPETENCE**

**Be able to:**

- a. Use appropriate internal control material and molecular kit controls when processing samples for HPV testing.
- b. Prepare suitable IQC material.
- c. Undertake appropriate IQA testing.
- d. Validate materials and processing to ensure suitability for HPV testing.
- e. Use Levy-Jennings and CT values where appropriate to monitor for issues with assay drift and measurement of uncertainty.
- f. Take part in EQA and/or inter-laboratory testing schemes.
- g. Validate HPV assay(s) being used.
- h. Undertake environmental swabbing and testing where appropriate to technique.
- i. Validate electronic interfaces between the HPV platform, LIMS and middleware where appropriate.
- j. Complete all relevant documentation in accordance with laboratory quality assurance systems and audit requirements.

**EVIDENCE OF ACHIEVEMENT**

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

**Section 7A.3 Human Papillomavirus (HPV) Molecular**  
**Subsection 7A.3g Validation and authorising of HPV results**

**KNOWLEDGE**

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

1. Theory and practice of human papillomavirus (HPV) testing assays.
2. Principles and limitations of the different molecular techniques.
3. What factors affect sample integrity relevant to HPV testing techniques.
4. What factors affect molecular assays and testing systems.
5. Risks and hazards associated with sample processing.

**COMPETENCE**

**Be able to:**

- a. Validate HPV testing assays and systems for use.
- b. Interpret data, evaluate results and anomalies.
- c. Authorise valid results.
- d. Investigate anomalies.

**EVIDENCE OF ACHIEVEMENT**

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

### **Section 7A.3 Reflective Practice**

This section is used to demonstrate that 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 Part 1.**

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

### **Section 7A.3 Candidate's Reflective Practice Statement Part 2.**

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

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

REFERENCE

## Section 7B

Candidates must have successfully completed the City and Guilds or NHSCSP training in Cervical Cytology portfolio and been awarded the Diploma in Cervical Cytology Screening.

### Section 7B.1 Cervical Cytopathology Subsection 7B.1a Female genital tract

#### KNOWLEDGE

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

1. Relationship between the cytomorphology, histology and colposcopic appearances of the cervix.
2. Pathophysiology of malignancy of the female genital tract.
3. Metaplasia and the types of metaplastic process seen in female genital tract.

#### COMPETENCE

##### Be able to:

- a. Recognise and describe the cytological and histological features of a normal cervix.
- b. Recognise and describe the cytological and histological features of metaplastic processes.
- c. Recognise and describe the cytological and histological features of dyskaryosis and cervical intraepithelial neoplasia (CIN).
- d. Recognise and describe the cytological and histological features of malignancy.
- e. Recognise and describe the cytological and histological features of glandular abnormalities.
- f. Relate all of the above to colposcopic findings.
- g. Relate cytological and histological findings to clinical factors in health and disease.

**EVIDENCE OF ACHIEVEMENT**

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

**Section 7B.1      Cervical Cytopathology**  
**Subsection 7B.1b      Cervical screening programmes**

**KNOWLEDGE**

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

1. Theory and practice of screening programmes.
2. Multidisciplinary nature of a cervical screening programme.
3. Purpose, aims and organisation of the NHS Cervical Screening Programme (NHSCSP) or equivalent screening programme for your country of work.
4. Cervical screening programmes of the other UK countries.
5. Role cytology plays in a national screening programme.

**COMPETENCE**

**Be able to:**

- a. Access, analyse and interpret information relating to a cervical screening programme (KC 53, KC61, KC65 data or equivalent).
- b. Locate relevant documentation pertaining to the screening programme in the laboratory (NHSCSP guidelines or equivalent).
- c. Define epidemiological and statistical terms used in relation to screening.
- d. Relate overall changes in the NHS to screening (e.g. National Health Application & Infrastructure Services NHAIS).

