Higher National Unit specification

General information

Unit title: Immunological Techniques (SCQF level 8)

Unit code: H92E 35

Superclass: RH

Publication date: May 2015

Source: Scottish Qualifications Authority

Version: 02

Unit purpose

This Unit is designed to enable learners to understand the principles underlying immunological techniques, and to develop an understanding of how antibodies are produced in vivo and their use in diagnostics and research. Learners will also develop practical skills in techniques relevant to immunology. The Unit is suitable for learners studying at HND level, and will provide the necessary underpinning knowledge and skills to enable progression to further study of immunology at degree level or to seek employment in science based industries.

Outcomes

On successful completion of the Unit the learner will be able to:

1 Describe and explain the principles of acquired immunity.
2 Explain the procedures used in the production of polyclonal and monoclonal antisera.
3 Explain the underlying principles of immunological techniques and their use in diagnostics and research.
4 Perform practical experiments related to immunology.

Credit points and level

1 Higher National Unit credit at SCQF level 8: (8 SCQF credit points at SCQF level 8)

Higher National Unit specification: General information (cont)

Unit title: Immunological Techniques (SCQF level 8)

Recommended entry to the Unit

Entry is at the discretion of the centre, however it is recommended that learners should have completed the HN Units H92W 33 *Fundamental Chemistry: An Introduction* and H927 34 *Cell Biology: Theory and Laboratory Skills* or equivalent.

Core Skills

Achievement of this Unit gives automatic certification of the following Core Skills component:

Complete Core Skill None

Core Skill component Critical Thinking at SCQF level 6

There are also opportunities to develop aspects of Core Skills which are highlighted in the Support Notes of this Unit specification.

Context for delivery

If this Unit is delivered as part of a Group Award, it is recommended that it should be taught and assessed within the subject area of the Group Award to which it contributes.

The Assessment Support Pack (ASP) for this Unit provides assessment and marking guidelines that exemplify the national standard for achievement. It is a valid, reliable and practicable assessment. Centres wishing to develop their own assessments should refer to the ASP to ensure a comparable standard. A list of existing ASPs is available to download from SQA's website **(http://www.sqa.org.uk/sqa/46233.2769.html)**.

Equality and inclusion

This Unit specification has been designed to ensure that there are no unnecessary barriers to learning or assessment. The individual needs of learners should be taken into account when planning learning experiences, selecting assessment methods or considering alternative evidence.

Further advice can be found on our website **www.sqa.org.uk/assessmentarrangements**.

Higher National Unit specification: Statement of standards

Unit title: Immunological Techniques (SCQF level 8)

Acceptable performance in this Unit will be the satisfactory achievement of the standards set out in this part of the Unit specification. All sections of the statement of standards are mandatory and cannot be altered without reference to SQA.

Where evidence for Outcomes is assessed on a sample basis, the whole of the content listed in the Knowledge and/or Skills section must be taught and available for assessment. Learners should not know in advance the items on which they will be assessed and different items should be sampled on each assessment occasion.

Outcome 1

Describe and explain the principles of acquired immunity.

Knowledge and/or Skills

- Role of T cell lymphocytes in activating B lymphocytes
- Role of B lymphocytes in the production of antibodies
- Structure and function of the components of antibodies
- Properties of an antigen and an immunogen
- Binding between antibody and antigen with reference to valency, specificity, affinity/avidity and factors affecting binding equilibrium

Outcome 2

Explain the procedures used in the production of polyclonal and monoclonal antisera.

Knowledge and/or Skills

- Principle of immunisation
- Choice of animal available for production of antisera
- Need for immunisation schedules
- Use of adjuvants
- Formation and selection of hybridoma cells in monoclonal antibody production

Outcome 3

Explain the underlying principles of immunological techniques and their use in diagnostics and research.

