RECORD OF LABORATORY TRAINING FOR THE IBMS SPECIALIST DIPLOMA CLINICAL IMMUNOLOGY

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

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

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

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

Contents

1. INTRODUCTION

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

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

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

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

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

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

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

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

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

2. TRAINING

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

on your training, and whether additional support is required or available. Targets to complete stages of your training can be set and deadlines for meeting them, agreed.

3. EVIDENCE

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

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

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

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

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

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

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

4. COMPLETING THE RECORD OF LABORATORY TRAINING

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

4.2. You are required to complete a reflective practice statement at the end of each module to justify your selection of evidence.

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

5. END-POINT ASSESSMENT

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

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

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

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

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

5.6. During the laboratory tour with *viva voce* the external examiner will not assess your practical competence; this was the responsibility of your trainer. However, they will expect you to be able to demonstrate knowledge and understanding of the practical

aspects underpinning a techniques and corrective action you might take if things go wrong.

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

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

6. COMPLETION OF REPORTS AND AWARD

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

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

Section 7:
Clinical Immunology

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

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

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

Section 7.1 Rheumatological Diseases
Subsection 7.1a Antinuclear antibodies

KNOWLEDGE

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

1. Principles, practice and limitations of the following methods in the context of the detection and quantification of antinuclear antibodies:
   - Indirect immunofluorescence using Liver / Hep2 / Hep2000
   - Enzyme-linked immunosorbent assay (ELISA)
   - Multiplex technologies
2. Advantages and disadvantages of the different techniques.
3. The use and preparation of different substrates.
4. Methods for the production of monoclonal and polyclonal antibodies.
5. Methods for the preparation of conjugated antisera.
6. Properties of different fluorescent compounds.
7. Principles of light and fluorescence microscopy and the application of fluorescence microscopy in the detection and quantification of antinuclear antibodies.
8. Patterns of common antinuclear antibodies and their association with individual ANA specificities and clinical disease:
   - Homogeneous
   - Speckled – coarse, fine
   - Nucleolar
   - Centromere
   - Nuclear matrix/large speckled
9. What follow up tests to perform as a result of positive tests.
10. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

a. Perform assays in accordance with standard laboratory procedures.
b. Recognise all common antinuclear antibody patterns by indirect immunofluorescence.
c. Detect and quantify antibodies in accordance with own laboratory methodology.
d. Critically evaluate results.
e. Technically report results.
f. Complete all relevant documentation in accordance with quality control and audit requirements.

EVIDENCE OF ACHIEVEMENT

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7.1 Rheumatological Diseases
Subsection 7.1b dsDNA antibodies

KNOWLEDGE

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

1. Principles, practice and limitations of the following methods for detection and quantification of dsDNA antibodies:
   - Indirect immunofluorescence
   - ELISA
2. Pathogenesis of dsDNA antibodies and disease association.
3. The clinical difference between high and low affinity antibodies.
4. The use and preparation of different substrates.
5. Advantages and disadvantages of the different techniques.
6. Pathogenesis of DNA antibodies, and their association with rheumatological and non-rheumatological disease.
7. Show awareness of the histological findings of skin and kidney biopsy in SLE patients.
8. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

a. Perform assays in accordance with standard laboratory procedures.
b. Detect and quantify antibodies.
c. Critically evaluate results.
d. Technically report results.
e. Complete all relevant documentation in accordance with quality control and audit requirements.

EVIDENCE OF ACHIEVEMENT

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7.1 Rheumatological Diseases
Subsection 7.1c Extractable nuclear antigens

KNOWLEDGE

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

1. Most commonly detected extractable nuclear antigen (ENA) antibodies and their target antigens, namely:
   - SSA (Ro60/52)
   - SSB
   - Sm
   - SM/RNP
   - Scl-70
   - Jo-1
   - PM-Scl
2. Clinical significance of antibodies to extractable nuclear antigens in relation to:
   - Sjögren's syndrome.
   - Overlapping connective tissue diseases:
     - Myositis
     - Scleroderma
     - Systemic Lupus Erythematosus (SLE)
3. For each of the following techniques understand the principles, limitations, advantages and disadvantages of that technique in the context of ENA antibody testing. Where appropriate this should include an understanding of antibody-antigen reaction kinetics (i.e. affinity, avidity and prozone):
   - Immunofluorescence
   - Immunodiffusion
   - Electrophoresis
   - ELISA
   - Immunoblotting
   - Multiplex technologies
4. Advantages and disadvantages of the different investigative techniques.
5. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

a. Perform assays in accordance with standard laboratory procedures.
b. Detect and identify specific ENA antibodies.
c. Critically evaluate results.
d. Technically report results.
e. Complete all relevant documentation in accordance with quality control and audit requirements.