**EVIDENCE OF ACHIEVEMENT**

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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Internal Assessor's signature:

Internal Assessor's name:

Date:

**Section 7B.1 Cervical Cytopathology**  
**Subsection 7B.1c Aetiology and epidemiology of cervical cancer**

**KNOWLEDGE**

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

1. Incidence and prevalence of cervical cancer and the worldwide variation in rates.
2. Relationship between risk factors, cervical neoplasia and cancer.

**COMPETENCE**

**Be able to:**

- a. Analyse and interpret data on incidence and mortality from national and international statistics.
- b. Relate risk factors to the development of cervical cancer.
- c. Explain the full range of risk factors and rank these factors for cervical cancer predisposition.

**EVIDENCE OF ACHIEVEMENT**

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

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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:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

**Section 7B.1      Cervical Cytopathology**  
**Subsection 7B.1d      Quality assurance and audit**

**KNOWLEDGE**

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

1. Audit cycle.
2. Principle of multidisciplinary audit.
3. Quality assurance structure for the NHS Cervical Screening Programme (NHSCSP) or equivalent.
4. Importance of internal quality control as part of good laboratory practice.
5. Importance of external quality assessment as part of good laboratory practice.
6. How quality assurance data are used to help monitor the effectiveness of the NHSCSP or equivalent.
7. Principles of accreditation.
8. Role of the NHSCSP Quality Assurance Team and the relationships with the Cervical Screening Programme Lead (CSPL).
9. Principles of error logging and Serious Untoward Incidents (SUIs).

**COMPETENCE**

**Be able to:**

- a) Interpret quality assurance data to analyse your own performance.
- b) Identify performance outside national performance indicators.
- c) Interpret quality assurance data to analyse your laboratory's performance.
- d) Prepare data for accreditation and quality assurance visits.
- e) Discuss the principles of error logging.
- f) Participate in investigation of SUIs.

**EVIDENCE OF ACHIEVEMENT**

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

**Section 7B.1      Cervical Cytopathology**  
**Subsection 7B.1e      Diagnosis and treatment of malignancies of the female genital tract**

**KNOWLEDGE**

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

1. Wider clinical aspects of malignancy.
2. Role of the gynaecologist in the diagnosis, treatment and management of cervical and non-cervical disease.
3. Role of multidisciplinary team meetings in the management of cancer.
4. Difference between screening and clinical presentation (symptomatic) in non-cervical disease.

**COMPETENCE**

**Be able to:**

- a. Describe the role of the gynaecologist and colposcopist in the diagnosis, treatment and management of malignancy.
- b. Provide information for multidisciplinary team meeting as required.
- c. Describe the process of staging in malignancy.
- d. Describe treatment modalities.

**EVIDENCE OF ACHIEVEMENT**

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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Internal Assessor's signature:

Internal Assessor's name:

Date:

**Section 7B.1      Cervical Cytopathology**  
**Subsection 7B.1f      New technologies and ancillary techniques in screening**

**KNOWLEDGE**

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

1. Scientific principles of semi-automated and automated scanning devices.
2. Technology and application of molecular biological techniques.
3. Role of human papillomavirus (HPV) testing.
4. Underlying principles of vaccination.

**COMPETENCE**

**Be able to:**

- a. Describe the potential use of new technologies and how these may be introduced into the NHS Cervical Screening Programme (NHSCSP) or equivalent.
- b. Describe how the principles of vaccination apply to the availability and introduction of HPV vaccines.
- c. Describe the use of molecular biological techniques (e.g. polymerase chain reaction [PCR], hybrid capture).

**EVIDENCE OF ACHIEVEMENT**

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

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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 7B.1      Cervical Cytopathology**  
**Subsection 7B.1g    Primary care processing**

**KNOWLEDGE**

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

1. Role of primary care staff in obtaining samples for cervical screening.
2. Principle of audit of sample takers.
3. How transformation zone sampling is assessed.

