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Pearson Edexcel Level 3 NVQ Diploma in Laboratory Science

Specification

Competence-based qualification

First registration June 2011

Issue 2

Pearson

Edexcel, BTEC and LCCI qualifications

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This specification is Issue 2. Key changes are listed in summary table on next page. We will inform centres of any changes to this issue. The latest issue can be found on the Pearson website: qualifications.pearson.com

This qualification was previously known as:

Level 3 NVQ Diploma in Laboratory Science (QCF)

The QN remain the same.

References to third party material made in this specification are made in good faith. Pearson does not endorse, approve or accept responsibility for the content of materials, which may be subject to change, or any opinions expressed therein. (Material may include textbooks, journals, magazines and other publications and websites.)

All information in this specification is correct at time of going to publication.

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Summary of Pearson Edexcel Level 3 NVQ Diploma in Laboratory Science Issue 2 changes

Summary of changes made between previous issue and this current issue	Page number
All references to QCF have been removed throughout the specification	
Definition of TQT added	1
Definition of sizes of qualifications aligned to TQT	2
TQT value added	6
Guided learning definition updated	11
QCF references removed from unit titles and unit levels in all units	15-233

Earlier issue(s) show(s) previous changes.
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.

Contents

Introducing Pearson Edexcel NVQ qualifications

What are NVQ qualifications?

National Vocational Qualifications (NVQs) are work-based qualifications that give learners the opportunity to develop and demonstrate their competence in the area of work or job role to which the qualification relates.

NVQs are based on the National Occupational Standards (NOS) for the appropriate sector. NOS define what employees, or potential employees, must be able to do and know, and how well they should undertake work tasks and work roles. At Level 2 and above, these qualifications are recognised as the competence component of Apprenticeship Frameworks. Qualifications at Level 1 can be used in Traineeships, which are stepping-stones to Apprenticeship qualifications. NVQs qualifications can also be delivered as stand-alone for those who wish to take a work-based qualification.

NVQs qualifications are outcomes-based with no fixed learning programme – allowing flexible delivery that meets the individual learner's needs. They are suitable for those in employment or those who are studying at college and have a part-time job or access to a substantial work placement so that they are able to demonstrate the competencies that are required for work.

Most learners will work towards their qualification in the workplace or in settings that replicate the working environment as specified in the assessment requirements/strategy for the sector. Colleges, training centres and/or employers can offer these qualifications provided they have access to appropriate physical and human resources.

Sizes of NVQ/Competence-based qualifications

For all regulated qualifications, Pearson specify a total number of hours that is estimated learners will require to complete and show achievement for the qualification – this is the Total Qualification Time (TQT). The TQT value indicates the size of a qualification.

Within the 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 tutors 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 tutors or assessors will include private study, preparation for assessment and undertaking assessment when not under supervision, such as preparatory reading, revision and independent research.

As well as TQT and GLH, qualifications can also have a credit value – equal to one tenth of TQT, rounded to the nearest whole number.

TQT and credit values are assigned after consultation with users of the qualifications.

NVQ/Competence-based qualifications are available in the following sizes:

- Award – a qualification with a TQT value of 120 or less (equivalent to a range of 1–12 credits)
- Certificate – a qualification with a TQT value in the range of 121–369 (equivalent to a range of 13–36 credits)
- Diploma – a qualification with a TQT value of 370 or more (equivalent to 37 credits and above).

Qualification title covered by this specification

This specification gives you the information you need to offer the Pearson Edexcel Level 3 Diploma in Laboratory Science:

Qualification title	Qualification Number (QN)	Regulation start date
Pearson Edexcel Level 3 Diploma in Laboratory Science	600/1732/6	08/04/11

Qualifications eligible and funded for post-16-year-olds can be found on the funding Hub. The Skills Funding Agency also publishes a funding catalogue that lists the qualifications available for 19+ funding.

You should use the Qualification Accreditation Number (QN), when you wish to seek public funding for your learners. Each unit within a qualification will also have a unique reference number, which is listed in this specification.

The qualification title and unit reference numbers will appear on the learners' final certification document. Learners need to be made aware of this when they are recruited by the centre and registered with Pearson.

Key features of the Pearson Edexcel Level 3 Diploma in Laboratory Science

This qualification:

- is nationally recognised
- is based on the Level 3 Laboratory Science National Occupational Standards (NOS). The NOS, assessment requirements/strategy and qualification structure(s) are owned by SEMTA.

