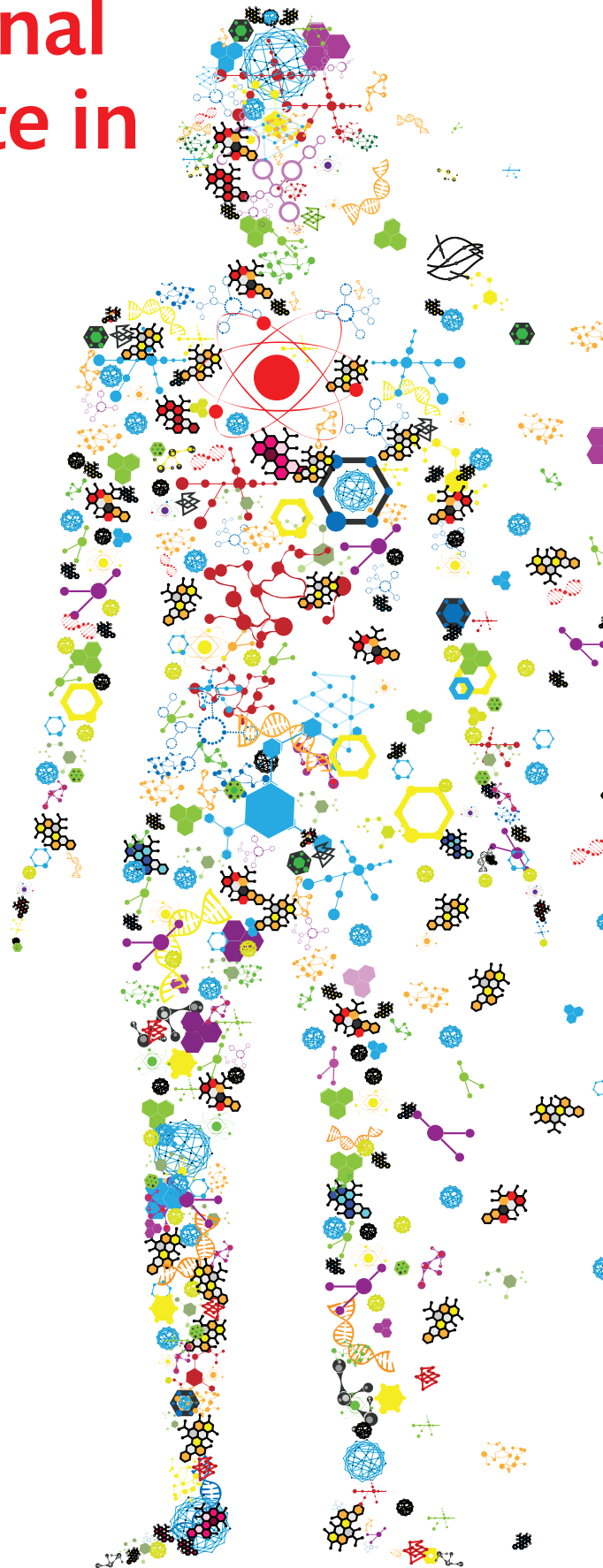


Pearson BTEC Level 3 National Extended Certificate in Applied Human Biology



Specification

First teaching from January 2018

First certification from 2019

Issue 6

Pearson BTEC Level 3 National Extended Certificate in Applied Human Biology Specification

First teaching September 2018

Issue 6

Edexcel, BTEC and LCCI qualifications

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This specification is Issue 6. We will inform centres of any changes to this issue. The latest issue can be found on our website.

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Welcome

With a track record built over 30 years of learner success, BTEC Nationals are widely recognised by industry and higher education as the signature vocational qualification at Level 3. They provide progression to the workplace either directly or via study at a higher level. Proof comes from YouGov research, which shows that 62 per cent of large companies have recruited employees with BTEC qualifications. What's more, well over 100,000 BTEC students apply to UK universities every year and their BTEC Nationals are accepted by over 150 UK universities and higher education institutes for relevant degree programmes either on their own or in combination with A Levels.

Why are BTECs so successful?

BTECs embody a fundamentally learner-centred approach to the curriculum, with a flexible, unit-based structure and knowledge applied in project-based assessments. They focus on the holistic development of the practical, interpersonal and thinking skills required to be able to succeed in employment and higher education.

When creating the BTEC Nationals in this suite, we worked with many employers, higher education providers, colleges and schools to ensure that their needs are met. Employers are looking for recruits with a thorough grounding in the latest industry requirements and work-ready skills such as teamwork. Higher education needs students who have experience of research, extended writing and meeting deadlines.

We have addressed these requirements with:

- a range of BTEC sizes, each with a clear purpose, so there is something to suit each learner's choice of study programme and progression plans
- refreshed content that is closely aligned with employers' and higher education needs for a skilled future workforce
- assessments and projects chosen to help learners progress to the next stage. This means some are set by you to meet local needs, while others are set and marked by Pearson so that there is a core of skills and understanding that is common to all learners. For example, a written test can be used to check that learners are confident in using technical knowledge to carry out a certain job.

We provide a wealth of support, both resources and people, to ensure that learners and their teachers have the best possible experience during their course. See *Section 10* for details of the support we offer.

A word to learners

Today's BTEC Nationals are demanding, as you would expect of the most respected applied learning qualification in the UK. You will have to choose and complete a range of units, be organised, take some assessments that we will set and mark and keep a portfolio of your assignments. But you can feel proud to achieve a BTEC because, whatever your plans in life – whether you decide to study further, go on to work or an Apprenticeship, or set up your own business – your BTEC National will be your passport to success in the next stage of your life.

Good luck, and we hope you enjoy your course.

Collaborative development

Learners completing their BTEC Nationals in Applied Human Biology will be aiming to go on to employment, often via the stepping stone of higher education. It was, therefore, essential that we developed these qualifications in close collaboration with experts from professional bodies, businesses and universities, and with the providers who will be delivering the qualifications. To ensure that the content meets providers' needs and provides high-quality preparation for progression, we engaged experts. We are very grateful to all the university and further education lecturers, teachers, employers, professional body representatives and other individuals who have generously shared their time and expertise to help us develop these new qualifications.

In addition, universities, professional bodies and businesses have provided letters of support confirming that these qualifications meet their entry requirements. These letters can be viewed on our website.

Summary of Pearson BTEC Level 3 National Extended Certificate in Applied Human Biology specification Issue 6 changes

Summary of changes made between the previous issue and this current issue	Page number
The last paragraph of the <i>Qualification and unit content</i> section has been amended to allow centres delivering the qualification above to alter the content to reflect the context of the country where it is being delivered.	Page 5

If you need further information on these changes or what they mean, contact us via our website at: qualifications.pearson.com/en/support/contact-us.html.

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Introduction to BTEC National qualifications for the applied human biology sector

This specification contains the information you need to deliver the Pearson BTEC Level 3 National Extended Certificate in Applied Human Biology. The specification signposts you to additional handbooks and policies. It includes all the units for this qualification.

This qualification is part of the suite of Applied Human Biology qualifications offered by Pearson. In the suite there are qualifications that focus on different progression routes, allowing learners to choose the one best suited to their aspirations.

All qualifications in the suite share some common units and assessments, allowing learners some flexibility in moving between sizes. The qualification titles are given below.

Some BTEC National qualifications provide a broad introduction that gives learners transferable knowledge and skills. These qualifications are for post-16 learners who want to continue their education through applied learning. The qualifications prepare learners for a range of higher education courses and job roles related to a particular sector. They provide progression either by meeting entry requirements in their own right or by being accepted alongside other qualifications at the same level and adding value to them.

In Applied Human Biology these qualifications are:

Pearson BTEC Level 3 National Certificate in Applied Human Biology (603/3041/7)

Pearson BTEC Level 3 National Extended Certificate in Applied Human Biology (603/3040/5).

The Extended Certificate (360 GLH) is approved as an Applied General qualification for 2020 performance measures by the DFE. The Certificate (180 GLH) is not currently recognised for performance measures. Please check our website for details of subsequent availability for future DFE performance measures.

This specification signposts all the other essential documents and support that you need as a centre in order to deliver, assess and administer the qualification, including the staff development required. A summary of all essential documents is given in *Section 7*. Information on how we can support you with this qualification is given in *Section 10*.

The information in this specification is correct at the time of publication.

Total Qualification Time

For all regulated qualifications, Pearson specifies a total number of hours that it is estimated learners will require to complete and show achievement for the qualification: this is the Total Qualification Time (TQT). Within TQT, Pearson identifies the number of Guided Learning Hours (GLH) that we estimate a centre delivering the qualification might provide. Guided learning means activities, such as lessons, tutorials, online instruction, supervised study and giving feedback on performance, that directly involve teachers and assessors in teaching, supervising and invigilating learners. Guided learning includes the time required for learners to complete external assessment under examination or supervised conditions.

In addition to guided learning, other required learning directed by teachers or assessors will include private study, preparation for assessment and undertaking assessment when not under supervision, such as preparatory reading, revision and independent research.

BTEC Nationals have been designed around the number of hours of guided learning expected. Each unit in the qualification has a GLH value of 60, 90 or 120. There is then a total GLH value for the qualification.

Each qualification has a TQT value. This may vary within sectors and across the suite, depending on the nature of the units in each qualification and the expected time for other required learning. The following table shows all the qualifications in this sector and their GLH and TQT values.

Qualifications, sizes and purposes at a glance

Title	Size and structure	Summary purpose
Pearson BTEC Level 3 National Certificate in Applied Human Biology*	180 GLH (205 TQT) Equivalent in size to 0.5 of an A Level. Two units, both mandatory, of which one is external. Mandatory content (100%). External assessment (50%).	An introduction to a vocational sector through applied learning. For learners for whom an element of human biology would be complementary, the qualification supports progression to higher education when taken as part of a programme of study that includes other vocational or general qualifications.
Pearson BTEC Level 3 National Extended Certificate in Applied Human Biology	360 GLH (405 TQT) Equivalent in size to one A Level. Eight units of which three are mandatory and two are external. Mandatory content (83%). External assessment (58%).	A broad basis of study for the health science sector. Designed to support progression to higher education when taken as part of a programme of study that includes other appropriate BTEC Nationals or A Levels.

* This qualification is not currently recognised by DFE for performance measures.

Structures of the qualifications at a glance

This table shows all the units and the qualifications to which they contribute. The full structure for this Pearson BTEC Level 3 National Extended Certificate in Applied Human Biology is shown in *Section 2*. **You must refer to the full structure to select units and plan your programme.**

Key

	Unit assessed externally		Mandatory units		Optional units
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Unit (number and title)	Unit size (GLH)	Certificate* (180 GLH)	Extended Certificate (360 GLH)
1 Principles of Applied Human Biology	90	M	M
2 Practical Microbiology and Infectious Diseases	90	M	M
3 Human Biology and Health Issues	120		M
4 Functional Physiology	60		O
5 Diseases, Disorders, Treatments and Therapies	60		O
6 Genetics and Genetic Engineering	60		O
7 Biomedical Science	60		O
8 Human Reproduction and Fertility	60		O

* This qualification is not currently recognised by DFE for performance measures.

Qualification and unit content

Pearson has developed the content of the new BTEC Nationals in collaboration with employers and representatives from higher education and relevant professional bodies. In this way, we have ensured that content is up to date and that it includes the knowledge, understanding, skills and attributes required in the sector.

Each qualification in the suite has its own purpose. The mandatory and optional content provides a balance of breadth and depth, while retaining a degree of choice for individual learners to study content relevant to their own interests and progression choices. Also, the content may be applied during delivery in a way that is relevant to local employment needs.

The proportion of mandatory content ensures that all learners are following a coherent programme of study and acquiring the knowledge, understanding and skills that will be recognised and valued. Learners are expected to show achievement across mandatory units as detailed in *Section 2*.

BTEC Nationals have always required applied learning that brings together knowledge and understanding (the cognitive domain) with practical and technical skills (the psychomotor domain). This is achieved through learners performing vocational tasks that encourage the development of appropriate vocational behaviours (the affective domain) and transferable skills. Transferable skills are those such as communication, teamwork and research and analysis, which are valued in both higher education and the workplace.

Our approach provides rigour and balance, and promotes the ability to apply learning immediately in new contexts. Further details can be found in *Section 2*.

Centres should ensure that delivery of content is kept up to date. Some of the units within the specification may contain references to legislation, policies, regulations and organisations, which may not be applicable in the country you deliver this qualification in (if teaching outside of England), or which may have gone out-of-date during the lifespan of the specification. In these instances, it is possible to substitute such references with ones that are current and applicable in the country you deliver subject to confirmation by your Standards Verifier.

Assessment

Assessment is specifically designed to fit the purpose and objective of the qualification. It includes a range of assessment types and styles suited to vocational qualifications in the sector. There are three main forms of assessment that you need to be aware of: external, internal and synoptic.

Externally-assessed units

Each external assessment for a BTEC National is linked to a specific unit. All of the units developed for external assessment are of 90 or 120 GLH to allow learners to demonstrate breadth and depth of achievement. Each assessment is taken under specified conditions, then marked by Pearson and a grade awarded. Learners are permitted to resit external assessments during their programme. You should refer to our website for current policy information on permitted retakes.

The styles of external assessment used for qualifications in the Applied Human Biology suite are:

- examinations – all learners take the same assessment at the same time, normally with a written outcome.
- set tasks – learners take the assessment during a defined window and demonstrate understanding through completion of a vocational task

Some external assessments include a period of preparation using set information. External assessments are available twice a year. For detailed information on the external assessments please see the table in *Section 2*. For further information on preparing for external assessment see *Section 5*.

Internally-assessed units

Most units in the sector are internally assessed and subject to external standards verification. This means that you set and assess the assignments that provide the final summative assessment of each unit, using the examples and support that Pearson provides. Before you assess you will need to become an approved centre, if you are not one already. You will need to prepare to assess using the guidance in *Section 6*.

In line with the requirements and guidance for internal assessment, you select the most appropriate assessment styles according to the learning set out in the unit. This ensures that learners are assessed using a variety of styles to help them develop a broad range of transferable skills. Learners could be given opportunities to:

- write up the findings of their own research
- use case studies to explore complex or unfamiliar situations
- carry out projects for which they have choice over the direction and outcomes
- demonstrate practical and technical skills using appropriate equipment and processes.

You will make grading decisions based on the requirements and supporting guidance given in the units. Learners may not make repeated submissions of assignment evidence. For further information see *Section 6*.

Synoptic assessment

Synoptic assessment requires learners to demonstrate that they can identify and use effectively, in an integrated way, an appropriate selection of skills, techniques, concepts, theories and knowledge from across the whole sector as relevant to a key task. BTEC learning has always encouraged learners to apply their learning in realistic contexts using scenarios and realistic activities that will permit learners to draw on and apply their learning. For these qualifications we have formally identified units that contain a synoptic assessment task. Synoptic assessment must take place after the teaching and learning of other mandatory units in order for learners to be able to draw from the full range of content. The synoptic assessment gives learners an opportunity to independently select and apply learning from across their programmes in the completion of a vocational task. Synoptic tasks may be in internally- or externally-assessed units. The particular unit that contains the synoptic tasks for this qualification is shown in the structure in *Section 2*.

Language of assessment

Assessment of the internal and external units for these qualifications will be available in English. All learner work must be in English. A learner taking the qualifications may be assessed in British or Irish Sign Language where it is permitted for the purpose of reasonable adjustment. For information on reasonable adjustments see *Section 7*.

Grading for units and qualifications

Achievement in the qualification requires a demonstration of depth of study in each unit, assured acquisition of a range of practical skills required for employment or progression to higher education, and successful development of transferable skills. Learners achieving a qualification will have achieved across mandatory units, including external and synoptic assessment.

Units are assessed using a grading scale of Distinction (D), Merit (M), Pass (P), Near Pass (N) and Unclassified (U). The grade of Near Pass is used for externally-assessed units only. All mandatory and optional units contribute proportionately to the overall qualification grade, for example a unit of 120 GLH will contribute double that of a 60 GLH unit.

Qualifications in the suite are graded using a scale of P to D*, **or** PP to D*D*, **or** PPP to D*D*D*. Please see *Section 9* for more details. The relationship between qualification grading scales and unit grades will be subject to regular review as part of Pearson's standards monitoring processes on the basis of learner performance and in consultation with key users of the qualification.

UCAS Tariff points

The BTEC Nationals attract UCAS points. Please go to the UCAS website for full details of the points allocated.

1 Qualification purpose

In this section you will find information on the purpose of the qualification.

Pearson BTEC Level 3 National Extended Certificate in Applied Human Biology

In this section, you will find information on the purpose of this qualification and how its design meets that purpose through the qualification objective and structure. We publish a full 'Statement of Purpose' for each qualification on our website. These statements are designed to guide you and potential learners to make the most appropriate choice about the size of qualification suitable at recruitment.

In this qualification learners will study applied human biology which forms the foundation of the health and health science sectors. The sectors are wide ranging, including, for example, nursing, midwifery, allied health and sciences including life sciences, clinical biomedical sciences and physiological sciences. There are approximately 50,000 people employed in applied health science occupations and over 3 million nurses in the UK.

Who is this qualification for?

The Pearson BTEC Level 3 National Extended Certificate in Applied Human Biology is intended to be an Applied General qualification for post-16 students wanting to continue their education through applied learning, and who aim to progress to higher education and ultimately to employment, possibly in the health and health science sectors. The qualification is equivalent in size to 1 A Level and it has been designed to be part of a typical two-year study programme, alongside A Levels or other applied general qualifications at Level 3.

No prior study of the sector is needed, but learners should normally have a range of achievement at Level 2, in GCSEs or equivalent qualifications, including science GCSE.

What does this qualification cover?

The content of this qualification has been developed in consultation with academics to ensure that it supports progression to higher education.

The qualification provides the knowledge, understanding and skills that will prepare learners for further study or training.

Everyone taking this qualification will study three mandatory units, covering the following content areas:

- Unit 1: Principles of Applied Human Biology
- Unit 2: Practical Microbiology and Infectious Diseases
- Unit 3: Human Biology and Health Issues.

The mandatory content allows learners to concentrate on the development of their knowledge and understanding as well as essential practical and research skills relevant in applied human biology and health science areas, over an extended period.

Learners will also choose one optional unit, which has been designed to support progression to applied human biology, health and health science courses in higher education. This will allow learners to choose a specific specialist area in which they wish to develop their knowledge and skills, such as:

- Unit 4: Functional Physiology
- Unit 5: Diseases, Disorders, Treatments and Therapies
- Unit 6: Genetics and Genetic Engineering
- Unit 7: Biomedical Science
- Unit 8: Human Reproduction and Fertility.

What could this qualification lead to?

The qualification carries UCAS points and is recognised by higher education providers as contributing to admission requirements of many relevant applied human biology/health science courses.

When combined with other qualifications within a two-year study programme, such as AS/A Levels or a BTEC National Foundation Diploma or a BTEC National Diploma in a complementary sector, learners can progress into higher education, such as:

- BSc (Hons) in Occupational Health if taken alongside, for example, a Pearson BTEC Level 3 Diploma in Health and Social Care
- BSc in Nursing or Midwifery if taken alongside, for example, a Pearson BTEC Level 3 Extended Certificate in Health and Social Care
- BSc (Hons) in Sport Science if taken alongside, for example, a Pearson BTEC Level 3 in Sport
- BSc (Hons) in Nursing if taken alongside, for example, A Levels in Psychology and Sociology

Learners should always check the entry requirements for degree programmes with the specific higher education providers.

In addition to the applied human biology specific content outlined above, the requirements of the qualification will mean that learners develop the transferable and higher-order skills that are highly regarded by higher education and employers; for example, an opportunity to concentrate over an extended period on their research and investigative techniques – a key skill needed to progress successfully into higher education, employment or self-employment.

This qualification also offers the opportunity to develop learners' technical skills through a process of self-evaluation, practice and review, in preparation for entry to higher education.

How does the qualification provide employability skills?

In the BTEC National units, there are opportunities during the teaching and learning phase to give learners practice in developing employability skills. Where employability skills are referred to in this specification, we are generally referring to skills in the following three main categories:

- **cognitive and problem-solving skills:** using critical thinking, approaching non-routine problems applying expert and creative solutions, using systems and technology
- **interpersonal skills:** communicating, working collaboratively, negotiating and influencing, self-presentation
- **intrapersonal skills:** self-management, adaptability and resilience, self-monitoring and development.

There are also specific requirements in some units for assessment of these skills where relevant, for example, where learners are required to undertake real or simulated activities.

How does the qualification provide transferable knowledge and skills for higher education?

All BTEC Nationals provide transferable knowledge and skills that prepare learners for progression to university. The transferable skills that universities value include:

- the ability to learn independently
- the ability to research actively and methodically
- the ability to give presentations and be active group members.

BTEC learners can also benefit from opportunities for deep learning where they are able to make connections among units and select areas of interest for detailed study. BTEC Nationals provide a vocational context in which learners can develop the knowledge and skills required for particular degree courses, including:

- reading technical texts
- analytical skills
- preparation for assessment methods used in degrees.

2 Structure

Qualification structure

Pearson BTEC Level 3 National Extended Certificate in Applied Human Biology

Mandatory units

There are three mandatory units, one internal and two external. Learners must complete and achieve at Near Pass grade or above in all mandatory external units and achieve a Pass or above in all mandatory internal units.

Optional units

Learners must complete at least one optional unit.

Pearson BTEC Level 3 National Extended Certificate in Applied Human Biology				
Unit number	Unit title	GLH	Type	How assessed
Mandatory units – learners complete and achieve all units				
1	Principles of Applied Human Biology	90	Mandatory	External
2	Practical Microbiology and Infectious Diseases	90	Mandatory	Internal
3	Human Biology and Health Issues	120	Mandatory and Synoptic	External
Optional units – learners complete one unit				
4	Functional Physiology	60	Optional	Internal
5	Diseases, Disorders, Treatments and Therapies	60	Optional	Internal
6	Genetics and Genetic Engineering	60	Optional	Internal
7	Biomedical Science	60	Optional	Internal
8	Human Reproduction and Fertility	60	Optional	Internal

External assessment

This is a summary of the type and availability of external assessment, which is of units making up 58 per cent of the total qualification GLH. See *Section 5* and the units and sample assessment materials for more information.

Unit	Type	Availability
Unit 1: Principles of Applied Human Biology	<ul style="list-style-type: none">• Written examination set and marked by Pearson.• 1.5 hours.• 80 marks.	Jan and May/June First assessment May/June 2019
Unit 3: Human Biology and Health Issues	<ul style="list-style-type: none">• A task set and marked by Pearson and completed under supervised conditions.• The supervised assessment period is 3 hours and must be completed in one sitting on a day timetabled by Pearson.• 60 marks.	Jan and May/June First assessment January 2020

Synoptic assessment

The mandatory synoptic assessment requires learners to select and apply learning from across the qualification to the completion of a defined vocational task. In the synoptic assessment for *Unit 3: Human Biology and Health Issues*, learners will interpret, analyse and evaluate scientific information related to health issues and initiatives and explore the presentation of this information for a defined purpose and audience.

They will select and apply their knowledge of human biology to demonstrate their understanding of health issues and initiatives presented in articles, and reporting drawn from the topics explored in *Unit 1: Principles of Applied Human Biology* and *Unit 2: Practical Microbiology and Infectious Diseases*.

Additionally, in order to effectively analyse and make judgements, learners will use their underpinning understanding of the scientific methods developed while carrying out the scientific investigation in *Unit 2: Practical Microbiology and Infectious Diseases*.

Learners complete the task using knowledge and understanding from their studies of the sector and apply both transferable and specialist knowledge and skills.

In delivering the unit you need to encourage learners to draw on their broader learning so they will be prepared for the assessment.

Employer involvement in assessment and delivery

You are encouraged to give learners opportunities to be involved with employers. See *Section 4* for more information.

3 Units

Understanding your units

The units in this specification set out our expectations of assessment in a way that helps you to prepare your learners for assessment. The units help you to undertake assessment and quality assurance effectively.

Each unit in the specification is set out in a similar way. There are two types of unit format:

- internal units
- external units.

This section explains how the units work. It is important that all teachers, assessors, internal verifiers and other staff responsible for the programme review this section.

