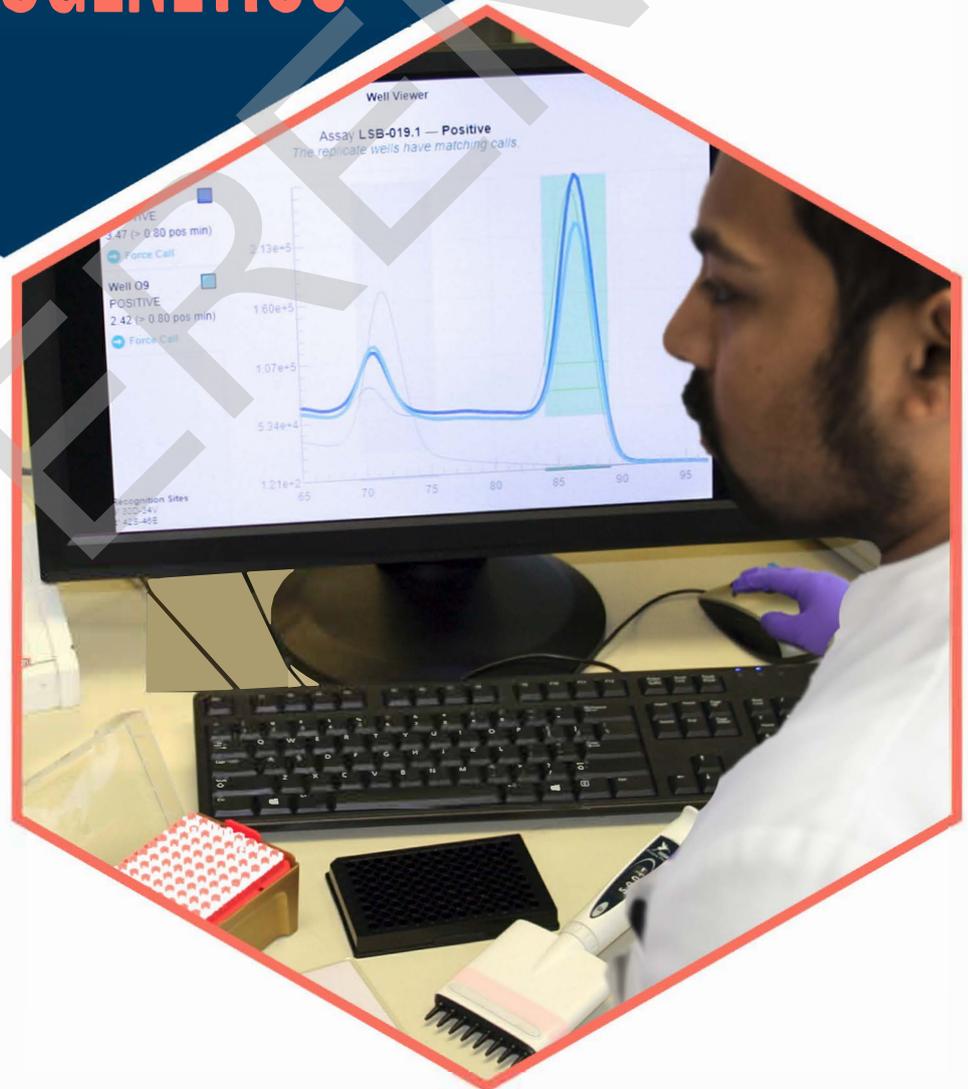
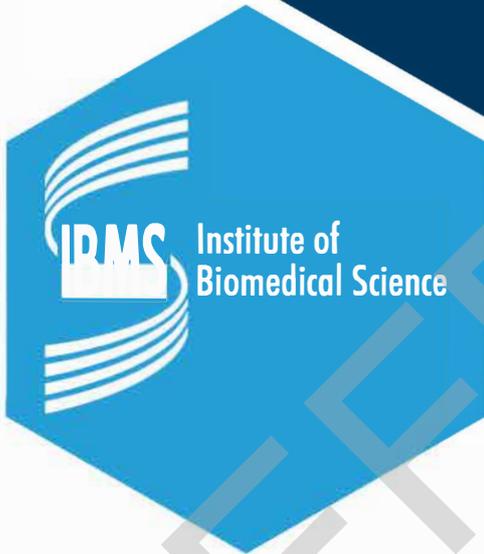


RECORD OF LABORATORY TRAINING FOR THE IBMS SPECIALIST DIPLOMA **HISTOCOMPATIBILITY AND IMMUNOGENETICS**



Institute of Biomedical Science
12 Coldbath Square
London
EC1R 5HL

Tel 020 7713 0214

Web www.ibms.org

Email specialistdiploma@ibms.org

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

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

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

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1. INTRODUCTION

- 1.1. In order for you to be awarded an Institute Specialist Diploma you must be a current member of the Institute since the time you were issued with the portfolio. You must have held corporate membership for at least one year and be a current member at the time of the examination.
- 1.2. The Institute of Biomedical Science (Institute/IBMS) Specialist Portfolio provides the opportunity for you to gain recognition that you have finished a programme of structured, standardised post-registration training. This requires you to complete the IBMS Record of Training for the Specialist Diploma (Specialist Portfolio), submit a portfolio of evidence for assessment and undertake an oral examination of your specialist knowledge and understanding in your chosen field, in order to be awarded the Institute's Specialist Diploma.
- 1.3. Holding a Specialist Diploma demonstrates that you have been assessed against a benchmark standard for a specialist practitioner in your chosen discipline. It can be used by your employer to demonstrate specialist knowledge and skills linked to career and pay progression.
- 1.4. The Specialist Portfolio is considered to be the property of the individual as it represents a commitment by the employer for professional development specific to them. It is not 'owned' by the laboratory. If you are re-employed in another laboratory and you wish to continue with a partially completed portfolio, it is at the discretion of your new employer whether or not they wish to continue with the same portfolio or restart the process. If they opt to continue with the existing portfolio, the new employer is responsible for reviewing the evidence in your portfolio and confirming your competence in line with the requirements of your position.
- 1.5. To support completion of this Specialist Portfolio a separate guidance document has been produced (*Institute of Biomedical Science Specialist Portfolio Guidance for Candidates, Training Officers and External Examiners*). This provides all of the information required to ensure the portfolio is completed and assessed in accordance with the Institute's requirements. Following the guidance in this document is essential to your success.
- 1.6. It is strongly recommended that you and your training officer/mentor read and understand this document. Failure to do so could jeopardise your chances of success. External examiners for the portfolio are required to read and understand it as part of their responsibility as a representative of the Institute.