Knowledge and/or Skills

- Principles and uses of precipitation reactions
- Principles and uses of agglutination reactions
- Basic principles of immunoassay design: solid phase, choice of primary antibody and secondary antibody-enzyme conjugates, detection methods
- Principles and uses of immunoassays using labelled antibodies or antigens

Higher National Unit specification: Statement of standards (cont)

Unit title: Immunological Techniques (SCQF level 8)

Outcome 4

Perform practical experiments related to immunology.

Knowledge and/or Skills

- Immunology experiments
- Working safely, within current health and safety regulations
- Consistent and accurate results
- Recording observations and results
- Evaluation skills
- Result analysis and conclusions

Evidence Requirements for this Unit

Written and/or oral recorded evidence for Outcomes 1–3 should be assessed using a holistic closed-book assessment under supervised conditions. The assessment will use a sampling approach to the Knowledge and/or Skills as detailed below. It is recommended that the assessment should be completed within 90 minutes.

Written and/or oral recorded evidence for Outcome 4 should be assessed by production of a full laboratory report, or by completion of an appropriate pro forma. An assessor's observation checklist could be used to record performance evidence of practical experiments.

Outcome 1

The assessment will sample three of the five Knowledge and/or Skills items. Learners will not have prior knowledge of which items are being assessed. Those items which are not sampled must be covered in the alternative (re-sit) assessment.

Where an item is sampled, a leaner's response will be judged satisfactory where the evidence shows that the learner can:

- Explain the role of T cell lymphocytes in activating B lymphocytes.
- Explain the role of B lymphocytes in the production of antibodies.
- Explain the function of the structural components of antibodies.
- Describe the properties of an antigen and an immunogen.
- Describe the binding between antibody and antigen with reference to either valency, specificity, affinity/avidity or factors affecting binding equilibrium.

Higher National Unit specification: Statement of standards (cont)

Unit title: Immunological Techniques (SCQF level 8)

Outcome 2

The assessment will sample three of the five Knowledge and/or Skills items. Learners will not have prior knowledge of which items are being assessed. Those items which are not sampled must be covered in the alternative (re-sit) assessment.

Where an item is sampled, a leaner's response will be judged satisfactory where the evidence shows that the learner can:

- Explain the principle of immunisation (primary and secondary response).
- Explain why a particular animal is chosen for the production of antisera.
- Explain why a particular immunisation schedule is chosen.
- Explain why certain adjuvants are chosen.
- Describe how hybridoma cells are formed and selected in monoclonal antibody production.

Outcome 3

The assessment will sample three of the four Knowledge and/or Skills items. Learners will not have prior knowledge of which items are being assessed. Those items which are not sampled must be covered in the alternative (re-sit) assessment.

Where an item is sampled, a leaner's response will be judged satisfactory where the evidence shows that the learner can:

- Explain the principles and uses of precipitation reactions.
- Explain the principles and uses of agglutination reactions.
- Explain the choice of the different solid phases, the choice of primary antibody, secondary antibody-enzyme conjugates, and the different detection methods used in immunoassays.
- Explain the principles and uses of immunoassays using labelled antibodies or antigens.

Outcome 4

Learners will perform a minimum of one practical experiment, the content of which will be related to Outcome 3. A learner's response will be judged satisfactory where the evidence shows that the learner can achieve all of the following:

- Plan and perform experiments related to immunological techniques.
- Work in a safe manner regarding current health and safety regulations.
- Achieve consistent and accurate results.
- Record experimental observations and results clearly and accurately.
- Evaluate validity of results in terms of sources of and values of experimental errors.
- Analyse results correctly and state valid conclusions.

Higher National Unit specification: Statement of standards (cont)

Unit title: Immunological Techniques (SCQF level 8)

An assessor observation checklist will be used to record the learner's planning and performance of the practical work in line with health and safety requirements.

Learners should complete a laboratory diary throughout the practical experiments. Learners must report the practical experiments by production of a full laboratory report. Where a learner does not perform an assessed practical experiment to the required standard, they will be given the chance to either reattempt the same practical experiments, or to undertake a different practical experiment of similar complexity. Where a laboratory report does not meet the required standard, then the learner will be given a single opportunity to re-draft. If the required standard is still not attained, then an alternative practical experiment will be set.