Internal units

Section	Explanation
Unit number	The number is in a sequence in the sector. Numbers may not be sequential for an individual qualification.
Unit title	This is the formal title that we always use and it appears on certificates.
Level	All units are at Level 3 on the national framework.
Unit type	This shows if the unit is internal or external only. See structure information in <i>Section 2</i> for full details.
GLH	Units may have a GLH value of 120, 90 or 60. This indicates the numbers of hours of teaching, directed activity and assessment expected. It also shows the weighting of the unit in the final qualification grade.
Unit in brief	A brief formal statement on the content of the unit that is helpful in understanding its role in the qualification. You can use this in summary documents, brochures etc.
Unit introduction	This is designed with learners in mind. It indicates why the unit is important, how learning is structured, and how learning might be applied when progressing to employment or higher education.
Learning aims	These help to define the scope, style and depth of learning of the unit. You can see where learners should be learning standard requirements ('understand') or where they should be actively researching ('investigate'). You can find out more about the verbs we use in learning aims in <i>Appendix 2</i> .
Summary of unit	This new section helps teachers to see at a glance the main content areas against the learning aims and the structure of the assessment. The content areas and structure of assessment are required. The forms of evidence given are suitable to fulfil the requirements.
Content	This section sets out the required teaching content of the unit. Content is compulsory except when shown as 'e.g.'. Learners should be asked to complete summative assessment only after the teaching content for the unit or learning aim(s) has been covered.

Section	Explanation
Assessment criteria	<p>Each learning aim has Pass and Merit criteria. Each assignment has at least one Distinction criterion.</p> <p>A full glossary of terms used is given in <i>Appendix 2</i>. All assessors need to understand our expectations of the terms used.</p> <p>Distinction criteria represent outstanding performance in the unit. Some criteria require learners to draw together learning from across the learning aims.</p>
Essential information for assignments	<p>This shows the maximum number of assignments that may be used for the unit to allow for effective summative assessment, and how the assessment criteria should be used to assess performance.</p>
Further information for teachers and assessors	<p>The section gives you information to support the implementation of assessment. It is important that this is used carefully alongside the assessment criteria.</p>
Resource requirements	<p>Any specific resources that you need to be able to teach and assess are listed in this section. For information on support resources see <i>Section 10</i>.</p>
Essential information for assessment decisions	<p>This information gives guidance for each learning aim or assignment of the expectations for Pass, Merit and Distinction standard. This section contains examples and essential clarification.</p>
Links to other units	<p>This section shows you the main relationship among units. This section can help you to structure your programme and make best use of materials and resources.</p>
Employer involvement	<p>This section gives you information on the units that can be used to give learners involvement with employers. It will help you to identify the kind of involvement that is likely to be successful.</p>

External units

Section	Explanation
Unit number	The number is in a sequence in the sector. Numbers may not be sequential for an individual qualification.
Unit title	This is the formal title that we always use and it appears on certificates.
Level	All units are at Level 3 on the national framework.
Unit type	This shows if the unit is internal or external only. See structure information in <i>Section 2</i> for full details.
GLH	Units may have a GLH value of 120, 90 or 60 GLH. This indicates the numbers of hours of teaching, directed activity and assessment expected. It also shows the weighting of the unit in the final qualification grade.
Unit in brief	A brief formal statement on the content of the unit.
Unit introduction	This is designed with learners in mind. It indicates why the unit is important, how learning is structured, and how learning might be applied when progressing to employment or higher education.
Summary of assessment	This sets out the type of external assessment used and the way in which it is used to assess achievement.
Assessment outcomes	These show the hierarchy of knowledge, understanding, skills and behaviours that are assessed. Includes information on how this hierarchy relates to command terms in sample assessment materials (SAMs).
Essential content	For external units all the content is obligatory, the depth of content is indicated in the assessment outcomes and sample assessment materials (SAMs). The content will be sampled through the external assessment over time, using the variety of questions or tasks shown.
Grade descriptors	We use grading descriptors when making judgements on grade boundaries. You can use them to understand what we expect to see from learners at particular grades.
Key terms typically used in assessment	These definitions will help you analyse requirements and prepare learners for assessment.
Resources	Any specific resources that you need to be able to teach and assess are listed in this section. For information on support resources see <i>Section 10</i> .
Links to other units	This section shows the main relationship among units. This section can help you to structure your programme and make best use of materials and resources.
Employer involvement	This section gives you information on the units that can be used to give learners involvement with employers. It will help you to identify the kind of involvement that is likely to be successful.

Index of units

This section contains all the units developed for this qualification. Please refer to *page 4* to check which units are available in all qualifications in the applied human biology sector.

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Unit 8:	Human Reproduction and Fertility	85

Unit 1: Principles of Applied Human Biology

Level: **3**

Unit type: **External**

Guided learning hours: **90**

Unit in brief

Learners will explore the biological principles that underpin human biology.

Unit introduction

Do you want a career where you can make a difference to the health of others? Then you will need to know how the human body works, in good and poor health. There are many different ways that human health can be affected, from individual biology and genetic makeup to lifestyle decisions and actions taken by individuals and populations.

In this unit, you will study how the human body functions at a genetic, cellular and tissue level. You will gain understanding of how human biology and lifestyle factors interact to affect the health of individuals and populations. You will also explore the many ways that this knowledge can be applied in order to improve diagnostic and health outcomes.

This unit will give you a foundation for biological study, as you will gain theoretical knowledge of human body functioning, an insight into the factors and risks affecting health and knowledge of how biology is applied to make a positive impact on all our lives.

Summary of assessment

This unit will be assessed through a written examination worth 80 marks, which is set and marked by Pearson. The examination will last 1 hour and 30 minutes.

The paper will include a range of question types, including multiple choice, calculations, short answer and open response. These question types will assess knowledge and understanding of the content in this unit.

Sample assessment materials will be available to help centres to prepare learners for assessment.

Assessment outcomes

AO1 Demonstrate knowledge of human biology, health and disease facts, terms, definitions

AO2 Demonstrate understanding of human biology, health and disease concepts, procedures, processes and techniques and their application

AO3 Analyse, interpret and evaluate information and data relating to human biology, health and disease to make judgements and reach conclusions

AO4 Make connections, use and integrate different areas of knowledge and understanding of human biology, health and disease concepts, procedures, processes or techniques

Essential content

The essential content is set out under content areas. Learners must cover all specified content before the assessment.

A Fundamental development and function

A1 Cells, tissues and biological molecules

Learners will understand the relationship between the structure, function and activities in cells and tissues. Knowledge of specific chemical structures is only for those molecules listed under the heading of 'structure and function of specific biological molecules'. Where understanding of a polymer is required, learners are expected to know these in general terms of functional groups of monomers and the type of linkages formed in polymers, both between monomers and chains of the polymer.

- General structure and function of biological molecules:
 - carbohydrates
 - proteins, to include primary, secondary, tertiary and quaternary structures of globular and fibrous proteins
 - triglycerides
 - glycoproteins.
- Structure and function of specific biological molecules:
 - alpha (α) and beta (β) glucose
 - deoxyribonucleic acid (DNA)
 - ribonucleic acid (RNA), to include messenger RNA (mRNA) and transfer RNA (tRNA)
 - adenosine triphosphate (ATP)
 - collagen.
- Cellular ultrastructure and function, to include recognition in light and electron micrographs:
 - nucleus, nucleolus, mitochondria, rough and smooth endoplasmic reticulum (ER), Golgi apparatus, vesicles, conventional lysosomes, 80S ribosomes, centrosomes
 - fluid mosaic model of plasma membrane
 - calculation of magnification and size of cells and organelles, including conversion between millimetres (mm), micrometres (μm) and nanometres (nm).
- Transport of substances into and out of cells, including reference to drug delivery, cell recognition and signalling:
 - active and passive transport
 - diffusion
 - endocytosis, exocytosis and phagocytosis
 - osmosis.
- Cellular activities, to include function, reactants, products and locations:
 - stages in aerobic and anaerobic respiration, to include glycolysis, link reaction and Krebs cycle. Learners are not expected to be able to describe the chemical structures of chemical intermediates in these processes beyond recall of the number of carbon atoms in each.
 - enzyme-controlled reactions as modelled by ATPase.
- Stages and cellular activities during the cell cycle and divisions:
 - gap and synthesis stages in interphase
 - haploid and diploid cells
 - relative potency of cells, including somatic.
- Chromosome formation and nuclear division, to include the recognition of each stage from images:
 - phases of mitosis and meiosis: interphase, prophase, metaphase, anaphase, telophase
 - homologous and non-homologous chromosomes.

- Principles of homeostasis, to include negative feedback loops.
- Control of body temperature and physiological responses to extremes of temperature, to include hypothermia, hyperthermia, burns and frostbite.

A2 Nervous system

Learners will understand the structure and function of the nervous system limited to the normal function within the body. Names for specific parts of the brain or individual nerves not required.

- Sensory, motor and relay neurones.
- Central and peripheral nervous system.
- Transmission of action potential to include:
 - the role of sodium and potassium ions in controlling membrane potential
 - effect of myelination on transmission speeds.
- Synaptic transmission:
 - structure of the synapse, to include: presynaptic neurone, post synaptic neurone, synaptic cleft
 - role of neurotransmitters in synaptic transmission (named examples not required).
- Reflex actions and reflex arcs.

A3 Cardiovascular and respiratory system

Learners will understand the relationship between the structure, function and processes of the cardiovascular and respiratory systems linked to health. Learners should be able to describe risk factors for the conditions listed but a detailed understanding of the development of the conditions is not required.

- Circulatory and respiratory system structure and function:
 - heart, to include vascularisation, innervation, chambers, valves and direction of blood flow
 - lungs, to include trachea, bronchi, bronchioles, alveoli
 - blood composition, to include red blood cells, white blood cells, plasma, platelets
 - blood vessels, including arteries, arterioles, capillary networks, venules, veins
 - pulmonary and systemic circulation
 - lymph nodes, lymphatic vessels
 - ventilation and gas exchange
 - exchange of substances between blood and tissues
 - formation of tissue fluid and lymph
 - regulation of heart rate and blood pressure.
- Causes and common symptoms of coronary heart disease (CHD), stroke, chronic obstructive pulmonary disease (COPD), hypertension and hypotension.

A4 Digestive and excretory system

Learners will understand the relationship between the structure, function and processes of the digestive and excretory systems linked to health.

- Structure and function of the kidneys, nephron, ureters, urinary bladder and urethra.
- Water balance control, and its effect on blood pressure.
- Structure and function of the stomach, pancreas, gall bladder, duodenum, ileum and colon.
- Digestion, absorption and assimilation of carbohydrates, lipids and proteins.
- Location and conditions required for effective action of digestive enzymes, including amylase, lipase, trypsin, pepsin.
- Control of blood glucose levels:
 - role of alpha and beta cells in pancreas, insulin and glucagon
 - role of the liver limited to its function as a store of glycogen
 - causes of diabetes mellitus (type I and II).

- Dietary needs:
 - sources and role of nutrients, including water, fibre, vitamins and minerals
 - calorific value of food
 - exclusion and calorie-controlled diets.
- Assessing dietary and nutritional problems:
 - interpretation of BMI charts and ranges, including recall of the range of values for a normal BMI as 18.5-25. Learners will not be expected to calculate BMI or to recall the names of specific BMI categories outside of the normal range.

A5 Cellular injury and repair

Learners will understand how and why cells and tissues respond and adapt, and the relevance of observing these changes in the diagnoses of diseases and disorders.

- Cellular responses, to include cellular swelling, effect on ATP production.
- Cell adaptations:
 - hyperplasia
 - hypertrophy
 - atrophy
 - metaplasia.
- Responses of tissues to injury:
 - blood clotting and scab formation
 - swelling and bruising
 - burst blood vessels.
- Causes, mechanisms and health consequences of reversible and irreversible cell and tissue injury:
 - ischemia, to include hypoxia and anoxia
 - trauma, to include major membrane damage and disturbance of membrane function
 - cellular atrophy and necrosis, to include chronic diabetes and pressure sores.

A6 Diagnostic techniques

Learners will understand the purposes and the basis of the techniques used to determine normal and abnormal function in humans. Learners are expected to describe the methods of diagnostic tests limited to the readings/samples taken by the healthcare provider and the results as would be reported to the patient. In depth details of sample processing or data analysis performed during the testing are not required.

Learners are only required to comment on results of the diagnostic tests in the context of how an abnormal result may indicate a patient's health has been affected.

- Basic methods, equipment, result format, unit of measurement and interpretation for the following diagnostic techniques:
 - manual and automated observation of vital signs, including heart rate, blood pressure, respiratory rate and temperature, including the normal ranges for these vital signs in adults
 - observation of tissue perfusion and blood oxygen saturation
 - electrocardiograms (ECG) for arrhythmia, coronary heart disease and myocardial infarction, including:
 - basic P-QRS-T wave sequence
 - changes to the P-QRS-T wave sequence for the conditions named above
 - use of ECG to calculate heart rate
 - assessment of nervous system function through reflex testing and nerve conduction tests.
- Haematology:
 - full blood counts
 - blood tests for autoantibodies
 - blood tests for c-reactive protein (CRP). The mechanism for production of CRP in the body is not required
 - blood typing limited to ABO blood types.

B Immune response, dysfunction and treatment of immune disorders

Learners will understand the immune response, the causes, types and treatment of immune diseases.

B1 Immune response

Learners will understand the processes involved in responding to pathogens limited to the roles of the immune cells listed below, details of sub types of the immune cells listed is not required. Learners are not required to know the details of how immune cells develop or of the mechanism of antigen-presentation. Details of pathogen life cycles, to include those of viruses, are not required.

- Innate (non-specific) physical, chemical and biological defences:
 - role of physical barriers
 - chemical defences and their location within the body, to include the inflammation response and its consequences. Specific details of the chemicals involved in inflammation are not required
 - biological defences to include: mast cells, phagocytes, basophils and eosinophils, natural killer cells. The roles of complement and natural killer T cells are not required.
- Adaptive primary immunity:
 - recognition of self and non-self
 - humoral and cell-mediated responses, to include the roles of helper T cells, killer T cells and B cells. The mechanism behind antigen presentation is not required.
- Adaptive secondary immunity:
 - the role of T and B memory cells
 - artificial adaptive immunity, to include vaccinations.
- Passive immunity:
 - natural passive immunity
 - artificial passive immunity.

B2 Immune dysfunction

Learners will understand the theoretical causes, symptoms and treatment of diseases of the immune system. Description of treatment for immune diseases is limited to how methods of treatment help to restore immune function – in depth details of treatment plans are not required.

- Autoimmune diseases, to include:
 - diabetes mellitus (type I)
 - multiple sclerosis (MS)
 - Crohn's
 - rheumatoid arthritis.
- Primary and secondary immunodeficiency diseases, to include:
 - severe combined immunodeficiency (SCID)
 - HIV
 - immune deficiency due to chemotherapy
 - immunodeficiency due to organ transplants.
- Allergies and allergens, to include:
 - allergy-induced asthma
 - anaphylaxis
 - dermatitis.

C Genetics and health

Learners will understand the structures and processes involved in inheritance of characteristics, diseases and genetic conditions.

C1 Gene expression

Learners will understand the major stages involved in gene expression, including location, and the effect of mutations on the end products.

- Transcription of DNA to RNA, to include reference to role of RNA polymerase.
- Translation and splicing of RNA to produce proteins to include codons, anticodons, introns and exons.
- Hereditary and acquired genetic mutations.

C2 Genetic disorders and diagnosis

Learners will understand the causes, progression and diagnosis of genetic and chromosomal disorders.

- Understand the terms allele, dominant, recessive, genotype, phenotype, heterozygous, homozygous, sex linkage, carrier, affected/sufferer, non-affected/non-sufferer.
- Genetic and chromosomal disorders, to include cystic fibrosis (CF), Huntington's, Down's syndrome, haemophilia.
- Characteristics of benign and malignant tumour growth. Characteristics are limited to behaviour on a cellular level or greater.
- Effects of mutations in oncogenes and tumour suppressing genes.
- Interpretation of genetic diagrams, to include familial pedigrees.
- Methods and limitations of obtaining DNA samples, to include swabs and body fluids. Learners are not expected to know how DNA is extracted from samples or to be able to describe the process of DNA sequencing.
- Diagnostic tests for genetic and chromosomal disorders, to include amniocentesis and chorionic villus sampling. Learners are required to describe diagnostic tests limited to how and when samples are taken and the interpretation of the results in the context of health of the foetus.

Grade descriptors

To achieve a grade learners are expected to demonstrate these attributes across the essential content of the unit. The principle of best fit will apply in awarding grades.

Level 3 Pass

Learners will demonstrate a sound understanding of human biology, health and disease. They are able to apply their understanding of normal biological processes to health and disease issues. They are able to make a simple analysis, interpretation and evaluation of information and data in realistic human biology contexts. They make straightforward connections between normal biological processes and health and disease in realistic human biology contexts.

Level 3 Distinction

Learners will demonstrate detailed knowledge and understanding, drawing on a range of areas within human biology, health and disease. They are able to apply a detailed understanding of biological processes, linking these to more complex health and disease issues. Learners are able to analyse, interpret and evaluate information in realistic human biology contexts, drawing conclusions that are well reasoned and supported with evidence. They make complex connections between biological processes and health and disease in realistic human biology contexts.

Key terms typically used in assessment

The following table shows the key words that will be used consistently by Pearson in our assessments to ensure learners are rewarded for demonstrating the necessary skills.

Please note: the list below will not necessarily be used in every paper/session and is provided for guidance only.

Only a single command word will be used per item.

Command or term	Definition
Calculate	Obtain a numerical answer, showing relevant working. If the answer has a unit, this must be included. This can include using an equation to calculate a numerical answer.
Compare	Looking for the similarities and/or differences of two (or more) things. Should not require the drawing of a conclusion. Answer must relate to both (or all) things mentioned in the question.
Complete	Requires the completion of a table/diagram.
Describe	Give an account, or details, of 'something' or give an account of a 'process' (in sequence where required). Statements in the response need to be developed as they are often linked but do not need to include a justification or reason.
Discuss	Consider the different aspects in detail of an issue, situation, problem or argument and how they interrelate.

Command or term	Definition
Evaluate	Consider various aspects of a subject's qualities in relation to its context such as: strengths or weaknesses, advantages or disadvantages, pros or cons. Come to a judgement supported by evidence which will often be in the form of a conclusion.
Explain	Requires identification of a point and linked justification / exemplification of that point. The answer must contain some linked reasoning.
Give/Name/State	All of these command words are really synonyms. They generally all require recall of one or more pieces of information, or, provide examples, justifications and/or reasons to a context.

Links to other units

This unit links to all other units in the qualification as it covers some basic ideas and theories that will recur in other areas of study.

Employer involvement

Centres may involve employers in the delivery of this unit if there are local opportunities. There is no specific guidance related to this unit.

Unit 2: Practical Microbiology and Infectious Diseases

Level: **3**

Unit type: **Internal**

Guided learning hours: **90**

Unit in brief

Learners will investigate the effect of antimicrobial agents on the growth of microorganisms, by selecting and applying knowledge of microorganisms and infectious diseases. They will draw on their wider scientific understanding and skills to plan and carry out a range of practical techniques.

Unit introduction

Microbiology is a fascinating aspect of applied human biology and is an essential element within pathology, clinical and infection sciences and also in veterinary science. Over 15 million people die every year from infectious diseases, with emerging diseases and our inability to provide appropriate treatments a constant threat. An understanding of the nature of microorganisms will enable you to appreciate the various methods available to treat or cure diseases and to recognise the need to continue to develop new and innovative treatments.

In this unit, you will carry out your own investigation into the effect of antimicrobial agents on the growth of microorganisms and will recognise the importance of disease management to modern human society. This investigation will enable you to begin to understand the role of clinical microbiologists as it is a typical investigation that is carried out in industry. To carry out your investigation, you will explore a variety of tests and techniques using essential laboratory practice. In order to carry out this investigation, you will first develop an understanding of the significance of microorganisms in their role as pathogens. You will link your understanding of cell and tissue adaptation, function of biological molecules and the relationship between the structure, function and processes of key body systems with your knowledge of the immune response to understand how diseases develop.

In this key vocational task, you will select and apply knowledge on cells, tissues, biological molecules, human body systems and their functions, and the immune response from *Unit 1: Principles of Applied Human Biology*.

The investigation within this unit will benefit progression to higher education, because it requires you to work independently to bring together understanding of scientific principles with practical skills to conduct an investigation to achieve a purpose. Through the unit, you will develop transferable skills such as interpreting data, and evaluating methods and techniques.

Learning aims

In this unit you will:

- A** Understand the classification and nature of microorganisms
- B** Examine the transmission and treatments of infectious diseases
- C** Explore the application of techniques to culture and identify microorganisms
- D** Investigate the effects of antimicrobial agents on the growth of microorganisms.

Summary of unit

Learning aim	Key content areas	Recommended assessment approach
<p>A Understand the classification and nature of microorganisms</p>	<p>A1 Characteristics of different microorganisms A2 Methods of pathogenicity A3 Classification strategies</p>	<p>A portfolio of evidence to include a flow diagram. Details should include annotations of the classification and characterisation of each type of microorganism, including growth patterns and how pathogens can cause damage to tissues and cells in the body.</p>
<p>B Examine the transmission and treatments of infectious diseases</p>	<p>B1 Classification overview of infectious disease B2 Transmission of infectious agents B3 Infectious diseases, signs, symptoms and progression B4 Prevention and treatment of infectious diseases</p>	<p>A report that includes details of how the chosen diseases are transmitted, how the pathogen attaches to and invades tissue, and how it causes damage to the host. Appropriateness of treatments and future developments should be included in the report. The effectiveness of the treatments should be examined in relation to the type of pathogen, including transmission and control.</p>
<p>C Explore the application of techniques to culture and identify microorganisms</p>	<p>C1 Health and safety C2 Microscopy and staining techniques C3 Culture of microorganisms</p>	<p>Laboratory notebooks recording the practical work completed plus observations of practical work carried out by suitably qualified staff. Details should include a written report on the practical work that learners have carried out, detailing all of the outcomes, health and safety requirements and an evaluation of the procedures used. Practical work will be supported by appropriate research into the techniques used.</p>
<p>D Investigate the effects of antimicrobial agents on the growth of microorganisms</p>	<p>D1 Investigating the substances that inhibit the growth of microorganisms D2 Interpretation, analysis and evaluation</p>	<p>A written report that includes a hypothesis, preliminary work, method, variables, results, analysis and evaluation.</p>

Content

Learning aim A: Understand the classification and nature of microorganisms

Learners will investigate the types of pathogen and their characteristics and understand their mechanisms of virulence. They will be able to apply their fundamental understanding of the structure of cells and normal cell/tissue activity from *Unit 1: Principles of Applied Human Biology* to explore the virulent nature of pathogens and how they can cause infection and disease.

A1 Characteristics of different microorganisms

- Prokaryotes:
 - physical characteristics, to include – cellular structure, including the cell wall (Gram negative and positive), appendages for movement, genome and plasmids
 - growth characteristics, to include – binary fission, growth curves, reproductive strategies, the effect of temperature on the rate of enzyme activity and its impact on microorganism growth.
- Eukaryotes:
 - protists – eukaryotic nature of single-celled protists, classification based on mode of movement such as amoeboid (e.g. *Entamoeba histolytica*), flagellate (e.g. *Giardia duodenalis*), ciliate (e.g. *Balantidium coli*) and sporozoa (e.g. *Plasmodium falciparum*), structures and life cycles
 - fungi – structures, reproductive strategies.
- Acellular viruses and prions:
 - main characteristics, to include – structure of the virion, types of genetic material in viruses, capsid, possibility of envelope, structure of prions
 - reproductive strategies of viruses (lysogenic and lytic cycles), characteristics of prions.

A2 Methods of pathogenicity

- Virulence factors of bacteria:
 - access to the host
 - the role of adhesins, endotoxins and exotoxins, damage to host cells and tissues
 - evasion of the immune system
 - incubation periods.
- Virulence factors of eukaryotes:
 - access to the host
 - the production of proteases and endotoxins in fungi
 - use of adhesins, toxins
 - antigenic variation
 - the ability to survive inside phagocytic vesicles.
- Virulence mechanisms of viruses and prions:
 - access to the host
 - direct cell damage
 - latency
 - misfolded proteins.
- Underlying mechanism for the evaluation of pathogens:
 - mutations, e.g. in relation to bacteria, tuberculosis and viruses, HIV.

A3 Classification strategies

- Phenotypic methods to classify bacteria:
 - shape and cell structure, e.g. cocci, bacilli, flagellate rods, spirilla, vibrios
 - structure of cell wall (Gram positive and Gram negative)
 - oxygen requirements, e.g. aerobes, obligate aerobes, anaerobes, facultative anaerobes.

- Classification of viruses:
 - Baltimore classification using type of nucleic acid and mode of replication
 - other methods, e.g. size, host organism, capsule structure.
- Classification of protists, e.g. cell structures, metabolisms, and methods of motility.