The Pearson Edexcel Level 3 NVQ Diploma in Laboratory Science have been approved as components for the Level 3 Laboratory Technicians Apprenticeship framework.

What is the purpose of this qualification?

The Pearson Edexcel Level 3 NVQ Diploma in Laboratory Science provides recognition of the skills and knowledge of individuals who work in a laboratory. It covers health and safety; effective working relationships; dealing with laboratory specimens/samples and communicating information. It contains two Pathways: Clinical Analysis and Compound Analysis.

Who is this qualification for?

This qualification is for all learners aged 18 and above who are capable of reaching the required standards.

Pearson's policy is that the qualification should:

- be free from any barriers that restrict access and progression
- ensure equality of opportunity for all wishing to access the qualification(s).

What are the potential job roles for those working towards this qualification?

- Analytical scientist
- Biochemist
- Biomedical scientist
- Biologist
- Biotechnologist
- Clinical scientist
- Microbiologist
- Physicist
- Research scientist
- Education laboratory technician
- Laboratory technician

- Medical laboratory technician
- Scientific laboratory technician

What progression opportunities are available to learners who achieve this qualification?

Progression from this qualification can be to other relevant level 2 and/or level 3 qualifications, for example:

- directly into employment
- Pearson BTEC Level 4 HNC in Applied Biology
- Pearson BTEC Level 4 HNC in Applied Chemistry.

What is the qualification structure for the Pearson Edexcel Level 3 Diploma in Laboratory Science?

The Total Qualification Time (TQT) for this qualification is 710.

The Guided Learning Hours (GLH) for this qualification is 465.

Learners must achieve a minimum of 71 credits by completing five common mandatory units and four optional units. One of these optional units must come from Group A and the other three optional units must come from Group B.

Unit	Title	Credit	Level
Common Mandatory units			
Unit 1:	Maintaining health and safety in a laboratory environment	5	2
Unit 2:	Maintaining effective and efficient working relationships in the laboratory	5	2
Unit 3:	Providing leadership for a laboratory team	16	3
Unit 15:	Measuring, weighing and preparing compounds and solutions for laboratory use	16	3
Unit 22:	Using and communicating laboratory information to authorised personnel	6	3

Unit	Title	Credit	Level
Group A - Optional units			
Unit 4:	Encouraging problem solving and innovation in a laboratory team	16	3
Unit 5:	Managing budgets for laboratory projects	8	3
Unit 24:	Using statistical process control (SPC) for laboratory measurement processes	8	4
Group B - Optional units			
Unit 6:	Analysing laboratory samples using High Performance Liquid Chromatography (HPLC)	16	3
Unit 7:	Analysing laboratory samples using Gas Chromatography (GC)	8	3
Unit 8:	Analysing laboratory samples using Gas Chromatography-Mass Spectrometry (GCMS)	12	3
Unit 9:	Analysing laboratory samples using Gas Chromatography-Thermal Conductivity (GCTC)	8	3

Unit	Title	Credit	Level
Unit 10:	Analysing DNA/RNA samples using Polymerase Chain Reaction (PCR) and Quantitative PCR (QPCR)	8	3
Unit 11:	Amplifying DNA samples using Polymerase Chain Reaction (PCR)	8	3
Unit 12:	Maintaining cell lines for laboratory activities using cryogenic storage	6	3
Unit 13:	Culturing/fermenting cells for laboratory activities using controlled fed batch or continuous culture fermentation	12	3
Unit 14:	Maintaining cell lines for laboratory activities using sub-culture	8	3
Unit 16:	Separating samples for laboratory activities using centrifugation	3	3
Unit 17:	Analysing laboratory samples using light microscopy	6	3
Unit 18:	Analysing laboratory samples using ultraviolet-visible spectrophotometer (UV-Vis)	8	3
Unit 19:	Analysing laboratory samples using Circular Dichroism (CD)	16	3
Unit 20:	Analysing laboratory samples using Fourier-transform infrared (FT-IR) spectroscopy	8	3
Unit 21:	Analysing laboratory samples using Chromatography	9	3
Unit 23:	Analysing DNA using gel electrophoresis	8	3

How is the qualification graded and assessed?

