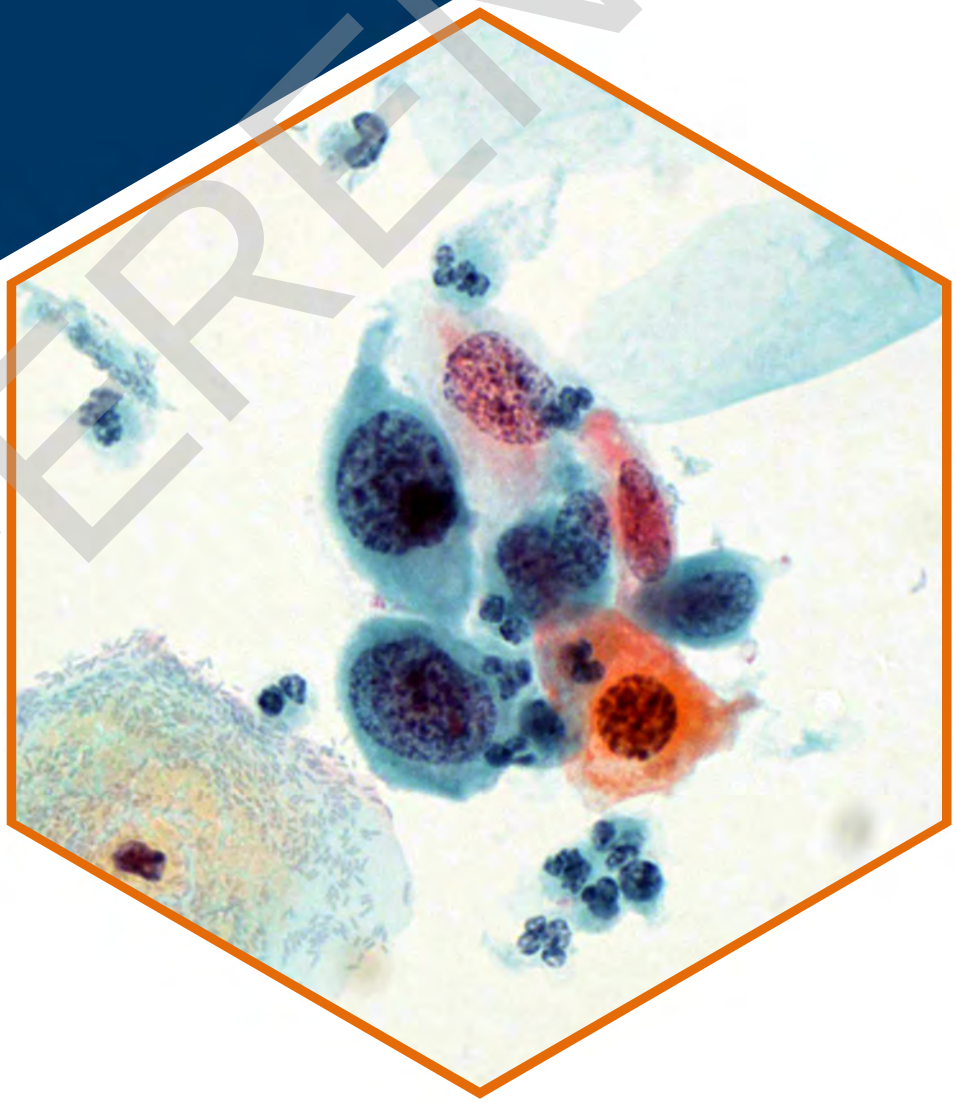
RECORD OF LABORATORY TRAINING FOR THE IBMS SPECIALIST DIPLOMA CERVICAL CYTOLOGY



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FOREWORD

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

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

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

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

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

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

Kirstie Rice

Chair Cytopathology Advisory Panel

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

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

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

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

Contents

Section 7A Cervical Cytology

For those who have completed the NHS Cervical Screening Programme training logbook & awarded the NHSCSP certificate in cervical screening.

Section 7B Cervical Cytology

For those who have completed the City and Guilds or NHSCSP training in Cervical Cytology Portfolio route and been awarded the Diploma in Cervical Cytology Screening.