- 1.7. A discipline specific portfolio reflects the range of analyses that are considered to be relevant to your specialty. All sections must be completed in order to express your ability to operate at the specialist level. Completion of the sections should follow the formal training programme that is submitted by your laboratory to the IBMS as part of the laboratory training approval process.
- 1.8. The IBMS Specialist Portfolio can only be completed in laboratories which hold IBMS approval for post-registration training.
- 1.9. The following sections highlight some key points **but are not a substitute** for reading the information contained in the *Institute of Biomedical Science Specialist Portfolio Guidance for Candidates, Training Officers and External Examiners*.

2. TRAINING

- 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: Histocompatibility & Immunogenetics

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

Subsection 7.1a MHC Genes

KNOWLEDGE

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

1. Location of the HLA genes.
2. Clinical relevance of HLA genes.
3. Other genes within the MHC, for example:
 1. Non-classical HLA
 2. C2, C4, Bf
 3. TAP
 4. LMP
 5. TNF
 6. DM
 7. DO
 8. HFE
4. Structure of HLA genes:
 - Organisation
 - Class I
 - Class II

COMPETENCE

Be able to:

- a. Describe the structure of HLA genes.
- b. Describe the clinical relevance of HLA genes.

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 MHC and Basic Immunology

Subsection 7.1b WHO Nomenclature

KNOWLEDGE

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

1. Current WHO nomenclature for serological and molecular HLA typing:
 1. Numeric principles
 2. Locus identifiers
 3. Specificity/allele
 4. Broad and split
 5. Nulls, low expressors and other variants
2. The concept of 'public' and 'private' epitopes including:
 - Bw4/Bw6
 - Shared amino acid sequences
 - Crossreactivity

COMPETENCE

Be able to:

- a. Describe current WHO nomenclature.
- b. Describe the concept of 'public' and 'private' epitopes.

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 MHC and Basic Immunology
Subsection 7.1c MHC antigens

KNOWLEDGE

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

1. Structure and function of HLA Class I.
2. Structure and function of HLA Class II.
3. Distribution of MHC antigen.

COMPETENCE

Be able to:

- a. Describe the structure and function of MHC antigens.

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 MHC and Basic Immunology
Subsection 7.1d Genetics of HLA

KNOWLEDGE

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

1. Mode of inheritance of HLA genes:
 - a. Autosomal co-dominant
 - b. Recombination
 - c. Family pedigree
2. Linkage disequilibrium and its implications.
3. Recombination and its implications:
 - a. Frequency
4. Meaning of phenotype, genotype and haplotype.
5. Statistical methods used in population genetics.
6. Likely mechanisms that generate HLA polymorphisms.

COMPETENCE

Be able to:

- a. Explain the terminology associated with MHC genes.
- b. Assign haplotypes in a family study using HLA typing information.

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 MHC and Basic Immunology
Subsection 7.1e Innate and adaptive immunity

KNOWLEDGE

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

1. Innate and adaptive immunity and their interaction.
2. The terms, antigen, super antigen, antibody, epitope and idiotope.
3. The concepts of self and non-self.
4. Differences between apoptotic and necrotic cell death.
5. Current theories of B- and T-cell tolerance.

COMPETENCE

Be able to:

- a. Explain the terminology associated with innate and adaptive immunity.

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 MHC and Basic Immunology

Subsection 7.1f Immunoglobulins, the T-cell receptor and NK cell receptors

KNOWLEDGE

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

1. Classes and structure of immunoglobulins.
2. Structure of the T-cell receptor.
3. Mode of action of immunoglobulins and the T-cell receptor.
4. Mechanisms for immunoglobulin and T-cell receptor diversity.
5. NK cell receptors:
 - Killer-cell immunoglobulin-like receptors (KIRs)
6. Location and genetic organisation of *KIR* genes.

COMPETENCE

Be able to:

- a. Describe the structure, function and genetic organisation of immunoglobulins, T-cell receptors and KIRs.

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 MHC and Basic Immunology
Subsection 7.1g Effector mechanisms

KNOWLEDGE

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

1. Role of cytokines in the immune response.
2. Mechanism for immunoglobulin class switching.
3. Roles of molecules of the immune system in the cell killing mechanism.
4. Role of chemokines.
5. Cascade of events leading to leucocyte transmigration during the inflammatory response.

COMPETENCE

Be able to:

- a. Describe effector mechanisms in the immune response.

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 MHC and Basic Immunology
Subsection 7.1h Cellular function of the immune system

KNOWLEDGE

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

1. The cells involved in immune responses, their development, primary functions and characteristics, including:
 - Granulocytes
 - Macrophage/dendritic cells and other APCs
 - Th0, Th1, Th2, Th17, Tc1, Tc2 and regulatory T cells
 - B cells
 - NK Cells
 - Endothelial cells
 - Platelets
2. Role of the lymphatics and the morphology of lymph nodes, MALT, PALS and Peyer's patches.

COMPETENCE

Be able to:

- a. Describe the major characteristics and function of cells in the immune system.

