# RECORD OF LABORATORY TRAINING FOR THE IBMS SPECIALIST DIPLOMA MOLECULAR PATHOLOGY



**Institute of Biomedical Science**
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| Personal Details |
|---|
| Name: |
| IBMS Membership Number: |
| IBMS Membership Grade: |
| HCPC Registration Number: |
| Date of HCPC Registration: |
| Employment Address: |
| Telephone Number: |
| Date Specialist Training Commenced: |
| Name of Training Officer: |

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

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

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

## 1. INTRODUCTION

1.1. The Institute of Biomedical Science (IBMS) Cellular Pathology Specialist Portfolio incorporates an optional additional module in Molecular Pathology. In addition to this being available to new candidates commencing specialist training, this is also available as a stand-alone module to already trained and experienced individuals working in cellular pathology and now wishing to extend their knowledge and skills to accommodate the integration of molecular pathology techniques.

1.2. Applicants for this module must, as a minimum requirement, hold the IBMS membership class of Licentiate and be working in a laboratory with Institute approval for post-registration training. It is not available to Associate members of the Institute or individuals undertaking pre-registration training.

1.3. The Molecular Pathology module, whether completed as part of the Cellular Pathology Specialist Portfolio or as a stand-alone module, will be examined in an external location, not the candidate's employing laboratory. This will usually be the Institute's London office but may be an alternative location that is more convenient to both candidate and examiners.

1.4. The Molecular Pathology module does not confer eligibility for the award of a Specialist Diploma in its own right neither does it confer eligibility to upgrade from Licentiate to Member.

1.5. The following information is specific for candidates completing this module.

*Candidates not completing the Molecular Pathology module as part of the Cellular Pathology Specialist Portfolio are asked to refer to the Institute's website to see the full candidate guidance on completion of Specialist Portfolios. This contains specific instructions on portfolio compilation and selection of evidence.*

## 2. APPLICATION

Candidates who are already qualified and experienced at or above the specialist level are eligible to take this module in a standalone capacity and must complete the optional module application form. The Molecular Pathology module is issued on receipt of payment and acceptance of the application by the Institute. The fee is inclusive of the end-point assessment. Please note that the fee does not cover the cost of candidate travelling expenses for the end-point assessment, for which the candidate or candidate's employer is responsible.

## 3. COMPLETING THE MOLECULAR PATHOLOGY MODULE

3.1. Each section of this module requires the candidate to demonstrate knowledge and competence of their practice. If the candidate's employing laboratory does not undertake some, or all, of the prescribed molecular pathology techniques and does not employ individuals with the knowledge and experience to deliver the necessary training, there may need to be an arrangement with another laboratory to provide the required additional training experience.

3.2. The Training Review sheet on page 2 must be completed as evidence of structured training.

## 4. COMPLETION TIME

4.1. Candidates taking only the optional Molecular Pathology module should expect to complete it within six months. While there is currently no time limit for completion of the module there is a requirement for evidence to be relevant to the candidate's current practice, i.e. within two years of the end-point assessment. Evidence older than two years should not be included unless, in exceptional circumstances, relevance can be confirmed by the trainer. When the candidate is ready for external examination an application must be submitted to the IBMS by the trainer or laboratory manager.

4.2. Candidates are expected to meet the following learning outcomes adapted from the guidance document for Specialist Portfolios.

**Knowledge and understanding**

The successful candidate will be able to:

a. Demonstrate knowledge and understanding of complex scientific and technical aspects of molecular pathology 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.
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**

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**

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

## 5. END-POINT ASSESSMENT

5.1. The Molecular Pathology module will be examined in an external location, not the candidate's employing laboratory. This will usually be the Institute's London office but may be an alternative location that is more convenient to both candidate and examiners.

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

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

Part one: a review of the record of laboratory training to check all components have been signed off and to verify appropriate training has been undertaken, through a review of the Portfolio of Evidence.