**COMPETENCE**

**Be able to:**

- a. Liaise with and advise primary care staff on issues related to sampling.
- b. Identify, refer or return mismatching or incomplete samples to smear takers.
- c. Audit samples taken within a primary care service.

**EVIDENCE OF ACHIEVEMENT**

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

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

Date of completion:

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

Date of completion:

Trainer's name:

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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:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

## **Section 7B.1 Reflective Practice**

This section is used to demonstrate that 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 Part 1.**

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

## **Section 7B.1 Candidate's Reflective Practice Statement Part 2.**

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

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

REFERENCE

**Section 7B.2      Non-Cervical Cytopathology**  
**Subsection 7B.2a    General non-cervical cytology**

**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 non-cervical samples.
4. How to prepare all types of non-cervical samples using various concentration methods, air drying or fixing as appropriate.
5. How to prepare all types of non-cervical samples using routine staining methods, special staining methods, and ancillary methods.
6. Risks and hazards associated with fixed and unfixed samples.
7. 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. Optimally prepare all types of non-cervical sample.
- c. Identify and rectify any problems encountered in specimen preparation.
- d. Stain non-cervical preparations using routine stains, special stains or immunological methods.
- e. Complete all the relevant 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 module. (Evidence to support this is required).**

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

**KNOWLEDGE**

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

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

## **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. Complete all the relevant documentation (paper or electronic) in accordance with quality assurance and audit requirements.

REFERENCE

**EVIDENCE OF ACHIEVEMENT**

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

**Section 7B.2      Non-Cervical Cytopathology**  
**Subsection 7B.2c    Urinary tract**

**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. Principles behind industrial screening.
4. Methods of sample collection.
5. Relevance and importance of optimising preparatory techniques in samples from urinary tract cytology.
6. Appearance of contaminants and artefacts.
7. Normal cytological features of urine samples.
8. Appearance and significance of the presence of crystals and casts in urine.
9. Appearance and/or cytopathic effects of urinary tract infections.
10. Iatrogenic changes in urinary tract.
11. Cytomorphological features of neoplastic disease and malignancy.
12. Grading criteria of papillary carcinoma.
13. Diagnostic pitfalls.
14. Role of ancillary techniques.

**COMPETENCE**

**Be able to:**

- a. Work in accordance with standard operating procedures to optimise specimen preparation.
- b. Recognise common artefacts, contaminants and infective agents.
- c. Recognise the differences between normal, reactive and malignant cells.
- d. Complete all the relevant 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 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 7B.2 Non-Cervical Cytopathology**  
**Subsection 7B.2d Serous cavities**

**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. Normal cytological features of effusions.
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 pitfalls.
11. 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 serous fluids peritoneal washings and cytology samples from serous cavities.
- b. Recognise the difference between normal, reactive and malignant cells.
- c. Complete all the relevant 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 module. (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:

Trainer's signature:

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Internal Assessor's signature:

Internal Assessor's name:

Date:

**Section 7B.2****Non-Cervical Cytopathology****Subsection 7B.2e****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 techniques in superficial sites and utilising imaging techniques.
2. Understand procedures available to optimise sample preparation.

**COMPETENCE****Be able to:**

- a. Optimise specimen preparation.
- b. Stain slides in accordance with standard operating procedures and critically evaluate results.
- c. Complete all the relevant 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.

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Internal Assessor's signature:

Internal Assessor's name:

Date:

**Section 7B.2      Non-Cervical Cytopathology**  
**Subsection 7B.2f      Laboratory procedures**

**KNOWLEDGE**

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

1. Relationship between cell structure and function.
2. Normal cytological features of abraded, aspirated and exfoliated material from tissues or epithelia.
3. General cytological features of reactive and malignant cells.
4. How to correlate cytological features with histology.
5. Relevance of immediate diagnosis.
6. Current government recommendation on cancer waiting times.