The overall grade for the qualification is a 'pass'. The learner must achieve all the required units within the specified qualification structure.

To pass a unit the learner must:

- achieve **all** the specified learning outcomes
- satisfy **all** the assessment criteria by providing sufficient and valid evidence for each criterion
- show that the evidence is their own.

The qualifications are designed to be assessed:

- in the workplace or
- in conditions resembling the workplace, as specified in the assessment requirements/strategy for the sector, or
- as part of a training programme.

Assessment requirements/strategy

The assessment strategy for this qualification has been included in *Annexe C*. It has been developed by SEMTA in partnership with employers, training providers, awarding organisations and the regulatory authorities. The assessment strategy includes details on:

- criteria for defining realistic working environments
- roles and occupational competence of assessors, expert witnesses, internal verifiers and standards verifiers
- quality control of assessment
- evidence requirements.

Evidence of competence may come from:

- **current practice** where evidence is generated from a current job role
- a **programme of development** where evidence comes from assessment opportunities built into a learning/training programme whether at or away from the workplace
- the **Recognition of Prior Learning (RPL)** where a learner can demonstrate that they can meet the assessment criteria within a unit through knowledge, understanding or skills they already possess without undertaking a course of learning. They must submit sufficient, reliable and valid evidence for internal and standards verification purposes. RPL is acceptable for accrediting a unit, several units or a whole qualification
- a **combination** of these.

It is important that the evidence is:

Valid	relevant to the standards for which competence is claimed
Authentic	produced by the learner
Current	sufficiently recent to create confidence that the same skill, understanding or knowledge persist at the time of the claim
Reliable	indicates that the learner can consistently perform at this level
Sufficient	fully meets the requirements of the standards.

Types of evidence (to be read in conjunction with the assessment strategy in Annexe C)

To successfully achieve a unit the learner must gather evidence which shows that they have met the required standard in the assessment criteria. Evidence can take a variety of different forms including the examples below. Centres should refer to the assessment strategy for information about which of the following are permissible.

- direct observation of the learner's performance by their assessor (O)
- outcomes from oral or written questioning (Q&A)
- products of the learner's work (P)
- personal statements and/or reflective accounts (RA)
- outcomes from simulation, where permitted by the assessment strategy (S)
- professional discussion (PD)
- assignment, project/case studies (A)
- authentic statements/witness testimony (WT)
- expert witness testimony (EPW)
- evidence of Recognition of Prior Learning (RPL).

The abbreviations may be used for cross-referencing purposes.

Learners can use one piece of evidence to prove their knowledge, skills and understanding across different assessment criteria and/or across different units. It is, therefore, not necessary for learners to have each assessment criterion assessed separately. Learners should be encouraged to reference the assessment criteria to which the evidence relates.

Evidence must be made available to the assessor, internal verifier and Pearson standards verifier. A range of recording documents is available on the Pearson website: qualifications.pearson.com. Alternatively, centres may develop their own.

Centre recognition and approval

Centre recognition

Centres that have not previously offered Pearson qualifications need to apply for and be granted centre recognition as part of the process for approval to offer individual qualifications. New centres must complete both a centre recognition approval application and a qualification approval application.

Existing centres will be given 'automatic approval' for a new qualification if they are already approved for a qualification that is being replaced by the new qualification and the conditions for automatic approval are met. Centres already holding Pearson approval are able to gain qualification approval for a different level or different sector via Edexcel online.

Approvals agreement

All centres are required to enter into an approvals agreement which is a formal commitment by the head or principal of a centre to meet all the requirements of the specification and any linked codes or regulations. Pearson will act to protect the integrity of the awarding of qualifications, if centres do not comply with the agreement. This could result in the suspension of certification or withdrawal of approval.