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

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

5.5. This will trigger the appointment within six weeks of the external examiner with expertise in molecular pathology in the context of cellular pathology. The external examiner will be sent a copy of the record of laboratory training and portfolio of evidence for review within 2 weeks. The candidate's training officer will receive confirmation that this stage has been completed.

5.6. The following outcomes apply to part one:

- Outcome 1: Candidate has met all of the requirements for the record of laboratory training and portfolio of evidence and may proceed to part two;

- Outcome 2: Candidate has partially met the requirements record of laboratory training and portfolio of evidence and is required to submit further evidence to address specific standards of proficiency before they proceed to part two;

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

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

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

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

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

5.10. The external examiner will complete a report form to confirm the areas covered in the *viva voce* with example questions, and outcomes of the examination process.

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

5.12. If the candidate passes, feedback may be provided at the discretion of the examiner.

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

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

## 6. COMPLETION OF REPORTS AND AWARD

6.1. Following completion of the module and a successful examination outcome, candidates that have completed the Cellular Pathology Specialist Portfolio with the additional Molecular Pathology module will be eligible for the award of a Specialist Diploma denoting the addition of the optional Molecular Pathology module.

6.2. Candidates that have taken only the optional module will be awarded a certificate recognising their award of a specialist module in molecular pathology.

**Please note:** The Molecular Pathology module does not confer eligibility for the award of a Specialist Diploma in its own right neither does it confer eligibility to upgrade from Licentiate to Member.

**Appeals**

Unsuccessful candidates will have the opportunity to appeal on procedural matters related to the examination process. Appeals must be made by the training officer or manager and submitted with the laboratory feedback form within one week of the examination. Appeals must clearly state the reasons for the appeal with supporting evidence where appropriate. Appeals will be considered by an appeals panel of the external examiner and two HCPC registered members of the IBMS Council who are not associated with any aspect of the application.

# Section 7:

# Molecular Pathology

This section covers the range of molecular pathology procedures and diagnostic techniques that have been identified as being most relevant to practice as a specialist biomedical scientist in cellular pathology. Candidates completing this section are expected to be able to demonstrate the application of knowledge and skills defined in section 2 of this portfolio.

It is accepted that some of these tests may not be performed in the candidate's own laboratory. Whilst practical skills may not be achievable (for example through secondment to another laboratory) to the level of someone performing them regularly, knowledge and understanding of its application is still required and may be examined.

There may be other tests, outside of those listed in this portfolio, that are part of the training laboratory's basic repertoire in which the individual is required to be competent. These can be recorded in the reflective statement at the end of each sub-section.

## Section 7.1 Introduction to Cancer and Stratified Medicine – A Molecular Perspective

**KNOWLEDGE**

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

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

**COMPETENCE**

You must be able to:

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

**EVIDENCE OF ACHIEVEMENT**

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

## Section 7.1 Reflective Practice

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

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

## Candidate's Reflective Practice Statement Part 1.

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

## Section 7.1 Candidate's Reflective Practice Statement Part 2.

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

**Personal reflection on training and examples of evidence:**

## Section 7.2 Introduction to Gene Sequencing for Cellular Pathology Specimens

**KNOWLEDGE**

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

1. The relationship between genetics and cancer.
2. The difference between whole genome, whole exome and targeted sequencing, with the reasons for using each.
3. The role of proteomics.
4. The process of next generation sequencing (NGS), and how genomic data can aid with diagnosis.
5. The role played by the Human Genome Project and the potential contribution of the 100,000 Genomes Project.
6. Significance of identifying single nucleotide pleomorphisms (SNPs) in prostate cancer.
7. How the developing state of knowledge impacts on the value of the sequencing data.