1. INTRODUCTION

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

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

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

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

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

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

1.7. A discipline specific portfolio reflects the range of analyses that are considered to be relevant to your specialty. All sections must be completed in order to express your ability to operate at the specialist level. Completion of the sections should follow the formal training programme that is submitted by your laboratory to the IBMS as part of the laboratory training approval process.

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

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

2. TRAINING

Please note: You must achieve the required depth and breadth of knowledge specified in a minimum of either Section 7A or 7B. All units in a section must be completed

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

2.4. The Institute recommends that you have a regular review of your training (e.g. on a monthly basis) with your training officer in order to monitor your progress. These sessions will provide an opportunity for you to receive feedback on how your training and completion of your portfolio is progressing against the structured departmental

training programme you will be following (which is a requirement for IBMS training laboratory approval). It is a time to take into consideration issues that have impacted on your training, and whether additional support is required or available. Targets to complete stages of your training can be set and deadlines for meeting them, agreed.

3. EVIDENCE

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

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

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

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

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

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

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

4. COMPLETING THE RECORD OF LABORATORY TRAINING

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

4.2. You are required to complete a reflective practice statement to justify your selection of evidence. These are usually at the end of the section 7 or may be at the end of a set of common units within section 7.

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

5. END-POINT ASSESSMENT

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

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

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

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

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

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

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

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

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

6. COMPLETION OF REPORTS AND AWARD

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

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

Section 7A: Cervical Cytology

If completing Section 7A candidates must have successfully completed the NHS Cervical Screening Programme (NHSCSP) training logbook and have been awarded the NHSCSP Certificate in Cervical Screening.

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

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

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

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

Section 7A Cervical Cytology

Candidates must have successfully completed the NHS Cervical Screening Programme training logbook and have been awarded the NHSCSP Certificate in Cervical Screening.

Unit 7A.1 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: with the main focus on cervical histology.
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 unit. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Unit 7A.2 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. Systematic nature of cervical screening.
3. Operation of call and recall systems.
4. Rationales for the age range and intervals for cervical screening.
5. Potential impact of human papillomavirus (HPV) vaccination on the screening programme.
6. Multidisciplinary nature of a cancer/cervical screening programme.
7. Purpose, aims and organisation of the cancer/cervical screening programme (e.g. NHS Cervical Screening Programme (NHSCSP) appropriate to your country of work.)
8. Cervical screening programmes of the other UK countries.
9. 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).
c. Assess the appropriateness of a sample received based on call and recall history.
d. 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 unit. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Unit 7A.3 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. Different types of human papillomavirus (HPV).
4. Role of HPV in cervical neoplasia and cancer.
5. Nature and molecular structure of HPV.
6. Mode of transmission of HPV.
7. Molecular techniques for detecting HPV.
8. Relevance of HPV subtypes.

COMPETENCE

Be able to:

a. Analyse data on incidence and mortality from national statistics.
b. Relate risk factors to the development of cervical cancer.
c. Describe the structure of HPV, its genome and corresponding viral proteins.
d. Describe the role of HPV in oncogenesis.
e. 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 unit. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Unit 7A.4 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. Informed consent & counselling of patients.
3. Sampling devices.
4. Correct procedure for taking cervical screening samples.
5. Principle of audit of sample takers.

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 unit. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Unit 7A.5 Use of molecular systems in HPV testing

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 unit. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Unit 7A.6 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 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 unit. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Unit 7A.7 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 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 unit. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Unit 7A.8 Validation, quality control and quality assurance of HPV results

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 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 unit. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7A Units 7A.1-7A.8 Reflective Practice Part 1.

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

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

Candidate's Reflective Practice Statement

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

Section 7A Units 7A.1-7A.8 Reflective Practice Part 2.

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

Candidate's Reflective Practice Statement

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

Unit 7A.9 Processing LBC cervical samples for cytological evaluation

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. 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. Risk and hazards associated with sample processing.
6. Principles and application of light microscopy.