Quality assurance

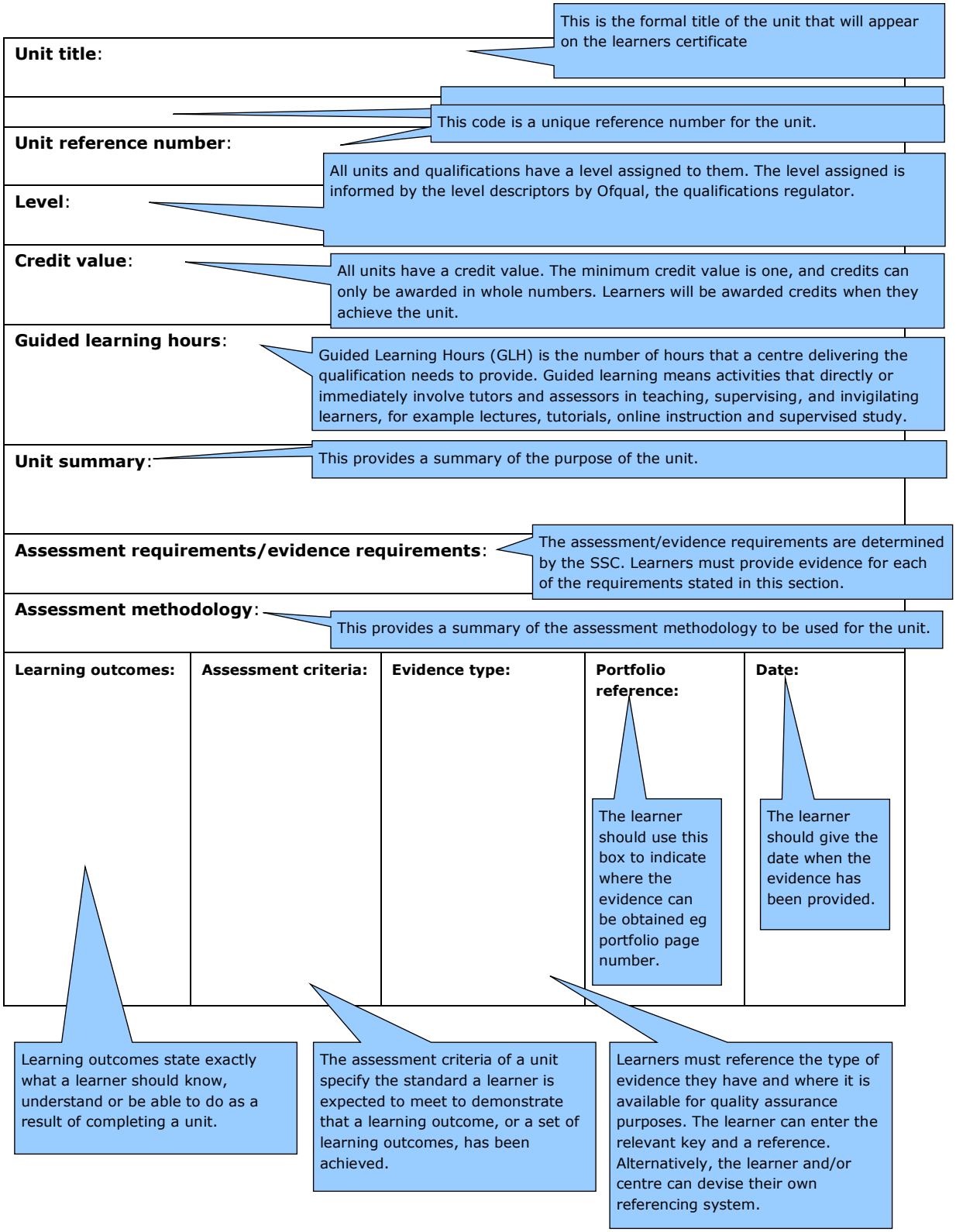
Detailed information on Pearson's quality assurance processes is given in *Annexe A*.

What resources are required?

This qualification is designed to support learners working in the Laboratory Science sector. Physical resources need to support the delivery of the qualifications and the assessment of the learning outcomes and must be of industry standard. Centres must meet any specific resource requirements outlined in *Annexe C: Assessment strategy*. Staff assessing the learner must meet the requirements within the overarching assessment strategy for the sector.

Unit format

Each unit in this specification contains the following sections.



Units

Unit 1: Maintaining health and safety in a laboratory environment

Unit reference number: K/601/1703

Level: 2

Credit value: 5

Guided learning hours: 35

Unit summary

This unit covers the skills and knowledge needed to prove the competences required to maintain health and safety in the laboratory. The learner is required to observe all legal, statutory and organisational requirements, and the learner must be able to identify any potential hazards and risks to health and safety. The learner must also know what actions to take in case of an emergency and, as well as ensuring their own safety, they must show responsibility towards their colleagues and others. The learner will be required to work to the relevant standard operation procedures, legislation and organisational policy, and to follow Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP).