**COMPETENCE**

You must be able to:

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

**EVIDENCE OF ACHIEVEMENT**

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

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

Date of completion:

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Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

## Section 7.2 Reflective Practice

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

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

## Candidate's Reflective Practice Statement Part 1.

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

## Section 7.2 Candidate's Reflective Practice Statement Part 2.

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

**Personal reflection on training and examples of evidence:**

## Section 7.3 Sample Handling

### Subsection 7.3a Pre-analytical considerations

**KNOWLEDGE**

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

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

**COMPETENCE**

You must be able to:

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

**EVIDENCE OF ACHIEVEMENT**

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

## Section 7.3 Sample Handling

### Subsection 7.3b Tissue selection for molecular studies

**KNOWLEDGE**

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

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

**COMPETENCE**

You must be able to:

a. Discuss the rationale of tissue selection procedures for molecular testing.
b. Select and dissect appropriate tissues for molecular testing.
c. Ensure tissue for molecular testing is handled appropriately.

**EVIDENCE OF ACHIEVEMENT**

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

## Section 7.3 Sample Handling

### Subsection 7.3c Cryotomy

**KNOWLEDGE**

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

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

**COMPETENCE**

You must be able to:

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

**EVIDENCE OF ACHIEVEMENT**

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

## Section 7.3 Sample Handling

### Subsection 7.3d Tissue processing, embedding and microtomy

**KNOWLEDGE**

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

1. Effects of formalin-fixed paraffin wax embedding (FFPE) on molecular samples.
2. Requirements for processing, orientating mirror-blocks and producing sections.

**COMPETENCE**

You must be able to:

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

**EVIDENCE OF ACHIEVEMENT**

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

## Section 7.3 Reflective Practice

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

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

## Candidate's Reflective Practice Statement Part 1.

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

## Section 7.3 Candidate's Reflective Practice Statement Part 2.

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

**Personal reflection on training and examples of evidence:**

## Section 7.4 Assessment of Cellularity

**KNOWLEDGE**

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

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

**COMPETENCE**

You must be able to:

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

**EVIDENCE OF ACHIEVEMENT**

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

## Section 7.4 Reflective Practice

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

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

## Candidate's Reflective Practice Statement Part 1.

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

## Section 7.4 Candidate's Reflective Practice Statement Part 2.

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

**Personal reflection on training and examples of evidence:**

## Section 7.5 Extraction Techniques in Molecular Pathology

**KNOWLEDGE**

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

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

**COMPETENCE**

You must be able to:

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

**EVIDENCE OF ACHIEVEMENT**

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

## Section 7.5 Reflective Practice

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

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

## Candidate's Reflective Practice Statement Part 1.

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

## Section 7.5 Candidate's Reflective Practice Statement Part 2.

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

**Personal reflection on training and examples of evidence:**

## Section 7.6 Quality Considerations in Molecular Pathology

**KNOWLEDGE**

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

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

**COMPETENCE**

You must be able to:

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

**EVIDENCE OF ACHIEVEMENT**

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

## Section 7.6 Reflective Practice

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

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

## Candidate's Reflective Practice Statement Part 1.

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

## Section 7.6 Candidate's Reflective Practice Statement Part 2.

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

**Personal reflection on training and examples of evidence:**

## Section 7.7 *In Situ* Hybridisation

**KNOWLEDGE**

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

1. Principles of *in situ* hybridisation techniques, including the use of fluorescence and chromogenic methodologies.
2. Role of the clinical application of in-situ hybridisation in diagnostic pathology.
3. Key diagnostic and prognostic information supported by ISH techniques.
4. Selection, interpretation and troubleshooting of in-situ hybridisation methodologies as an adjunct to histopathological analysis.
5. Indicative demonstration methods: *Her2*, HPV, *EML4-Alk* fusions, EBV, immunoglobulin mRNA.