COMPETENCE

Be able to:

a. Prepare liquid based cytology 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 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 unit. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Unit 7A.10 Screening of cervical samples – normal cellular appearance

KNOWLEDGE

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

1. Constituents of 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. Distinguish between satisfactory and 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 documentation in accordance with quality assurance and audit requirements.

EVIDENCE OF ACHIEVEMENT

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Unit 7A.11 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. Use of additional (deeper) levels in the assessment of histological cervical screening samples.
9. Use of p16 immunocytochemistry and other relevant immunocytochemical stains in the assessment of histological cervical screening samples.
10. Use of special stains e.g.: PAS+/- diastase in the assessment of histological cervical screening samples.
11. Relevance of correlation and non-correlation between histology and cytology findings for cervical screening cases.
12. 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.
d. Recognise cytological features of malignancy.
e. Recognise borderline nuclear changes.
f. Complete all the documentation in accordance with quality assurance and audit requirements.

EVIDENCE OF ACHIEVEMENT

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Unit 7A.12 Screening of cervical samples - microorganisms

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 documentation (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 unit. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Unit 7A.13 Quality assurance and audit

KNOWLEDGE

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

1. Audit cycle.
2. Principles of multidisciplinary audit, clinical and service audits.
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.
d. Undertake service audits to UKAS (ISO) standards, identify non-conformances and act upon findings appropriately.
e. Undertake clinical audit and present and discuss audit findings.

EVIDENCE OF ACHIEVEMENT

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Unit 7A.14 Management of cervical screening 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 colposcopist in diagnosis and follow-up of diagnostic cytology abnormalities.
5. Relevant internal and external quality assurance procedures.

COMPETENCE

Be able to:

a. Identify where it is appropriate to perform HPV testing +/- cytology according to clinical history.
b. Make the correct management recommendations for unsatisfactory or normal cervical screening reports.
c. Describe and record the correct management recommendations for abnormal cervical screening reports.
d. Complete all documentation in accordance with quality assurance and audit requirements.

EVIDENCE OF ACHIEVEMENT

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Unit 7A.15 Colposcopy and gynaecology

KNOWLEDGE

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

1. Role of the colposcopist and use of colposcopy in the diagnosis, treatment and management of cervical disease and non-cervical disease.
2. Role of adjunctive technologies used in colposcopy e.g. DYSIS
3. Role of multidisciplinary team meetings in the management of cervical disease.
4. Difference between screening and clinical presentation (symptomatic) in non-cervical disease.
5. Relevant internal and external quality assurance procedures

COMPETENCE

Be able to:

a. Describe the role of colposcopy in the diagnosis, treatment and management of cervical disease.
b. Describe treatment modalities.
c. Describe the process of staging in malignancy.
d. Discuss the selection of appropriate cases for MDT meetings.
e. 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:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Unit 7A.16 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 programmes.

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 unit. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Unit 7A.17 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. Use of biomarker tests.
4. Potential application of self-sampling devices in the screening programme.

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. Explain the use of primary and ancillary testing in cervical screening and the possible 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 unit. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7A Units 7A.9-7A.17 Reflective Practice Part 1.

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

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

Candidate's Reflective Practice Statement

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

Section 7A Units 7A.9-7A.17 Reflective Practice Part 2.

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

Candidate's Reflective Practice Statement

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

Section 7B: Cervical Cytology

If completing Section 7B candidates must have successfully completed the City and Guilds or NHSCSP training in Cervical Cytology Portfolio route and have been awarded the Diploma in Cervical Cytology Screening.

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

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

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

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

Section 7B Cervical Cytology

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

Unit 7B.1 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: with the main focus on cervical histology.
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 unit. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Unit 7B.2 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. Systematic nature of cervical screening.
3. Operation of call and recall systems.
4. Rationales for the age range and intervals for cervical screening.
5. Potential impact of human papillomavirus (HPV) vaccination on the screening programme.
6. Multidisciplinary nature of a cancer/cervical screening programme.
7. Purpose, aims and organisation of the cancer/cervical screening programme (e.g. NHS Cervical Screening Programme [NHSCSP] appropriate to your country of work).
8. Cervical screening programmes of the other UK countries.
9. 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 documentation pertaining to the cancer screening programme in the laboratory (NHSCSP guidelines or equivalent).
c. Assess the appropriateness of a sample received based on call and recall history.
d. 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 unit. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Unit 7B.3 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. Different types of human papillomavirus (HPV).
4. Role of HPV in cervical neoplasia and cancer.
5. Nature and molecular structure of HPV.
6. Mode of transmission of HPV.
7. Molecular techniques for detecting HPV.
8. Relevance of HPV subtypes.