The learner's responsibilities will require them to comply with health and safety requirements and organisational policy and procedures for the laboratory work that is undertaken. The learner must be able to recognise the limitations of their own competence with the laboratory work, and ask for appropriate help and advice in when it is needed. The learner will work under a high level of supervision, whilst taking responsibility for their own actions and for the quality and accuracy of the work that they carry out.

The learner's underpinning knowledge will provide an understanding of their laboratory work, in order to apply safely the appropriate scientific principles and practices. The learner will be competent in the safe use of the materials, equipment, consumables and instruments used to perform the laboratory investigations, and with the procedures appropriate to their job. The learner's depth of knowledge will be sufficient to provide a sound basis for safely carrying out the laboratory activities, to a level that will allow the department to meet any agreed targets.

The learner will understand the safety precautions required when carrying out the laboratory activities for scientific operations and processes. The learner will be required to demonstrate safe working practices throughout, and will understand their responsibility for taking the necessary safeguards to protect themselves and others in the workplace.

Assessment requirements

Assessment requirements are set down in Annexe C: Assessment strategy.

Assessment methodology

This unit is assessed in the workplace. Learners can enter the types of evidence they are presenting for assessment and the submission date against each assessment criterion. Alternatively, centre documentation should be used to record this information.

Learning outcomes and assessment criteria

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
1 Maintain health and safety in a laboratory environment	1.1 Ensure that their work is carried out in accordance with standard operating procedures 1.2 Accurately assess health and safety in relation to their work and the laboratory 1.3 Identify health and safety standard operating procedures for all of the following: – laboratory hazards – manual handling – unsafe practices – VDU & RSI policies – spillages – other (please specify) 1.4 Use the appropriate personal protective clothing and equipment for the work 1.5 Make safe any health and safety hazards, and report them to the appropriate person as soon as possible 1.6 Maintain the security of the laboratory, in accordance with organisational requirements 1.7 Ensure that they maintain their work area to a standard of health and safety which is consistent with local policies and legal requirements			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	1.8 Maintain and use equipment and materials in accordance with manufacturers' instructions and local safety regulations			
2 Maintain health and safety in a laboratory environment (continued)	2.1 Dispose of hazardous materials, waste and waste containers, safely and correctly 2.2 Dispose of, safely, seven of the following, in accordance with approved procedures: – sharps – biological materials – metal – chemical (solid and liquid) – plastics – glass – cleaning wipes/tissues – aerosol containers – confidential records – domestic waste			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	2.3 Dispose of waste in three the following types of container, in accordance with approved practices: – sharps containers – colour-coded plastic bags – autoclave bins – solvent drums – proprietary containers 2.4 Prepare, use and dispose of disinfectants, safely and correctly 2.5 Carry out decontamination of work surfaces and floors effectively 2.6 Take the appropriate precautions to protect themselves and others during working 2.7 Handle safely three of the following hazardous substances, in accordance with approved procedures: – flammables – corrosive chemicals – toxic chemicals – biological materials 2.8 Follow the correct procedure, without delay, if an emergency arises or is suspected			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	2.9 Follow established procedures for all of the following emergencies: – laboratory fire – spillage of hazardous substances – gas escapes – other emergencies (please specify)			
3 Know how to maintain health and safety in a laboratory environment	3.1 Describe the health and safety requirements of the area in which the learner is carrying out the laboratory activities 3.2 Describe the implications of not taking account of legislation, regulations, standards and guidelines when conducting laboratory activities 3.3 Describe the standard operating procedures, as set down in local laboratory operating manuals 3.4 Describe the importance of following manufacturers' instructions 3.5 Describe the principles of Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP) applied in the workplace 3.6 Describe the importance of wearing protective clothing, gloves and eye protection when handling specimens/samples			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	3.7 Describe the specific safety precautions to be taken when working with laboratory equipment and computer-based systems (to include such things as safety guidance relating to the use of visual display unit (VDU) equipment and work station environment (such as lighting, seating, positioning of equipment), and repetitive strain injury (RSI)) 3.8 Describe the identity of health and safety representatives (such as the Laboratory Safety Officer, Staff Health & Safety Representatives and First-Aiders) 3.9 Describe the location and correct use of emergency equipment (such as fire extinguishers, including the situations in which different types of fire extinguishers are used) 3.10 Describe the organisational requirements for maintaining the security of the workplace 3.11 Describe the lines of communication and responsibilities in their department, and their links with the rest of the organisation 3.12 Describe the limits of the learner's own authority and to whom they should report if they have problems that they cannot resolve 3.13 Explain why risks in the laboratory should be assessed, and the correct action to be taken			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
4 Know how to maintain health and safety in a laboratory environment (continued)	4.1 Explain how to prevent infection in laboratories 4.2 Describe local procedures for escape (including escape routes and assembly points) 4.3 Describe the location of fire alarms, and how to operate them 4.4 Describe the location of spillage kits, and the procedures to follow in the event of spillages of chemicals and/or biological fluids 4.5 Describe the control of substances hazardous to health (COSHH) regulations, and their application in the laboratory 4.6 Describe the types of hazards which may occur in the laboratory setting, and how these can be minimised 4.7 Describe the correct storage and disposal procedures for hazardous materials (including: flammables, corrosive, harmful and toxic chemicals) 4.8 Describe the hazards associated with disinfectants and other chemicals (including toxicity) 4.9 Explain the meaning of the terms 'disinfection' and 'decontamination', and the use of disinfectants 4.10 Describe the reasons for disinfecting/decontaminating laboratory surfaces and equipment			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	4.11 Explain why it is important to differentiate and segregate categories of waste (such as using waste colour-coding) 4.12 Describe the correct procedures for the storage, transport and disposal of waste			