**COMPETENCE**

You must be able to:

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

**EVIDENCE OF ACHIEVEMENT**

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

## Section 7.7 Reflective Practice

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

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

## Candidate's Reflective Practice Statement Part 1.

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

## Section 7.7 Candidate's Reflective Practice Statement Part 2.

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

**Personal reflection on training and examples of evidence:**

## 8. References


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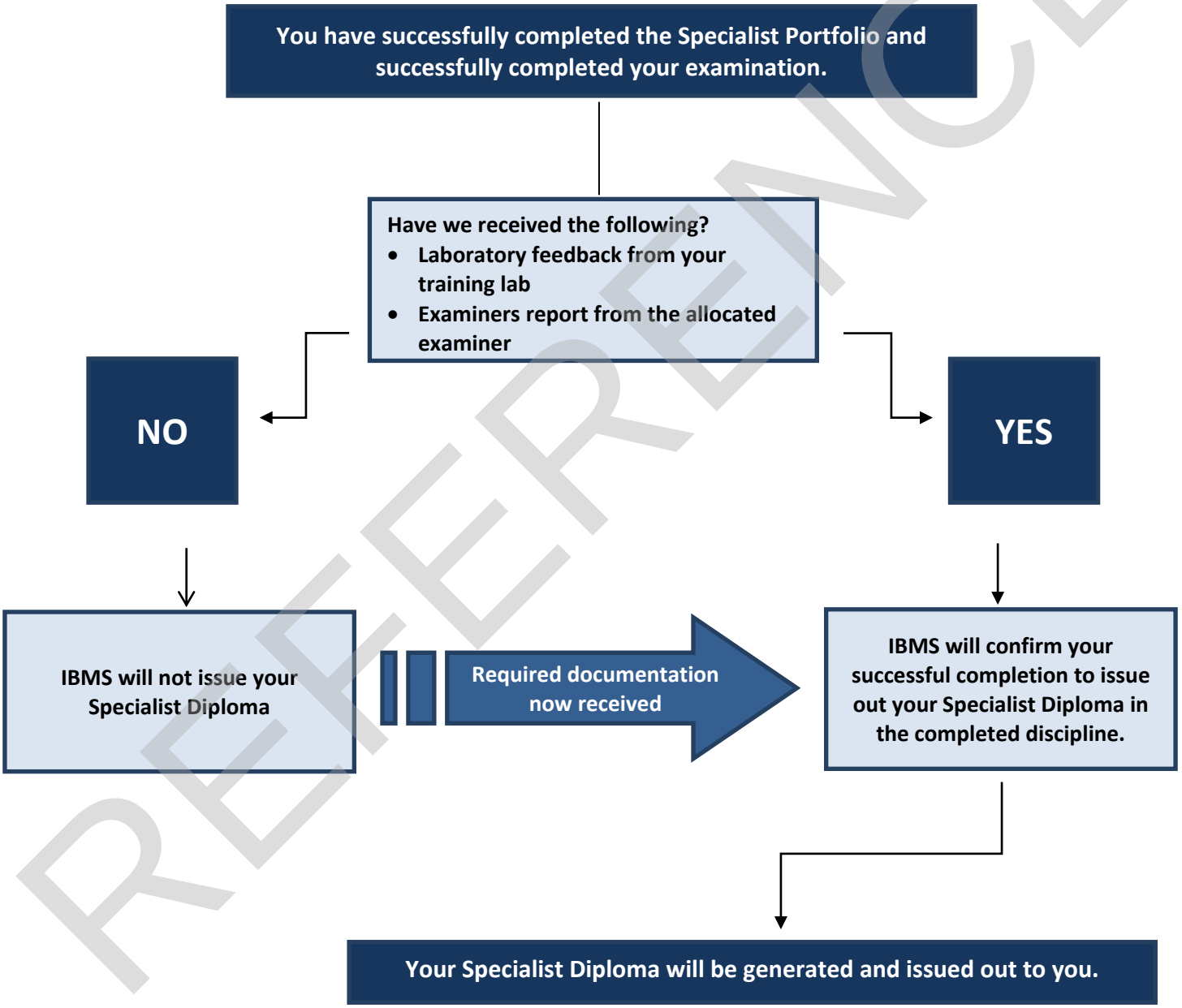
Qiagen Webinar Series (e.g., but not limited to, https://www.qiagen.com/gb/resources/e-learning/webinars/cancer-research/qsnucleicacids/) (this could be expanded to various manufacturers as needed if we feel appropriate to use commercial resources like this).

# 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

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