Learning aim B: Examine the transmission and treatments of infectious diseases

Learners will understand the types of pathogen that cause infectious disease, their transmission from infected host to host and their subsequent development in the body. They will be able to apply their understanding of symptomatic nature of the human body including immune response/dysfunction and diagnostic tests associated in identifying abnormal and normal function from *Unit 1: Principles of Applied Human Biology*. They will do this in order to determine how infections cause disease and to understand the nature of treatment required to treat and prevent spread of disease which can affect the organs and organ systems. They will select and apply knowledge on cardiovascular and respiratory systems, target organs and immune response from *Unit 1: Principles of Applied Human Biology*.

B1 Classification overview of infectious disease

- Target organ: intestinal, respiratory tract, blood, urinary, systemic.
- Agent: bacterial, viral, protozoan, fungal, prionic, helminthic, ectoparasitic.
- Source: anthroponoses, zoonoses and sapronoses.

B2 Transmission of infectious agents

- Direct:
 - physical contact, bodily fluids, across the placenta
 - animal contact, animal waste.
- Indirect:
 - transmission through intermediates (vectors), e.g. mosquito, fleas, lice, ticks
 - airborne, e.g. aerosols, droplets
 - vehicle borne, e.g. surfaces, objects
 - food and waterborne.
- Chain of infection: agent, host, reservoir, portals of exit, mode of transmission, portals of entry.

B3 Infectious diseases, signs, symptoms and progression

- Bacterial, e.g. *Mycobacterium tuberculosis*, meningitis, *Chlamydia*, cholera.
- Viral, e.g. human immunodeficiency virus (HIV), Ebola, norovirus, influenza, severe acute respiratory syndrome (SARS).
- Fungal, e.g. ringworm, mucormycosis, candidiasis.
- Prionic: Creutzfeldt-Jakob disease (CJD), acquired and variant, kuru.
- Parasitic: protozoal, e.g. malaria, *Giardia*, amoebic dysentery; helminthic, e.g. roundworm, tapeworms; ectoparasitic, e.g. pediculosis.

B4 Prevention and treatment of infectious diseases

- Prevention:
 - mode of action of vaccines (active and passive), vaccine types
 - use of antiseptics and disinfectants
 - behaviours, e.g. hospital strategies, safe sex
 - environmental, e.g. water sources, mosquito nets, sanitation facilities.
- Treatments:
 - antibiotics – disruption of the cell wall formation and cellular processes
 - antifungal agents – disruption of cell wall, disruption of reproductive process
 - antivirals – entry to cell, disruption of replication process
 - antiprotozoal drugs, specifically those used to treat malaria linked to stage of infection
 - antiparasitic drugs, to include anthelmintics and anti-ectoparasitic drugs.

- Current issues:
 - emergence of antibiotic resistance in bacterial populations, e.g. multi-drug resistant tuberculosis (MDRTB), Methicillin-resistant *Staphylococcus aureus* (MRSA), *C. difficile*, causes of antibiotic resistance, e.g. horizontal and vertical evolution
 - modern practices that have led to the increase in infectious diseases, e.g. overuse and inappropriate use of antibiotics, use in agriculture
 - significance of herd immunity
 - antigenic variation in viruses, e.g. influenza, human immunodeficiency virus (HIV)
 - advantages, disadvantages and ethics of alternative/innovative treatments, e.g. phage therapy, genetically modified bacteriocins, immunotherapy, monoclonal antibodies
 - mutations: emergence of antibiotic resistance and antigenic variance
 - contributory causes of hospital-acquired infections relating to antibiotic prescription and hospital practice.

Learning aim C: Explore the application of techniques to culture and identify microorganisms

Learners will apply their knowledge on the fundamentals of cells, tissues and biological molecules, from *Unit 1: Principles of Applied Human Biology* in diagnosing infections through microbiological techniques. They will then draw on this exploration for learning aim D.

C1 Health and safety

- Current legislation relating to the use of microorganisms in the workplace.
- Biosafety cabinets, biosafety classification levels, use of personal protective equipment (PPE).
- Methods of sterilisation and disinfection.
- Aseptic technique: to include reducing activity in the immediate vicinity of the area, reducing exposure, use of sterile equipment, consideration of airflow in the vicinity, use of Bunsen burner flame to draw air currents upwards, flaming the neck of bottles, use of a sterile loop, pipette or spreader, sterilisation and safe disposal after exposure.
- Safe culturing of microorganisms, to include – implications of temperature, contamination and sealing the Petri dishes, incubation time.

C2 Microscopy and staining techniques

- Microscopy and colony characterisation:
 - use of a microscope to observe microorganisms, to include hanging drop method to view protists; preparation of a smear slide, to include air drying, fixing, use of oil immersion lens
 - staining techniques, to include Gram staining of bacteria, methylene blue stain and India ink staining for capsules around bacteria and yeast cells, use of mordants
 - growth characteristics in broths, e.g. turbid, pellicle, sediment, flocculent, colony morphology identification on plates, e.g. form, elevation, margin
 - limitations of staining techniques and morphological studies for identifying microorganisms.

C3 Culture of microorganisms

- Types of media:
 - preparation of nutrient media, nutrient broth, nutrient agar
 - selective media, e.g. MacConkey agar, mannitol salt agar, blood agar, potato dextrose agar.
- Methods of cell culture:
 - stab cultures, pour plates, streaking, lawn spreads, slant tubes
 - broth cultures
 - incubation temperatures.
- Differential media, e.g. O-Nitrophenyl- β -D-galactopyranoside (ONPG) test for lactose fermentation, MacConkey for gram-positive and gram-negative bacteria, mannitol salt agar for selecting *Staphylococci*, starch hydrolysis test.
- Isolation of pure cultures from mixed populations.

C4 Quantitative analysis of microbes

- Total population count:
 - haemocytometer, counting chamber
 - turbidimetric methods.
- Viable counts: serial dilutions, streak/spread plating.

Learning aim D: Investigate the effect of antimicrobial agents on the growth of microorganisms

Learners will consolidate their knowledge on cells, tissues, microbiological molecules, human body systems and functioning and immune response from *Unit 1: Principles of Applied Human Biology* and knowledge and practical skills from learning aims A, B and C as part of their own practical investigation. They will understand the value of investigating activity of microorganisms in terms of the human body, including reducing the spread and prevention of disease and its impact on the normal functioning of biological systems.

D1 Investigating the substances that inhibit the growth of microorganisms

- Identification of variables to change and control.
- Suitability of pour plate or spread plate with confluent growth, incubation times, correct measurement of zones of inhibition.
- Antimicrobial susceptibility testing:
 - disinfectants/antiseptics/natural compounds, e.g. garlic, essential oils
 - concentration effects
 - bactericidal or bacteriostatic antibiotics
 - age of antibiotic
 - type of antibiotic (broad or narrow spectrum)
 - type of microorganism used.
- Measurement of antimicrobial susceptibility by zones of inhibition.

D2 Interpretation, analysis and evaluation

- Data collection and awareness of anomalous data, repeats and validity.
- Numerical data identified and presented, including graphs, tables and statistics as appropriate.
- Trends and patterns in data.
- Sources of error in data, including the use and interpretation of error bars.
- Draw conclusions in relation to the purpose of the investigation.
- Evidence to support conclusions/claims made.
- Common limitations, e.g. false susceptibility or resistance to antibiotic due to nonstandard confluent growth, use of old disks, disks not stored at 4 °C, depth of agar inconsistent resulting in non-standard diffusion of the antibiotic, incorrect growth conditions for the bacteria.
- Potential areas for further research and development identified.

Assessment criteria

Pass	Merit	Distinction
Learning aim A: Understand the classification and nature of microorganisms		AB.D1 Evaluate the treatments of the types of infectious disease and the current issues in the development of these treatments.
A.P1 Explain the methods used to classify microorganisms.	A.M1 Analyse the virulence mechanisms of microorganisms that cause infectious diseases and the methods used to classify microorganisms.	
A.P2 Explain the role of the structures found in microorganisms and the factors affecting their growth and virulence that cause infectious diseases.		
Learning aim B: Examine the transmission and treatments of infectious diseases		
B.P3 Describe the development of different types of disease.	B.M2 Discuss the development of infectious diseases and their associated prevention and treatment strategies.	
B.P4 Explain the prevention and treatment strategies for the different types of infectious disease.		
Learning aim C: Explore the application of techniques to culture and identify microorganisms		C.D2 Correctly use aseptic enumeration techniques and make judgements on the accuracy of the procedures used.
C.P5 Carry out morphological studies, microscopy and staining techniques to identify microorganisms.	C.M3 Compare the techniques used to identify and cultivate microorganisms in terms of the quality of results obtained.	
C.P6 Correctly select and use aseptic technique to cultivate microorganisms.	C.M4 Correctly select and use aseptic technique to grow and measure the growth of microorganisms, including the use of serial dilutions.	
Learning aim D: Investigate the effect of antimicrobial agents on the growth of microorganisms		D.D3 Evaluate the methods, techniques and data collected to determine the effect of antimicrobials on the growth of microorganisms and the wider impact on the functioning of an organism.
D.P7 Plan and carry out an investigation independently, selecting an appropriate method, into the effects of antimicrobials on the growth of organisms.	D.M5 Plan and carry out an investigation into the effects of antimicrobials on the growth of organisms with little or no contamination of results.	
D.P8 Interpret data collected in order to reach a conclusion, considering the impact on prevention and treatment of disease.	D.M6 Analyse the growth of microorganisms using data collected and in relation to the factors investigated in order to reach a valid conclusion, making links to the impact on prevention and treatment of disease.	

Essential information for assignments

The recommended structure of assessment is shown in the unit summary along with suitable forms of evidence. *Section 6* gives information on setting assignments and there is further information on our website.

There is a maximum number of three summative assignments for this unit. The relationship of the learning aims and criteria is:

Learning aims: A and B (A.P1, A.P2, B.P3, B.P4 A.M1, B.M2, AB.D1)

Learning aim: C (C.P5, C.P6, C.M3, C.M4, C.D2)

Learning aim: D (D.P7, D.P8, D.M5, D.M6, D.D3)

Further information for teachers and assessors

Resource requirements

For this unit, learners must have access to:

- a well-equipped laboratory suitable for Key Stage 5 standard microbiology
- an autoclave
- basic media preparation materials
- stains
- an incubator
- a colorimeter/spectrophotometer
- antibiotic sensitivity disks
- a selection of antimicrobial agents
- cultures of (minimum) *E.coli* and *S. aureus*.

Essential information for assessment decisions

Throughout this unit it is expected that learners will be made aware of the health and safety regulations relating to working with microorganisms. They will demonstrate adherence to safety procedures, including the use and writing (where appropriate) of suitable risk assessments.

For learning aim D, learners should be made aware of the level of demand at each standard to enable them to plan and carry out an investigation that will meet the criteria fully.

'Antimicrobial agents' can be taken to mean any substance that will kill or stop the growth of microorganisms. Care must be taken when considering the choice of investigation to ensure that the method used gives enough scope for statistical analysis and evaluation, particularly at distinction level.

To complete the practical assessment investigation in learning aim D, learners will draw on content from across the programme.

Learning aims A and B

For distinction standard, learners will recognise that the level of virulence of a disease is linked to a number of factors. They will evaluate their contributory effects, for example pathogenicity, transmissibility, host susceptibility and environmental factors. They will be able to evaluate the treatments of different types of disease and explore current issues in the development of these treatments. It is recommended that learners include issues relating to the emergence and causes of antibiotic resistance (over-prescribing, hygiene practices in hospitals, intensive farming), antigenic drift/shift and the advantages, disadvantages and ethical considerations of modern biologic agents such as the therapeutic use of lytic bacteriophages, bacteriocins and monoclonal antibodies. The minimum expected would be one pathogen from each subgroup (prokaryote, eukaryote, acellular).

Learners will demonstrate a thorough understanding of the issues facing the treatment of infectious diseases. They will provide a detailed explanation of some of the contributory events that have led to antibiotic resistance, the evasion of the immune system by some pathogens and problems with creating vaccinations owing to mutations and antigenic variation. They will then evaluate some of the current alternative treatments.

For merit standard, learners will analyse the classification methods for bacteria and viruses. For example, learners could explain the Baltimore system of classification of viruses and explain how each subgroup is different in their mode of infectivity. Learners will be able to analyse the basis for the classification of bacteria and viruses based on features such as nucleic acid content and shape in viruses and morphology, staining properties of the organism, as well as oxygen requirements in bacteria. Learners will explain the factors that affect the growth of microorganisms. They will explain some of the pathogenic strategies used by virus, fungi, bacteria and protists using named examples. They will link these ideas to the specific features of the microorganism, for example the

role of the attachment proteins or enzymes in a virus. Learners will analyse the mechanism of virulence of the pathogen, for example how a fungal pathogen invades and damages tissues by the production of extracellular enzymes, how a virus is able to replicate using the host cell machinery. They will explain coherently the pathogenic mechanisms for at least one organism from each subgroup (prokaryote, eukaryote, acellular). This should include (but should not be limited to) ideas about lytic and lysogenic cycles in viruses, the complex nature of some eukaryotic pathogens such as *Plasmodium spp.*, the role of plasmids in bacterial pathogenicity, the role of capsules in bacterial adherence and the production of extracellular enzymes. Learners are expected to include annotated diagrams to illustrate their explanations. The diagrams will be clearly labelled and accurate.

Learners will identify the chain of infection for each disease and will use this identification to discuss the development of infectious diseases by linking ideas about the mode of action of the treatments and prevention mechanisms for that disease. Learners will discuss the current issues facing disease prevention in relation to antigenic variation and antibiotic resistance, and will outline new and innovative treatments.

For pass standard, learners will explain the methods used to classify microorganisms. They will describe the main features of the different types of microorganism using a named example from each of the subgroups (prokaryotes, protists, fungi, viruses and prions). The roles of all of the structures found in bacteria, viruses and protists must be explained. Named examples and annotated diagrams will be used to illustrate their explanations. Learners will describe in simple terms the growth and virulence of microorganisms in terms of cell division, oxygen requirements and temperature factors. Learners will describe how a virus infects a cell and causes cell lysis.

Learners will research infectious diseases caused by at least three types of pathogen. They will describe the mode of transmission of each pathogen, and the development and progression of the resultant infectious diseases in terms of virulence and pathogenicity. Learners will explain methods to control the spread of, prevent or treat the diseases and will identify their advantages and disadvantages of the methods used. Learners are expected to include a range of methods of transmission and recognise current issues relating to the prevention and treatment of these diseases. Learners will be expected to include annotated diagrams to illustrate their explanations. The diagrams will be detailed, clearly labelled and accurate.

Learning aim C

For distinction standard, learners will use different techniques to determine the number of individual microbes in cultivated samples, for example using direct total cell counts and indirect counts (measurements of turbidity). Learners will carry out viable cell counts of cultures using serial dilutions and spread plating/smear slides to count individual colonies. In addition, learners will use a haemocytometer to perform a direct cell count. They will then evaluate these methods and provide judgements on the accuracy of the procedures. Learners will be expected to consider the procedures used in terms of subjectivity, quantitative versus qualitative data gained, difficulty of skill and cost implications in their evaluation. For example, learners could include factors such as: skewed estimates, inaccurate approximations, unequal cell distribution in samples, correct use of aseptic technique/contamination, density of serial dilutions, correct plating techniques. Consideration will be given to modern clinical microbiology techniques. For example, why is the Gram stain commonly used in the first stage of the identification of microorganisms? Why might a microbiologist employ various methods of culturing bacteria and what are the purposes of selective and differential media in microorganism identification? Why would a microbiologist use streak plating to isolate individual colonies?

For merit standard, learners will be expected to culture microorganisms, but are not expected to use selective media. Learners will carry out a viable cell count of cultures using serial dilutions and spread plating to count individual colonies.

Learners must compare the techniques used to cultivate microorganisms in terms of the quality of the results obtained. Comparisons will include the principles underlying the microbiological techniques used in terms of the staining procedures, colony characteristic identification methods, relevant aseptic technique and method of cultivation. This should include an explanation of aseptic technique and a comparison of the methods of inoculation. Learners are expected to explain the reasons for the health and safety procedures, aseptic technique and contamination issues, and to demonstrate skill and proficiency when carrying out these procedures.

For pass standard, learners will carry out morphological studies, microscopy and staining techniques to identify microorganisms. This should include the use of the Gram stain to identify Gram-negative and Gram-positive bacteria; colony characterisation from a mixed culture (possibly air-exposed Petri dishes or swabs from around the laboratory). This will also include correct use of aseptic technique to prepare growth medium and pour agar plates, which will be used to inoculate with microorganisms. The expectation is that learners will develop skills in the following techniques: making a spread plate, making a smear slide, making a pour plate. They will then suitably and safely incubate these plates and make observations of the growth patterns.

Learning aim D

For distinction standard, learners will evaluate their hypothesis and protocol (methods, techniques and data) to test the susceptibility of microorganisms to antimicrobial agents. It is expected that learners will use information from secondary sources in their evaluations. Learners will analyse their results in terms of the factors investigated, using appropriate statistical methods (numerical data identified and presented, graphs, tables and statistics as appropriate). They will evaluate how effective their methods were in being able to analyse the effects and will suggest suitable alternatives or extensions to the methods or equipment that would enhance their results. Learners will give a full account of the limitations of the procedures in terms of the health and safety procedures, aseptic technique and contamination opportunities, and will develop a rationale for improvement. They will also develop their evaluation to include the results of others, in order to provide a full and detailed report on the effect of antimicrobials on microbial growth. They will make links to the impact of the results on the functioning of an organism, drawing on theoretical understanding of infectious diseases and biological systems.

For merit standard, learners will use their knowledge of bacteria and the mode of action of antimicrobial agents alongside skills and techniques obtained from the preliminary investigation to develop a valid procedure and make a prediction. Learners will demonstrate good aseptic technique that leads to little or no contamination of results. They will measure the resultant microbial growth with precision, leading to a coherent analysis of the results from which valid conclusions can be drawn. Learners will use their results and consider the results of others to analyse the factors affecting the growth of microorganisms and the inhibition of their growth. Their conclusions will be based on knowledge gained throughout the unit, focusing on the wider impact on prevention and treatment of infectious diseases.

For pass standard, learners will carry out preliminary work by investigating the effect of antimicrobial agents on the growth of bacteria. They will decide on the best method to get confluent growth, the best length of time for incubation and how to measure the zone of inhibition. They will then use this information to plan an investigation into the effect of antimicrobial agents on the growth of bacteria. At this level, learners may need some help designing a procedure that will generate sufficient and valid data. After carrying out the investigation independently, they will identify trends and any anomalous results. From this, they will form simple conclusions from their results, including a comparison of their results with others. Learners will identify some limitations of their method. Learners will link their results to the impact on prevention and treatment of disease.

Links to other units

The synoptic assessment tasks for this unit allow learners to select and apply knowledge on cells, tissues, biological molecules, human body systems and functioning and the immune response from *Unit 1: Principles of Applied Human Biology*.

Employer involvement

Centres can involve employers in the delivery of this unit if there are local opportunities to do so. There is no specific guidance related to this unit.

Unit 3: Human Biology and Health Issues

Level: **3**

Unit type: **External**

Guided learning hours: **120**

Unit in brief

Learners will further develop their understanding of human biology and skills in researching and evaluating the impact of health issues, initiatives and scientific reporting.

Unit introduction

In this unit, you will interpret, analyse and evaluate scientific information related to health issues and initiatives and explore the presentation of this information for a defined purpose and audience. You will further your knowledge of human biology from *Unit 1: Principles of Applied Human Biology* and *Unit 2: Practical Microbiology and Infectious Disease*; to explore the impact of health issues on the world we live in, further developing your skills of analysis and interpretation. You will consider a range of health issues and associated initiatives from developments in food nutrition and healthy diets to advances in medical treatments, including stem cell therapy and genetic engineering.

You will research the impact of health initiatives, including their potential benefits and disadvantages. You will gain understanding of the different organisations and individuals and their influence on various health issues and initiatives. You will develop your critical thinking and analysis skills by learning how to assess the reliability of sources of published scientific information for a given health issue. You will explore the presentation of science reporting and its relationship with the reporting medium and target audience. You will evaluate and interpret qualitative and quantitative evidence for a given health issue and justify your judgements, drawing on the knowledge and skills you developed on scientific methods from the investigation you carried out in *Unit 2: Practical Microbiology and Infectious Diseases*.

In this unit, to complete the synoptic assessment tasks, you are expected to draw on your scientific knowledge and understanding of body systems from *Unit 1: Principles of Applied Human Biology*. Using your knowledge and understanding of collecting, analysing and evaluating data from *Unit 2: Practical Microbiology and Infectious Diseases*, you will apply this to explore the different types of scientific information and data presented for a given health issue. The skills you develop in this unit will support you in progressing to a variety of science- and science-related higher-education courses, and to employment in the science sector.

Summary of assessment

This unit will be assessed under supervised conditions. The supervised assessment task will assess learners' ability to understand a health issue covered in a scientific article.

The supervised assessment task must be completed in a single session of 3 hours, on a day timetabled by Pearson. During the supervised assessment session, learners will be given stimulus in the form of a scientific article. Learners will analyse and interpret this article in the context of how the health issue is being reported.

Pearson sets and marks the task. The number of marks for the unit is 60.

Sample assessment materials will be available to help centres prepare learners for assessment.

Assessment outcomes

AO1 Demonstrate knowledge and understanding of health issues and associated initiatives and reporting

AO2 Apply understanding of health issues and associated initiatives and reporting

AO3 Be able to interpret, analyse and evaluate different sources of scientific information

AO4 Be able to synthesise different sources of scientific information

Essential content

The essential content is set out under content areas. Learners must cover all specified content before the assessment.

A Contemporary health issues

A1 Understand health issues and associated initiatives and research

Learners will select and apply knowledge of fundamental human biology, such as cells and tissues, human body systems and functions, immune response and genetics from *Unit 1: Principles of Applied Human Biology* and microorganisms and infectious diseases from *Unit 2: Practical Microbiology and Infectious Diseases*. They will then develop an understanding of health issues, associated initiatives and research, and potential areas for further research and development:

- Infections:
 - reducing the transmission of infectious diseases
 - controlling the spread of antibiotic resistance in bacteria
 - antibiotic- and antimicrobial-resistant infections
 - role of vaccination programmes in controlling disease.
- Health and lifestyle initiatives related to:
 - cardiovascular diseases
 - respiratory diseases
 - ageing population
 - obesity
 - smoking, alcohol and substance misuse
 - sexually transmitted infections (STIs).
- Genetic initiatives:
 - genetic screening
 - genetic diseases
 - pre-implantation genetic diagnosis.
- Medical prevention and treatments:
 - cancer screening
 - medical imaging
 - stem-cell therapy, epigenetic modification and reprogramming
 - developing new drugs
 - hormone therapies.

A2 Understand the influence of organisations/individuals on health issues

Learners will understand the influence that different organisations/individuals have on health issues and any associated initiatives and research.

- Government and global organisations:
 - World Health Organization (WHO)
 - Public Health Agency
 - NHS
 - Health Education England (HEE).
- Non-government organisations, and associations:
 - General Medical Council (GMC)
 - the Nursing and Midwifery Council (NMC)
 - universities and research groups/teams
 - private and multinational organisations
 - pharmaceutical companies
 - charities and trusts.
- Individuals, such as pioneers; service users, such as patients.

B Interpretation, analysis and evaluation of scientific information

B1 Interpret, analyse and evaluate scientific information

Learners will interpret, analyse and evaluate scientific information that informs health issues to make judgements on the validity of conclusions drawn, selecting and applying knowledge of scientific methods from the investigation carried out in *Unit 2: Practical Microbiology and Infectious Diseases*.

- Primary and secondary research.
- Qualitative evidence – reference to established sources of information.
- Quantitative evidence – numerical data, including calculations, graphs, tables and statistics.
- Use of accurate/reliable sources of information.
- Trends/patterns/anomalous data and sources of error in data.
- Comparisons of primary and secondary data.
- Validity and reliability, including:
 - sample size
 - number and suitability of references to publications
 - use of peer review
 - use and misuse of data – extracting or misquoting data
 - authenticity – date of publication, author/source of information
 - article(s)
 - influence of funding source.
- Validity of conclusions identified and relevance to the purpose of the investigation.
- Evidence to support conclusions/claims made.

C Scientific reporting

C1 Understand how health issues and initiatives are reported in different media and for different audiences

Learners will understand how scientific information is presented in relation to the target audience and reporting medium, and be able to synthesise relevant information for different audiences.

- Reporting medium:
 - specialist journals, peer-reviewed journals
 - health science magazines
 - internet and social media
 - broadcasting media and newspaper articles.
- Target audience:
 - general public
 - healthcare professionals, healthcare users
 - scientific community
 - political representatives – MP, local councillor.
- Presentation and reporting:
 - detail and accuracy
 - level of language used
 - writing style and correct use of terminology, referencing, technical language and quotations
 - visuals – use of graphs, diagrams, tables, charts
 - use of bias
 - quantity and quality of scientific information, e.g. a scientific article versus tabloid extract.