EVIDENCE OF ACHIEVEMENT

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7.1 Rheumatological Diseases
Subsection 7.1d Phospholipid antibodies

KNOWLEDGE

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

1. Significance of antiphospholipid antibodies in the laboratory classification of antiphospholipid syndrome (APS) and the difference between primary and secondary disease.
2. The role of antiphospholipid antibodies in the clinical manifestations of APS and the significance of different antibody isotypes.
3. Relationships between and significance of the following APS:
   - Beta-2-glycoprotein I antibodies
   - Cardiolipin antibodies
   - Prothrombin antibodies
   - Phosphatidylserine antibodies
4. The nature and significance of 'Lupus Anticoagulant' activity.
5. Principles and practice of techniques available for the detection of phospholipid antibodies.
6. Internal quality control and external quality assessment procedures.
7. Relevant guidelines available to clinical laboratories for diagnosis of antiphospholipid syndrome.

COMPETENCE

Be able to:

a. Perform assays in accordance with standard laboratory procedures.
b. Detect and quantify types of phospholipid antibodies.
c. Critically evaluate results.
d. Technically report results.
e. Complete all relevant documentation in accordance with quality control and audit requirements.

EVIDENCE OF ACHIEVEMENT

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7.1 Rheumatological Diseases

Subsection 7.1e Antibodies used in the diagnosis and monitoring of rheumatoid arthritis

KNOWLEDGE

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

1. Pathogenesis of rheumatoid arthritis (RA) and the significance of immunoglobulin IgG, IgM and IgA rheumatoid factor (RF) and antibodies to Citrullinated Peptides in relation to the disease.
2. Clinical and imaging findings required in the diagnosis of RA and the role of autoantibody measurement in diagnosis and disease monitoring.
3. Principles and limitations of techniques available for the detection of antibodies, including:
   - Haemagglutination
   - Particle agglutination
   - ELISA
   - Nephelometry/turbidimetry
4. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

a. Perform assays in accordance with standard laboratory procedures.
b. Detect and quantify types of rheumatoid factor antibodies.
c. Critically evaluate results and report accordingly.
d. Complete all relevant documentation in accordance with quality control and audit requirements.

EVIDENCE OF ACHIEVEMENT

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7.1 Reflective Practice

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

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

Candidate's Reflective Practice Statement Part 1.

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

Section 7.1 Candidate's Reflective Practice Statement Part 2.

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

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

Section 7.2 Gastrointestinal Disorders
Subsection 7.2a Coeliac Disease

KNOWLEDGE

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

1. Incidence and clinical diversity in coeliac disease.
2. Incidence of antibodies present in coeliac disease and their diagnostic value, including antibodies to:
   - Endomysium
   - Tissue transglutaminase
   - Multiplex for TTG
   - Measurement of gliadin/deamidated gliadin peptides
3. Effect of IgA deficiency on diagnostic tests.
4. Use of jejunal biopsy in the diagnosis of coeliac disease.
5. HLA DQ2/DQ8 associations in coeliac disease and the molecular assays used in HLA typing.
6. Principles and limitations of techniques available in the context of the detection of the above antibodies including:
   - Indirect immunofluorescence
   - ELISA
   - Chemiluminescence assays
7. Effect of a gluten-free diet on diagnostic tests.
8. Relationship between coeliac disease and dermatitis herpetiformis.
9. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

a. Prepare tissue substrate if required.
b. Perform tests in accordance with standard laboratory procedures.
c. Distinguish between endomysial antibody pattern and other antibodies that may react with the tissue substrate.
d. Critically evaluate the results and report accordingly.
e. Complete all relevant documentation in accordance with quality control and audit requirements.