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 MHC and Basic Immunology
Subsection 7.1i Antigen presentation and processing

KNOWLEDGE

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

1. Role of professional and non-professional antigen presenting cells, including:
 - Processing of endogenous and exogenous peptides
 - Role of MHC class I and II
 - Cross presentation
 - Activation of T cells
2. Mechanisms in the current hypothesis of antigen presentation, including:
 - Peptide binding
 - T cell interaction
 - Role of CD3, CD4/8
 - Co-stimulatory molecules including CD28/B7 (CD80/CD86)
3. Significance of HLA polymorphism in antigen presentation (i.e. peptide binding, self/non-self).

COMPETENCE

Be able to:

- a. Describe the mechanisms for antigen presentation and processing.

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:

KNOWLEDGE

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

1. Different forms of graft:
 - Autograft
 - Allograft
 - Xenograft
2. Different categories of rejection and their principles:
 - Hyperacute
 - Acute
 - Accelerated
 - Chronic
3. Immunological processes of graft rejection:
 - Cytotoxic T cells
 - Antibody formation
 - ADCC
 - Inflammation
 - Antibody and complement
4. Different immunosuppressive therapies and their mode of action:
 - Methotrexate, prednisilone, cyclosporin and tacrolimus
 - Mono, triple and quadruple therapy
 - Monoclonal antibodies
 - Prophylaxis / rejection therapies
 - Conditioning regimes
5. Mechanism of graft versus host disease and graft versus leukaemia effect.
6. Non-HLA systems that are important in transplant outcome.

COMPETENCE

Be able to:

- a. Describe the principles and concepts of transplant immunology.

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 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. 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.

REFERENCE

Section 7.2 Serological HLA Assays
Subsection 7.2a Principles of the lymphocytotoxicity assay

KNOWLEDGE

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

1. Principles involved in the lymphocytotoxicity assay
 - Antigen/antibody reaction
 - Complement activation
 - Visualisation
2. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

- a. Describe the principles of the lymphocytotoxicity assay.
- b. Describe the modes of action of complement and the different activation pathways.
- c. Describe the different commonly used dyes and stains, and their modes of action, available for visualisation of lymphocytotoxicity assays.
- d. Describe the International Histocompatibility Workshop (IHW) and local systems for scoring reactivity in lymphocytotoxicity assays.

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:

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Date of completion:

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Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7.2 Serological HLA Assays
Subsection 7.2b Reagent preparation

KNOWLEDGE

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

1. Purpose and application of reagents used in lymphocytotoxicity assays.
2. Potential sources of HLA typing sera and the principles of reagent sera selection.
3. Use of monospecific and multispecific typing sera.
4. Characteristics and principles of production of monoclonal antibodies.
5. Use of monoclonal antibodies as typing sera.
6. Use of replicate specificities.
7. Selection, standardisation, handling and storage of complement.
8. National and international guidelines and standards.
9. Internal quality control and external quality assessment procedures.
10. Procedures for the safe handling of reagents used in lymphocytotoxicity assays.

COMPETENCE

Be able to:

- a. Select appropriate sera for HLA typing.
- b. Prepare complement for use in lymphocytotoxicity assays.
- c. Describe the method for standardisation of complement.
- d. Prepare and handle commonly used dyes and stains used in lymphocytotoxicity assays, safely and correctly.
- e. Handle, store and dispose of reagents for lymphocytotoxicity assays safely and appropriately.
- f. Maintain correct stock control levels and records.

EVIDENCE OF ACHIEVEMENT

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Date of completion:

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Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7.2 Serological HLA Assays
Subsection 7.2c Lymphocyte isolation

KNOWLEDGE

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

1. Principles involved in lymphocyte isolation:
 - Density gradient
 - Differential centrifugation
 - Carbonyl iron/methyl cellulose
2. Principles and procedures available for T- and B-cell isolation, including:
 - Monoclonal antibodies/complement lysis
 - Immunomagnetic beads
3. Principles of lymphocyte storage for:
 - Short/medium-term storage
 - Long-term cryopreservation
4. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

- a. Prepare viable lymphocytes for HLA serological typing, free from platelets, red cells and granulocytes from lymph node, spleen and peripheral blood.
- b. Prepare T and B lymphocytes for use in lymphocytotoxicity assays.
- c. Assess the viability and enumerate lymphocytes.
- d. Prepare lymphocytes for storage.
- e. Use the local inventory system.

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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Date of completion:

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Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7.2 Serological HLA Assays
Subsection 7.2d Serological HLA typing

KNOWLEDGE

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

1. Principles of the lymphocytotoxicity assay as applied to HLA typing:
 - Source of antibodies
 - Source(s) of cells
 - Advantages and disadvantages of serological HLA typing
2. Causes of false-positive and false-negative results in serological HLA typing, and how to prevent/minimise their occurrence.
3. Internal quality control and external quality assessment procedures.
4. How serological HLA typing is utilised with different patient and donor groups according to local rules and clinical need.

COMPETENCE

Be able to:

- a. Prioritise HLA typing requests based on clinical need, in accordance with local rules.
- b. Interpret HLA serological typing data and assign HLA antigens.
- c. Perform the lymphocytotoxicity test in accordance with standard laboratory procedures and assess cell death using the IHW international scoring system.
- d. Critically evaluate results and resolve problems.
- e. Determine the need for further investigation and reporting.
- 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).

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Date of completion:

Trainer's name:

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Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7.2 Reflective Practice

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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. 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.

REFERENCE

Section 7.3 Molecular HLA Typing
Subsection 7.3a Molecular HLA typing

KNOWLEDGE

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

1. Principles and applications of the reagents used in molecular typing:
 - Probes
 - Primers
 - Enzymes
 - Cofactors

COMPETENCE

Be able to:

- a. Prepare reagents for molecular typing.
- b. Describe the function of the component reagents used in molecular typing tests.