COMPETENCE

Be able to:

a. Analyse data on incidence and mortality from national statistics.
b. Relate risk factors to the development of cervical cancer.
c. Describe the structure of HPV, its genome and corresponding viral proteins.
d. Describe the role of HPV in oncogenesis.
e. 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 unit. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Unit 7B.4 Diagnosis and treatment of pre-malignant changes and malignancies of the female genital tract

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. Use of additional (deeper) levels in the assessment of histological cervical screening samples.
4. Use of p16 immunocytochemistry and other relevant immunocytochemical stains in the assessment of histological cervical screening samples.
5. Use of special stains e.g.: PAS+/- diastase in the assessment of histological cervical screening samples.
6. Relevance of correlation and non-correlation between histology and cytology findings for cervical screening cases.
7. Wider clinical aspects of malignancy.
8. Role of the gynaecologist and colposcopist in the diagnosis, treatment and management of cervical and non-cervical disease.
9. Role of multidisciplinary team meetings in the management of cancer.
10. Difference between screening and clinical presentation (symptomatic) in non-cervical disease.
11. Relevant internal and external quality assurance procedures.

COMPETENCE

Be able to:

a. Describe the role of the pathologist, gynaecologist and colposcopist in the diagnosis, treatment and management of malignancy.
b. Describe the process of staging in malignancy.
c. Describe treatment modalities.
d. Discuss the selection of appropriate cases for MDT meetings.
e. 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 trainer to work in accordance with standard laboratory procedures. (No other evidence is required)

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Unit 7B.5 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. Informed consent & counselling of patients.
3. Sampling devices.
4. Correct procedure for taking cervical screening samples.
5. Principle of audit of sample takers.

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 unit. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7B Units 7B.1 – 7B.5 Reflective Practice Part 1.

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

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

Candidate's Reflective Practice Statement

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

Section 7B Units 7B.1 – 7B.5 Reflective Practice Part 2.

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

Candidate's Reflective Practice Statement

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

Unit 7B.6 Use of molecular systems in HPV testing

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 unit. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Unit 7B.7 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 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 unit. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Unit 7B.8 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 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 unit. (Evidence to support this is required).

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Unit 7B.9 Validation, quality control and quality assurance of HPV results

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 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:

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Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Unit 7B.10 Quality assurance and audit

KNOWLEDGE

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

1. Audit cycle.
2. Principles of multidisciplinary audit, clinical and service audits
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.
d. Undertake service audits to UKAS (ISO) standards, identify non-conformances and act upon findings appropriately.
e. Undertake clinical audit and present and discuss audit findings

EVIDENCE OF ACHIEVEMENT

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Unit 7B.11 Management of cervical screening 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 colposcopist in diagnosis and follow-up of diagnostic cytology abnormalities.
5. Relevant internal and external quality assurance procedures.

COMPETENCE

Be able to:

a. Identify where it is appropriate to perform HPV testing +/- cytology according to clinical history.
b. Make the correct management recommendations for unsatisfactory or normal cervical screening reports.
c. Describe and record the correct management recommendations for abnormal cervical screening reports.
d. Complete all documentation in accordance with quality assurance and audit requirements.

EVIDENCE OF ACHIEVEMENT

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Unit 7B.12 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. Use of biomarker tests.
4. Potential application of self-sampling devices in the screening programme.

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. Explain the use of primary and ancillary testing in cervical screening and the possible 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).

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Date of completion:

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Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7B Units 7B.6 – 7B.12 Reflective Practice Part 1.

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

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

Candidate's Reflective Practice Statement

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

Section 7B Units 7B.6 – 7B.12 Reflective Practice Part 2.