Higher National Unit Support Notes

Unit title: Immunological Techniques (SCQF level 8)

Unit Support Notes are offered as guidance and are not mandatory.

While the exact time allocated to this Unit is at the discretion of the centre, the notional design length is 40 hours.

Guidance on the content and context for this Unit

This Unit is intended as part of the framework for HND Applied Biological Sciences but may be suitable for inclusion in other HN Science awards. It is designed to develop the theoretical and practical aspects of immunological techniques, and to enable an understanding of the way antibodies are produced in vivo, how polyclonal and monoclonal antiserum is prepared and how these antibodies are used in different types of immunoassays.

Outcome 1 — Describe and explain the principles of aquired immunity

General overview of the immune system including innate and acquired immune response.
T cell types (helper and killer T cells) and their activation by antigen presenting cells.
T cell-dependant B cell activation to produce plasma cells and memory cells.
Clonal selection and expansion.
Role of cytokine in B and T cell regulation.

Structure of antibodies: light and heavy chains, antigen binding sites at F(ab), Fc linked to effector function, variable and constant domains, hinge region, diversity of hypervariable region (VDJ rearrangement) and affinity maturation, isotypes of immunoglobulins (IgA, IgE, IgD, IgG, IgM) and valency of these isotypes.

Antigen and epitope definition, properties of B cell and T cell recognised epitopes.
Immunogenicity of antigens: foreignness to host, molecular size, chemical composition and degradability of protein.

Binding between antibody and antigen: non-covalent forces involved, definition of and difference between affinity and avidity, antibody specificity and cross-reactivity, effect of temperature, pH, concentration and time on antibody-antigen binding equilibrium.

Higher National Unit Support Notes (cont)

Unit title: Immunological Techniques (SCQF level 8)

Outcome 2 — Explain the procedures used in the production of polyclonal and monoclonal antisera

Immunisation: differences in antibody production between primary and secondary response, preparation of vaccine: methods of making haptens immunogenic using carriers, use of adjuvants in animals (Freund's complete and incomplete adjuvant).

Choice of animal and methods to obtain antisera from them, need for Home Office licence for animal experiments, immunisation schedules (boosters, timings of immunisations).

Formation of hybridoma cells: isolation of B cells, use of PEG to fuse with myeloma cells. Selection of hybridoma cells: use of HAT medium, role of each component within HAT medium.

Screening of hybridomas for monoclonal antibodies: use of ELISA.

Outcome 3 — Explain the underlying principles of immunological techniques and their use in diagnostics and research

Precipitation reaction: principles of antigen excess, antibody excess and equivalence. Precipitation assays: Single Radial Immunodiffusion and/or Ouchterlony.

Agglutination reaction: interaction between antibody and particular antigen, prozone effect. Agglutination assays: haemagglutination/blood typing, passive and indirect agglutination, agglutination inhibition.

Basic principles of immunoassay design.

Solid phase: paramagnetic beads, polystyrene plates, glass fibre matrix.

Primary antibody detecting antigen: monoclonal or polyclonal.

Secondary antibody-enzyme conjugates: choice of secondary antibodies to bind primary antibody. Enzyme conjugate: Horse Radish Peroxidase, Alkaline Phosphatase, beta-galactosidase, Biotin. Substrates: TMB, pNPP.

Types of detection: Chromogenic/Colourimetric, Chemiluminescence, Fluorescence, Radioactivity.

Types of assays: competitive, non-competitive, homogenous, and heterogeneous.
Link these definitions to appropriate immunoassays from list below.

Principles of labelled antibody assays: the principles underlying ELISA (direct, indirect, sandwich and competitive), Western Blotting and Immunofluorescence microscopy (direct versus indirect method with fluorochrome labelled antibodies using light microscopy).