Grade descriptors

To achieve a grade learners are expected to demonstrate these attributes across the essential content of the unit. The principle of best fit will apply in awarding grades.

Level 3 Pass

Learners will demonstrate a sound understanding of the health issues, initiatives and reporting. They will be able to interpret, analyse and evaluate scientific information and select relevant evidence to support judgements made. They will show application of understanding by identifying the impact of the health issue and any associated initiatives. They will give a basic explanation of the influence of different organisations/individuals.

Learners will be able to demonstrate sound knowledge and understanding of factors that affect the reliability of scientific reporting, to make comments on the validity of information. They will use evidence to identify potential areas for further development and/or research.

Learners will apply their knowledge and understanding to select and organise relevant information.

Level 3 Distinction

Learners will demonstrate a thorough understanding of the health issue, associated initiatives and reporting in the arguments they articulate and will justify their conclusions. They will be able to reach valid judgements on the health issue and associated initiatives, formed through a critical approach to the interpretation, analysis and evaluation of the source material.

Learners will make links in and across articles, showing application of understanding to implications. They will explain the influence from different organisations and/or individuals, supported through links and application to scientific information.

Learners will present reasoned judgements on the validity of information, demonstrating their knowledge and understanding of the factors that affect the reliability of scientific reporting. They will use detailed evidence to make reasoned recommendations on potential areas for further development/research.

Learners will be able to apply their knowledge and understanding of the issue and synthesise information in order to compare and contrast different sources.

Key terms typically used in assessment

The following table shows the key words that will be used consistently by Pearson in our assessments to ensure learners are rewarded for demonstrating the necessary skills.

Please note: the list below will not necessarily be used in every paper/session and is provided for guidance only.

Command or term	Definition
Bias	Inclination or prejudice in a way considered to be unfair.
Discuss	Consider the different aspects in detail of an issue, situation, problem or argument and how they interrelate.
Economic issue	Related to the best use of limited, or scarce, resources.
Ethical issue	Ethically related aspects that may have affected how research was carried out.
Explain	Requires identification of a point and linked justification / exemplification of that point. The answer must contain some linked reasoning.
Health initiative	Identified in the article and related to the impact it has in the health issue.
Health issue	Issue or problem that has been identified, which is often open ended and has multiple potential solutions.
Implication	Effects or consequences of an action or decision that may happen although not explicitly stated.
Influence	The capacity or power to have an effect on the development, actions, behaviours or opinions.
Issue	May be used on its own to describe the subject that the article is describing.
Media	The means of mass communication through reporting medium.
Primary research	Research compiled directly from the original source, which may not have been compiled before.
Qualitative data	Descriptive data, such as data drawn from open-ended questions in questionnaires.
Quantitative data	Data in numerical form, which can be categorised and used to construct graphs or tables of raw data, such as data drawn from results of experiments.
Referencing	Acknowledgement of sources of information used within an article.

Command or term	Definition
Reliability	The extent to which an experiment, test or measuring procedure yields the same results on repeated trials.
Research methods	Refers to how the research described in the article was carried out, for example through quantitative methods such as analysis of numerical data or qualitative-based observations.
Secondary sources/research	Published research reports and data, likely to be based on analysis of primary research.
Social issue	An issue that influences and is opposed by a considerable number of individuals in society.
Suggest	Use your knowledge to propose a likely solution to a problem.
Target audience	A specific group at which the article is aimed.
Technical language	Specific terminology directly relating to the subject matter presented in the article.

Links to other units

The synoptic assessment tasks for this unit allow learners to select and apply knowledge developed from *Unit 1: Principles of Applied Human Biology* and *Unit 2: Practical Microbiology and Infectious Diseases*.

This unit also links to the following optional units:

- Unit 4: Functional Physiology
- Unit 5: Diseases, Disorders, Treatments and Therapies
- Unit 6: Genetics and Genetic Engineering
- Unit 7: Biomedical Science
- Unit 8: Human Reproduction and Fertility.

Employer involvement

Centres may involve employers in the delivery of this unit if there are local opportunities. There is no specific guidance related to this unit.

Unit 4: Functional Physiology

Level: **3**

Unit type: **Internal**

Guided learning hours: **60**

Unit in brief

Learners will explore the muscular, skeletal, endocrine and nervous systems, their associated disorders and the role of homeostasis in controlling and coordinating the body systems.

Unit introduction

Physiology, the working of the human body, is a fascinating topic. In this unit, you will have the opportunity to explore growth and development of four body systems and homeostasis and its role in the body. There will be opportunity to research common disorders, their causes in relation to these systems and the impact they have on a person's life. The unit provides a strong foundation for human biology study, it gives you theoretical knowledge of the structure, function and role of the muscular, skeletal, nervous and endocrine systems.

You will gain insight into the importance of homeostasis in maintaining a constant internal environment that allows the body systems to function properly. Knowledge and understanding of these systems will provide an insight into how biology works in action to make a positive impact on all our lives.

This unit will help you to progress to higher education and then to a career in health promotion, public health, teaching, health service management, medical sales, nursing, counselling and social work or sports and exercise therapy. The unit can also help you to access an Apprenticeship in the health sector.

Learning aims

In this unit you will:

- A** Examine the structure, function and disorders of the muscular and skeletal systems
- B** Understand the structure, function and disorders of the endocrine and nervous systems
- C** Understand the role of homeostasis in controlling and coordinating the body systems.

Summary of unit

Learning aim	Key content areas	Recommended assessment approach
A Examine the structure, function and disorders of the muscular and skeletal systems	A1 Muscular tissue A2 Skeletal system A3 Disorders of the muscular and skeletal systems	Practical work to draw the structure of muscle tissue. An illustrated report/leaflet explaining the relationship between structure and function of muscles and bones. Leaflets or case studies of disorders of the musculoskeletal systems and their impact on the life of an individual(s).
B Understand the structure, function and disorders of the endocrine and nervous systems	B1 Endocrine system B2 Disorders of the endocrine system B3 Nervous system B4 Disorders of the nervous system	A booklet(s) which: <ul style="list-style-type: none"> explains the organisation and role of the endocrine and nervous system and analyses the changes that occur throughout the life of an individual(s) discusses the impact of overproduction and underproduction of hormones discusses the advantages/disadvantages of the nervous system.
C Understand the role of homeostasis in controlling and coordinating the body systems	C1 Homeostasis C2 Interrelationship between nervous and endocrine system C3 Disturbance of homeostasis	A leaflet which explains the relationship between the nervous and endocrine systems in maintaining homeostasis and analyses the disruptive effects of some substances on homeostasis.

Content

Learning aim A: Examine the structure, and function and disorders of the muscular and skeletal systems

Learners will explore muscular and skeletal anatomy, how they are interrelated, and the impact of changes in the structure and function of these systems throughout a person's life. Learners will use practical techniques to record key structural features of muscle tissue.

A1 Muscular tissue

- Characteristics and ultrastructure of muscular tissue:
 - smooth (visceral/involuntary)
 - striated (skeletal/voluntary)
 - cardiac
 - structure of the following – sarcolemma, sarcoplasmic reticulum, motor end plate, muscle fibres, adenosine triphosphate (ATP), myosin, actin, myofibrils.
- Function of the muscular system, movement, levers, motor units:
 - antagonistic pairs (agonist, antagonist)
 - synergist
 - fixator.
- Attachment of muscles:
 - to bone
 - via tendons
 - to fascia.
- Contraction of muscle:
 - contraction cycle, motor neurons, neuromuscular junctions, neurotransmitters, sliding filament theory, electrochemical gradient, calcium ions.

A2 Skeletal system

- Structure of skeletal system to include major bones of the:
 - axial skeleton
 - appendicular skeleton.
- Structure/ultrastructure and function of bones to include:
 - long bones, short bones, flat bones, irregular bones, sesamoid bones
 - basic structure of a typical long bone to include, articular cartilage, spongy bone, bone marrow, endosteum, compact bone, periosteum, medullary cavity and blood vessels (for blood supply to and circulation within bones).
- Function of the skeletal system:
 - protection
 - support
 - assisting movement, attachment for skeletal muscle
 - source of blood cell production
 - store minerals.
- Structure and function of tendons, ligaments and cartilage:
 - tendons, strength, arrangement of fibres
 - ligaments, resistance, control of movement, arrangement of fibres
 - cartilage, chondrocytes, matrix, support
 - articular cartilage
 - medullary cavity.

- Classification of joints:
 - fibrous/fixed, e.g. skull
 - cartilaginous/slightly moveable, e.g. sternum, pubic symphysis, mandible
 - synovial/freely moveable: classification of synovial joints by movement: hinge, saddle, plane, pivot, condyloid and ball and socket.

A3 Disorders of muscular and skeletal systems

- Muscular:
 - genetic, e.g. muscular dystrophy/Duchenne muscular dystrophy
 - degenerative, e.g. tendinosis, muscle fatigue, loss of muscle strength, speech, chewing, swallowing
 - accidental, e.g. sprains and strains
 - autoimmune, e.g. myasthenia gravis.
- Skeletal:
 - accidental, e.g. fractures, dislocations
 - degenerative, e.g. osteoarthritis, osteoporosis
 - autoimmune, e.g. rheumatoid arthritis
 - cancer, e.g. leukemia, osteosarcoma (bone cancer).

Learning aim B: Understand the structure, function and disorders of the endocrine and nervous systems

Learners will understand the organisation, role and disorders of the endocrine and nervous systems, how they are interrelated, and the impact of changes in these systems throughout a person's life:

B1 Endocrine system

- Target organs, ductless glands, hormones, transported in blood.
- Hypothalamus – control of pituitary gland via releasing hormones, control of daily rhythms.
- Pituitary gland – control of growth, function of sex organs, osmoregulation.
- Thyroid gland – regulation of growth and function of many body systems, role in regulation of blood calcium levels.
- Pancreas – regulation of blood sugar via production of insulin and glucagon.
- Adrenal glands – the 'fight or flight' response via the hormone adrenaline, regulation of blood pressure via the hormone aldosterone.
- Ovaries – production of oestrogen and progesterone (sex hormones).
- Testes – production of androgen hormones which are involved in the development of maleness and the production of sperm.

B2 Disorders of the endocrine system

Learners will understand the significance and impact of:

- Under production of hormones, e.g. Cushing's disease, hypothyroidism.
- Overproduction of hormones, e.g. gigantism (acromegaly), polycystic ovary syndrome.

B3 Nervous System

Learners will understand the components, organisation and role of:

- The central nervous system (CNS):
 - brain and spinal cord, motor neurons, sensory neurons, nerve cells, reflex arc
 - coordination of both voluntary and involuntary activities of the body
 - conduction of nerve impulses to and from the CNS.

- The peripheral nervous system (PNS):
 - nerves and ganglia outside the brain and spinal cord
 - somatic nervous system
 - autonomic nervous system.
- The parasympathetic nervous system.
- The sympathetic nervous system.

B4 Disorders of the nervous system

Learners will understand the causes and symptoms of:

- Parkinson's disease
- multiple sclerosis (MS)
- motor neurone disease.

Learning aim C: Understand the role of homeostasis in controlling and coordinating the body systems

Learners will understand the purpose of homeostasis, and how different body systems are interrelated to maintain it, and the impact of different factors that can disrupt homeostasis throughout a person's life:

C1 Homeostasis

Learners will understand the purpose of homeostasis in relation to:

- terminology, optimum, variable, stimulus, receptors/sensors, control centres, effectors, feedback
- negative feedback loops, blood pressure, body fluids (osmoregulation), gas concentration, blood sugar levels
- positive feedback loops, blood clotting, labour contractions, lactation.

C2 Interrelationship between nervous and endocrine system

Learners will understand the relationship between the nervous and endocrine system:

- role of the autonomic nervous system, breathing, heartbeat
- role of adrenal glands (fight and flight, heart rate)
- hypothalamus, link between endocrine and nervous system
- regulation of hunger, sleep rhythms, secretion of various hormones
- peripheral nervous system, autonomic system, relaying information to the brain.

C3 Disturbance of homeostasis

Learners will understand the disruptive effects of different factors on homeostasis:

- ageing, weakening of feedback loops, heart failure, diabetes
- interruption, deficiency (pathways blocked and cells lack vitamins or minerals)
- genetics, e.g. diabetes
- lifestyle, nutrition, physical activity. Drug/alcohol abuse, too much sugary food, lack of exercise/too much exercise.

Assessment criteria

Pass	Merit	Distinction
Learning aim A: Examine the structure, function and disorders of the muscular and skeletal systems		A.D1 Use photomicrographs and diagrams to assess how disorders of the musculoskeletal system arise and the impact and significance of the disorders.
A.P1 Explain how the gross structure of the skeletal system relates to its functions.	A.M1 Use electron micrographs and diagrams to discuss the interrelationship between muscles and skeletal system in relation to contraction and movement.	
A.P2 Use a light microscope to record key structural features of muscle tissue.		
A.P3 Explain how key structural features of muscle tissue relate to the function of muscles.		
Learning aim B: Understand the structure, function and disorders of the endocrine and nervous systems		B.D2 Evaluate the impact of changes to the nervous and hormonal systems throughout life.
B.P4 Explain the organisation of the endocrine system in relation to its function.	B.M2 Analyse how the functions of the nervous and endocrine systems are interrelated.	
B.P5 Explain the organisation of the nervous system in relation to its function.		
Learning aim C: Understand the role of homeostasis in controlling and coordinating the body systems		C.D3 Evaluate the disruptive effects of factors affecting homeostasis.
C.P6 Explain the purpose and need for homeostasis.	C.M3 Analyse the relationship between the endocrine and nervous system in maintaining homeostasis.	

Essential information for assignments

The recommended structure of assessment is shown in the unit summary along with suitable forms of evidence. *Section 6* gives information on setting assignments and there is further information on our website.

There is a maximum number of 3 summative assignments for this unit. The relationship of the learning aims and criteria is:

Learning aim: A (A.P1, A.P2, A.P3, A.M1, A.D1)

Learning aim: B (B.P4, B.P5, B.M2, B.D2)

Learning aim: C (C.P6, C.M3, C.D3)

Further information for teachers and assessors

Resource requirements

For this unit learners will need access to the internet and secondary sources for research.

Essential information for assessment decisions

Learning aim A

For distinction standard, learners will each choose at least one muscular and at least one skeletal disorder and examine, in detail, the cause(s) of each of the condition(s). Learners will source and reference their own photomicrographs and diagrams and use these materials to assess how the disorders arise and their effect on the anatomy/structure of the musculoskeletal systems. The impact and significance on the growth, development and lifestyle of individuals with the disorders will be examined.

Some disorders have both a muscular and a skeletal aspect. These disorders can be used but there must be a clear focus on the implication of a muscular and of a skeletal disorder. Two disorders must be presented as evidence. It is not acceptable for all learners to choose the same disorders.

For merit standard, learners will use electron photomicrographs and diagrams of the ultrastructure of striated muscle tissue along with observations they have made using a light microscope to explain muscle contraction. Learners will source and reference their own photomicrographs and diagrams. Sliding filament theory will be discussed. The interrelationship of skeletal muscles, bones, joints, cartilage and ligaments in bringing about movement must be discussed.

For pass standard, learners will find and reference secondary source diagrams of the skeletal system, the structure of bones, types of joint and the positions of ligaments and cartilage. These will be used by learners to explain how the structure of the skeleton relates to its five main functions.

Learners will observe the gross structure and use a light microscope to observe and record the structure of smooth, striated and cardiac muscle tissue. Prepared slides can be used, but it would be good practice to allow learners to prepare their own and use pre-prepared slides to ensure accurate details are observed and recorded. Good practice in drawing should be demonstrated, clear, sharp lines, no heavy shading, field of view, and magnification should be shown. Diagrams should have a title and be accurately labelled to show the key features.

The key structural features of muscle tissue determined from observations will then be explained in relation to their function. The nature of antagonistic pairs of muscles will be included.

Learning aim B

For distinction standard, learners will evaluate changes relating to age, and to degeneration and/or disorders of the nervous and hormonal systems. One endocrine and one nervous disease/disorder must be included. The impact of changes to the hormone and nervous systems throughout a person's life will be considered and analysed. This will include developmental milestones, gross and fine motor skills, puberty, menopause and emotional and intellectual changes.

For merit standard, learners will analyse the benefits of having both a nervous and an endocrine system. Speed of transmission, longevity of response, role of synapses should be included. The relationship between the functions of the two systems in relation to coordination and control will be analysed in detail.

For pass standard, learners will use their own referenced, secondary sourced diagrams to show the organisation of the endocrine system. These diagrams will be used to explain how the location of the organs/glands in the system is important in relation to the target organ and the speed of response. Names and details of the function(s) of the main hormones should be given for each gland. The implications of overproduction of one hormone and underproduction of a different hormone will be explained. The relationship between different hormones should be examined and discussed. This could be in relation to one gland producing a hormone(s) to control other glands or how two hormones can work together to control blood sugar levels.

Learners will use diagrams to provide a brief explanation of the organisation of the nervous system in relation to its functions. The central nervous system, peripheral nervous system, parasympathetic and sympathetic systems must be included.

Learning aim C

For distinction standard, learners will evaluate two factors from ageing, deficiency, toxicity, genetics, lifestyle, that can have disruptive effects on homeostasis. An evaluation of the physiological effects must be given in terms of the impact on growth and development of the individual.

For merit standard, learners will analyse how the endocrine and nervous system work together to maintain a constant environment for biological systems to work effectively. The hypothalamus and its links to both systems must be analysed in detail.

For pass standard, learners will provide an explanation of homeostasis, what it is and why it is important to biological systems. An example of negative and positive feedback loops will be given. Correct scientific terminology must be used. Learners can submit secondary source diagrams of feedback loops but must provide a clear explanation of what they are showing and how they work.

Links to other units

This unit links to:

- Unit 1: Principles of Applied Human Biology
- Unit 2: Practical Microbiology and Infectious Diseases
- Unit 5: Diseases, Disorders, Treatments and Therapies.

Employer involvement

Centres can involve employers in the delivery of this unit if there are local opportunities to do so. There is no specific guidance related to this unit.

Unit 5: Diseases, Disorders, Treatments and Therapies

Level: **3**

Unit type: **Internal**

Guided learning hours: **60**

Unit in brief

Learners will explore biological molecules and pathways, and their relevance to diseases, disorders, treatments and therapies.

Unit introduction

This unit gives you theoretical knowledge of diseases and disorders, an insight into current and future treatments, and knowledge of how biology is applied to make a positive impact on our lives. This unit builds on the knowledge of biological molecules from *Unit 1: Principles of Applied Human Biology* to give you an understanding of how the molecules affect human health.

Biological molecules are at the forefront of treating many diseases and disorders. In this unit, you will have the opportunity to research how drugs and medicines are discovered, altered, designed and synthesised in order to treat physiological and psychological diseases and disorders. New and innovative technological advances allow for the development of new medicines and alternative treatments. This unit requires you to become familiar with current treatments and their potential benefits, while understanding their potential adverse effects. Potential treatments for the future are often covered in news stories and in television documentaries, for example the BBC documentary series *Surgeons: At the Edge of Life*, and in this unit you will explore and research how new treatments are discovered. You will also explore the moral, ethical and legal implications of treating or not treating individuals.

This unit will help you to progress to higher education and then to a career in health promotion, public health, teaching, health service management, medical sales, nursing, counselling and social work. The unit can also help you to access an Apprenticeship in the health sector.

Learning aims

In this unit you will:

- A** Understand biological molecules and pathways and their effect on the body
- B** Understand the effects of physiological diseases and disorders and associated treatments
- C** Understand the causes and effects of psychological diseases and disorders and associated treatments
- D** Examine the development of innovative and future types of treatment for physiological and psychological diseases and disorders.

Summary of unit

Learning aim	Key content areas	Recommended assessment approach
A Understand biological molecules and pathways and their effect on the body	<p>A1 Structure and function of biological molecules</p> <p>A2 Roles of proteins and lipids in maintaining physiological and psychological health</p> <p>A3 Disruption of biological processes in living organisms</p>	A report on biological molecules and how their structure affects their role, and how structural disruption can lead to physiological and psychological diseases and disorders.
B Understand the effects of physiological diseases and disorders and associated treatments	<p>B1 Physiological diseases and disorders</p> <p>B2 Treatments for physiological diseases and disorders</p> <p>B3 Effects on the body</p>	A report on causes, effects and treatments of physiological and psychological disorders.
C Understand the causes and effects of psychological diseases and disorders and associated treatments	<p>C1 Overview of brain structure and function</p> <p>C2 Psychological diseases and disorders</p> <p>C3 Causes of psychological diseases and disorders</p> <p>C4 Treatments for psychological diseases and disorders</p> <p>C5 Effects of treatments for psychological disorders</p>	
D Examine the development of innovative and future types of treatment for physiological and psychological diseases and disorders	<p>D1 Drug and medicine discovery and development</p> <p>D2 Innovative treatments</p> <p>D3 Ethical, legal and moral issues</p>	A report or case study on the development and testing of drugs and medicines and associated ethical, moral and legal issues relating to treatments of physiological and psychological diseases and disorders.

Content

Learning aim A: Understand biological molecules and pathways and their effect on the body

Learners will build on their core knowledge of proteins, nucleic acids and lipids from *Unit 1: Principles of Applied Human Biology* to develop an understanding of the structures, formation, functions and importance of proteins, nucleic acids and lipids in maintaining physiological and psychological health.

A1 Structure and function of biological molecules

- General structure and function of biological molecules:
 - carbohydrates
 - proteins, to include primary, secondary, tertiary and quaternary structures of globular and fibrous proteins
 - triglycerides
 - glycoproteins
 - high-density lipoproteins (HDLs) and low-density lipoproteins (LDLs)
 - phospholipids.
- Structure and function of specific biological molecules:
 - deoxyribonucleic acid (DNA)
 - ribonucleic acid (RNA), to include messenger RNA (mRNA), transfer RNA (tRNA) and short interfering RNA (siRNA)
 - adenosine triphosphate (ATP)
 - collagen.

A2 Roles of proteins and lipids in maintaining physiological and psychological health

- Roles of proteins:
 - as enzymes that control metabolism
 - as peptide neurotransmitters
 - as antibodies
 - as hormones
 - for transport of other components
 - for body tissue growth and repair
 - for muscle contraction in animals (actin and myosin interaction – detailed knowledge of the sliding filament theory not required)
 - for reducing the chance of blood clotting.
- Roles of lipids:
 - as energy sources
 - as insulation of nerves and organ protection
 - as phospholipids in membranes
 - in association with vitamins
 - in the production of hormones.

A3 Disruption of biological processes in living organisms

Learners will explore the causes and effects of disruption to biochemical processes, to include:

- cancer: prostate, cervical, breast, lung
- coronary heart disease (CHD) – atherosclerosis, coronary vascular disease (CVD)
- diabetes – regulation of glucose metabolism by hormones
- mental health:
 - Alzheimer’s disease
 - anxiety and mood disorders
 - psychotic disorders
 - personality disorders
 - addiction disorders.

Learning aim B: Understand the effects of physiological diseases and disorders, and associated treatments

B1 Physiological diseases and disorders

Learners will research and understand the possible effects of the following:

- cancer – e.g. prostate, cervical, breast, lung
- coronary heart disease (CHD) – atherosclerosis, coronary vascular disease (CVD)
- diabetes – diabetes mellitus types 1 and 2.

B2 Treatments for physiological diseases and disorders

Learners will understand the types of treatment, therapies and the associated benefits of each when used in relation to specific physiological diseases and disorders, e.g.

- Radiotherapy, including brachytherapy.
- Chemotherapy.
- Hormone therapy.
- Surgery.
- Targeted biological therapy and immunotherapy, e.g. monoclonal antibody therapy, angiogenesis inhibitors, T-cell therapy.
- Gene therapy, e.g. replacing a mutated gene, inactivating a mutated gene, introducing a new gene.
- Stem cell therapy.

B3 Effects on the body

- Learners will understand the possible effects on the body of the treatments listed above.
- Positive effects (advantages and benefits), e.g. partial cure, cure, ability to lead a normal life.
- Negative effects (disadvantages, potential harm), e.g. side effects of treatments.
- Risks associated with treatments, e.g. exposure to increased levels of radioactivity during radiotherapy.

Learning aim C: Understand the causes and effects of psychological diseases and disorders and associated treatments

C1 Overview of brain structure and function

Cerebral cortex:

- left and right hemispheres, corpus callosum, lateralisation of functions, e.g. speech, handedness
- frontal lobe – location and functions, e.g. voluntary movement, planning, expression of emotions
- parietal lobe – spatial awareness, body orientation, attention, touch sensation
- occipital lobe – visual processing
- temporal lobe – sensory input, speech and language, hearing, memory.