EVIDENCE OF ACHIEVEMENT

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7.2 Gastrointestinal Disorders
Subsection 7.2b Liver disease

KNOWLEDGE

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

1. Clinical significance of mitochondrial, liver kidney microsomal (LKM), and smooth muscle antibodies and their disease associations.
2. Significance and methodology for mitochondrial antibody sub-typing.
3. Principles and limitations of techniques available in the context of the detection of liver antibodies.
4. How to recognise immunofluorescent staining patterns for antibodies to:
   - Mitochondria
   - LKM
   - Smooth muscle
   - LC-1 (liver cytosol 1)
   - SLA (soluble liver antigen)
5. Principles and limitations of ELISA and immunoblots for liver disease.
6. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

a. Prepare tissue substrate if required.
b. Perform tests in accordance with standard laboratory procedures.
c. Critically evaluate results and report accordingly.
d. Complete all relevant documentation in accordance with quality control and audit requirements.

EVIDENCE OF ACHIEVEMENT

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7.2 Gastrointestinal Disorders
Subsection 7.2c Pernicious anaemia

KNOWLEDGE

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

1. Clinical significance of antibodies to intrinsic factor and gastric parietal cell antibodies and their disease association.
2. Principles and limitations of techniques available for the detection of antibodies, including:
   - Indirect Immunofluorescence
   - ELISA
3. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

a. Prepare tissue substrate if required.
b. Perform test in accordance with standard laboratory procedures.
c. Critically evaluate results and report accordingly.
d. Complete all relevant documentation in accordance with quality control and audit requirements.

EVIDENCE OF ACHIEVEMENT

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7.2 Reflective Practice

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

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

Candidate's Reflective Practice Statement Part 1.

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

Section 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 develop. As a candidate for the award how you complete this section is personal to your own circumstances. It should be approached by recognising you have a responsibility to demonstrate self-awareness when analysing gaps in your knowledge. This is therefore an opportunity to reflect on aspects of training, the application of new knowledge and skills, and how goals have been achieved.

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

Section 7.3 Renal Disease

Subsection 7.3a Antineutrophil cytoplasmic antibodies

KNOWLEDGE

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

1. The correct and suitable conditions for the preparation of tissue samples for the detection of antibodies to anti-neutrophil cytoplasmic antibodies (ANCA).
2. Clinical significance of ANCA and main disease associations.
3. Principles and limitations of techniques available in the context of the detection of ANCA, including methods for differentiating ANCA from other autoantibodies which may be reactive with neutrophils.
4. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

a. Prepare tissue substrate if required.
b. Perform indirect immunofluorescence assay in accordance with laboratory standard operating procedures. Critically evaluate results and report accordingly.
c. Complete documentation in accordance with quality control and audit requirements.

EVIDENCE OF ACHIEVEMENT

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7.3 Renal Disease

Subsection 7.3b Myeloperoxidase and proteinase 3 antibodies

KNOWLEDGE

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

1. Clinical significance of antibodies to myeloperoxidase and proteinase 3 and their disease associations.
2. Principles and limitations of techniques available for the detection of myeloperoxidase and proteinase 3 antibodies, including:
   - ELISA
   - Other solid phase assays
   - Membrane assays (e.g. dot-blots, rapid assays)
3. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

a. Perform tests in accordance with laboratory standard operating procedures.
b. Detect and quantify myeloperoxidase and proteinase 3 antibodies.
c. Critically evaluate results and report accordingly, knowing telephone action limits where appropriate.
d. Complete documentation in accordance with quality control and audit requirements.

EVIDENCE OF ACHIEVEMENT

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7.3 Renal Disease

Subsection 7.3c Glomerular basement membrane antibodies

KNOWLEDGE

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

1. Clinical significance of antibodies to glomerular basement membrane (GBM) and their disease association.
2. Principles and limitations of techniques available in the context of the detection of GBM antibodies, including:
   - Indirect immunofluorescence
   - ELISA
   - Other solid phase assays
   - Immunoblot
3. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

a. Prepare tissue substrate if required.
b. Perform tests in accordance with laboratory standard operating procedures.
c. Critically evaluate results and report accordingly.
d. Complete all relevant documentation in accordance with quality control and audit requirements.