Higher National Unit Support Notes (cont)

Unit title: Immunological Techniques (SCQF level 8)

Labelled antibody assays: the uses of techniques applying labelled antibodies and antigens are extremely widespread and examples should be chosen with consideration of the background and aspirations of the learner.

Examples might include: diagnostic kits using RIA, EIA eg ELISA for screening of hybridoma supernatants or MEIA; Tuberculosis test using ELISPOT assay, drug testing using FPIA; disease marker detection by Flow cytometry, diagnostic tests using Immunofluorescence microscopy.

Summary of uses of monoclonal and polyclonal antibodies: protein purification (affinity chromatography), tumour detection, tumour killing, diagnostic kits, research applications, food industry applications.

Outcome 4 — Perform practical experiments related to immunology

Guidance on suitable practical experiments for assessment purposes is given elsewhere in this document. However, it is envisaged that learners will also participate in a range of other practical experiments which will both develop their laboratory skills and support the theory covered in Outcome 3.

In carrying out such activities, learners should follow Good Laboratory Practice (GLP) and carry out or be familiar with the risk and Control of Substances Hazardous to Health (COSHH) assessments on all procedures undertaken. Opportunities should be taken to develop awareness of the sources of experimental error and of the accuracy of measurements, with quantification of errors where possible.

Guidance on approaches to delivery of this Unit

Outcomes 1–4 would best be delivered in order. However, to understand the principles of immunoassays in Outcome 3, it would be beneficial to support the learning by incorporating several practical experiments and hands-on simulations.

It is envisaged that delivery of Outcome 1 could commence with a general overview of the response of the innate and adaptive immune system to an infection with bacteria or virus. The main cellular players of both immune systems (eg T helper cells, B cells, macrophages, platelets) can be introduced using cut-outs and playing out the processes of inflammation. The humoral immune response could then be covered, starting with the activation of T helper cells through antigen presenting cells, eg macrophages, leading to the subsequent activation of B cells and antibody production.

Learners should be aware of the general structure of the IgG antibody with specific emphasis on the structure and function of the antigen binding sites, and this could be introduced through model building. At this level, only a limited explanation of the VDJ rearrangement and affinity maturation (with emphasis on the development from IgM affinity to IgG affinity) should be given to explain the variety of antigen binding sites of B cell receptors/antibodies.

Higher National Unit Support Notes (cont)

Unit title: Immunological Techniques (SCQF level 8)

Delivery of the topic 'antigen and immunogen' could include comparing different infectious and non-infectious agents in regards to their antigenicity and immunogenicity.

The antibody-antigen equilibrium should be introduced using the reversible chemical equation between antigen and antibody as well as the equilibrium constant. The effects of temperature, pH, concentration and time on antibody-antigen binding equilibrium should be briefly covered to show their importance in immunoassay design.

Outcome 2 is intended to give a brief introduction to the topic of immunisation and vaccine design in order to raise polyclonal antibodies in animals. Therefore it is suggested to only focus on Freund's complete and Freund's incomplete adjuvants and the way their components contribute to a greater vaccine efficiency. The procedure of making monoclonal antibodies must be covered in great detail. This should include the role of each component within HAT medium and PEG in cell fusion. The screening of hybridoma supernatants for the correct antibodies with ELISA could be mentioned at this stage, but ELISA should be described in detail in Outcome 3.

It is envisaged that Outcome 3 commences with the more basic homogenous techniques of precipitation and agglutination to promote understanding of large (visible) antibody-antigen lattices forming in equivalence zone. The understanding of the principles can be supported by incorporating practical experiments like the Ouchterlony test or blood typing. Moving on from these cheaper, more time-consuming techniques learners could be introduced to the basic setup of modern immunoassays, leading on to principles of ELISA, Western Blotting and Immunofluorescence. It is recommended to emphasise the choices the learners will have to make when designing an immunoassay: direct versus indirect assay, homogenous versus heterogeneous assay, competitive versus non-competitive assay. Learners should discuss which of these types of assays leads to greater signal amplification/ sensitivity, is less time-consuming and comes with greater cost. Immunoassay development is a fast moving field. Therefore newer assays like FPIA could be introduced beside classical ones like ELISA to show parallels and differences. It is envisaged to conclude the Outcome with internet research on uses of polyclonal and monoclonal antibodies in assays used in a research, clinical, diagnostic or food industry setting. A visit to a local company or NHS laboratory using these types of immunoassays would demonstrate their practical applications.