**COMPETENCE**

**Be able to:**

- a. Set up and use a microscope.
- b. Recognise normal cells from various non-cervical samples.
- c. Stain and assess immediately made cytology preparations, either in the laboratory or at a remote location.
- d. Complete all the relevant 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).**

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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 7B.2 Reflective Practice**

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 Part 1.**

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

## **Section 7B.2 Candidate's Reflective Practice Statement Part 2.**

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

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

REFERENCE

**Section 7B.3 Human Papillomavirus (HPV) Molecular**  
**Subsection 7B.3a Human papillomavirus**

**KNOWLEDGE**

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

1. Different types of human papilloma virus (HPV).
2. Role of HPV in cervical cancer.
3. Nature and molecular structure of HPV.
4. Mode of transmission of HPV.
5. Molecular techniques for detecting HPV
6. Relevance of HPV subtypes.

**COMPETENCE**

**Be able to:**

- a. Describe the structure of HPV, its genome and corresponding viral proteins.
- b. Describe the role of HPV in oncogenesis.
- c. Describe the use of molecular techniques in the detection of HPV.

**EVIDENCE OF ACHIEVEMENT**

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

**Section 7B.3 Human Papillomavirus (HPV) Molecular**  
**Subsection 7B.3b Molecular assays for HPV testing of cervical samples**

**KNOWLEDGE**

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

1. Various human papilloma virus (HPV) testing assays available for use in the NHS Cervical Screening Programme (NHSCSP).
2. Theory and practice of HPV testing assays.
3. Principles and limitations of the different molecular techniques.
4. Know what factors affect sample integrity relevant to HPV testing techniques.
5. Risks and hazards associated with sample processing.

**COMPETENCE**

**Be able to:**

- a. Apply knowledge to critically evaluate molecular assays for HPV testing.
- b. Evaluate the advantages and disadvantages of the different HPV testing assays available.
- c. Understand the principles of the assay(s) used within their laboratory, interpret data, evaluate results and anomalies.

**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 module. (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.**

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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 7B.3 Human Papillomavirus (HPV) Molecular**  
**Subsection 7B.3c Use of molecular systems in HPV testing of cervical samples**

**KNOWLEDGE**

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

1. Various human papilloma virus (HPV) testing systems available for use in the UK Cervical Screening programmes.
2. Theory and practice of HPV testing.
3. Principles of the different molecular techniques.
4. The factors that affect sample integrity relevant to HPV testing techniques.
5. Risks and hazards associated with sample processing.

**COMPETENCE**

**Be able to:**

- a. Identify suitable HPV testing systems for cervical samples.
- b. Apply knowledge to critically evaluate molecular systems for HPV testing.
- c. Evaluate the advantages and disadvantages of the different HPV testing systems available.
- d. Understand the workflow of samples ensuring efficiency while allowing for down time.

**EVIDENCE OF ACHIEVEMENT**

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

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Internal Assessor's name:

Date:

**Section 7B.3 Human Papillomavirus (HPV) Molecular**  
**Subsection 7B.3d Pre-analytical processing and integrity of HPV Samples**

**KNOWLEDGE**

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

1. Different pre-analytical automated systems available.
2. What factors affect sample integrity with relevance to human papilloma virus (HPV) testing techniques.
3. Risks and hazards associated with pre-analytical processing.

**COMPETENCE**

**Be able to:**

- a. Operate automated pre-analytical systems where appropriate for the technology in use.
- b. Undertake all relevant maintenance of equipment.
- c. Identify risks and hazards when preparing samples for HPV processing.
- d. Identify samples where integrity or suitability for HPV testing is compromised, and manage these appropriately.
- e. Undertake waste management and reagent replenishment, and monitor stock levels.
- f. Undertake cleaning schedules as appropriate to the technique in use.
- g. Complete all relevant documentation in accordance with laboratory quality assurance systems and audit requirements.