EVIDENCE OF ACHIEVEMENT

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7.3 Renal Disease

Subsection 7.3d Phospholipase A2 receptor (PLA2R) antibodies

KNOWLEDGE

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

1. Clinical significance of antibodies to phospholipase A2 receptor and disease association.
2. Principles and limitations of techniques available in the context of the detection of phospholipase A2 receptor antibodies.
3. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

a. Perform tests in accordance with laboratory standard operating procedures.
b. Critically evaluate results and reports.
c. Complete all documentation in accordance with quality control and audit requirements.

EVIDENCE OF ACHIEVEMENT

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7.3 Reflective Practice

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

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

Candidate's Reflective Practice Statement Part 1.

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

Section 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 develop. As a candidate for the award how you complete this section is personal to your own circumstances. It should be approached by recognising you have a responsibility to demonstrate self-awareness when analysing gaps in your knowledge. This is therefore an opportunity to reflect on aspects of training, the application of new knowledge and skills, and how goals have been achieved.

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

Section 7.4 Neurological Disease

Autoantibodies associated with neurological disease

KNOWLEDGE

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

1. How antibodies may be used in the diagnosis of neurological disease and understand their clinical sensitivities and specificities, including antibodies to:
   - Neuronal antigens (paraneoplastic)
   - Gangliosides
   - Acetylcholine receptors
   - Muscle-specific kinase (MUSK)
   - Striated muscle
   - Glutamic acid decarboxylase (GAD)
   - Aquaporin-4
   - Calcium and potassium voltage gated channels
2. Storage requirements of tissue slides for the detection of antibodies to neurological tissues.
3. Principles and limitations of techniques available in the context of the detection of the above antibodies, including:
   - Indirect immunofluorescence
   - Immunoenzyme methods
   - ELISA
   - Immunoblotting
   - RIA
4. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

a. Describe the preparation of tissue substrates if required.
b. Describe principles and practice of assays used to detect antibodies present in neurological disease.
c. Describe how to identify antibodies and distinguish between positive, negative and equivocal results.

EVIDENCE OF ACHIEVEMENT

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7.4 Reflective Practice

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

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

Candidate's Reflective Practice Statement Part 1.

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

Section 7.4 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 develop. As a candidate for the award how you complete this section is personal to your own circumstances. It should be approached by recognising you have a responsibility to demonstrate self-awareness when analysing gaps in your knowledge. This is therefore an opportunity to reflect on aspects of training, the application of new knowledge and skills, and how goals have been achieved.

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

Section 7.5 Endocrine Disease
Subsection 7.5a Adrenal cortex, ovary and testis

KNOWLEDGE

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

1. Clinical significance of adrenal, ovary and testis antibodies and their disease association.
2. Storage conditions of tissue slides for the detection of antibodies to:
   - Adrenal
   - Ovary
   - Testis
3. Principles and limitations of techniques available for the detection of antibodies to adrenal, ovary and testis.
4. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

a. Describe the principles and practice of assays used to detect antibodies to adrenal cortex, ovary and testis.
b. Describe how to identify antibodies and distinguish between positive, negative and equivocal results.

EVIDENCE OF ACHIEVEMENT

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7.5 Endocrine Disease
Subsection 7.5b Type I diabetes mellitus

KNOWLEDGE

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

1. Clinical significance of antibodies to:
   - Pancreatic islet cells
   - Glutamic acid decarboxylase (GAD)
   - Insulinoma antigen 2 (IA2)
   - Insulin
2. Storage conditions for tissue slides of pancreas.
3. Principles and limitations of techniques available in the context of the detection of the above antibodies.
4. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

a. Describe the preparation of tissue substrates if required.
b. Describe principles and practice of assays used to detect antibodies to pancreatic islet cells, GAD, IA2 and insulin.
c. Describe how to identify these antibodies and distinguish between positive, negative and equivocal results.