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:

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

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Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7.3 Molecular HLA Typing
Subsection 7.3b DNA extraction

KNOWLEDGE

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

1. Principles involved in extraction of DNA and the major problems that can be encountered, including:
 - Type of sample
 - Quality
 - Yield
 - Contamination
2. Awareness of the different techniques available for DNA extraction.
3. Requirement for high-quality DNA, including:
 - Protein/RNA contamination
 - Heparin contamination
 - DNA degradation
4. Principles of quantifying DNA.
5. Principles of estimating purity of DNA and potential contaminants.

COMPETENCE

Be able to:

- a. Extract DNA from blood or tissue samples.
- b. Quantify DNA.
- c. Adjust concentration of DNA.

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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Internal Assessor's signature:

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Date:

Section 7.3 Molecular HLA Typing
Subsection 7.3c Gel electrophoresis

KNOWLEDGE

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

1. Principles of gel electrophoresis.
2. Use of DNA molecular weight markers.

COMPETENCE

Be able to:

- a. Prepare appropriate agarose gels.
- b. Load gels and perform electrophoresis.
- c. Use molecular weight markers.
- d. Record results in accordance with standard laboratory procedures.
- 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).

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Internal Assessor's name:

Date:

Section 7.3 Molecular HLA Typing
Subsection 7.3d Polymerase chain reaction (PCR)

KNOWLEDGE

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

1. Principles of PCR and its application to HLA typing.
2. Different applications of various PCR-based typing systems, including:
 - SSO/SSP/SBT/NGS
 - Low/medium/high resolution
 - HLA class I/II
 - Turnaround times
 - Batch/single testing of samples
3. Advantages and disadvantages of PCR-based typing systems.
4. Potential problems of PCR contamination and how to prevent and detect it.
5. Internal and external quality assurance procedures.

COMPETENCE

Be able to:

- a. Prioritise HLA typing on the basis of clinical need in accordance with local procedures.
- b. Determine loci to be tested, resolution required, select procedure and perform HLA typing using PCR-based procedures.
- c. Interpret HLA typing data.
- d. Assign HLA type using WHO nomenclature.
- e. Determine the need for further investigation and reporting.
- 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.

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Date of completion:

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Internal Assessor's name:

Date:

Section 7.3 Molecular HLA Typing
Subsection 7.3e HLA allele specificity identification

KNOWLEDGE

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

1. Ethnic racial differences in allele frequencies and associations.
2. Differing resolution and limitations of methods used.
3. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

- a. Interpret HLA molecular typing data and assign HLA alleles.
- b. Determine the need for further investigation and reporting.
- 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 name:

Date:

Section 7.3 Molecular HLA Typing
Subsection 7.3f Polymerase chain reaction (PCR) design

KNOWLEDGE

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

1. Principles of primer design, including:
 - Identification of target sequences/motifs
 - Length of primer
 - T_m values
 - 5' end labelling
 - Annealing temperature
2. How varying parameters affects polymerase chain reaction (PCR):
 - DNA concentration
 - Primer concentration
 - Buffers
 - Reaction mix
 - Source and nature of polymerase
 - Cycling times and temperatures
3. Procedure for optimising PCR.

COMPETENCE

Be able to:

- a. Describe the principles and practice of primer design and PCR optimisation.
- b. Describe the factors that can affect the performance of PCR-based assays.

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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Date:

Section 7.3 Molecular HLA Typing
Subsection 7.3g Sequence-based typing

KNOWLEDGE

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

1. Principles of sequencing DNA, including:
 - Sanger sequencing
 - Use of dye primers and dye terminators
 - Use of slab gel and capillary gel matrix
 - Next generation sequencing:
 - Illumina MiSeq/HiSeq
 - Life Technologies Ion Torrent
 - PacBio Single Molecular Real-Time (SMRT)
 - Other newer methods
2. Common artefacts, problems and limitations of sequence based typing.

COMPETENCE

Be able to:

- a. Describe the application of sequence-based typing and interpret sequence-based typing data.
- b. Describe the principles of the main next-generation sequencing methods in general use and their application to HLA typing.
- c. Assign HLA alleles using WHO nomenclature.

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 7.3 Reflective Practice

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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. 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.

REFERENCE

Section 7.4 HLA Antibody Detection and Identification
Subsection 7.4a Reagent preparation

KNOWLEDGE

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

1. Principles and applications of the reagents used for antibody detection, including:
 - Buffers
 - Complement
 - Dyes
 - Conjugated antibodies
 - AHG
 - Substrate
2. Principles and applications of panel cell/antigen selection, including:
 - Effects of linkage disequilibrium
 - Selected and random cells/antigen panels
 - Distinguishing class I and II antibodies
3. Level of phenotyping.

COMPETENCE

Be able to:

- a. Prepare reagents for antibody detection.
- b. Prepare reagents for antibody identification.

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 name:

Trainer's signature:

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Date of completion:

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Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

KNOWLEDGE

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

1. Principles of the lymphocytotoxicity assay as applied to HLA antibody detection and identification:
 - Source of antibodies
 - Source(s) of cells
 - Controls
2. Application of antibody titration, absorption and blocking techniques.
3. Methods available for the differentiation of HLA and non-HLA antibodies.
4. Methods available for increasing sensitivity of the assay, specifically extended incubation and AHG.
5. Advantages, disadvantages and limitations of lymphocytotoxicity HLA antibody detection.
6. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

- a. Perform lymphocytotoxicity testing for HLA antibody detection and identification in accordance with standard laboratory procedures.
- b. Assess cell death using the International Histocompatibility Working Group (IHWG) and local scoring systems.
- c. Manage problems likely to be encountered, for example:
 - Cellular and microbial contamination
 - False negative and false positive reactions
 - Poor viability of cells.
- d. Describe the advantages, disadvantages and limitations of flow cytometry antibody detection and identification
- e. Complete documentation in accordance with quality control and audit requirements.