**EVIDENCE OF ACHIEVEMENT**

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Internal Assessor's name:

Date:

**Section 7B.3 Human Papillomavirus (HPV) Molecular**  
**Subsection 7B.3e Processing of samples for the detection of HPV**

**KNOWLEDGE**

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

1. Different automated systems available for the detection of human papilloma virus (HPV) in cervical screening samples.
2. What factors affect sample integrity with relevance to HPV testing techniques.
3. Risks and hazards associated with processing of samples for the detection of HPV.

**COMPETENCE**

**Be able to:**

- a. Ensure integrity of specimens for HPV testing methodology used.
- b. Undertake pre-analytical processing of specimens for HPV testing.
- c. Identify factors that might influence effective processing and analysis of samples.
- d. Undertake HPV molecular testing techniques.
- e. Operate processing systems.
- f. Undertake all relevant maintenance of equipment.
- g. Identify risks and hazards when preparing and processing samples.
- h. Undertake waste management and reagent replenishment, and monitor stock levels.
- i. Undertake cleaning schedules as appropriate to the technique in use.
- j. Complete all relevant documentation in accordance with laboratory quality assurance systems and audit requirements.

**EVIDENCE OF ACHIEVEMENT**

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Date:

**Section 7B.3 Human Papillomavirus (HPV) Molecular**  
**Subsection 7B.3f Validation, quality control and quality assurance**

**KNOWLEDGE**

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

1. Importance of validation, quality control and quality assurance in human papilloma virus (HPV) testing.
2. Importance of external quality assurance and inter-laboratory schemes.
3. Relevant standards in relation to HPV testing and laboratory accreditation.
4. Principles of measurement of uncertainty.
5. Use of Levy-Jennings plots and CT values to monitor assay drift where appropriate.
6. Importance of calibration and servicing of equipment.

**COMPETENCE**

**Be able to:**

- a. Use appropriate internal control material and molecular kit controls when processing samples for HPV testing.
- b. Prepare suitable IQC material.
- c. Undertake appropriate IQA testing.
- d. Validate materials and processing to ensure suitability for HPV testing.
- e. Use Levy-Jennings and CT values where appropriate to monitor for issues with assay drift and measurement of uncertainty.
- f. Take part in EQA and/or inter-laboratory testing schemes.
- g. Validate HPV assay(s) being used.
- h. Undertake environmental swabbing and testing where appropriate to technique.
- i. Validate electronic interfaces between the HPV platform, LIMS and middleware where appropriate.
- j. Complete all relevant documentation in accordance with laboratory quality assurance systems and audit requirements.

**EVIDENCE OF ACHIEVEMENT**

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Internal Assessor's signature:

Internal Assessor's name:

Date:

**Section 7B.3 Human Papillomavirus (HPV) Molecular**  
**Subsection 7B.3g Validation and authorising of HPV results**

**KNOWLEDGE**

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

1. Theory and practice of human papilloma virus (HPV) testing assays.
2. Principles and limitations of the different molecular techniques.
3. The factors that affect sample integrity relevant to HPV testing techniques.
4. The factors that affect molecular assays and testing systems.
5. Risks and hazards associated with sample processing.

**COMPETENCE**

Be able to:

- a. Validate HPV testing assays and systems for use.
- b. Interpret data, evaluate results and anomalies.
- c. Authorise valid results.
- d. Investigate anomalies.

**EVIDENCE OF ACHIEVEMENT**

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### **Section 7B.3 Reflective Practice**

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).