Hindbrain:

- cerebellum – coordination of voluntary muscular movement, posture and balance
- brain stem – midbrain, pons, medulla; functions (control of breathing, autonomic reflexes, sleep, heart rate, blood pressure, connections between higher centres and spinal cord).

Limbic system:

- amygdala – emotions, recognition of threats (fight or flight)
- hippocampus – memory formation from past experiences
- thalamus – relay and redistribution of impulses, regulation of consciousness and sleep
- hypothalamus – pituitary (anterior and posterior) and control of hormone output, appetite, thirst and water balance, body temperature, physical manifestations of emotional reactions (pleasure, rage, fear), sleeping and waking cycles, sexual behaviour.

Neurophysiology:

- grey and white matter
- cell bodies, dendrites, axons, axon terminals, synapses
- spinal reflex arc – receptors, sensory neurons, interneurons, motor neurons, effectors, synapses
- meninges and cerebrospinal fluid.

C2 Psychological diseases and disorders

Learners will research the following in order to have an understanding of their causes and treatments.

- Alzheimer's disease.
- Anxiety/mood disorders, e.g. depression, seasonal affective disorder (SAD), self-harm.
- Psychotic disorders, e.g. schizophrenia, bipolar disorder, dementia.
- Personality disorders, e.g. borderline personality disorder, antisocial personality disorder.
- Eating disorders and impulse control and addiction disorders.
- Obsessive-compulsive disorder (OCD).
- Post-traumatic stress disorder (PTSD).

C3 Causes of psychological diseases and disorders

Learners will research and understand possible causes, links and effects of the following:

- genetic/inherited factors
- biological medical conditions, side effects of prescribed medication, hormonal changes/imbalance
- environmental traumatic experiences, abuse, neglect
- physical brain tumour, brain damage
- monoamine oxidase (MAO) genetic link with psychological disorder genetics, e.g. impulsivity and aggression.

C4 Treatments for psychological diseases and disorders

Learners will understand the types of treatment and therapies used in relation to psychological diseases and disorders.

- Medication, e.g. serotonin, antipsychotics, acetylcholinesterase inhibitor (AChEI).
- Electroconvulsive therapy (ECT).
- Psychotherapy/talking therapies, behavioural, cognitive, interpersonal, psychodynamic.
- Support in the community, e.g. lifestyle, relationships, motivational, self-help, Samaritans, Mind.

C5 Effects of treatments for psychological disorders

Learners will understand the possible effects that treatments for psychological disorders can have.

- Positive effects (advantages and benefits), e.g. partial cure, cure, ability to lead a normal life.
- Negative effects (disadvantages, potential harm), e.g. side effects of treatments.
- Risks associated with treatments, e.g. reversible, irreversible.

Learning aim D: Examine the development of innovative and future types of treatment for physiological and psychological diseases and disorders

D1 Drug and medicine discovery and development

Learners will explore drug discovery and development to include:

- drugs derived from natural sources, e.g. plants and animals
- modification of natural products to develop drugs and medicines, e.g. isolation, purification, optimisation of the active compound
- process of drug development from discovery to regulatory approval, e.g. computer modelling, clinical trials.

D2 Innovative treatments

Learners will explore the development of innovative treatments for physiological and psychological diseases and disorders.

- Gene therapy:
 - identification, removal and modification of faulty genes
 - insertion of 'new' gene, vectors.
- Stem cell therapy:
 - to allow regulation of over- or underproduction of chemicals in the body
 - to regenerate cells and tissues.
- Surgical techniques – current research and development into less invasive ways to remove cells and tissues.

D3 Ethical, legal and moral issues

Learners will explore the ethical, legal and moral issues relating to treatments and drug development and testing.

- Ethical, social and professional rules, for example, confidentiality, informed consent, rights of individual versus rights of society, 'do no harm', 'can it be done?', 'should it be done?', use of animal testing, placebos, blind and double-blind clinical trials.

Assessment criteria

Pass	Merit	Distinction
Learning aim A: Understand biological molecules and pathways and their effect on the body		A.D1 Evaluate the impact of disruption for one physiological and one psychological disease or disorder.
A.P1 Explain the importance of proteins, nucleic acids and lipids in maintaining physiological health. A.P2 Explain the importance of proteins, nucleic acids and lipids in maintaining mental health.	A.M1 Discuss how disruption to biological molecules and processes can lead to one physiological and one psychological disease or disorder.	
Learning aim B: Understand the effects of physiological diseases and disorders and associated treatments		BC.D2 Evaluate the effects and treatments of physiological and psychological diseases and disorders.
B.P3 Explain the effects of physiological diseases and disorders.	B.M2 Analyse the associated effects of treatments of physiological diseases and disorders on the body.	
Learning aim C: Understand the causes and effects of psychological diseases and disorders and associated treatments		D.D3 Evaluate the ethical, legal and moral issues of drug/medicine development, testing and treatments for a physiological or a psychological disease or disorder.
C.P4 Describe the gross structure and function of the brain, including possible causes of psychological diseases and disorders.	C.M3 Analyse the causes, effects, treatments and therapies for psychological diseases and disorders.	
Learning aim D: Examine the development of innovative and future types of treatment for physiological and psychological diseases and disorders		
D.P5 Describe the development and testing of a drug/medicine derived from a natural source and one that has been synthesised for a specific purpose.	D.M4 Discuss the problems that may arise during development and testing of drugs/medicine and treatments.	

Essential information for assignments

The recommended structure of assessment is shown in the unit summary along with suitable forms of evidence. *Section 6* gives information on setting assignments and there is further information on our website.

There is a maximum number of three summative assignments for this unit. The relationship of the learning aims and criteria is:

Learning aim: A (A.P1, A.P2, A.M1, A.D1)

Learning aims: B and C (B.P3, B.M2, C.P4, C.M3 and BC.D2)

Learning aim: D (D.P5, D.M4, D.D3)

Further information for teachers and assessors

Resource requirements

For this unit, learners must have access to the internet and secondary sources for research.

Essential information for assessment decisions

A sensitive approach to this unit will be required, as learners may have family and friends who have experience of some of the diseases and disorders covered in the unit.

To help ensure validity and authenticity of the work being submitted for assessment, each learner will individually choose from the physiological and psychological disorder listed in the unit content to research and use for their assignment.

Learning aim A

For distinction standard, learners will draw on secondary source material (referenced) to evaluate the relevance and/or significance of the normal and disrupted state of biological molecules for the one physiological and one psychological disease or disorder they have chosen. A conclusion on the significance of the disruption will be given and justified.

For merit standard, learners will choose one physiological and one psychological disease or disorder from: cancer, coronary heart disease, diabetes, depression, dementia. Their discussion will give clear details, reasons and opinions as to how disruption of biological molecules may lead to the diseases or disorders that they have chosen.

Learners will need to give clear details of the changes to the structure of molecules and their implications, for example details of how inaccuracies in the secondary, tertiary and quaternary structure of proteins can affect their role. Learners will explain the importance of the accurate base pairing of nucleic acids in relation to diseases and disorders. They will explain the relevance of saturated and unsaturated fats to heart disease, atherosclerosis and the insulation of nerves, to enable the fast and accurate transmission of impulses.

For pass standard, learners will explain the importance of proteins, nucleic acids and lipids in terms of their structure and roles in the body. The explanations must relate to the importance of these biological molecules in maintaining physiological and psychological health.

Learning aims B and C

For distinction standard, learners will evaluate aspects of one physiological and one psychological disease or disorder and how they are similar and different in terms of causes, effects on the body and the individual, and effectiveness or otherwise of current treatments. Learners must give judgements that are supported by evidence.

For merit standard, learners will analyse the effects of current treatments and therapies for one physiological and one psychological disease or disorder from the categories given in the unit content. Positive and negative effects, where applicable, and risks will be included and analysed in relation to potential benefits.

For pass standard, learners will give clear explanations of the effects of two physiological diseases and disorders. Learners will include details of the associated biological molecules and their involvement in the disrupting processes resulting in the effects. The two diseases or disorders should be chosen from the four categories given in the unit content.

Learners will describe the gross structure of the brain and outline the main functions of each part and describe the components and functions of a spinal reflex arc. Annotated diagrams could be produced as evidence. Learners must also describe the changes in brain or nervous metabolism that are believed to cause two psychological disorders.

Learning aim D

For distinction standard, learners will evaluate the ethical, moral and legal issues relating to drug/medicine development and testing and the treatment(s) used for one physiological or one psychological disease or disorder. An understanding of the differences between ethics and morals will be demonstrated, and the dilemmas surgeons and health practitioners relating to 'do no harm' will be considered in relation to current treatments.

For merit standard, learners will use the testing of drugs, medicines and treatments to discuss the problems that could arise during development and testing for one physiological or one psychological disease or disorder. Innovative treatments, e.g. gene transfer, stem cell therapy and/or minimally invasive surgery will also be included.

For pass standard, learners will choose a drug or medicine derived from a plant or animal source that is used to treat a disease or disorder and briefly describe its development. They will also give a description of the development of a synthetic drug or medicine which is used for a named disorder or disease.

Learners must give an objective account of the stages of drug and medicine testing. They will need to include information on the requirements for drugs and medicines to be rigorously tested prior to being approved for use.

Learners must use technical language and demonstrate breadth of coverage of the unit content.

Links to other units

This unit links to:

- Unit 1: Principles of Applied Human Biology
- Unit 2: Practical Microbiology and Infectious Diseases
- Unit 4: Functional Physiology.

Employer involvement

This unit would benefit from employer involvement in the form of visiting speakers from:

- charities working with the diseases and disorders covered in this unit
- a pharmaceutical representative to discuss drug development and testing.

Unit 6: Genetics and Genetic Engineering

Level: **3**

Unit type: **Internal**

Guided learning hours: **60**

Unit in brief

Learners will study the basis of life itself. They will gain an understanding of the structure of DNA, cell division and the principles of Mendelian genetics and variation.

Unit introduction

Massive advances in DNA technology over the last 30 years have driven genetics forward at an extraordinary rate, creating enormous potential for future applications. This unit will allow you to develop a deeper practical and theoretical knowledge and understanding of genetics, and modern genetic engineering techniques and their uses. This may be of particular interest to learners wishing to follow a career in forensic science or research. There are often media reports of medical advances, for instance growing replacement body parts for transplantation, and advances in treatments for life-threatening and debilitating diseases. There will be opportunities to follow up some of these reports and to extend your knowledge and understanding of what might be possible in the future.

You will investigate the mechanisms of cell division and carry out research to explain how the behaviour of chromosomes during cell division relates to variation. There will be an opportunity to demonstrate and expand your knowledge of genetics and variation, to include how genes control the characteristics of living organisms by synthesising proteins using nucleic acids as a code. The principles of Mendelian genetics will be used to outline and explain patterns of inheritance and how this can influence variation and evolution. You will explore modern genetic techniques and their uses and have the opportunity to extract and work with DNA.

This unit will provide a basis for progression in the fields of medical, veterinary, agricultural, industrial or forensic science. Multiple pathways for career development are available. These may be through higher education courses, university, or by direct entry to these fields as science technicians or on Apprenticeship schemes.

Learning aims

In this unit you will:

- A** Understand the structure and function of nucleic acids in order to describe gene expression and the process of protein synthesis
- B** Explore how the process of cell division in eukaryotic cells contributes to genetic variation
- C** Explore the principles of inheritance and their application in predicting genetic traits
- D** Explore basic DNA techniques and the use of genetic engineering technologies.

Summary of unit

Learning aim	Key content areas	Recommended assessment approach
A Understand the structure and function of nucleic acids in order to describe gene expression and the process of protein synthesis	A1 Nucleic acids A2 The basis of the genetic code A3 Protein synthesis	A portfolio of evidence to include: <ul style="list-style-type: none"> • photographic evidence of DNA models that learners make • a leaflet/report explaining the structure of nucleic acids and how they code for protein synthesis • annotated diagrams of the stages of protein synthesis, how and where the stages occur and analysis of the impact of possible errors.
B Explore how the process of cell division in eukaryotic cells contributes to genetic variation	B1 Human chromosomes B2 Cell division and its role in variation B3 Practical demonstration of slide preparation of dividing cells	A portfolio of evidence to include: <ul style="list-style-type: none"> • a leaflet on the structure and function of human chromosomes • an observation record of microscope slide preparation of mitosis and meiosis • annotated diagrams identifying the stages in mitosis and meiosis • a report explaining and evaluating how the behaviour of the chromosomes during meiosis leads to variation.
C Explore the principles of inheritance and their application in predicting genetic traits	C1 Principles of classical genetics C2 Further genetics	A portfolio of evidence to include: <ul style="list-style-type: none"> • an observation record to validate the practical work carried out on <i>Drosophila</i> • statistical analysis of the patterns of inheritance ratios from practical work • genetic diagrams and a report using appropriate terminology to predict and describe the results of genetic crosses.
D Explore basic DNA techniques and the use of genetic engineering technologies	D1 DNA extraction D2 Gel electrophoresis D3 DNA amplification D4 Transformation of cells D5 Uses of genetic engineering	A portfolio of evidence to include: <ul style="list-style-type: none"> • a brief report on practical techniques carried out and their applications in industry and medicine • observation records to validate the practical work • a report on how restriction enzymes and electrophoresis work with an explanation of stem cell therapies and their uses.

Content

Learning aim A: Understand the structure and function of nucleic acids in order to describe gene expression and the process of protein synthesis

A1 Nucleic acids

Nucleotide structure, function and location of the following:

- DNA, to include stages and enzymes involved in DNA replication
- RNA, to include mRNA, tRNA, rRNA, siRNA.

A2 The basis of the genetic code

Definitions of the following and their importance in gene expression:

- triplet codes
- codon
- anticodon
- degenerate code
- non-overlapping.

A3 Protein synthesis

- Major stages involved in each stage (including location) and the effect of mutations on the end products.
- Transcription, to include introns, exons and splicing.
- Amino acid activation.
- Translation.
- Mutagenic agents, e.g. irradiation, chemical mutagens.
- Types of genetic mutation – missense, nonsense, silent, insertion, deletion, duplication, frameshift.

Learning aim B: Explore how the process of cell division in eukaryotic cells contributes to genetic variation

B1 Human chromosomes

The formation and structure of chromosomes, linked to their function:

- centromere
- chromatids
- autosomes
- sex chromosomes
- chromosome number and karyotyping
- homologous and non-homologous chromosomes.

B2 Cell division and its role in variation

- Stages of the cell cycle, to include cellular activities at each stage and the checkpoints involved in progressing from one stage to the next. Learners should be able to identify the stage a cell is in from given micrographs or specimens, describe the position of chromosomes and the events that take place within each stage of cell division.
- The cell cycle: G1, S phase, G2, division cytokinesis.
- The stages of mitosis, to include the similarities and differences between mitosis in animal and plant cells – interphase, prophase, metaphase, anaphase, telophase.
- The stages of meiosis in the production of gametes:
 - interphase, prophase I, metaphase I, anaphase I, telophase I, cytokinesis, interkinesis, prophase II, metaphase II, anaphase II, telophase II, cytokinesis.
- The role of centrioles (microtubule-organising centre).
- Haploid, diploid.
- Sex determination.

B3 Practical demonstration of slide preparation of dividing cells

- Equipment and techniques involved in the preparation of slides for examination using light microscopy.
- Mitosis, e.g. root tip squash.
- Meiosis, e.g. lily anther squash.

Learning aim C: Explore the principles of inheritance and their application in predicting genetic traits**C1 Principles of classical genetics**

- Inheritance of straightforward phenotypic traits in animals and plants, their predicted proportions and statistical analysis of phenotypic outcomes.
- The differences and complexities involved in continuous and discontinuous variation.
- Mendel's laws of inheritance: segregation and independent assortment.
- Practical investigation of mono and dihybrid phenotypic ratios.
- Use of Punnett squares and other genetic diagrams, to include use of the terms allele, genotype, phenotype, heterozygous, homozygous, carrier, affected/sufferer, non-affected/non-sufferer.
- Interpretation of Mendelian ratios from practical investigations.
- Chi-squared test.

C2 Further genetics

Description of genetic interaction, phenotypic traits and reasoned prediction of inheritance of the following:

- single gene disorders, e.g. Huntington's disease, sickle cell anaemia, cystic fibrosis
- incomplete dominance/blending, e.g. Tay-Sachs disease and co-dominance, e.g. blood groups
- sex linkage, e.g. colour blindness, haemophilia.
- chromosome mutation, e.g. Down's syndrome, Turner syndrome.
- epistasis, e.g. albinism.

Learning aim D: Explore basic DNA techniques and the use of genetic engineering technologies

Principles and practical application (where appropriate) of the techniques, equipment and consumables in each of the following:

D1 DNA extraction

- Genomic and plasmid DNA extraction.

D2 Gel electrophoresis

- Use of restriction enzymes.
- Principles of electrophoresis.

D3 DNA amplification

- Polymerase chain reaction (PCR).
- Purpose of utilising PCR to amplify DNA:
 - DNA fingerprinting
 - cancer diagnosis
 - tissue typing
 - preimplantation genetic diagnosis/screening.

D4 Transformation of cells

- Use of vectors.
- Plasmids.
- Use of marker genes.
- DNA ligase.
- Screening to identify transformed cells.

D5 Uses of genetic engineering

- Genetically modified (GM) crops.
- Diagnostic tests and gene therapy.
- Pharming.
- Genetic screening including preimplantation genetic diagnosis (PGD).
- Stem cell therapies, e.g. Parkinson's disease, macular degeneration, spinal cord injuries.
- Xenotransplantation.

Assessment criteria

Pass	Merit	Distinction
Learning aim A: Understand the structure and function of nucleic acids in order to describe gene expression and the process of protein synthesis		A.D1 Assess the impact of error in the stages of protein synthesis.
A.P1 Explain the structure and function of DNA and various nucleic acids.	A.M1 Discuss the functional role of nucleic acids in DNA in the stages of protein synthesis.	
Learning aim B: Explore how the process of cell division in eukaryotic cells contributes to genetic variation		B.D2 Evaluate how the behaviour of the chromosomes leads to variation.
B.P2 Prepare microscopic slides to observe and draw the stages of mitosis and meiosis.	B.M2 Demonstrate skilful preparation of microscopic slides to observe and draw the stages of mitosis and meiosis.	
B.P3 Explain the structure and function of human chromosomes.	B.M3 Discuss the behaviour of the chromosomes during the cell cycle stages of mitosis and meiosis.	
Learning aim C: Explore the principles of inheritance and their application in predicting genetic traits		C.D3 Make valid predictions on patterns of monohybrid and dihybrid inheritance and variation using principles of inheritance.
C.P4 Carry out investigations to collect and record data for mono and dihybrid phenotypic ratios.	C.M4 Analyse data to explain the correlation between observed pattern of monohybrid and dihybrid inheritance.	
C.P5 Explain genetic crosses between non-affected, affected and carriers of genetic conditions.	C.M5 Apply Mendel's laws of inheritance to the results of genetic crosses.	
Learning aim D: Explore basic DNA techniques and the use of genetic engineering technologies		D.D4 Evaluate possible future uses of genetic engineering technologies.
D.P6 Extract, separate and amplify DNA.	D.M6 Analyse the uses of genetic engineering technologies in industry and medicine.	
D.P7 Explain the use of genetic engineering technologies in industry and medicine.		

Essential information for assignments

The recommended structure of assessment is shown in the unit summary along with suitable forms of evidence. *Section 6* gives information on setting assignments and there is further information on our website.

There is a maximum number of four summative assignments for this unit. The relationship of the learning aims and criteria is:

Learning aim: A (A.P1, A.M1, A.D1)

Learning aim: B (B.P2, B.P3, B.M2, B.M3, B.D2)

Learning aim: C (C.P4, C.P5, C.M4, C.M5, C.D3)

Learning aim: D (D.P6, D.P7, D.M6, D.D4)

Further information for teachers and assessors

Resource requirements

For this unit, learners must have access to:

- a well-equipped laboratory
- commercially prepared materials/kits, which can be purchased to facilitate growing of *Drosophila* and for extracting DNA, gel electrophoresis, cell transformation and polymerase chain reactions.

Essential information for assessment decisions

Learning aim A

For distinction standard, learners will demonstrate a thorough understanding of the structure and function of DNA in relation to the stages of protein synthesis, with specific and accurate use of scientific terminology. Learners will make relevant links between possible errors that may occur during the different stages of protein synthesis, including transcription, translation and the cause and effect of mutations in DNA. They must also give an assessment of the impact of these errors to the end products of protein synthesis, which will be illustrated with examples.

For merit standard, learners will clearly use their knowledge of the genetic code to discuss the functional role of nucleic acids in protein synthesis. Learners will discuss the locations of each stage in protein synthesis and how the genetic code allows proteins to be synthesised with minimal errors taking place.

For pass standard, learners must explain the structure and main features of each nucleic acid listed in the unit content. Photographic evidence can be submitted and annotated if more kinaesthetic assessment tools are used, such as model making.

Learning aim B

For distinction standard, learners will use the information from their practical work and discussion on meiosis and mitosis to evaluate the significance of chromosomal behaviour during cell division. Arguments must be provided for and against the behaviour of independent assortment and crossing over leading to variation within an organism.

For merit standard, learners will skilfully prepare three microscope slides of squash preparations to show mitosis and meiosis, without guidance during assessment. They must use their slide preparations to produce diagrams to identify a minimum of four stages of mitosis and four stages of meiosis. The diagrams must demonstrate good practice – have a title, be drawn in pencil, have clear outlines (not sketched), no heavy shading, indicate the field of view, magnification and scale. Accurate labelling should be evident. Observation records will be required to validate the level of expertise demonstrated by the learner. Learners will provide a detailed discussion demonstrating an understanding of the behaviour of the chromosomes during mitosis and meiosis in each stage of cell division. Supplementary evidence using prepared slides and photomicrographs, provided and referenced by the learner, can be used to ensure all the required stages listed in the unit content can be identified.

For pass standard, learners will correctly prepare three microscope slides to allow them to observe, draw and label a minimum of four stages of mitosis and four stages of meiosis. Learners will follow instructions to prepare the material and apply a stain/fixer, if appropriate, having had an opportunity to practise the skills during teaching and learning. They should demonstrate good technique in applying a cover slip to ensure exclusion of air.

Learners must handle the microscope safely, set it up independently and be able to manoeuvre the slide(s) to obtain a field of view under different magnifications. Good technique includes the use of a pencil and statement of the magnification used for the drawing(s) submitted. Photomicrographs and diagrams sourced and referenced by the learners could be used to aid the explanation of the structure of human chromosomes. Detailed statements are required which demonstrate understanding of how/why the structure relates to the function of the chromosomes.

Learning aim C

For distinction standard, learners must demonstrate the ability to make valid predictions and analyse the outcomes of examples of monohybrid and dihybrid crosses between non-affected, affected and carriers of particular disorders and independent and linked genes. Learners must provide evidence of one disorder for monohybrid and one for dihybrid. Learners will use both their own data from investigations and use case studies to allow access to this criterion. Learners must include an explanation of why the observed ratio for each example is not exactly as would be expected.

For merit standard, learners will use the data from practical work they have carried out and effectively apply the chi-squared test to analyse the correlation between the observed and expected phenotypic results. An outcome from the statistical test is required, identifying if the ratios obtained are statistically significant or due to chance. Learners must then apply and use Mendel's laws of independent assortment and segregation to analyse the results of the genetic crosses, and explicitly state conclusions.

For pass standard, learners must follow instructions in a competent manner to obtain valid and reliable data from an investigation into monohybrid and dihybrid inheritance. An individual observation sheet will be required to validate their level of competency. Sufficient data to carry out a chi-squared analysis must be collected. Results can be shared/collated between individuals/groups of learners. Spreadsheets can be used. Use of simulations prior to starting the assignment will provide a good basis for the learners to carry out their own practical work and statistical analysis. Learners must produce their own write up to include the data from their investigations. Competent completion of the task will be characterised by adherence to the instructions, a very low error rate and the gaining of results close to that expected by the tutor in the context of the investigation.

Learners must accurately construct genetic diagrams representative of genetic conditions and explain the relationship between the genotypic and phenotypic ratios. The correct terminology will be applied throughout. The evidence submitted does not have to be solely related to humans.

Learning aim D

For distinction standard, learners will research the strengths and weaknesses, advantages and disadvantages of the genetic technologies explored in the relevant unit content. All sources consulted will be accurately referenced. They must use the research to support their own views, speculating in an informed manner about future uses of generic engineering technologies. They must provide counterarguments of the reliability and validity of the use of the technologies.