It is envisaged that Outcome 4 will be delivered alongside the theoretical based Outcome 3. A range of practical experiments could be utilised to both support understanding of the underlying theory and to prepare learners for undertaking the assessed practical experiments. Aspects suitable for experimental investigation might include Serial Radial Immunodiffusion to detect IgA in saliva, Ouchterlony test, Haemagglutination, Western Blotting and SAPS Botrytis ELISA.

Higher National Unit Support Notes (cont)

Unit title: Immunological Techniques (SCQF level 8)

Guidance on approaches to assessment of this Unit

Evidence can be generated using different types of assessment. The following are suggestions only. There may be other methods that would be more suitable to learners.

Outcomes 1–3 could be assessed by a single holistic closed-book assessment with an appropriate cut-off score that covers the sampling requirements as detailed in the Evidence Requirements. Assessment should be carried out in supervised conditions, and it is recommended that the assessment be completed within 90 minutes.

Where evidence of Outcomes 1–3 is assessed by sampling, the whole of the content listed in the Knowledge and/or Skills must be taught and available for assessment. Learners should not know in advance the items on which they will be assessed, and different items should be sampled on each assessment occasion. Any items not sampled in the first assessment, must be included in the alternative (re-sit) assessment.

In Outcome 4 learners are required to undertake one assessed practical experiment, the content of which will be related to Outcome 3. Examples of suitable experiments are given below. However, this list is not prescriptive, and other practical experiments of similar complexity may be used by the centre.

Suitable practical experiments for Outcome 3 are:

- Serial Radial Immunodiffusion to detect IgA in saliva
- Ouchterlony test
- Haemagglutination
- Western Blotting
- SAPS Botrytis ELISA

Assessed practical experiments will usually be performed individually. However, there may be some experiments that are suitable to be undertaken in pairs or small groups. If this is the case then the assessor should ensure that all participants are actively involved and are able to adequately demonstrate the required skills.

An exemplar instrument of assessment with marking guidelines has been produced to indicate the national standard of achievement at SCQF level 8.

Centres are reminded that prior verification of centre-devised assessments would help to ensure that the national standard is being met. Where learners experience a range of assessment methods, this helps them to develop different skills that should be transferable to work or further and higher education.

Higher National Unit Support Notes (cont)

Unit title: Immunological Techniques (SCQF level 8)

Opportunities for e-assessment

E-assessment may be appropriate for some assessments in this Unit. By e-assessment we mean assessment which is supported by Information and Communication Technology (ICT), such as e-testing or the use of e-portfolios or social software. Centres which wish to use e-assessment must ensure that the national standard is applied to all learner evidence and that conditions of assessment as specified in the Evidence Requirements are met, regardless of the mode of gathering evidence. The most up-to-date guidance on the use of e-assessment to support SQA's qualifications is available at **www.sqa.org.uk/e-assessment**.

Opportunities for developing Core and other essential skills

The delivery and assessment of this Unit will provide learners with the opportunity to develop the Core Skills of *Information and Communication Technology (ICT)* at SCQF level 4, *Numeracy* at SCQF level 5 and *Problem Solving* at SCQF level 6.

Information and Communication Technology (ICT) — Providing/Creating Information at SCQF level 4

Learners will make effective and appropriate use of ICT packages to produce a laboratory report in an appropriate format. Packages used will likely include word processing, spreadsheets, and graph drawing software. Learners will also be required to utilise internet search engines to source information on research topics.

Numeracy — Using Number at SCQF level 5

In context with the immunoassay practical experiment learners might be required to solve simple equations and perform data analysis, eg calculation of ring area and line of best fit.