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#### **Candidate's Reflective Practice Statement Part 1.**

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

### **Section 7B.3 Candidate's Reflective Practice Statement Part 2.**

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

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

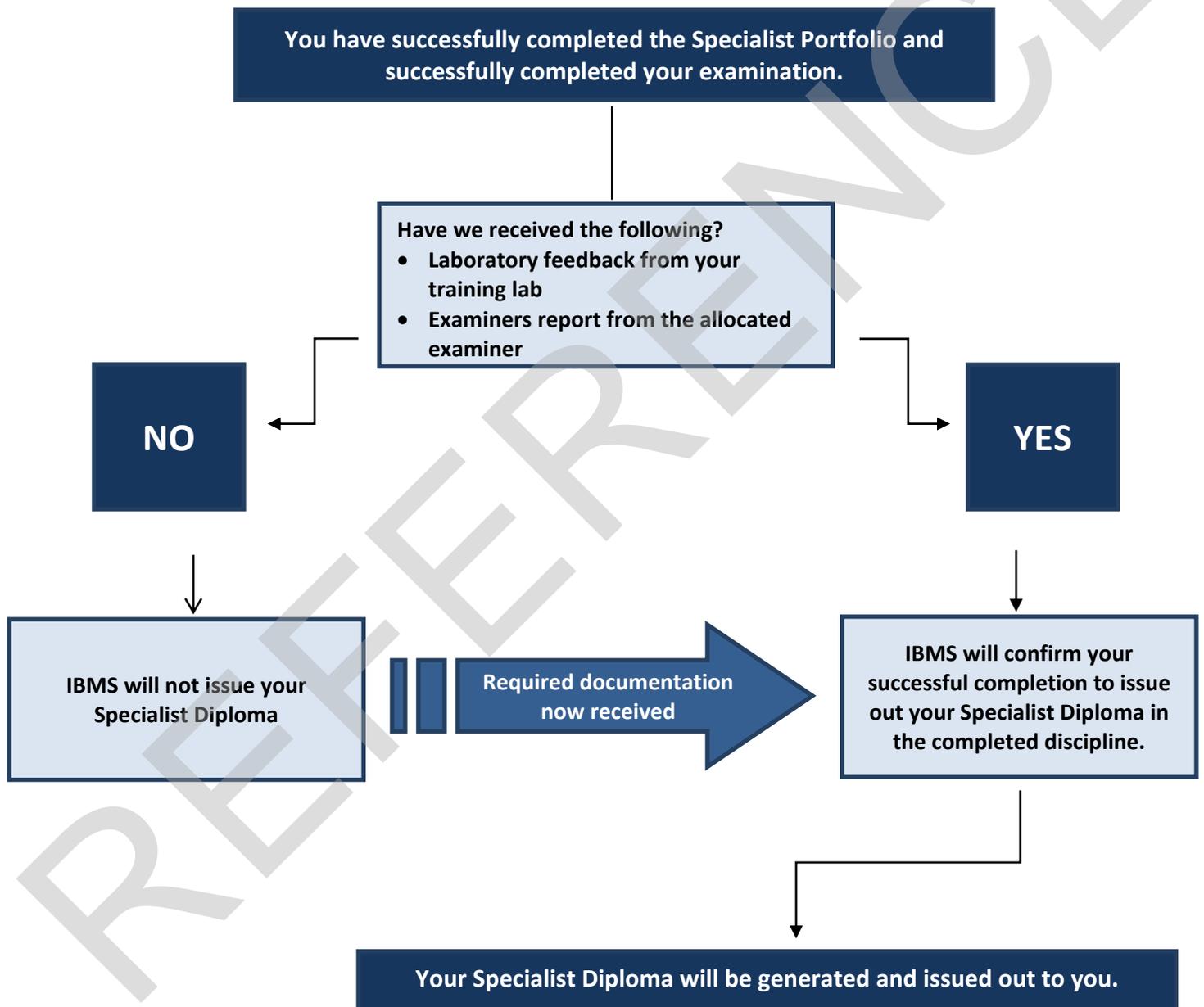
REFERENCE

# Steps to IBMS Specialist Diploma

## What is next: Your Specialist Diploma

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

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





## About this document

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

**Produced by:** Education and Professional Standards Committee

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**Version:** Version 4.2

**Active date:** July 2019

**Review date:** April 2021

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# ADVANCE



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