EVIDENCE OF ACHIEVEMENT

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Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7.4 HLA Antibody Detection and Identification
Subsection 7.4c Enzyme-linked immunosorbant assay (ELISA)

KNOWLEDGE

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

1. Principles of HLA antibody detection and identification by ELISA.
2. Application of the ELISA assay for HLA antibody detection and identification.
3. Advantages, disadvantages and limitations of ELISA antibody detection and identification.
4. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

- a. Describe the ELISA test for HLA antibody detection and identification.
- b. Describe the advantages, disadvantages and limitations of ELISA antibody detection and identification.

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:

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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 HLA Antibody Detection and Identification
Subsection 7.4d Flow cytometry

KNOWLEDGE

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

1. Principles of the flow cytometer.
2. Application of flow cytometry for antibody detection and identification.
3. Advantages, disadvantages and limitations of flow cytometry antibody detection and identification.
4. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

- a. Describe how to perform the detection and identification of HLA antibodies by flow cytometry.
- b. Describe the advantages, disadvantages and limitations of flow cytometry antibody detection and identification.

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 HLA Antibody Detection and Identification
Subsection 7.4e Luminex

KNOWLEDGE

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

1. Principles of the Luminex-based assays.
2. Application of Luminex for HLA antibody detection.
3. Application of Luminex for antibody identification.
4. Advantages, disadvantages and limitations of Luminex-based assays for HLA antibody detection and identification.
5. How median fluorescence intensity (MFI) cut-offs are used in the management of immunological risk stratification of patients.
6. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

- a. Perform HLA antibody detection and identification by Luminex-based assays.
- b. Discuss the advantages, disadvantages and limitations of Luminex-based assays for HLA antibody detection and identification.

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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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 HLA Antibody Detection and Identification

Subsection 7.4f Detection of HLA antibodies

KNOWLEDGE

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

1. Principles of HLA antibody detection.
2. Clinical significance of HLA and relevant non-HLA antibodies, including:
 - HLA class I and II antibodies
 - IgG and IgM antibodies
 - Red cell antibodies
 - Endothelial cell antibodies
3. Difference in sensitivity and specificity between different methods for antibody detection.
4. Use and significance of the Percentage Reactive Antibody (PRA) and Calculated Reaction Frequency (cRF).
5. Internal quality control and external quality assessment procedures.
6. National and international guidelines and standards.

COMPETENCE

Be able to:

- a. Select and apply protocol(s) used to determine when HLA antibodies are present.
- b. Critically evaluate results and correlate with previous findings.
- c. Calculate Percentage Reactivity Antibody (PRA).
- d. Determine the Calculated Reaction Frequency (cRF).
- e. Prioritise workload on clinical urgency according to local protocols.
- 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 7.4 HLA Antibody Detection and Identification
Subsection 7.4g Identification of HLA antibodies

KNOWLEDGE

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

1. Principles of HLA antibody identification.
2. Interpretation of HLA antibody specificity analysis, including:
 - Statistical techniques
 - Tail analysis
 - Computer analysis
 - Manual analysis
3. Difference in sensitivity and specificity between different methods for antibody identification.
4. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

- a. Select, and correctly apply, protocol(s) used to assign the specificity of HLA antibodies.
- b. Identify the relevant test or tests dependent on prior testing and patient category.
- c. Determine positive and negative reactions.
- d. Interpret specificity of each serum based on a panel of individual reactions.
- e. Distinguish between IgG- and IgM-specific HLA antibodies.
- 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).

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Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

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 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. 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.

REFERENCE

Section 7.5 Renal and Other Solid Organ Transplantation

Subsection 7.5a Crossmatch reagent preparation

KNOWLEDGE

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

1. Principles and applications of the reagents used in crossmatching, including:
 - Buffers
 - Complement
 - Dyes
 - Conjugated antibodies
 - AHG
 - Substrate
2. National and international guidelines and standards.
3. Standardisation, storage and handling of crossmatching reagents.
4. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

- a. Prepare reagents for lymphocytotoxic crossmatch.
- b. Prepare reagents for flow cytometric crossmatch.

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:

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 Renal and Other Solid Organ Transplantation

Subsection 7.5b Crossmatching

KNOWLEDGE

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

1. Principles of lymphocytotoxicity crossmatching, including:
 - Standard NIH method, enhanced methods and local variations
 - Selection and preparation of cells and patient sera
 - Use of controls
 - Use of dithiothreitol (DTT)
2. Principles of flow cytometric crossmatching:
 - Selection and preparation of cells and patient sera
 - Selection of conjugate(s)
 - Use of controls
3. Clinical significance of HLA and relevant non-HLA antibodies in interpretation of lymphocytotoxicity and flow cytometric crossmatches:
 - HLA class I and II antibodies
 - IgG and IgM antibodies
4. Difference in sensitivity and specificity between the different methods of crossmatching.
5. Advantages, disadvantages and limitations of different methods of crossmatching.
6. Local, national and international guidelines and standards.
7. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

- a. Select correctly and apply protocols to perform flow cytometry and lymphocytotoxicity crossmatches for renal and other solid organ transplants.
- b. Select appropriate positive and negative controls.
- c. Select appropriate patient sera based upon prior antibody test and HLA-specific sensitisation, in accordance with local policy.
- d. Assign positive and negative 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:

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Trainer's signature:

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Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7.5 Renal and Other Solid Organ Transplantation

Subsection 7.5c Deceased donor transplants

KNOWLEDGE

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

1. Importance of the ABO blood group system in solid organ transplants, including:
 - ABO antigens and 'naturally occurring' antibodies
 - ABO matching and compatibility
2. Application of HLA matching in deceased solid organ transplant:
 - HLA-A, -B, -DR hierarchy
 - Graft survival
 - Implications for subsequent re-grafts
3. Relevance of the patient's HLA antibody profile.
4. Significance of HLA and non-HLA antibodies in the context of allo-transplantation and their implications for graft survival and methods of differentiation.
5. Arrangements governing the placement of donor kidneys from NHSBT-ODT, including:
 - Patient registration
 - Organ allocation schemes
 - Paired pool exchange scheme
6. Local criteria for patient eligibility for solid organ transplant.
7. Importance of detection of infectious disease markers in potential organ donors.
8. Local, national and international guidelines and standards.