For merit standard, learners will analyse the use of genetic technologies in relation to industry and/or medicine. The analysis will take into account the reasons and science behind the technologies, benefits to the relevant sector of industry or medicine, and include an appreciation of efficacy and cost. This may be achieved effectively through the detailed examination of one real-life example for each technology.

For pass standard, learners will need to provide a laboratory record of how they have competently carried out three separate experiments: DNA extraction (chromosomes or plasmids), PCR and gel electrophoresis. An observation record is required to validate the competency of learners' participation in practical work, characterised by methodical preparation and avoidance of sample contamination. Learners will explain the genetic engineering technologies as listed in the unit content in terms of their relevance to industry and medicine, in addition to the basic principles behind how the technologies work.

Links to other units

This unit links to:

- Unit 1: Principles of Applied Human Biology
- Unit 2: Practical Microbiology and Infectious Diseases.

Employer involvement

Centres could approach a local university to try to arrange visits for learners to allow them to view commercial equipment used for extracting and carrying out genetic engineering techniques as well as the more advanced techniques not possible in centres' laboratories.

It may be possible to arrange visits from research scientists to give talks about their current research projects. A visit to a crop research faculty or a visit from scientists or technicians working there could enhance learner knowledge and understanding of the genetic research being undertaken and possible future developments.

Agricultural and horticultural colleges may be able to accommodate visits from learners to see how genetics has led to improved varieties of plants and animals.

A visit to an industrial state-of-the-art laboratory is recommended to help learners appreciate the sophistication of the modern-day high-tech laboratories compared with the basic equipment available in many educational laboratories.

Unit 7: Biomedical Science

Level: **3**

Unit type: **Internal**

Guided learning hours: **60**

Unit in brief

This unit will help learners understand the role biomedical scientists play in identifying the causes of disease and in helping medical personnel to offer suitable treatments.

Unit introduction

This unit will help you understand three key areas of biomedical science: haematology, histology/cytology and biochemical balance. The analytical and diagnostic testing carried out in these three areas supports other health professionals in screening, diagnosing, monitoring disease progression and treatment.

In this unit you will concentrate on biomedical science in relation to the human body, but many of the same techniques are used in veterinary science. Similar techniques are also valuable in the pharmaceutical industry, the blood and tissue transfusion and transplant service, forensic science and food technology.

You will have opportunities to investigate and understand blood and its importance, and how it can be used to diagnose and treat disease. Analysis of blood biochemistry provides important information to medical practitioners about the functions of the human body. You will consider the importance of maintaining 'norms' within the body and how deviations from these levels provide clues as to what is happening in the body to enable conditions to be diagnosed and treated.

Having completed this unit, you will be in a position to know which branch of biomedical science interests you and what further courses you can pursue to enter the profession. This may be entering as a trainee technician or after completing a biomedical science-related degree course.

Learning aims

In this unit you will:

- A** Understand the principles of haematology and its use in medical diagnosis
- B** Examine the use of histology and cytology in medicine
- C** Examine the use of urinalysis as an analytical and diagnostic tool.

Summary of unit

Learning aim	Key content areas	Recommended assessment approach
A Understand the principles of haematology and its use in medical diagnosis	A1 The components of blood A2 Changes to blood components and composition A3 Diagnostic techniques used in haematology	Practical work to investigate microscopically the components of blood and use of diagnostic techniques to identify disease. Observation records will be required. A report explaining blood component structure and function along with causes and consequences of dysfunction. Analysis of the use of diagnostic blood tests for different diseases.
B Examine the use of histology and cytology in medicine	B1 Tissue investigation and consequences of diagnosis B2 Role of informatics and record keeping	A report/presentation on the implications for society, the health service and individual patients of using histology and cytology in detecting and diagnosing disease occurrence, including how information is used and communicated to key stakeholders.
C Examine the use of urinalysis as an analytical and diagnostic tool	C1 Urine composition C2 Urinalysis	Practical work and a report on the use of urinalysis in diagnosing changes to health status.

Content

Learning aim A: Understand the principles of haematology and its use in medical diagnosis

A1 The components of blood

Structure and function of the following blood components:

- erythrocytes
- leucocytes
- thrombocytes (platelets)
- plasma and serum.

A2 Changes to blood components and composition

The effects of diseases and disorders on the overall composition of blood, including the effects on the structure and function of key blood components:

- erythrocytic diseases associated with types of anaemia, thalassaemia, vitamin B12 and foliate deficiency, sickle cell anaemia
- leucocytes (white blood cell) diseases associated with lymphocytosis, AIDS, infectious mononucleosis
- bone marrow failure
- leukaemia
- lymphomas such as Hodgkin's, non-Hodgkin's diseases
- haemostasis and thrombosis, and their significance to the body
- hepatitis B and C
- syphilis
- HIV.

A3 Diagnostic techniques used in haematology

The principles behind haematological diagnostic techniques, including the practical application of these techniques as appropriate:

- counts of red blood cells and platelets
- mean corpuscular and blood volumes
- analysis for iron deficiency
- coagulation/clotting
- haemoglobin tests
- blood grouping (typing).

Learning aim B: Examine the use of histology and cytology in medicine

B1 Tissue investigation and consequences of diagnosis

- Types and methods of sample removal, preservation and examination, including consideration of appearance of normal and abnormal results, methods of recording these and the implications of the results on patients, their families, the health service and society in general.
- Cell and tissue specimen analysis:
 - screening (bowel cancer)
 - aspirates (cerebrospinal fluid, amniocentesis)
 - surgical removal of tissues for disease identification (cervical, breast, prostate tissue)
 - allergic reactions tested by skin tests
 - tissue typing for bone marrow transplantation
 - purposes of specimens taken in autopsies to establish causes of death.

- Implications of disease diagnosis to individuals, the health service and society:
 - importance of correct and timely diagnosis and treatment
 - prognosis and quality of life for individuals and their families
 - financial implications of screening costs for early diagnosis as opposed to cost of treatment when disease is diagnosed later
 - confirmation of diseases likely to cause epidemics and resulting plans for prevention.

B2 Role of informatics and record keeping

Consideration of how information regarding diagnostic tests is recorded, stored and disseminated:

- right information to right person at right time
- processing and reporting, correct results matched with correct sample
- medical records – accurate and complete
- confidentiality.

Learning aim C: Examine the use of urinalysis as an analytical and diagnostic tool

C1 Urine composition

Main constituents of urine, including their biochemical sources in the body and how these vary in relation to healthy renal function:

- water
- organic solutes, e.g. urea, hormones, carbohydrates
- inorganic ions, e.g. sodium, chloride and potassium.

C2 Urinalysis

- Urine sampling to prevent misleading results in urinalysis:
 - why cleanliness of genitalia and sterility of collection vessels before sample collection is important
 - the purpose of mid-stream sample collection
 - why specific times of day for sample collection are sometimes recommended
 - length of time between sample collection and testing, and preservation methods of samples that will not be tested immediately.
- For each of the key indicators present in urine, the following must be considered:
 - normal ranges (as appropriate)
 - when each kind of test (visual, chemical or microscope) is considered appropriate
 - problems presented in result interpretation and steps to counter this, e.g. use of optical readers in digital pregnancy tests and automation of result reading
 - the mechanisms each analysis uses
 - health implications of changes in these levels, to include how and why the changes are brought about.
- Key indicators used in urinalysis:
 - visual – colour and clarity
 - chemical tests using test strips: specific gravity for determining concentration, pH, blood, protein, glucose, bilirubin, urobilirubin, ketones, nitrite, human chorionic gonadotropin (HCG)
 - under the microscope: crystalline structures, trichomonads, blood cells, micro-organisms, epithelial cells, casts.

Assessment criteria

Pass	Merit	Distinction
Learning aim A: Understand the principles of haematology and its use in medical diagnosis		A.D1 Evaluate the use of diagnostic testing of blood in relation to the detection of diseases.
A.P1 Explain the structure and function of the main components of blood. A.P2 Explain how diseases affect the composition of blood. A.P3 Correctly carry out diagnostic testing of blood.	A.M1 Discuss the basis of diagnostic tests for different diseases.	
Learning aim B: Examine the use of histology and cytology in medicine		B.D2 Evaluate the implications of screening and early disease diagnosis for the individual and for the health service and society.
B.P4 Explain the use of analytical investigation in disease screening. B.P5 Explain the use of analytical investigations of tissue samples. B.P6 Explain the use of informatics and data handling in biomedical science.	B.M2 Analyse how the interpretation and informatics of diagnostic test results are used as a tool for planning appropriate treatment.	
Learning aim C: Examine the use of urinalysis as an analytical and diagnostic tool		C.D3 Evaluate the use of urinalysis in domestic and clinical settings.
C.P7 Explain how urine composition may vary in relation to health. C.P8 Correctly carry out simple urinalysis.	C.M3 Analyse how the results of urinalysis are used in diagnoses of health status changes.	

Essential information for assignments

The recommended structure of assessment is shown in the unit summary along with suitable forms of evidence. *Section 6* gives information on setting assignments and there is further information on our website.

There is a maximum number of three summative assignments for this unit. The relationship of the learning aims and criteria is:

Learning aim: A (A.P1, A.P2, A.P3, A.M1, A.D1)

Learning aim: B (B.P4, B.P5, B.P6, B.M2, B.D2)

Learning aim: C (C.P7, C.P8, C.M3, C.D3)

Further information for teachers and assessors

Resource requirements

For this unit, learners must have access to:

- a well-equipped laboratory
- research facilities.

Essential information for assessment decisions

Learning aim A

For distinction standard, learners must clearly link the disease and blood composition, and make judgements about the appropriate selection, implementation and interpretation of diagnostic tests by medical workers. They will give a detailed consideration of the implications of misdiagnosis of disease, with the accurate use of appropriate scientific terminology throughout.

For merit standard, learners must consider how diagnostic testing of blood relates to accurate identification of two diseases. They must discuss changes to the composition of blood with reference to normal ranges in humans. Learners will make reference to required equipment and techniques used in each diagnostic test. They must give sustained lines of reasoning, free of fundamental errors.

For pass standard, learners must link the structure and function of each of the main components of blood. They must select two diseases associated with dysfunction or abnormality of blood components, and clearly state the cause of each disease and its effect on blood composition with reference to key indicators in blood composition. Observation records will be required to validate learners' practical work. At this level, learners must be able to follow instructions, work methodically and demonstrate awareness of good health and safety practice. Evidence of this should be identified in the write-up and records of the practical work produced by the learners should have a good level of accuracy in results/observations obtained.

Learning aim B

For distinction standard, learners must demonstrate an understanding of the value of screening for disease and how the early detection of disease can impact on prognosis and quality of life. They must evaluate the importance of early diagnosis leading to treatment and the implications of this, including a consideration of the associated emotional, economic and financial costs to the individual, the health service and society. Learners must demonstrate an understanding of the importance of accurately sampling and reporting diagnostic results, along with accurate medical records being available to the right people at the right time. It is expected that learners will access secondary data to support their conclusions about prevention and early treatment.

For merit standard, learners must provide a methodical and detailed examination of how the accuracy of testing and reporting of results to other health professionals is important in the treatment of the patient. They must consider how informatics are managed to ensure the prompt and accurate recording and dissemination of diagnostic test results. This will include an awareness of monitoring methods in automated sample analysis.

For pass standard, learners should consider the dual role of screening for disease and for detecting early signs of disease. They will describe different screening techniques and explain their role in early detection of disease. Learners should discuss the analysis of tissue samples removed surgically for examination in relation to how this can relate to the type of treatment that may be required. Learners must explain the use of informatics in biomedical science, including the management of data to maintain confidentiality while ensuring key personnel involved with the treatment of a patient have essential information in a timely and accessible format.

Learning aim C

For distinction standard, learners must demonstrate their understanding and knowledge of the normal biochemical functioning of body systems. They will need to be able to access and quote data identifying normal ranges of values for substances present in urine samples. Learners must evaluate the role of the biomedical scientist in providing the data requested by other health professionals to ensure effective monitoring of the progression and treatment of a patient in at least three cases. Learners will need to explain the issues related to sample collection, preservation and analysis in domestic and clinical settings, including a consideration of the implications of inaccurate interpretation of results and how errors can be reduced.

For merit standard, learners must identify and discuss how screening compares test results indicating abnormal values with normal values when attempting a diagnosis for particular diseases. They will make reference to how changes in health status along with contamination when collecting or preserving urine samples can cause abnormal levels of substances in three or more cases.

For pass standard, learners will provide clear details about how normal biochemical values are maintained in the body in relation to urine production, and why these are among the first tests ordered when diagnosing and treating patients.

Learners will carry out simple urinalysis tests, accurately identifying the changes in three or more substances in samples of urine and suggesting what these changes indicate in relation to health. They must specify how the samples of urine should be obtained in order to prevent misleading results.

Links to other units

This unit links to:

- Unit 1: Principles of Applied Human Biology
- Unit 2: Practical Microbiology and Infectious Diseases.

Employer involvement

Centres may involve employers in the delivery of this unit if there are local opportunities. Visiting speakers from health centres, the blood transfusion service, doctors' surgeries and pathology laboratories can give a valuable insight into their work.

All large hospitals have laboratories where blood products, cells and so on are dealt with. Since health and safety regulations may make it difficult to gain access, it is possibly best to approach the head of the medical services at a local hospital or the blood transfusion service to find out what access, speakers or other facilities are available to a centre teaching this unit.

Unit 8: Human Reproduction and Fertility

Level: **3**

Unit type: **Internal**

Guided learning hours: **60**

Unit in brief

Learners will gain an understanding of human reproduction, the role of hormones and examine the causes of infertility and possible treatments.

Unit introduction

The human body is a complex organisation of systems. Each system needs to be controlled in a well-defined range of parameters in order to contribute to the functions of the human body. In this unit, the focus is on human reproduction, its control mechanisms and associated fertility problems. There have been many advances in the treatment of human infertility in recent years and you will have the opportunity to explore them and the hormonal control of the reproductive system. This unit will help with your understanding of the key homeostatic principles in relation to human fertility, which are essential if the reproductive system is to function correctly.

You will be investigating the hormonal control of human reproduction and the medical and social effects if the system malfunctions in humans. This unit will help you to progress to higher education to study reproductive technologies and/or animal breeding. You could also progress to employment as a science technician, or to an Apprenticeship.

Learning aims

In this unit you will:

- A** Understand the anatomy and physiology of the human reproductive system
- B** Understand the role of hormones in the regulation and control of the reproductive system
- C** Examine the causes, treatments and impact of infertility on the health of human beings.

Summary of unit

Learning aim	Key content areas	Recommended assessment approach
A Understand the anatomy and physiology of the human reproductive system	A1 Structure and functions of the female and male reproductive organs A2 Female reproductive cycle A3 Puberty in males and females	A report looking at the organisation and function of the components of the human reproductive systems, including the use of detailed, annotated diagrams.
B Understand the role of hormones in the regulation and control of the reproductive system	B1 Reproductive processes B2 Foetal development and birth B3 Contraceptive methods and their health implications	A report, which includes detailed, annotated diagrams and a leaflet that includes contraceptive methods and their health implications.
C Examine the causes, treatments and impact of infertility on the health of human beings	C1 Causes of infertility C2 Potential treatments for infertility C3 The impact of infertility on the health and wellbeing of humans	A leaflet on the causes and treatments of infertility, focusing on the health and wellbeing of those facing fertility problems.

Content

Learning aim A: Understand the anatomy and physiology of the human reproductive system

A1 Structure and functions of the female and male reproductive organs

Learners will understand the structure and functions of the female and male reproductive organs.

- Female reproductive system: ovary, oviduct (fallopian tube), uterus, uterine horn, fimbriae, endometrium, cervix, vagina, labia.
- Male reproductive system: epididymis, seminal vesicle, Cowper's gland, prostate gland, testes, penis, scrotum, vas deferens, erectile tissue.

A2 Female reproductive cycle

Learners will understand the details of the female reproductive cycle, including:

- menstrual and ovarian cycles
- menopause, causes and effects on the female body
- processes leading to conception, to include: wafting of ova through fallopian tubes, semen delivery, fertilisation (including role of acrosome in penetration of the zona pellucida), implantation
- hormonal effects of fertilisation on the female reproductive cycle.

A3 Puberty in males and females

- Hormonal control and regulation of male and female reproductive functions, to include actions of male and female sex hormones.
- Development of secondary sexual characteristics.
- Comparison of changes in males and females during puberty.
- Effect of puberty on male and female behaviour.

Learning aim B: Understand the role of hormones in the regulation and control of the reproductive system

Learners will understand the stages of the reproductive process with timescales for each referenced. They will also understand the role of hormones in foetal development and birth.

B1 Reproductive processes

Gamete development and release:

- oogenesis from oogonia; formation of primary, secondary and Graafian follicles; ovulation; formation and role of corpus luteum
- normal/abnormal morphology of oocytes; ovulation disorders
- spermatogenesis from spermatogonia, formation of primary and secondary spermatocytes and spermatids; spermination, role of Sertoli and Leydig cells
- normal/abnormal morphology and abundance of sperm.

B2 Foetal development and birth

- Stages of development, including embryonic and foetal, including gestation times.
- Role of the placenta and umbilical cord.
- Parturition in terms of dilation, expulsion and placental.
- Pre- and post-natal check-ups, including routine screening, six-week check of the baby, mother's health check.

B3 Contraceptive methods and their health implications

- Oral, injection and implanted use of hormones to prevent pregnancy, physical barriers, emergency contraception, male and female sterilisation.
- Health workers' involvement in birth control, including giving advice, awareness of contraindications, awareness of social, welfare and other factors affecting a choice of contraception.

Learning aim C: Examine the causes, treatments and impact of infertility on the health of human beings

Learners will examine, through case studies, the causes, treatments and impact of infertility.

C1 Causes of infertility

- Erectile dysfunction.
- Low sperm production or low sperm motility.
- Physical problems, including blockage of sperm transport, damage caused by STDs.
- Hormone malfunctions.
- Antisperm antibodies.
- Effects of menopause.
- Hypo/hyperthyroidism.
- Problems with ovulation.
- Damage to fallopian tubes/cervix/uterus.

C2 Potential treatments for infertility

- Diagnosis of infertility, including urine/blood tests, physical examination, cervical and tissue samples, use of laparoscopy/x-ray hysterosalpingogram (HSG), ultrasound.
- Sperm donation.
- Artificial insemination (AI).
- In vitro fertilisation (IVF).
- Hormone replacement therapy.
- Induction of ovulation.
- Antibiotics if an infection is diagnosed, such as a sexually transmitted disease (STD).

C3 The impact of infertility on the health and wellbeing of humans

- Levels of infertility in the UK compared to other countries, to include 'developed' and 'developing' countries.
- Levels of infertility in males and females.
- Psychological effect of infertility, such as depression, non-fulfilment of a wish for a baby, anxiety, stress.
- Pressures of society to reproduce.
- Effects of infertility on relationships in different societies.

Assessment criteria

Pass	Merit	Distinction
Learning aim A: Understand the anatomy and physiology of the human reproductive system		
<p>A.P1 Describe the structure of the male and female human reproductive systems in terms of their anatomy and physiology.</p> <p>A.P2 Explain the complete female reproductive cycle and the male cycle.</p>	<p>A.M1 Analyse the functions of the structures of the male and female human reproductive systems.</p>	<p>A.D1 Evaluate the role of the reproductive organs and the physiological changes occurring at male and female puberty.</p>
Learning aim B: Understand the role of hormones in the regulation and control of the reproductive system		
<p>B.P3 Explain the stages in gamete production, foetal development and parturition.</p> <p>B.P4 Explain contraceptive methods and their health implications.</p>	<p>B.M2 Analyse the role of hormones and the effects of different contraceptive methods in human reproduction and conception.</p>	<p>B.D2 Evaluate the role of hormones in humans and the effects of different contraceptive methods on human fertility and conception.</p>
Learning aim C: Examine the causes, treatments and impact of infertility on the health of human beings		
<p>C.P5 Explain the causes and treatments of infertility.</p> <p>C.P6 Explain how infertility can affect the health and wellbeing of humans.</p>	<p>C.M3 Analyse how infertility treatments are tailored to specific fertility problems.</p> <p>C.M4 Analyse the effects of infertility on the interrelationships between humans and their societies.</p>	<p>C.D3 Evaluate the causes of infertility and justify the effectiveness of associated fertility treatments and their impact on the wellbeing of humans and their societies.</p>

Essential information for assignments

The recommended structure of assessment is shown in the unit summary along with suitable forms of evidence. *Section 6* gives information on setting assignments and there is further information on our website.

There is a maximum number of three summative assignments for this unit and the relationship of the learning aims and criteria is:

Learning aim: A (A.P1, A.P2, A.M1, A.D1)

Learning aim: B (B.P3, B.P4, B.M2, B.D2)

Learning aim: C (C.P5, C.P6, C.M3, C.M4, C.D3)

Further information for teachers and assessors

Resource requirements

For this unit, learners must have access to a suitably equipped laboratory so that they can carry out practical activities. The laboratory should include microscopes etc to view prepared slides and micrographs. There should also be models that show the structure of the human reproductive systems, and video materials that can show conception/contraception etc. It is expected that contraception will be dealt with scientifically in relation to healthcare and the choices made by people.

Learners will need access to a variety of research material associated with this topic. The teacher should guide them to appropriate online sites that can be used, along with medical and healthcare documents and books.

Essential information for assessment decisions

Learning aim A

For distinction standard, learners must show in their evaluation that they understand the processes involved in male and female puberty. They should include internal changes to the reproductive organs as well as the external alterations to a person's physical appearance. Learners will have researched data to show differences, such as when puberty starts in males and females, along with external factors such as health, environment etc. Learners can use charts and graphs to help in their evaluation. They will use the correct terminology and their evaluation will be accurate in terms of the evidence they present. Their summary must reflect the evidence that they have presented.

For merit standard, learners will analyse the specialisation shown by reproductive organs in relation to their function. Correct and accurate terminology will be used throughout. Learners may use annotated diagrams to show the organs, along with diagrams of the cells/tissues and then analyse their roles, for example the ovary and its cell structure could be shown along with which cells are receptive to which hormones.

For pass standard, learners will use relevant annotated diagrams and textual descriptions to provide enough detail that the structures and relevant functions can be identified as being accurate in terms of the male and female reproductive systems and their functions. The explanation of the female reproductive cycle must include details of menstruation, fertilisation and conception using correct and relevant biological terms. This could be a mixture of annotated diagrams and textual descriptions.

Learning aim B

For distinction standard, learners must show in their evaluation that they understand the various contraceptive measures available and their success rates in preventing fertilisation. They will understand that contraceptive methods may have other effects besides preventing fertilisation of an ovum by a sperm, for example chemical methods such as different types of the 'pill' having longer-term effects on fertility in some females. Charts, diagrams and graphs can be used to support their reports. It is expected that any conclusions drawn will be supported by such data. Lines of reasoning will be well developed and skilful, and correct terminology will be used.

For merit standard, learners must show in their analysis that they understand the role of hormones in terms of targeting specialised tissues. Part of the analysis needs to include the effect of the hormone on its target tissue and how it interacts with other reproductive processes.

It is not sufficient for learners to present a chart of hormones and the reproductive organs they target or to present detailed, annotated feedback diagrams to illustrate the points made; they must show analysis of the hormones mentioned in terms of, for example, their specificity may also be highlighted.

As part of this process, learners must be able to show how the different methods of contraception can prevent fertilisation whether they be physical, such as condoms, or chemical, such as pills. Again, correct terminology must be used throughout.

For pass standard, learners will explain the reproduction process including the hormonal control of gamete release and the development of the fertilised egg until it reaches full term and is born. Learners should show that they know the embryonic period is the first two months during which the principal organs are present and the placenta begins to function. This is followed by the foetal period, and the main changes for months three to nine should be demonstrated, for example month three: eyelids fused, external ears present, appendages form, nails develop, heartbeat detectable. Learners can use annotated diagrams or other suitable methods such as charts to show some details of primary germ layers and what they give rise to.

A clinical explanation of contraceptive methods should be given in any suitable format. Technically-correct terminology should be used. Learners must show knowledge of the health implications of the contraceptives they explain. There is no requirement for any judgements to be made either about contraception or its use. Learners will use terminology in the correct context.

Learning aim C

For distinction standard, learners must present an evaluation of fertility treatment that shows they have understood what infertility means and its impact on all those concerned. They will show the causes of infertility, relate them to the treatments available and then provide evidence of their effectiveness. Data would be expected to be included in the evaluation in order to back up learners' conclusions.

For merit standard, learners will need to show that they understand the basis of different fertility problems in order to analyse how treatments are modified to suit the fertility problem. For example, poor ovulation may result in targeted chemical treatment to increase ovulation rates.