EVIDENCE OF ACHIEVEMENT

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7.5 Endocrine Disease
Subsection 7.5c Thyroid antibodies

KNOWLEDGE

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

1. Available methods for the detection of antibodies to the thyroid including:
   - Thyroid peroxidase
   - TSH receptor
   - Thyroglobulin
2. Clinical significance of antibodies and disease association.
3. Significance of other antibodies to thyroid tissue or hormones.
4. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

a. Perform tests for thyroid peroxidase antibodies in accordance with standard laboratory procedures.
b. Critically evaluate results and report accordingly.
c. Complete documentation in accordance with quality control and audit requirements.

EVIDENCE OF ACHIEVEMENT

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7.5 Reflective Practice

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

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

Candidate's Reflective Practice Statement Part 1.

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

Section 7.5 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 develop. As a candidate for the award how you complete this section is personal to your own circumstances. It should be approached by recognising you have a responsibility to demonstrate self-awareness when analysing gaps in your knowledge. This is therefore an opportunity to reflect on aspects of training, the application of new knowledge and skills, and how goals have been achieved.

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

Section 7.6 Dermatological Disease:
Pemphigus and pemphigoid antibodies

KNOWLEDGE

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

1. The difference between epidermal basement membrane and desmosome.
2. Correct and suitable conditions for the storage of tissue slides for the detection of antibodies to epidermal basement membrane and desmosomes.
3. Clinical significance of antibodies and their disease association, including those to BP180 (epidermal basement membrane) and DSG 1/3 (desmosome).
4. The principles and limitations of immunofluorescence techniques available for the detection of skin antibodies using different tissue substrates.
5. Significance of interference from blood group antibodies.
6. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

a. Prepare tissue substrate if required.
b. Perform tests in accordance with standard laboratory procedures.
c. Critically evaluate results and report accordingly.
d. Complete documentation in accordance with quality control and audit requirements.

EVIDENCE OF ACHIEVEMENT

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7.6 Reflective Practice

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

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

Candidate's Reflective Practice Statement Part 1.

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

Section 7.6 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 develop. As a candidate for the award how you complete this section is personal to your own circumstances. It should be approached by recognising you have a responsibility to demonstrate self-awareness when analysing gaps in your knowledge. This is therefore an opportunity to reflect on aspects of training, the application of new knowledge and skills, and how goals have been achieved.

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

Section 7.7 Immunoglobulins

Subsection 7.7a Serum immunoglobulins G, A, M, D and E

KNOWLEDGE

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

1. Classes and structure of serum immunoglobulins.
2. Effects of time, temperature, pH and preservatives on immunoglobulins.
3. Relationship between serum, urine and CSF proteins.
4. Principles of total protein measurement and differences in technique.
5. Sample requirements for the investigation of paraproteins.
6. Difference between qualitative and quantitative analysis.
7. Principles and practice of a range of techniques, including:
   - Electrophoresis and densitometry
   - Nephelometry and turbidimetry
   - Immunofixation
   - Isoelectric focussing (for CSF samples)
8. Advantages and disadvantages of different techniques, including the principles of antigen excess.
9. Normal ranges and clinical significance of abnormal results.
10. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

a. Prepare sample and assay reagents.
b. Perform tests in accordance with standard laboratory procedures.
c. Detect and quantify serum immunoglobulins.
d. Clearly distinguish between normal and abnormal results.
e. Complete documentation in accordance with quality control and audit requirements.

EVIDENCE OF ACHIEVEMENT

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7.7 Immunoglobulins

Subsection 7.7b Immunoglobulin light chains and Bence-Jones protein

KNOWLEDGE

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

1. Classes and structure of immunoglobulin light chains.
2. Effects of time, temperature, pH and preservatives on immunoglobulin light chains.
3. Relationship between serum and urine proteins.
4. Principles of urine concentration techniques.
5. Sample requirements for the investigation of paraproteins.
6. Difference between qualitative and quantitative analysis.
7. Awareness of the principles and limitations of different techniques for the measurement of free light chains in serum and urine, including:
   - Immunodiffusion
   - Electrophoresis
   - Nephelometry and turbidimetry
   - Immunofixation
8. Normal ranges and clinical significance of abnormal results.
9. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

a. Prepare sample and assay reagents.
b. Perform tests in accordance with standard laboratory procedures.
c. Detect and quantify immunoglobulin light chains/Bence-Jones protein in urine.
d. Clearly distinguish between normal and abnormal results.
e. Complete documentation in accordance with quality control and audit requirements.