COMPETENCE

Be able to:

- a. Follow local procedures for recipient selection.
- b. Determine ABO compatibility of recipients and donors.
- c. Determine the degree of HLA match and mismatch between recipients and donors.
- d. Identify the presence of donor-specific antibodies in the recipient's HLA antibody profile.

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 Renal and Other Solid Organ Transplantation

Subsection 7.5d Living donor transplants

KNOWLEDGE

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

1. Importance of family studies, including:
 - Genetic relationship
 - Donor selection
 - Haplotype assignment
2. Importance of the ABO blood group system in solid organ transplants:
 - ABO antigens and 'naturally occurring' antibodies
 - ABO matching and compatibility
3. Application of HLA matching in living solid organ transplant:
 - HLA-A, -B, -DR hierarchy
 - Graft survival
 - Implications for subsequent re-grafts
4. Methods in use to transplant across HLA antibody and ABO incompatibilities.
5. Legislation and regulations governing living donor transplants.
6. Local, national and international guidelines and standards.

COMPETENCE

Be able to:

- a. Follow laboratory procedures for donor and recipient selection.
- b. Determine ABO compatibility of recipients and donors.
- c. Determine the degree of HLA match and mismatch between recipients and donors.
- d. Identify the presence of donor specific antibodies in the recipient's HLA antibody profile.

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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Date of completion:

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

Date of completion:

Trainer's name:

Trainer's signature:

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Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7.5 Renal and Other Solid Organ Transplantation

Subsection 7.5e Human Tissue Act

KNOWLEDGE

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

1. The Human Tissue Act and any amendments to the Act, Statutes or Regulations.
2. How the Human Tissue Act is applied in the H&I laboratory.
3. Role of the Human Tissue Authority.
4. Implications for consent, storage and use of human tissue.
5. Local policy and procedures for consent, storage and use of human tissue.

COMPETENCE

Be able to:

- a. Conduct laboratory testing, sample handling, storage and disposal of human tissues in compliance with the Human Tissue Act.
- b. Describe the procedures in place in the H&I laboratory to ensure compliance with the Human Tissue Act.

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).

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Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7.5 Renal and Other Solid Organ Transplantation

Subsection 7.5f Post-transplant monitoring

KNOWLEDGE

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

1. Application of post-transplant HLA antibody screening.
2. Significance of detection of graft specific HLA antibodies in transplanted patients.
3. National and international guidelines and standards.

COMPETENCE

Be able to:

- a. Describe the application of post-transplant HLA antibody screening.

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:

Trainer's name:

Trainer's signature:

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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 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. 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.

REFERENCE

KNOWLEDGE

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

1. Principles of haemopoietic stem cell transplantation.
2. Current clinical indications for haemopoietic stem cell transplant.
3. Pre-transplant treatment of patient, including conditioning.
4. Donor acceptance criteria and counselling.
5. Potential post-transplant complications, including:
 - Acute and chronic GVHD
 - Rejection
 - Infection
 - Secondary malignancy
6. Process of collection and processing of haemopoietic stem cells, including:
 - Harvesting of bone marrow
 - Peripheral blood stem cell collection
 - Umbilical cord blood collection
 - Processing of haemopoietic stem cells
 - Cryopreservation and storage of haemopoietic stem cells
 - T-cell depletion of haemopoietic stem cells
7. Factors affecting clinical outcome following haemopoietic stem cell transplantation, including:
 - Type of donor (e.g. autologous / related / unrelated / cord blood)
 - Disease type and stage
 - Alloimmunisation status
 - Conditioning (e.g. non-myeloablative)
 - T-cell depletion
 - Virology status of patient and donor (e.g. CMV)
 - Age of recipient and donor
 - Gender of patient and donor
 - Graft versus leukaemia (GVL)

KNOWLEDGE (continued)

8. Significance of infectious disease marker screening.
9. Internal and external guidance and standards, e.g. JACIE*

*Joint Accreditation Committee of the International Society for Cellular Therapy and EBMT which was initiated and developed by the European Society for Blood and Marrow Transplantation (EBMT).

COMPETENCE

Be able to:

- a. Describe the principles of haemopoietic stem cell transplantation.
- b. Describe the clinical indications for haemopoietic stem cell transplantation.
- c. Describe the role of the H&I laboratory in haemopoietic stem cell transplantation.

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:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

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Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7.6 Haemopoietic Stem Cell Transplantation

Subsection 7.6b Haemopoietic stem cell (HSC) sources and types of transplant

KNOWLEDGE

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

1. Advantages, disadvantages and therapeutic use of the different types of haemopoietic stem cell (HSC) transplants.
2. Requirement for blood grouping, HLA typing and antibody screening of the patient, sibling and other family members in allografts, including:
 - Phenotypic and genotypic identity
 - Resolution of typing
 - Blood components
 - Family pedigree
 - Haplotype assignment
3. Local policy for matching criteria and selection of a related donor, including:
 - Resolution of match
 - Donor and patient CMV
 - Donor gender
 - Donor age
4. Principles of donor selection for unrelated donor transplants, including:
 - Donor registry searches
 - Donor availability
 - Level of matching
 - Further HLA typing of selected donor(s)
 - Matching criteria (HLA, CMV, gender and age)

COMPETENCE

Be able to:

- a. Assign HLA phenotype and genotype and identify potential related donors.
- b. Identify the most suitable unrelated donor.