Learners will be expected to show how infertility in different societies and cultures affects the people concerned. They should be able to explain how societal pressure can impact on people's relationships, including those with extended families. An appreciation should be shown about how society views infertility. Coherent analyses and explanations must be demonstrated using the correct terminology.

For pass standard, learners could give a factual list of infertility causes and their associated treatments. This could be given as a chart but correct and accurate terminology must be used. The description regarding infertility and its impact needs to show the research that learners have carried out and some facts and figures to back up the work. Learners should be able to describe how infertility can affect people.

Links to other units

This unit links to:

- Unit 1: Principles of Applied Human Biology
- Unit 4: Functional Physiology.

Employer involvement

This unit would benefit from employer involvement in the form of:

- a local fertility clinic, which may be able to provide a visiting speaker to give information relating to reasons for infertility and possible treatment options
- an endocrinologist to discuss with learners the work they do, the importance of hormones and the reproductive systems, and the effects of imbalance within them
- a visit from a sexual health nurse who could bring in different contraception.

4 Planning your programme

How do I choose the right BTEC National qualification for my learners?

BTEC Nationals come in a range of sizes, each with a specific purpose. You will need to assess learners very carefully to ensure that they start on the right size of qualification to fit into their 16–19 study programme, and that they take the right pathways or optional units that allow them to progress to the next stage.

Some learners may want to take a number of complementary qualifications or keep their progression options open. These learners may be suited to taking a BTEC National Certificate or Extended Certificate.

As a centre, you may want to teach learners who are taking different qualifications together. You may also wish to transfer learners between programmes to meet changes in their progression needs. You should check the qualification structures and unit combinations carefully as there is no exact match among the different sizes. You may find that learners need to complete more than the minimum number of units when transferring.

When learners are recruited, you need to give them accurate information on the title and focus of the qualification for which they are studying.

Is there a learner entry requirement?

As a centre it is your responsibility to ensure that learners who are recruited have a reasonable expectation of success on the programme. There are no formal entry requirements but we expect learners to have qualifications at or equivalent to Level 2.

Learners are most likely to succeed if they have:

- five GCSEs at good grades and/or
- BTEC qualification(s) at Level 2
- achievement in English and mathematics through GCSE or Functional Skills.

Learners may demonstrate ability to succeed in various ways. For example, learners may have relevant work experience or specific aptitude shown through diagnostic tests or non-educational experience.

What is involved in becoming an approved centre?

All centres must be approved before they can offer these qualifications – so that they are ready to assess learners and so that we can provide the support that is needed. Further information is given in *Section 8*.

What level of sector knowledge is needed to teach these qualifications?

We do not set any requirements for teachers but recommend that centres assess the overall skills and knowledge of the teaching team to ensure that they are relevant and up to date. This will give learners a rich programme to prepare them for employment in the sector.

What resources are required to deliver these qualifications?

As part of your centre approval you will need to show that the necessary material resources and work spaces are available to deliver BTEC Nationals. For some units, specific resources are required. This is indicated in the units.

How can myBTEC help with planning for these qualifications?

myBTEC is an online toolkit that supports the delivery, assessment and quality assurance of BTECs in centres. It supports teachers with activities, such as choosing a valid combination of units, creating assignment briefs and creating assessment plans. For further information see *Section 10*.

Which modes of delivery can be used for these qualifications?

You are free to deliver BTEC Nationals using any form of delivery that meets the needs of your learners. We recommend making use of a wide variety of modes, including direct instruction in classrooms or work environments, investigative and practical work, group and peer work, private study and e-learning.

What are the recommendations for employer involvement?

BTEC Nationals are vocational qualifications and, as an approved centre, you are encouraged to work with employers on the design, delivery and assessment of the course to ensure that learners have a programme of study that is engaging and relevant and that equips them for progression. There are suggestions in many of the units about how employers could become involved in delivery and/or assessment but these are not intended to be exhaustive and there will be other possibilities at local level.

What support is available?

We provide a wealth of support materials, including curriculum plans, delivery guides, authorised assignment briefs, additional papers for external assessments and examples of marked learner work.

You will be allocated a Standards Verifier early on in the planning stage to support you with planning your assessments. There will be extensive training programmes as well as support from our Subject Advisor team.

For further details see *Section 10*.

How will my learners become more employable through these qualifications?

BTEC Nationals are mapped to relevant occupational standards (see *Appendix 1*).

Employability skills, such as team working and entrepreneurialism, and practical hands-on skills have been built into the design of the learning aims and content. This gives you the opportunity to use relevant contexts, scenarios and materials to enable learners to develop a portfolio of evidence that demonstrates the breadth of their skills and knowledge in a way that equips them for employment.

5 Assessment structure and external assessment

Introduction

BTEC Nationals are assessed using a combination of *internal assessments*, which are set and marked by teachers, and *external assessments* which are set and marked by Pearson:

- mandatory units have a combination of internal and external assessments
- all optional units are internally assessed.

We have taken great care to ensure that the assessment method chosen is appropriate to the content of the unit and in line with requirements from employers and higher education.

In developing an overall plan for delivery and assessment for the programme, you will need to consider the order in which you deliver units, whether delivery is over short or long periods and when assessment can take place. Some units are defined as synoptic units (see *Section 2*). Normally, a synoptic assessment is one that a learner would take later in a programme and in which they will be expected to apply learning from a range of units. Synoptic units may be internally or externally assessed. Where a unit is externally assessed you should refer to the sample assessment materials (SAMs) to identify where there is an expectation that learners draw on their wider learning. For internally-assessed units, you must plan the assignments so that learners can demonstrate learning from across their programme. A unit may be synoptic in one qualification and not another because of the relationship it has to the rest of the qualification.

We have addressed the need to ensure that the time allocated to final assessment of internal and external units is reasonable so that there is sufficient time for teaching and learning, formative assessment and development of transferable skills.

In administering internal and external assessment, the centre needs to be aware of the specific procedures and policies that apply, for example to registration, entries and results. An overview with signposting to relevant documents is given in *Section 7*.

Internal assessment

Our approach to internal assessment for these qualifications will be broadly familiar to experienced centres. It offers flexibility in how and when you assess learners, provided that you meet assessment and quality assurance requirements. You will need to take account of the requirements of the unit format, which we explain in *Section 3*, and the requirements for delivering assessment given in *Section 6*.

External assessment

A summary of the external assessment for this qualification is given in *Section 2*. You should check this information carefully, together with the unit specification and the sample assessment materials, so that you can timetable learning and assessment periods appropriately.

Learners must be prepared for external assessment by the time they undertake it. In preparing learners for assessment you will want to take account of required learning time, the relationship with other external assessments and opportunities for retaking. You should ensure that learners are not entered for unreasonable amounts of external assessment in one session. Learners may resit an external assessment to obtain a higher grade of near pass or above. If a learner has more than one attempt, then the best result will be used for qualification grading, up to the permitted maximum. It is unlikely that learners will need to or benefit from taking all assessments twice so you are advised to plan appropriately. Some assessments are synoptic and learners are likely to perform best if these assessments are taken towards the end of the programme.

Key features of external assessment of the BTEC Level 3 National Extended Certificate in Applied Human Biology

In applied human biology, after consultation with stakeholders, we have developed the following:

- *Unit 1: Principles of Applied Human Biology*, an exam-based assessment, in which learners will be asked to respond to a range of different question-types, including multiple-choice, calculations, short-answer, and extended open-response questions demonstrating their knowledge and understanding of key areas of applied human biology. This assessment covers the biological principles that underpin applied human biology. Learners will analyse, interpret and evaluate information and data in realistic health science-related contexts.
- *Unit 3: Human Biology and Health Initiatives*, a task-based assessment in which learners will demonstrate their understanding and skills in researching and evaluating the impact of health science issues and how they are discussed in media articles and health science reports. Learners will develop research and critical thinking skills by learning how to assess the reliability of sources of published scientific information.

Units

The externally-assessed units have a specific format which we explain in *Section 3*. The content of units will be sampled across external assessments over time, through appropriate papers and tasks. The ways in which learners are assessed are shown through the assessment outcomes and grading descriptors. External assessments are marked and awarded using the grade descriptors. The grades available are Distinction (D), Merit (M), Pass (P) and Near Pass (N). The Near Pass (N) grade gives learners credit below a Pass, where they have demonstrated evidence of positive performance which is worth more than an unclassified result but not yet at the Pass standard.

Sample assessment materials

Each externally-assessed unit has a set of sample assessment materials (SAMs) that accompanies this specification. The SAMs are there to give you an example of what the external assessment will look like in terms of the feel and level of demand of the assessment. In the case of units containing synoptic assessment, the SAMs will also show where learners are expected to select and apply from across the programme.

The SAMs show the range of possible question types that may appear in the actual assessments. They give you a good indication of how the assessments will be structured. While SAMs can be used for practice with learners as with any assessment, the content covered and specific details of the questions asked will change in each assessment.

A copy of each of these assessments can be downloaded from our website. To allow your learners further opportunities for practice, an additional sample of each of the Pearson-set units will be available before the first sitting of the assessment.

6 Internal assessment

This section gives an overview of the key features of internal assessment and how you, as an approved centre, can offer it effectively. The full requirements and operational information are given in the *Pearson Quality Assurance Handbook*. All members of the assessment team need to refer to this document.

For BTEC Nationals it is important that you can meet the expectations of stakeholders and the needs of learners by providing a programme that is practical and applied. Centres can tailor programmes to meet local needs and use links with local employers and the wider vocational sector.

When internal assessment is operated effectively it is challenging, engaging, practical and up to date. It must also be fair to all learners and meet national standards.

Principles of internal assessment

Assessment through assignments

For internally-assessed units, the format of assessment is an assignment taken after the content of the unit, or part of the unit if several assignments are used, has been delivered. An assignment may take a variety of forms, including practical and written types. An assignment is a distinct activity completed independently by learners that is separate from teaching, practice, exploration and other activities that learners complete with direction from, and formative assessment by, teachers.

An assignment is issued to learners as an assignment brief with a defined start date, a completion date and clear requirements for the evidence that they need to provide. There may be specific observed practical components during the assignment period. Assignments can be divided into tasks and may require several forms of evidence. A valid assignment will enable a clear and formal assessment outcome based on the assessment criteria.

Assessment decisions through applying unit-based criteria

Assessment decisions for BTEC Nationals are based on the specific criteria given in each unit and set at each grade level. To ensure that standards are consistent in the qualification and across the suite as a whole, the criteria for each unit have been defined according to a framework. The way in which individual units are written provides a balance of assessment of understanding, practical skills and vocational attributes appropriate to the purpose of qualifications.

The assessment criteria for a unit are hierarchical and holistic. For example, if an M criterion requires the learner to show 'analysis' and the related P criterion requires the learner to 'explain', then to satisfy the M criterion a learner will need to cover both 'explain' and 'analyse'. The unit assessment grid shows the relationships among the criteria so that assessors can apply all the criteria to the learner's evidence at the same time. In *Appendix 2* we have set out a definition of terms that assessors need to understand.

Assessors must show how they have reached their decisions using the criteria in the assessment records. When a learner has completed all the assessment for a unit then the assessment team will give a grade for the unit. This is given simply according to the highest level for which the learner is judged to have met all the criteria. Therefore:

- to achieve a Distinction, a learner must have satisfied all the Distinction criteria (and therefore the Pass and Merit criteria); these define outstanding performance across the unit as a whole
- to achieve a Merit, a learner must have satisfied all the Merit criteria (and therefore the Pass criteria) through high performance in each learning aim
- to achieve a Pass, a learner must have satisfied all the Pass criteria for the learning aims, showing coverage of the unit content and therefore attainment at Level 3 of the national framework.

The award of a Pass is a defined level of performance and cannot be given solely on the basis of a learner completing assignments. Learners who do not satisfy the Pass criteria should be reported as Unclassified.

The assessment team

It is important that there is an effective team for internal assessment. There are three key roles involved in implementing assessment processes in your centre, each with different interrelated responsibilities, the roles are listed below. Full information is given in the *Pearson Quality Assurance Handbook*.

- The Lead Internal Verifier (the Lead IV) has overall responsibility for the programme, its assessment and internal verification to meet our requirements, record keeping and liaison with the Standards Verifier. The Lead IV registers with Pearson annually. The Lead IV acts as an assessor, supports the rest of the assessment team, makes sure that they have the information they need about our assessment requirements and organises training, making use of our guidance and support materials.
- Internal Verifiers (IVs) oversee all assessment activity in consultation with the Lead IV. They check that assignments and assessment decisions are valid and that they meet our requirements. IVs will be standardised by working with the Lead IV. Normally, IVs are also assessors but they do not verify their own assessments.
- Assessors set or use assignments to assess learners to national standards. Before taking any assessment decisions, assessors participate in standardisation activities led by the Lead IV. They work with the Lead IV and IVs to ensure that the assessment is planned and carried out in line with our requirements.

Effective organisation

Internal assessment needs to be well organised so that the progress of learners can be tracked and so that we can monitor that assessment is being carried out in line with national standards. We support you through, for example, providing training materials and sample documentation. Our online myBTEC service can help support you in planning and record keeping. Further information on using myBTEC can be found in *Section 10* and on our website.

It is particularly important that you manage the overall assignment programme and deadlines to make sure that learners are able to complete assignments on time.

Learner preparation

To ensure that you provide effective assessment for your learners, you need to make sure that they understand their responsibilities for assessment and the centre's arrangements.

From induction onwards, you will want to ensure that learners are motivated to work consistently and independently to achieve the requirements of the qualifications. Learners need to understand how assignments are used, the importance of meeting assignment deadlines and that all the work submitted for assessment must be their own.

You will need to give learners a guide that explains how assignments are used for assessment, how assignments relate to the teaching programme and how learners should use and reference source materials, including what would constitute plagiarism. The guide should also set out your approach to operating assessment, such as how learners must submit work and request extensions.

Setting effective assignments

Setting the number and structure of assignments

In setting your assignments, you need to work with the structure of assignments shown in the *Essential information for assignments* section of a unit. This shows the structure of the learning aims and criteria that you must follow and the recommended number of assignments that you should use. For some units we provide authorised assignment briefs. For all the units we give you suggestions on how to create suitable assignments. You can find these materials along with this specification on our website. In designing your own assignment briefs you should bear in mind the following points.

- The number of assignments for a unit must not exceed the number shown in *Essential information for assignments*. However, you may choose to combine assignments, for example to create a single assignment for the whole unit.
- You may also choose to combine all or parts of different units into single assignments, provided that all units and all their associated learning aims are fully addressed in the programme overall. If you choose to take this approach, you need to make sure that learners are fully prepared so that they can provide all the required evidence for assessment and that you are able to track achievement in the records.
- A learning aim must always be assessed as a whole and must not be split into two or more tasks.
- The assignment must be targeted to the learning aims but the learning aims and their associated criteria are not tasks in themselves. Criteria are expressed in terms of the outcome shown in the evidence.
- For units containing synoptic assessment, the planned assignments must allow learners to select and apply their learning using appropriate self-management of tasks.
- You do not have to follow the order of the learning aims of a unit in setting assignments but later learning aims often require learners to apply the content of earlier learning aims and they may require learners to draw their learning together.
- Assignments must be structured to allow learners to demonstrate the full range of achievement at all grade levels. Learners need to be treated fairly by being given the opportunity to achieve a higher grade if they have the ability.
- As assignments provide a final assessment, they will draw on the specified range of teaching content for the learning aims. The specified content is compulsory. The evidence for assessment need not cover every aspect of the teaching content as learners will normally be given particular examples, case studies or contexts in their assignments. For example, if a learner is carrying out one practical performance, or an investigation of one organisation, then they will address all the relevant range of content that applies in that instance.

Providing an assignment brief

A good assignment brief is one that, through providing challenging and realistic tasks, motivates learners to provide appropriate evidence of what they have learned.

An assignment brief should have:

- a vocational scenario, this could be a simple situation or a full, detailed set of vocational requirements that motivates the learner to apply their learning through the assignment
- clear instructions to the learner about what they are required to do, normally set out through a series of tasks
- an audience or purpose for which the evidence is being provided
- an explanation of how the assignment relates to the unit(s) being assessed.

Forms of evidence

BTEC Nationals have always allowed for a variety of forms of evidence to be used, provided that they are suited to the type of learning aim being assessed. For many units, the practical demonstration of skills is necessary and for others, learners will need to carry out their own research and analysis. The units give you information on what would be suitable forms of evidence to give learners the opportunity to apply a range of employability or transferable skills. Centres may choose to use different suitable forms for evidence to those proposed. Overall, learners should be assessed using varied forms of evidence.

Full definitions of types of assessment are given in *Appendix 2*. These are some of the main types of assessment:

- written reports
- projects
- time-constrained practical assessments with observation records and supporting evidence
- recordings of performance
- sketchbooks, working logbooks, reflective journals
- presentations with assessor questioning.

The form(s) of evidence selected must:

- allow the learner to provide all the evidence required for the learning aim(s) and the associated assessment criteria at all grade levels
- allow the learner to produce evidence that is their own independent work
- allow a verifier to independently reassess the learner to check the assessor's decisions.

For example, when you are using performance evidence, you need to think about how supporting evidence can be captured through recordings, photographs or task sheets.

Centres need to take particular care that learners are enabled to produce independent work.

For example, if learners are asked to use real examples, then best practice would be to encourage them to use their own or to give the group a number of examples that can be used in varied combinations.

Making valid assessment decisions

Authenticity of learner work

Once an assessment has begun, learners must not be given feedback on progress towards fulfilling the targeted criteria.

An assessor must assess only learner work that is authentic, i.e. learners' own independent work. Learners must authenticate the evidence that they provide for assessment through signing a declaration stating that it is their own work.

Assessors must ensure that evidence is authentic to a learner through setting valid assignments and supervising them during the assessment period. Assessors must take care not to provide direct input, instructions or specific feedback that may compromise authenticity.

Assessors must complete a declaration that:

- the evidence submitted for this assignment is the learner's own
- the learner has clearly referenced any sources used in the work
- they understand that false declaration is a form of malpractice.

Centres can use Pearson templates or their own templates to document authentication.

During assessment, an assessor may suspect that some or all of the evidence from a learner is not authentic. The assessor must then take appropriate action using the centre's policies for malpractice. Further information is given in *Section 7*.

Making assessment decisions using criteria

Assessors make judgements using the criteria. The evidence from a learner can be judged using all the relevant criteria at the same time. The assessor needs to make a judgement against each criterion that evidence is present and sufficiently comprehensive. For example, the inclusion of a concluding section may be insufficient to satisfy a criterion requiring 'evaluation'.

Assessors should use the following information and support in reaching assessment decisions:

- the *Essential information for assessment decisions* section in each unit gives examples and definitions related to terms used in the criteria
- the explanation of key terms in *Appendix 2*
- examples of assessed work provided by Pearson
- your Lead IV and assessment team's collective experience, supported by the standardisation materials we provide.

Pass and Merit criteria relate to individual learning aims. The Distinction criteria as a whole relate to outstanding performance across the unit. Therefore, criteria may relate to more than one learning aim (for example A.D1) or to several learning aims (for example DE.D3). Distinction criteria make sure that learners have shown that they can perform consistently at an outstanding level across the unit and/or that they are able to draw learning together across learning aims.

Dealing with late completion of assignments

Learners must have a clear understanding of the centre policy on completing assignments by the deadlines that you give them. Learners may be given authorised extensions for legitimate reasons, such as illness at the time of submission, in line with your centre policies.

For assessment to be fair, it is important that learners are all assessed in the same way and that some learners are not advantaged by having additional time or the opportunity to learn from others. Therefore, learners who do not complete assignments by your planned deadline or the authorised extension deadline may not have the opportunity to subsequently resubmit.

If you accept a late completion by a learner, then the assignment should be assessed normally when it is submitted using the relevant assessment criteria.

Issuing assessment decisions and feedback

Once the assessment team has completed the assessment process for an assignment, the outcome is a formal assessment decision. This is recorded formally and reported to learners.

The information given to the learner:

- must show the formal decision and how it has been reached, indicating how or where criteria have been met
- may show why attainment against criteria has not been demonstrated
- must not provide feedback on how to improve evidence
- must be validated by an IV before it is given to the learner.

Resubmission of improved evidence

An assignment provides the final assessment for the relevant learning aims and is normally a final assessment decision, except where the Lead IV approves one opportunity to resubmit improved evidence based on the completed assignment brief.

The Lead IV has the responsibility to make sure that resubmission is operated fairly. This means:

- checking that a learner can be reasonably expected to perform better through a second submission, for example that the learner has not performed as expected
- making sure that giving a further opportunity can be done in such a way that it does not give an unfair advantage over other learners, for example through the opportunity to take account of feedback given to other learners
- checking that the assessor considers that the learner will be able to provide improved evidence without further guidance and that the original evidence submitted remains valid.

Once an assessment decision has been given to the learner, the resubmission opportunity must have a deadline within 15 working days in the same academic year.

A resubmission opportunity must not be provided where learners:

- have not completed the assignment by the deadline without the centre's agreement
- have submitted work that is not authentic.

Retake of internal assessment

A learner who has not achieved the level of performance required to pass the relevant learning aims after resubmission of an assignment may be offered a single retake opportunity using a new assignment. The retake may only be achieved at a Pass.

The Lead Internal Verifier must only authorise a retake of an assignment in exceptional circumstances where they believe it is necessary, appropriate and fair to do so. For further information on offering a retake opportunity, you should refer to the *BTEC Centre Guide to Internal Assessment*. We provide information on writing assignments for retakes on our website (www.btec.co.uk/keydocuments).

Planning and record keeping

For internal processes to be effective, an assessment team needs to be well organised and keep effective records. The centre will also work closely with us so that we can quality assure that national standards are being satisfied. This process gives stakeholders confidence in the assessment approach.

The Lead IV must have an assessment plan, produced as a spreadsheet or using myBTEC.

When producing a plan, the assessment team may wish to consider:

- the time required for training and standardisation of the assessment team
- the time available to undertake teaching and carry out assessment, taking account of when learners may complete external assessments and when quality assurance will take place
- the completion dates for different assignments
- who is acting as IV for each assignment and the date by which the assignment needs to be verified
- setting an approach to sampling assessor decisions through internal verification that covers all assignments, assessors and a range of learners
- how to manage the assessment and verification of learners' work so that they can be given formal decisions promptly
- how resubmission opportunities can be scheduled.

The Lead IV will also maintain records of assessment undertaken. The key records are:

- verification of assignment briefs
- learner authentication declarations
- assessor decisions on assignments, with feedback given to learners
- verification of assessment decisions.

Examples of records and further information are given in the *Pearson Quality Assurance Handbook*.

7 Administrative arrangements

Introduction

This section focuses on the administrative requirements for delivering a BTEC qualification. It will be of value to Quality Nominees, Lead IVs, Programme Leaders and Examinations Officers.

Learner registration and entry

Shortly after learners start the programme of learning, you need to make sure that they are registered for the qualification and that appropriate arrangements are made for internal and external assessment. You need to refer to the *Information Manual* for information on making registrations for the qualification and entries for external assessments.

Learners can be formally assessed only for a qualification on which they are registered. If learners' intended qualifications change, for example if a learner decides to choose a different pathway specialism, then the centre must transfer the learner appropriately.

Access to assessment

Both internal and external assessments need to be administered carefully to ensure that all learners are treated fairly, and that results and certification are issued on time to allow learners to progress to chosen progression opportunities.

Our equality policy requires that all learners should have equal opportunity to access our qualifications and assessments, and that our qualifications are awarded in a way that is fair to every learner. We are committed to making sure that:

- learners with a protected characteristic are not, when they are undertaking one of our qualifications, disadvantaged in comparison to learners who do not share that characteristic
- all learners achieve the recognition they deserve for undertaking a qualification and that this achievement can be compared fairly to the achievement of their peers.

Further information on access arrangements can be found in the Joint Council for Qualifications (JCQ) document *Access Arrangements, Reasonable Adjustments and Special Consideration for General and Vocational Qualifications*.

Administrative arrangements for internal assessment

Records

You are required to retain records of assessment for each learner. Records should include assessments taken, decisions reached and any adjustments or appeals. Further information can be found in the *Information Manual*. We may ask to audit your records so they must be retained as specified.

Reasonable adjustments to assessment

A reasonable adjustment is one that is made before a learner takes an assessment to ensure that they have fair access to demonstrate the requirements of the assessments. You are able to make adjustments to internal assessments to take account of the needs of individual learners. In most cases this can be achieved through a defined time extension or by adjusting the format of evidence. We can advise you if you are uncertain as to whether an adjustment is fair and reasonable. You need to plan for time to make adjustments if necessary.