EVIDENCE OF ACHIEVEMENT

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7.7 Immunoglobulins
Subsection 7.7c Cryoglobulin

KNOWLEDGE

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

1. Sample requirements for the investigation of cryoglobulins and problems associated with unsuitable samples.
2. Modifications required to measure cryoglobulins.
3. Clinical significance of abnormal findings.
4. Clinical association of cryoglobulin types I, II, and III.
5. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

a. Prepare sample and assay reagents.
b. Perform tests in accordance with standard laboratory procedures.
c. Detect and quantify cryoglobulins.
d. Complete documentation in accordance with quality control and audit requirements.

EVIDENCE OF ACHIEVEMENT

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7.7 Immunoglobulins

Subsection 7.7d Immunoglobulin subclasses and specific antibodies

KNOWLEDGE

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

1. Subclasses and structure of immunoglobulins G and A.
2. Sample requirements for the investigation of:
   - Immunoglobulin subclasses
   - Pneumococcal (including pneumococcal serotype-specific) antibodies
   - Tetanus antibodies
   - *Haemophilus* antibodies
3. Principles and limitations of techniques for measuring:
   - Immunoglobulin subclasses
   - Specific antibodies
4. Normal ranges and clinical significance of abnormal results in relation to immunodeficiency.
5. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

a. Describe how to detect and quantify immunoglobulin subclasses.
b. Describe the techniques available to test for specific antibodies.
c. Describe how to distinguish between normal and abnormal results.

EVIDENCE OF ACHIEVEMENT

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7.7 Immunoglobulins
Subsection 7.7e Total IgE and allergen-specific IgE

KNOWLEDGE

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

1. Causes of and physiological basis of allergy and hypersensitivity.
2. Principles and limitations of a range of techniques (e.g. chemiluminescence assays, skin prick test).
3. Advantages and disadvantages of the techniques.
4. Clinical situations where specific IgE analysis may be particularly relevant (e.g. bee and wasp venom sensitivity, penicillin sensitivity).
5. Awareness of other areas of hypersensitivity investigation (e.g. adverse reactions to anaesthetic, allergen cross-reactivity).
6. Ranges and values for interpretation of results relating to allergies and hypersensitivities.
7. Clinical relevance of laboratory investigations for allergies and hypersensitivities.
8. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

a. Perform tests in accordance with standard laboratory procedures.
b. Detect and quantify total IgE and allergen-specific IgE.
c. Perform measurement of serum mast cell tryptase.
d. Perform assays for the investigation of allergic alveolitis (IgG).
e. Clearly distinguish between normal and abnormal results.
f. Complete documentation in accordance with quality control and audit requirements.

EVIDENCE OF ACHIEVEMENT

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7.7 Immunoglobulins
Subsection 7.7f Oligoclonal bands

KNOWLEDGE

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

1. Principles of measuring oligoclonal bands.
2. Advantages and disadvantages of the technique.
3. How to interpret oligoclonal bands.
4. Clinical relevance of laboratory investigations for oligoclonal banding.
5. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

a. Describe the principles and practice of assays available for the detection of oligoclonal bands.
b. Interpret the results of these assays with regard to clinical significance.

EVIDENCE OF ACHIEVEMENT

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7.7 Reflective Practice

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

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

Candidate's Reflective Practice Statement Part 1.

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

Section 7.7 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 develop. As a candidate for the award how you complete this section is personal to your own circumstances. It should be approached by recognising you have a responsibility to demonstrate self-awareness when analysing gaps in your knowledge. This is therefore an opportunity to reflect on aspects of training, the application of new knowledge and skills, and how goals have been achieved.

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

Section 7.8 Complement and Other Acute Phase Proteins

Subsection 7.8a Complement cascade

KNOWLEDGE

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

1. Components of the:
   - Classical complement pathway
   - Alternative complement pathway
   - Mannan binding lectin pathway
   - Terminal pathway
2. Effects of time, temperature, pH and preservatives on complement components.
3. Principles and limitations of techniques for the investigation and quantification of complement components including:
   - Immunodiffusion
   - Nephelometry
   - Turbidimetry
   - Functional assays
4. Significance of abnormal findings.
5. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

a. Prepare sample and assay reagents.
b. Perform tests in accordance with standard laboratory procedures.
c. Detect and quantify complement components of the complement pathways.
d. Clearly distinguish between normal and abnormal results.
e. Complete documentation in accordance with quality control and audit requirements.