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 7.6 Haemopoietic Stem Cell Transplantation
Subsection 7.6c Unrelated donor registries and cord blood banks

KNOWLEDGE

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

1. Principles of UK and international donor registries, including:
 - Function
 - Size
 - Donor recruitment and selection
 - HLA typing strategies
 - Accreditation of registries and cord blood banks e.g. World Marrow Donor Association (WMDA), Foundation for the Accreditation of Cellular Therapy (FACT)
2. Procedure for obtaining a donor/cord from the registries:
 - Patient HLA typing
 - Donor/cord searching
 - Donor/cord selection criteria
 - Confirmatory typing
3. UK and international registries:
 - Anthony Nolan
 - British Bone Marrow Registry (BBMR)
 - Welsh Bone Marrow Donor Registry (WBMDR)
 - National Marrow Donor Panel (NMDP - USA)
 - DKMS (Germany)
 - Other international registries
 - Bone Marrow Donors Worldwide (BMDW)
 - NETCORD

COMPETENCE

Be able to:

- a. Describe the role of donor registries.
- b. Describe the process for identifying a suitable unrelated donor or cord for a patient.
- c. Describe the function of the H&I laboratory in the unrelated donor search.

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:

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 7.6 Haemopoietic Stem Cell Transplantation
Subsection 7.6d Post-transplant chimaerism monitoring

KNOWLEDGE

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

1. The need for post-transplant chimaerism monitoring (e.g. detection of engraftment and/or relapse).
2. Theoretical basis and potential use of cellular/functional assays.
3. Use of further molecular tests for post-transplant monitoring, including:
 - VNTR
 - STR
 - FISH

COMPETENCE

Be able to:

- a. Identify loci to be tested for chimaerism and conduct chimaerism testing.
- b. Identify alleles present and accurately discriminate between donor and recipient, giving a percentage level of chimaerism.

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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Date of completion:

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Date of completion:

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Internal Assessor's signature:

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Date:

Section 7.6 Reflective Practice

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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. 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.

REFERENCE

KNOWLEDGE

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

1. Application of HLA in the clinical situation:
 - Predisposition in family studies
 - Aid to diagnosis
 - Aid to selection of therapy
2. Commonly proposed mechanisms for disease association, including:
 - Preferential peptide binding
 - Aberrant T-cell repertoire
 - Molecular mimicry
3. Examples of aetiology (autoimmune, immune complex, non-immune) of the common associations:
 - Ankylosing spondylitis
 - Behçet's disease
 - Haemochromatosis
 - Multiple sclerosis
 - Rheumatoid arthritis
 - IDDM
 - Narcolepsy
 - Coeliac disease
4. Methods for testing for associations:
 - Study design
 - Statistical methods (Relative Risk)
 - Selection of controls
5. Other genes within MHC associated with disease susceptibility / resistance:
 - TAP
 - TNF

COMPETENCE

Be able to:

- a. Identify locus or loci to be tested for disease association.
- b. Describe the most common HLA disease associations.
- c. Describe mechanisms for disease association.

REFERENCE

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 name:

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Date of completion:

Trainer's name:

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Date of completion:

Trainer's name:

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Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7.7 **Other Clinical Applications of HLA**
Subsection 7.7b **HLA pharmacogenetics**

KNOWLEDGE

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

1. Relationship between HLA and patients' adverse responses to therapeutic drugs.
2. HLA alleles most commonly associated with immune-mediated adverse drug reactions, including:
 - B*57:01 and abacavir
 - B*58:01 and allopurinol
 - Others
3. Effects of the immune-mediated drug reactions in the patient.
4. Current methods and tests in use to identify patients at risk of adverse drug reactions.
5. Other non-HLA genes associated with increased, decreased and adverse responses to drugs.

COMPETENCE

Be able to:

- a. Select the appropriate HLA test for each drug sensitivity request.
- b. Interpret the HLA result in the context of the patient's drug sensitivity.

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:

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Date of completion:

Trainer's name:

Trainer's signature:

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

Date of completion:

Trainer's name:

Trainer's signature:

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

Internal Assessor's signature:

Internal Assessor's name:

Date:

Section 7.7 Other Clinical Applications of HLA
Subsection 7.7c Blood transfusion

KNOWLEDGE

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

1. Significance of blood transfusion in the development of HLA antibodies.
2. The following methods of preventing sensitisation:
 - Leucodepletion
 - Immunosuppression
 - Donor selection (HLA matched)
3. Clinical significance and management following HLA antibody formation in:
 - Febrile non-haemolytic transfusion reactions
 - Refractoriness to platelet transfusions
 - Transfusion-related acute lung injury (TRALI)
4. Production and use of HLA typed blood donor panels in the provision of HLA matched/compatible platelets, including:
 - Panel size
 - Level of typing
 - Selection of compatible units
 - Use of crossmatching
5. National and international guidelines and standards.

COMPETENCE

Be able to:

- a. Apply HLA to investigations in blood transfusion and the selection of compatible/matched platelets in refractoriness to platelet transfusions.
- b. Select appropriate HLA antibody investigation.
- c. Interpret laboratory tests and selected the best possible donor/product.

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 Other Clinical Applications of HLA
Subsection 7.7d HLA and pregnancy

KNOWLEDGE

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

1. Development and significance of HLA antibodies during pregnancy, including:
 - Principles of antibody development
 - Significance to mother/fetus
 - Recurrent miscarriage studies
2. Application of HLA typing for paternity testing.
3. Role of HLA in the development of other antibodies during pregnancy.

COMPETENCE

Be able to:

- a. Describe the significance and role of HLA antibodies in pregnancy.
- b. Describe the application of HLA typing in paternity testing.

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 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. 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.