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

Candidate's Reflective Practice Statement

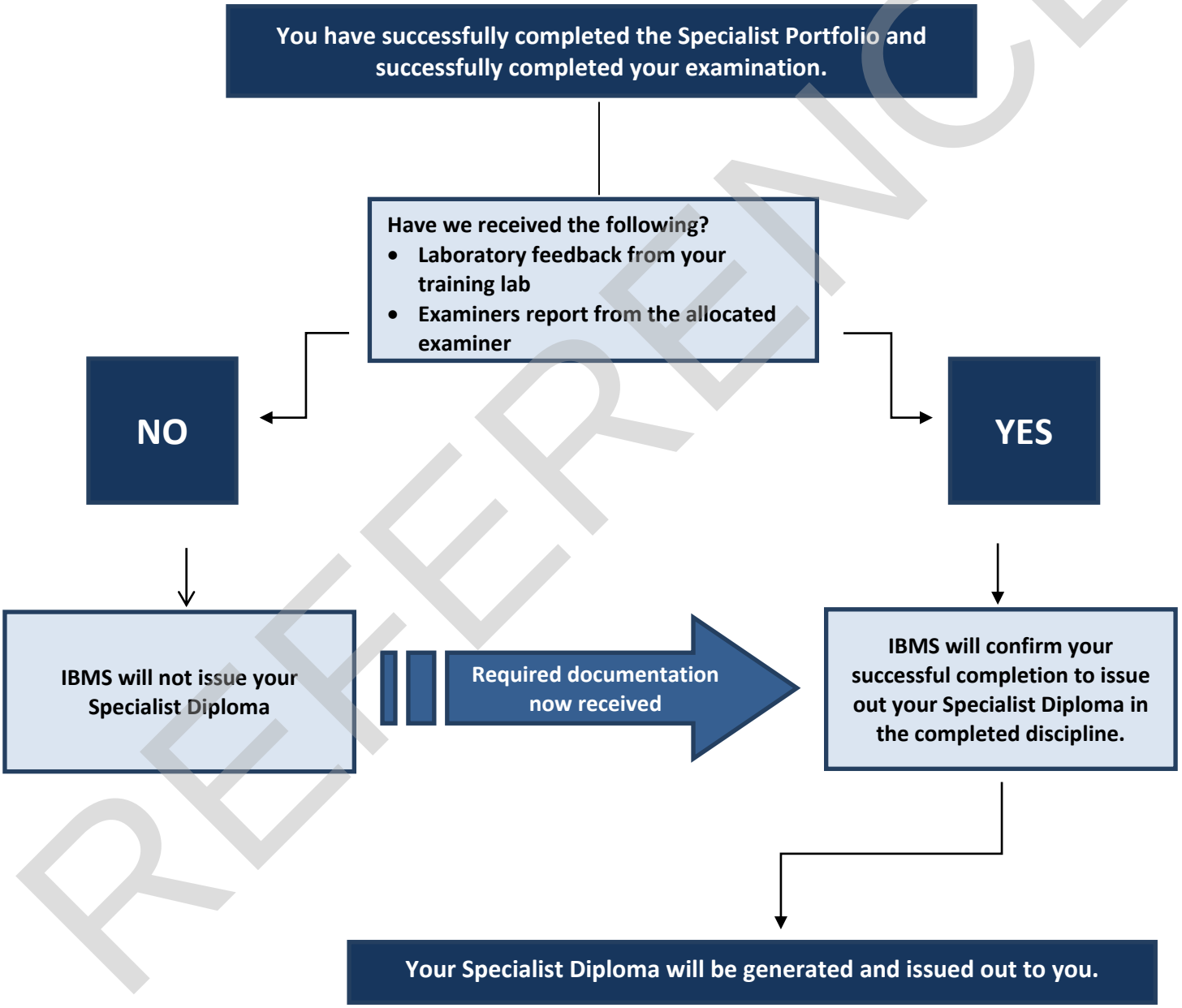
Personal reflection on training and examples of evidence for this section.

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 Cervical Cytology

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