EVIDENCE OF ACHIEVEMENT

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

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7.8 Complement and Other Acute Phase Proteins

Subsection 7.8b Disorders of complement

KNOWLEDGE

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

1. Significance of complement in inflammation and disease, including complement deficiency.
2. Effects of time, temperature, pH and preservatives on interpretation of complement results.
3. Ranges and values for interpretation of results relating to complement detection and measurement, including:
   - C3 and C4
   - C1 esterase inhibitor
   - Haemolytic complement – classical and alternative pathways
   - Components of the classical and alternative pathways
   - Regulatory proteins of the complement cascades

COMPETENCE

Be able to:

a. Distinguish between normal and abnormal results.
b. Describe the relationship between the complement components and how this aids the interpretation of results.
c. Describe the clinical significance of complement abnormalities and deficiencies.

EVIDENCE OF ACHIEVEMENT

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

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

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Trainer's signature:

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Date of completion:

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

Date of completion:

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Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7.8 Complement and other Acute-Phase Proteins

Subsection 7.8c Acute-phase proteins

KNOWLEDGE

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

1. Significance of acute-phase proteins in inflammation and disease.
2. Methods for the investigation and quantification of alpha-1-antitrypsin and C-reactive protein (e.g. Immunodiffusion, Nephelometry, Turbidimetry).
3. Advantages and limitations of the techniques.
4. Ranges and values for interpretation of results relating to alpha-1-antitrypsin and C-reactive protein measurement.
5. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

a. Perform tests in accordance with standard laboratory procedures.
b. Clearly distinguish between normal and abnormal results.
c. Complete documentation in accordance with quality control and audit requirements.

EVIDENCE OF ACHIEVEMENT

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

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Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7.8 Reflective Practice

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

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

Candidate's Reflective Practice Statement Part 1.

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

Section 7.8 Candidate's Reflective Practice Statement Part 2.

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

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

Section 7.9 Cellular Immunology
Subsection 7.9a Immunophenotyping T and B cells

KNOWLEDGE

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

1. Blood cell morphology and phenotypic variation. This should include CD nomenclature with reference to lineage, maturation and activation. Thorough knowledge of lymphocyte subsets is required.
2. How this is used in the investigation of immunodeficiency and haematological malignancy.
3. Principles and limitations of flow cytometry (e.g. Instrument set up and compensation, gating strategies, absolute counting).
4. Relevant current guidelines.
5. Principles and limitations of the use of appropriate panels in the investigation of a range of immunodeficiencies.
6. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

a. Describe the principles of immunophenotyping in accordance with laboratory standard operating procedures.
b. Identify lymphocyte subsets by CD markers, including what combinations may be required.
c. Critically evaluate results and significance to the clinical question.

EVIDENCE OF ACHIEVEMENT

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

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Trainer's signature:

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Date of completion:

Trainer's name:

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Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7.9 Cellular Immunology

Subsection 7.9b T lymphocyte and natural killer cell function

KNOWLEDGE

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

1. Principles of T-cell activation and function.
2. Principles of NK-cell activation and function.
3. Principles of aseptic technique.
4. How to count cells using a haemocytometer.
5. Use of tritiated thymidine uptake as a method of measuring T-cell function.
6. The range of techniques available for the measurement to T-cell function.
7. Methods for measuring NK cytotoxicity and the use of target cells.
8. Examples of conditions where T- or NK-cell function might be impaired.
9. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

a. Describe how to perform assays to measure T-cell proliferation and NK-cell killing.

EVIDENCE OF ACHIEVEMENT

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Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7.9 Cellular Immunology
Subsection 7.9c Neutrophil function tests

KNOWLEDGE

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

1. Principles of neutrophil activation, phagocytosis and killing.
2. The range of assays available to measure neutrophil function.
3. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

a. Describe how to measure neutrophil oxidative burst.
b. Describe what results you might find in chronic granulomatous disease (CGD) and a carrier of X-linked CGD.