REFERENCE

Section 7.8 Platelet Antigen Typing and Antibody Testing

KNOWLEDGE

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

1. Indications and reasons for platelet typing and antibody testing.
2. Clinical significance of platelet antibodies:
 - Post-transfusion purpura
 - Neonatal alloimmune thrombocytopenia
 - Idiopathic thrombocytopenia purpura
 - Refractoriness to platelet transfusion
3. The major platelet antigen system and nomenclature.
4. Principles, advantages and disadvantages of the main methods in use for typing of platelets.
5. Principles, advantages and disadvantages of the main methods in use for the detection and identification of anti-platelet antibodies.
6. Laboratory management of sensitised patients requiring platelet transfusion.
7. National and international guidelines and standards.
8. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

- a. Describe the need for testing for platelet type and antibodies.
- b. Describe the platelet antigen system.
- c. Describe the methods for platelet typing.
- d. Describe the methods for platelet antibody detection and identification.
- e. Interpret platelet typing and antibody detection data.

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 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 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. 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.

REFERENCE

Section 7.9 Granulocyte Antigen Typing and Antibody Testing

KNOWLEDGE

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

1. Indications and reasons for granulocyte typing and antibody testing.
2. Clinical significance of granulocyte antibodies:
 - Transfusion related acute lung injury (TRALI)
 - Alloimmune neutropenia
 - Autoimmune neutropenia
3. Major granulocyte antigen systems and nomenclature.
4. Principles, advantages and disadvantages of the main methods in use for typing of granulocytes.
5. Principles, advantages and disadvantages of the main methods in use for the detection and identification of anti-granulocyte antibodies.
6. National and international guidelines and standards.
7. Internal quality control and external quality assessment procedures.

COMPETENCE

Be able to:

- a. Describe the need for testing for granulocyte type and antibodies.
- b. Describe the granulocyte antigen system.
- c. Describe the methods for granulocyte typing.
- d. Describe the methods for granulocyte antibody detection and identification.
- e. Interpret granulocyte typing and antibody detection data.

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 7.9 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 role within the laboratory in the context of this section.

Section 7.9 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. 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.

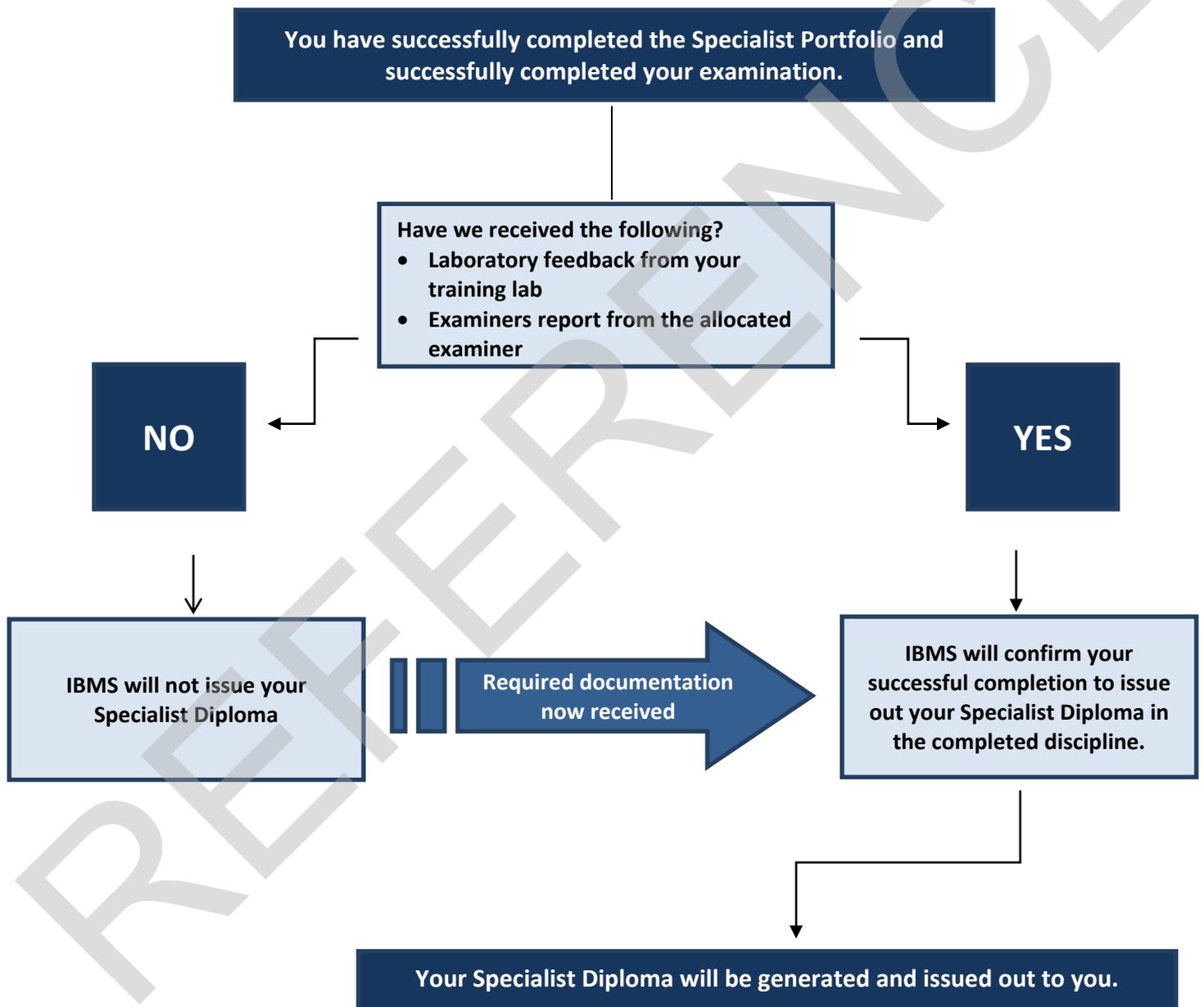
REFERENCE

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About this document

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Produced by: Education and Professional Standards Committee

Contact: Education Department

T: + 44 (0)20 7713 0214, **E:** education@ibms.org

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