Further details on how to make adjustments for learners with protected characteristics are given on our website in the document *Supplementary guidance for reasonable adjustment and special consideration in vocational internally-assessed units*.

Special consideration

Special consideration is given after an assessment has taken place for learners who have been affected by adverse circumstances, such as illness. You must operate special consideration in line with our policy (see previous paragraph). You can provide special consideration related to the period of time given for evidence to be provided or for the format of the assessment if it is equally valid. You may not substitute alternative forms of evidence to that required in a unit, or omit the application of any assessment criteria to judge attainment. Pearson can consider applications for special consideration in line with the policy.

Appeals against assessment

Your centre must have a policy for dealing with appeals from learners. These appeals may relate to assessment decisions being incorrect or assessment not being conducted fairly. The first step in such a policy could be a consideration of the evidence by a Lead IV or other member of the programme team. The assessment plan should allow time for potential appeals after assessment decisions have been given to learners. If there is an appeal by a learner, you must document the appeal and its resolution. Learners have a final right of appeal to Pearson but only if the procedures that you have put in place have not been followed. Further details are given in the document *Enquiries and appeals about Pearson vocational qualifications and end point assessment policy*.

Administrative arrangements for external assessment

Entries and resits

For information on the timing of assessment and entries, please refer to the annual examinations timetable on our website.

Access arrangements requests

Access arrangements are agreed with Pearson before an assessment. They allow students with special educational needs, disabilities or temporary injuries to:

- access the assessment
- show what they know and can do without changing the demands of the assessment.

Access arrangements should always be processed at the time of registration. Learners will then know what type of arrangements are available in place for them.

Granting reasonable adjustments

For external assessment, a reasonable adjustment is one that we agree to make for an individual learner. A reasonable adjustment is defined for the individual learner and informed by the list of available access arrangements.

Whether an adjustment will be considered reasonable will depend on a number of factors, to include:

- the needs of the learner with the disability
- the effectiveness of the adjustment
- the cost of the adjustment; and
- the likely impact of the adjustment on the learner with the disability and other learners.

Adjustment may be judged unreasonable and not approved if it involves unreasonable costs, timeframes or affects the integrity of the assessment.

Special consideration requests

Special consideration is an adjustment made to a learner's mark or grade after an external assessment to reflect temporary injury, illness or other indisposition at the time of the assessment. An adjustment is made only if the impact on the learner is such that it is reasonably likely to have had a material effect on that learner being able to demonstrate attainment in the assessment.

Centres are required to notify us promptly of any learners who they believe have been adversely affected and request that we give special consideration. Further information can be found in the special requirements section on our website.

Conducting external assessments

Centres must make arrangements for the secure delivery of external assessments. External assessments for BTEC qualifications include examinations, set tasks and performance.

Each external assessment has a defined degree of control under which it must take place. Some external assessments may have more than one part and each part may have a different degree of control. We define degrees of control as follows.

High control

This is the completion of assessment in formal invigilated examination conditions.

Medium control

This is completion of assessment, usually over a longer period of time, which may include a period of controlled conditions. The controlled conditions may allow learners to access resources, prepared notes or the internet to help them complete the task.

Low control

These are activities completed without direct supervision. They may include research, preparation of materials and practice. The materials produced by learners under low control will not be directly assessed.

Further information on responsibilities for conducting external assessment is given in the document *Instructions for Conducting External Assessments*, available on our website.

Dealing with malpractice in assessment

Malpractice means acts that undermine the integrity and validity of assessment, the certification of qualifications, and/or that may damage the authority of those responsible for delivering the assessment and certification.

Pearson does not tolerate actions (or attempted actions) of malpractice by learners, centre staff or centres in connection with Pearson qualifications. Pearson may impose penalties and/or sanctions on learners, centre staff or centres where incidents (or attempted incidents) of malpractice have been proven.

Malpractice may arise or be suspected in relation to any unit or type of assessment within the qualification. For further details regarding malpractice and advice on preventing malpractice by learners, please see Pearson's *Centre guidance: Dealing with malpractice and maladministration in vocational qualifications*, available on our website.

The procedures we ask you to adopt vary between units that are internally-assessed and those that are externally assessed.

Internally-assessed units

Centres are required to take steps to prevent malpractice and to investigate instances of suspected malpractice. Learners must be given information that explains what malpractice is for internal assessment and how suspected incidents will be dealt with by the centre. The *Centre Guidance: Dealing with Malpractice* document gives full information on the actions we expect you to take.

Pearson may conduct investigations if we believe that a centre is failing to conduct internal assessment according to our policies. The above document gives further information, examples and details the penalties and sanctions that may be imposed.

In the interests of learners and centre staff, centres need to respond effectively and openly to all requests relating to an investigation into an incident of suspected malpractice.

Externally-assessed units

External assessment means all aspects of units that are designated as external in this specification, including preparation for tasks and performance. For these assessments, centres must follow the JCQ procedures set out in the latest version of *JCQ Suspected Malpractice in Examinations and Assessments Policies and Procedures* (www.jcq.org.uk).

In the interests of learners and centre staff, centres need to respond effectively and openly to all requests relating to an investigation into an incident of suspected malpractice.

Learner malpractice

Heads of Centres are required to report incidents of any suspected learner malpractice that occur during Pearson external assessments. We ask that centres do so by completing a *JCQ Form M1* (available at www.jcq.org.uk/exams-office/malpractice) and emailing it and any accompanying documents (signed statements from the learner, invigilator, copies of evidence, etc.) to the Investigations Team at candidatemalpractice@pearson.com. The responsibility for determining appropriate sanctions or penalties to be imposed on learners lies with Pearson.

Learners must be informed at the earliest opportunity of the specific allegation and the centre's malpractice policy, including the right of appeal. Learners found guilty of malpractice may be disqualified from the qualification for which they have been entered with Pearson.

Teacher/centre malpractice

Heads of Centres are required to inform Pearson's Investigations Team of any incident of suspected malpractice by centre staff, before any investigation is undertaken. Heads of centres are requested to inform the Investigations Team by submitting a *JCQ Form M2(a)* (available at www.jcq.org.uk/exams-office/malpractice) with supporting documentation to pqsmalpractice@pearson.com. Where Pearson receives allegations of malpractice from other sources (for example Pearson staff or anonymous informants), the Investigations Team will conduct the investigation directly or may ask the head of centre to assist.

Incidents of maladministration (accidental errors in the delivery of Pearson qualifications that may affect the assessment of learners) should also be reported to the Investigations Team using the same method.

Heads of Centres/Principals/Chief Executive Officers or their nominees are required to inform learners and centre staff suspected of malpractice of their responsibilities and rights; see Section 6.15 of the *JCQ Suspected Malpractice in Examinations and Assessments Policies and Procedures* document.

Pearson reserves the right in cases of suspected malpractice to withhold the issuing of results and/or certificates while an investigation is in progress. Depending on the outcome of the investigation results and/or certificates may be released or withheld.

You should be aware that Pearson may need to suspend certification when undertaking investigations, audits and quality assurances processes. You will be notified within a reasonable period of time if this occurs.

Sanctions and appeals

Where malpractice is proven we may impose sanctions or penalties.

Where learner malpractice is evidenced, penalties may be imposed such as:

- mark reduction for external assessments
- disqualification from the qualification
- being barred from registration for Pearson qualifications for a period of time.

If we are concerned about your centre's quality procedures we may impose sanctions such as:

- working with you to create an improvement action plan
- requiring staff members to receive further training
- placing temporary blocks on your certificates
- placing temporary blocks on registration of learners
- debarring staff members or the centre from delivering Pearson qualifications
- suspending or withdrawing centre approval status.

The centre will be notified if any of these apply.

Pearson has established procedures for centres that are considering appeals against penalties and sanctions arising from malpractice. Appeals against a decision made by Pearson will normally be accepted only from Heads of Centres (on behalf of learners and/or members of staff) and from individual members (in respect of a decision taken against them personally). Further information on appeals can be found in our *Enquiries and appeals about Pearson vocational qualifications and end point assessment policy*, which is on our website. In the initial stage of any aspect of malpractice, please notify the Investigations Team by email via pqsmalpractice@pearson.com who will inform you of the next steps.

Certification and results

Once a learner has completed all the required components for a qualification, even if final results for external assessments have not been issued, then the centre can claim certification for the learner, provided that quality assurance has been successfully completed. For the relevant procedures please refer to our *Information Manual*. You can use the information provided on qualification grading to check overall qualification grades.

Results issue

After the external assessment session, learner results will be issued to centres. The result will be in the form of a grade. You should be prepared to discuss performance with learners, making use of the information we provide and post-results services.

Post-assessment services

Once results for external assessments are issued, you may find that the learner has failed to achieve the qualification or to attain an anticipated grade. It is possible to transfer or reopen registration in some circumstances. The *Information Manual* gives further information.

Changes to qualification requests

Where a learner who has taken a qualification wants to resit an externally-assessed unit to improve their qualification grade, you firstly need to decline their overall qualification grade. You may decline the grade before the certificate is issued. For a learner receiving their results in August, you should decline the grade by the end of September if the learner intends to resit an external assessment.

Additional documents to support centre administration

As an approved centre you must ensure that all staff delivering, assessing and administering the qualifications have access to this documentation. These documents are reviewed annually and are reissued if updates are required.

- *Pearson Quality Assurance Handbook*: this sets out how we will carry out quality assurance of standards and how you need to work with us to achieve successful outcomes.
- *Information Manual*: this gives procedures for registering learners for qualifications, transferring registrations, entering for external assessments and claiming certificates.
- *Lead Examiners' Reports*: these are produced after each series for each external assessment and give feedback on the overall performance of learners in response to tasks or questions set.
- *Instructions for the Conduct of External Assessments (ICEA)*: this explains our requirements for the effective administration of external assessments, such as invigilation and submission of materials.
- *Regulatory policies*: our regulatory policies are integral to our approach and explain how we meet internal and regulatory requirements. We review the regulated policies annually to ensure that they remain fit for purpose. Policies related to this qualification include:
 - adjustments for candidates with disabilities and learning difficulties, access arrangements and reasonable adjustments for general and vocational qualifications
 - age of learners
 - centre guidance for dealing with malpractice
 - recognition of prior learning and process.

This list is not exhaustive and a full list of our regulatory policies can be found on our website.

8 Quality assurance

Centre and qualification approval

As part of the approval process, your centre must make sure that the resource requirements listed below are in place before offering the qualification.

- Centres must have appropriate physical resources (for example equipment, IT, learning materials, teaching rooms) to support the delivery and assessment of the qualification.
- Staff involved in the assessment process must have relevant expertise and/or occupational experience.
- There must be systems in place to ensure continuing professional development for staff delivering the qualification.
- Centres must have in place appropriate health and safety policies relating to the use of equipment by learners.
- Centres must deliver the qualification in accordance with current equality legislation.
- Centres should refer to the teacher guidance section in individual units to check for any specific resources required.

Continuing quality assurance and standards verification

On an annual basis, we produce the *Pearson Quality Assurance Handbook*. It contains detailed guidance on the quality processes required to underpin robust assessment and internal verification.

The key principles of quality assurance are that:

- a centre delivering BTEC programmes must be an approved centre, and must have approval for the programmes or groups of programmes that it is delivering
- the centre agrees, as part of gaining approval, to abide by specific terms and conditions around the effective delivery and quality assurance of assessment; it must abide by these conditions throughout the period of delivery
- Pearson makes available to approved centres a range of materials and opportunities, through online standardisation, intended to exemplify the processes required for effective assessment, and examples of effective standards. Approved centres must use the materials and services to ensure that all staff delivering BTEC qualifications keep up to date with the guidance on assessment
- an approved centre must follow agreed protocols for standardisation of assessors and verifiers, for the planning, monitoring and recording of assessment processes, and for dealing with special circumstances, appeals and malpractice.

The approach of quality-assured assessment is through a partnership between an approved centre and Pearson. We will make sure that each centre follows best practice and employs appropriate technology to support quality-assurance processes, where practicable. We work to support centres and seek to make sure that our quality-assurance processes do not place undue bureaucratic processes on centres. We monitor and support centres in the effective operation of assessment and quality assurance.

The methods we use to do this for BTEC Level 3 include:

- making sure that all centres complete appropriate declarations at the time of approval
- undertaking approval visits to centres
- making sure that centres have effective teams of assessors and verifiers who are trained to undertake assessment
- assessment sampling and verification, through requested samples of assessments, completed assessed learner work and associated documentation
- an overarching review and assessment of a centre's strategy for delivering and quality assuring its BTEC programmes, for example making sure that synoptic units are placed appropriately in the order of delivery of the programme.

Centres that do not fully address and maintain rigorous approaches to delivering, assessing and quality assurance cannot seek certification for individual programmes or for all BTEC Level 3 programmes. An approved centre must make certification claims only when authorised by us and strictly in accordance with requirements for reporting.

Centres that do not comply with remedial action plans may have their approval to deliver qualifications removed.

9 Understanding the qualification grade

Awarding and reporting for the qualification

This section explains the rules that we apply in awarding a qualification and in providing an overall qualification grade for each learner. It shows how all the qualifications in this sector are graded.

The awarding and certification of these qualifications will comply with regulatory requirements.

Eligibility for an award

In order to be awarded a qualification, a learner must complete all units, achieve a Near Pass (N) or above in all external units and a Pass or above in all mandatory units, unless otherwise specified. Please refer to the structure in *Section 2*.

To achieve any qualification grade, learners must:

- complete and **have an outcome** (D, M, P, N or U) for all units in a valid combination
- achieve the **required units at Pass or above** shown in *Section 2* and, for the Extended Diploma, achieve a minimum 900 GLH at Pass or above (or N or above in external units)
- achieve the **minimum number of points** at a grade threshold.

It is the responsibility of a centre to ensure that a correct unit combination is adhered to. Learners who do not achieve the required minimum grade (N or P) in units shown in the structure will not achieve a qualification.

Learners who do not achieve sufficient points for a qualification or who do not achieve all the required units may be eligible to achieve a smaller qualification in the same suite provided they have completed and achieved the correct combination of units and met the appropriate qualification grade points threshold.

Calculation of the qualification grade

The final grade awarded for a qualification represents an aggregation of a learner's performance across the qualification. As the qualification grade is an aggregate of the total performance, there is some element of compensation in that a higher performance in some units may be balanced by a lower outcome in others.

In the event that a learner achieves more than the required number of optional units, the mandatory units along with the optional units with the highest grades will be used to calculate the overall result, subject to the eligibility requirements for that particular qualification title.

BTEC Nationals are Level 3 qualifications and are awarded at the grade ranges shown in the table below.

Qualification	Available grade range
Certificate, Extended Certificate, Foundation Diploma	P to D*
Diploma	PP to D*D*
Extended Diploma	PPP to D*D*D*

The *Calculation of qualification grade* table, shown further on in this section, shows the minimum thresholds for calculating these grades. The table will be kept under review over the lifetime of the qualification. The most up to date table will be issued on our website.

Pearson will monitor the qualification standard and reserves the right to make appropriate adjustments.

Learners who do not meet the minimum requirements for a qualification grade to be awarded will be recorded as Unclassified (U) and will not be certificated. They may receive a Notification of Performance for individual units. The *Information Manual* gives full information.

Points available for internal units

The table below shows the number of **points** available for internal units. For each internal unit, points are allocated depending on the grade awarded.

	Unit size	
	60 GLH	90 GLH
U	0	0
Pass	6	9
Merit	10	15
Distinction	16	24

Points available for external units

Raw marks from the external units will be awarded **points** based on performance in the assessment. The table below shows the **minimum number of points** available for each grade in the external units.

	Unit size	
	90 GLH	120 GLH
U	0	0
Near Pass	6	8
Pass	9	12
Merit	15	20
Distinction	24	32

Pearson will automatically calculate the points for each external unit once the external assessment has been marked and grade boundaries have been set. For more details about how we set grade boundaries in the external assessment please go to our website.

Claiming the qualification grade

Subject to eligibility, Pearson will automatically calculate the qualification grade for your learners when the internal unit grades are submitted and the qualification claim is made. Learners will be awarded qualification grades for achieving the sufficient number of points within the ranges shown in the relevant *Calculation of qualification grade* table for the cohort.

Calculation of qualification grade

Applicable for registration from 1 September 2018.

Certificate		Extended Certificate	
180 GLH		360 GLH	
Grade	Points threshold	Grade	Points threshold
U	0	U	0
Pass	18	P	36
Merit	26	M	52
Distinction	42	D	74
Distinction*	48	D*	90

The table is subject to review over the lifetime of the qualification. The most up-to-date version will be issued on our website.

Examples of grade calculations based on table applicable to registrations from September 2018

Example 1: Achievement of an Extended Certificate with a P grade

	GLH	Type (Int/Ext)	Grade	Unit points
Unit 1	90	Ext	Near Pass	6
Unit 2	90	Int	Pass	9
Unit 3	120	Ext	Merit	20
Unit 4	60	Int	Distinction	16
Totals	360		P	51

The learner has achieved a Near Pass or above in Units 1 and 3 and a Pass or above in Unit 2.

The learner has sufficient points for a P grade.

Example 2: Achievement of an Extended Certificate with a D grade

	GLH	Type (Int/Ext)	Grade	Unit points
Unit 1	90	Ext	Merit	15
Unit 2	90	Int	Merit	15
Unit 3	120	Ext	Distinction	32
Unit 4	60	Int	Distinction	16
Totals	360		D	78

The learner has sufficient points for a D grade.

Example 3: An Unclassified Result for an Extended Certificate

	GLH	Type (Int/Ext)	Grade	Unit points
Unit 1	90	Ext	Merit	15
Unit 2	90	Int	Unclassified	0
Unit 3	120	Ext	Distinction	32
Unit 4	60	Int	Merit	10
Totals	360		U	57

The learner has a U in Unit 2.

The learner has sufficient points for an M but has not met the minimum requirement for a Pass or above in Unit 2.

10 Resources and support

Our aim is to give you a wealth of resources and support to enable you to deliver BTEC National qualifications with confidence. On our website you will find a list of resources to support teaching and learning, and professional development.

Support for setting up your course and preparing to teach

Specification

This **specification** (for teaching from September 2018) includes details on the administration of qualifications and information on all the units for the qualification.

Delivery Guide

This free guide gives you important advice on how to choose the right course for your learners and how to ensure you are fully prepared to deliver the course. It explains the key features of BTEC Nationals (for example employer involvement and employability skills). It also covers guidance on assessment (internal and external) and quality assurance. The guide tells you where you can find further support and gives detailed unit-by-unit delivery guidance. It includes teaching tips and ideas, assessment preparation and suggestions for further resources.

Schemes of work

Free sample schemes of work are provided for each mandatory unit. These are available in Word™ format for ease of customisation.

Curriculum models

These show how the BTECs in the suite fit into a 16–19 study programme, depending on their size and purpose. The models also show where other parts of the programme, such as work experience, maths and English, tutorial time and wider study, fit alongside the programme.

Study skills activities

A range of case studies and activities is provided; they are designed to help learners develop the study skills they need to successfully complete their BTEC course. The case studies and activities are provided in Word™ format for easy customisation.

myBTEC

myBTEC is a free, online toolkit that lets you plan and manage your BTEC provision from one place. It supports the delivery, assessment and quality assurance of BTECs in centres and supports teachers with the following activities:

- checking that a programme is using a valid combination of units
- creating and verifying assignment briefs (including access to a bank of authorised assignment briefs that can be customised)
- creating assessment plans and recording assessment decisions
- tracking the progress of every learner throughout their programme.

To find out more about myBTEC, visit the myBTEC page on the support services section of our website. We will add the new BTEC National specifications to myBTEC as soon as possible.

Support for assessment

Sample assessment materials for externally-assessed units

Sample assessments are available for the Pearson-set units. One copy of each of these assessments can be downloaded from the website/available in print. For each suite, an additional sample for one of the Pearson-set units is also available, allowing your learners further opportunities for practice.

Further sample assessments will be made available through our website on an ongoing basis.

Sample assessment materials for internally-assessed units

We do not prescribe the assessments for the internally-assessed units. Rather, we allow you to set your own, according to your learners' preferences and to link with your local employment profile.

We do provide a service in the form of Authorised Assignment Briefs, which are approved by Pearson Standards Verifiers. They are available via our website or free on myBTEC.

Sample marked learner work

To support you in understanding the expectation of the standard at each grade, examples of marked learner work at PM/MD grades are linked to the Authorised Assignment Briefs.

Training and support from Pearson

People to talk to

There are many people who are available to support you and provide advice and guidance on delivery of your BTEC Nationals. These include:

- Subject Advisors – available for all sectors. They understand all Pearson qualifications in their sector and so can answer sector-specific queries on planning, teaching, learning and assessment
- Standards Verifiers – they can support you with preparing your assignments, ensuring that your assessment plan is set up correctly, and support you in preparing learner work and providing quality assurance through sampling
- Curriculum Development Managers (CDMs) – they are regionally based and have a full overview of the BTEC qualifications and of the support and resources that Pearson provides. CDMs often run network events
- Customer Services – the 'Support for You' section of our website gives the different ways in which you can contact us for general queries. For specific queries, our service operators can direct you to the relevant person or department.

Training and professional development

Pearson provides a range of training and professional development events to support the introduction, delivery, assessment and administration of BTEC National qualifications. These sector-specific events, developed and delivered by specialists, are available both face to face and online.

'Getting Ready to Teach'

These events are designed to get teachers ready for delivery of the BTEC Nationals. They include an overview of the qualifications' structures, planning and preparation for internal and external assessment, and quality assurance.

Teaching and learning

Beyond the 'Getting Ready to Teach' professional development events, there are opportunities for teachers to attend sector- and role-specific events. These events are designed to connect practice to theory; they provide teacher support and networking opportunities with delivery, learning and assessment methodology.

Details of our training and professional development programme can be found on our website.

Appendix 1 Links to industry standards

BTEC Nationals have been developed in consultation with industry and appropriate sector bodies to ensure that the qualification content and approach to assessment aligns closely to the needs of employers. Where they exist, and are appropriate, National Occupational Standards (NOS) and professional body standards have been used to establish unit content.

Appendix 2 Glossary of terms used for internally-assessed units

This is a summary of the key terms used to define the requirements in the units.

Term	Definition
Analyse	Learners present the outcome of methodical and detailed examination either: <ul style="list-style-type: none"> • breaking down a theme, topic or situation in order to interpret and study the interrelationships between the parts and/or • of information or data to interpret and study key trends and interrelationships. Analysis can be through performance, practice, written or, less commonly, verbal presentation.
Apply	Application of skills, knowledge and understanding to or within context/situation.
Assess	Learners present a careful consideration of varied factors or events that apply to a specific situation or, to identify those which are the most important or relevant and arrive at a conclusion.
Carry out	Related to use and demonstration of practical equipment/techniques/procedures.
Describe	Learners' work gives a clear, objective account in their own words showing recall and, in some cases, application of the relevant features and information about a subject. Use of this verb normally requires breadth of content coverage. Evidence will normally be written but could be through presentation or, less frequently, performance or practice.
Discuss	Learners consider different aspects of: <ul style="list-style-type: none"> • a theme or topic • how they interrelate • the extent to which they are important. A conclusion is not required.
Evaluate	Learners' work draws on varied information, themes or concepts to consider aspects such as: <ul style="list-style-type: none"> • strengths or weaknesses • advantages or disadvantages • alternative actions • relevance or significance. Learners' inquiries should lead to a supported judgement showing relationship to its context. This will often be in a conclusion.
Examine	Learners are expected to select and apply knowledge to less familiar contexts.

Term	Definition
Explain	Learners' work shows clear details and gives reasons and/or evidence to support an opinion, view or argument. It could show how conclusions are drawn (arrived at). Learners are able to show that they comprehend the origins, functions and objectives of a subject, and its suitability for purpose.
Understand	Learners are expected to select and apply knowledge to familiar contexts.

This is a key summary of the types of evidence used for BTEC Nationals.

Type of evidence	Definition and purpose
Case study	A specific example to which all learners must select and apply knowledge. Used to show application to a realistic context where direct experience cannot be gained.
Development log	A record kept by learners to show the process of development. Used to show method, self-management and skill development.
Individual project	A self-directed, large-scale activity requiring planning, research, exploration, outcome and review. Used to show self-management, project management and/or deep learning, including synopticity.
Observations sheets	A witness statement related to the format of the evidence, e.g. practicals.
Presentation	A visual or audio presentation of findings that demonstrate knowledge and understanding of a concept.
Report writing	A report, consisting of analysis of findings, could be through research or primary investigations conducted.

Pearson BTEC Level 3 Nationals in Applied Human Biology

Certificate in Applied Human Biology

Extended Certificate in Applied Human Biology

For more information about Edexcel, BTEC or LCCI qualifications
visit qualifications.pearson.com

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