EVIDENCE OF ACHIEVEMENT

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Section 7.9 Candidate's Reflective Practice Statement Part 2.

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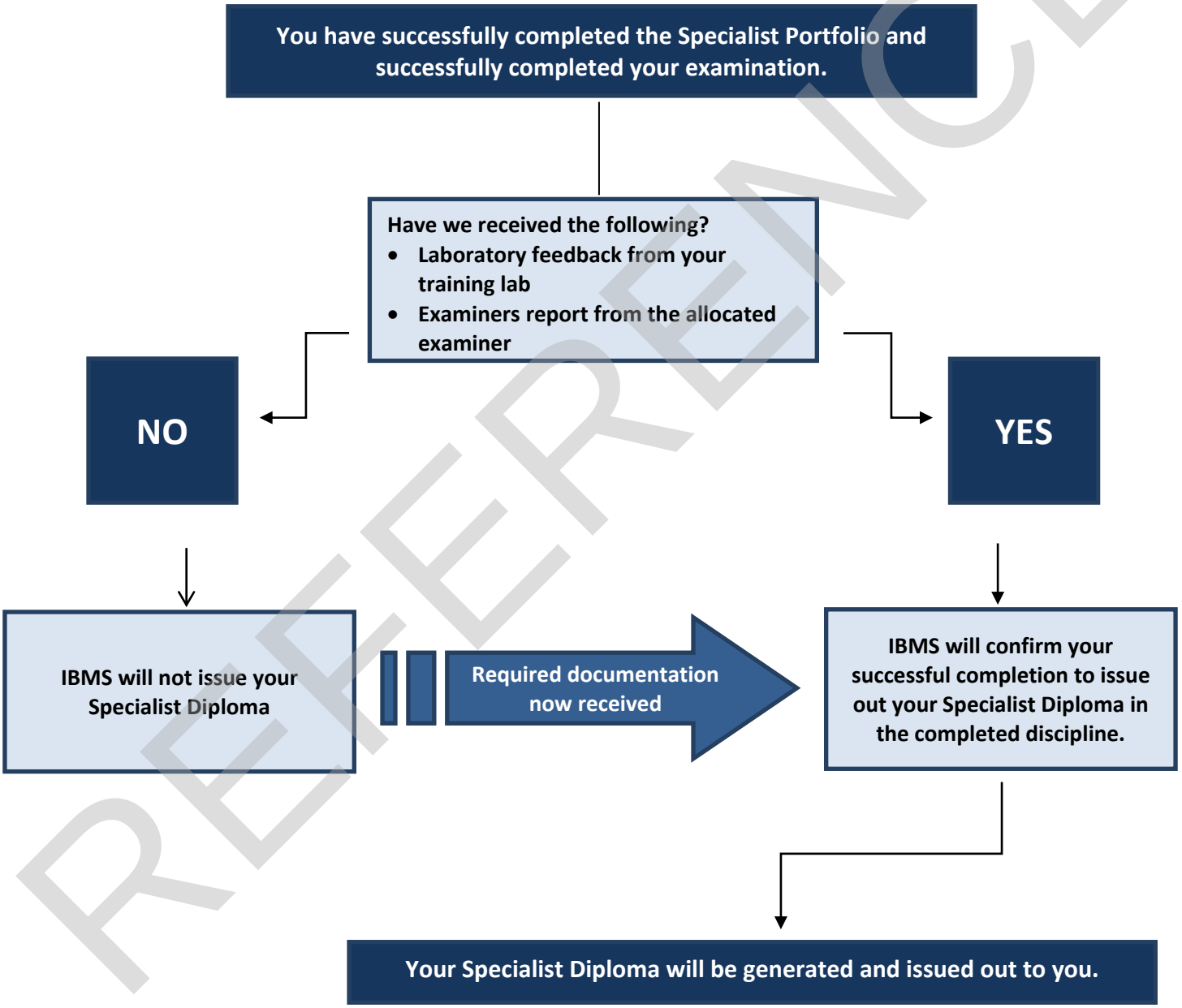
Steps to IBMS Specialist Diploma

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 Clinical Immunology

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