Problem Solving — Reviewing and Evaluating at SCQF level 6

Following assessed practical experiments learners will be required to review and evaluate the effectiveness of the exercise with a thorough interpretation of random and systematic sources or error. Learners will be required to reach sound conclusions on the basis of the data collected and the inherent errors.

Sustainability

Sustainability can be embedded in delivery of the Unit in a variety of ways. For example, by encouraging minimum usage, correct disposal procedures and possible recycling during practical experiments.

Citizenship

Citizenship will be encouraged by developing learners who are scientifically literate on topics such as the use of animals in research. This will enable learners to make effective choices and contributions to public debates on the issue.

This Unit has the Critical Thinking components of Problem Solving embedded in it. This means that when candidates achieve the Unit, their Core Skills profile will also be updated to show they have achieved Critical Thinking at SCQF level 6

History of changes to Unit

Version	Description of change	Date
02	Core Skills Component Critical Thinking at SCQF level 6 embedded	July 2015

General information for learners

Unit title: Immunological Techniques (SCQF level 8)

This section will help you decide whether this is the Unit for you by explaining what the Unit is about, what you should know or be able to do before you start, what you will need to do during the Unit and opportunities for further learning and employment.

This is a 1 credit Unit at SCQF level 8, which you are likely to be studying as part of the second year of an HND Science programme. Before progressing to this Unit it would be beneficial to have completed the HN Units H92W 33 *Fundamental Chemistry: An Introduction* and H927 34 *Cell Biology: Theory and Laboratory Skills*. This Unit will provide you with the underpinning knowledge to understand how polyclonal and monoclonal antisera are produced and how they have their applications in some of the most common immunological techniques used in a wide variety of research, clinical and industrial laboratories. Emphasis is on you being provided with the opportunity to gain hands-on experience of some of these techniques.

On completion of the Unit you should be able to:

1 Describe and explain the principles of acquired immunity.
2 Explain the procedures used in the production of polyclonal and monoclonal antisera.
3 Explain the underlying principles of immunological techniques and their use in diagnostics and research.
4 Perform practical experiments related to immunology.

Outcome 1

In this Outcome you will find out how B and T-lymphocytes are involved in the production of polyclonal antibodies and you will learn about the structure and diverse functions of these antibodies. You will also discover the reasons why some molecules (antigens) are very good at causing the production of antibodies whereas other molecules are not. Finally, you will learn about the optimal conditions for an antigen and an antibody to bind to each other.

Outcome 2

In this Outcome you will explore how immunisation works and the methods used to produce polyclonal antiserum and monoclonal antibodies. You will find out how the production of maximal antibody amounts is achieved using different animals and vaccine designs.

Outcome 3

In this Outcome you will be given information about the underlying principles of a variety of immunological techniques such as precipitation, agglutination and immunoassays involving labelled antibodies and antigens. You will also explore details about the applications of the techniques. Many of these techniques are in regular use in a wide range of laboratories, including those involved in clinical medicine, research and industry.

General information for learners (cont)

Unit title: Immunological Techniques (SCQF level 8)

Outcome 4

In this Outcome you will undertake practical experiments, based on the content of Outcome 3.

During this practical work, you will also be expected to develop good laboratory practices as well as improve your skills of manipulation, observation and measurement. You will also be encouraged to develop safe working practices and to strive constantly to improve the accuracy and reliability of your results. The reporting and analysis of experimental data is an important aspect of the practical sessions.

Assessment

For Outcomes 1 to 3 you will take a closed-book, end of Unit assessment.

Outcome 4 will be assessed after you have learned the necessary practical skills, and will take the form of one practical experiment, for which you will report your results either in a full laboratory report, or by completion of a pro forma.

Core Skills

You will have opportunities to develop the Core Skills of *Information and Communication Technology (ICT)* at SCQF level 4, *Numeracy* at SCQF level 5 and *Problem Solving* at SCQF level 6.