Learner name: _____ Date: _____

Learner signature: _____ Date: _____

Assessor signature: _____ Date: _____

Internal verifier signature: _____ Date: _____
(*if sampled*)

Unit 2: Maintaining effective and efficient working relationships in the laboratory

Unit reference number: M/601/1895

Level: 2

Credit value: 5

Guided learning hours: 25

Unit summary

This unit covers the skills and knowledge needed to prove the competences required to work effectively and efficiently in the laboratory, in accordance with approved procedures and practices. Prior to undertaking the laboratory activity, the learner will be required to carry out all the necessary preparations, within the scope of their responsibility. This may include preparing the work area and ensuring that it is in a safe condition for the intended activities, and ensuring that any materials, equipment and other resources required are available and are in a safe and usable condition. They will be required to work to the relevant standard operation procedures, legislation and organisational policy, and to follow Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP).

On completion of the laboratory activity, the learner will be required to return their immediate work area to an acceptable condition before undertaking further work requirements. This may involve placing completed work items in the correct location, returning and/or storing any materials and equipment in the correct condition/area, identifying any waste and arranging for its disposal, and reporting any defects or damage to the materials and equipment used.

The learner's responsibilities will require them to comply with organisational policy and procedures for the laboratory investigations undertaken, and to report any problems with the activities, materials or equipment that they cannot personally resolve, or that are outside their permitted authority, to the relevant people. The learner will work under a high level of supervision, whilst taking responsibility for their own actions and for the quality and accuracy of the work that they carry out.

The learner's underpinning knowledge will provide a good understanding of their work, and will provide an informed approach to working efficiently and effectively in a laboratory environment. The learner will understand the need to work efficiently and effectively, and will know about the things that they need to consider when preparing and tidying up the work area. The learner will also need to know how to contribute to improvements, deal with problems, maintain effective working relationships, and how to agree and achieve their development objectives and targets, in adequate depth to provide a sound basis for carrying out the activities safely and correctly.

The learner will understand the safety precautions required when carrying out laboratory activities. The learner will be required to demonstrate safe working practices throughout, and will understand the responsibility they owe to themselves and others in the workplace.

Assessment requirements

Assessment requirements are set down in Annexe C: Assessment strategy.

Assessment methodology

This unit is assessed in the workplace. Learners can enter the types of evidence they are presenting for assessment and the submission date against each assessment criterion. Alternatively, centre documentation should be used to record this information.

Learning outcomes and assessment criteria

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
1 Maintain effective and efficient working relationships in the laboratory	1.1 Ensure that their work is carried out in accordance with standard operating procedures 1.2 Work safely at all times, complying with health and safety and other relevant regulations and guidelines 1.3 Establish and maintain effective working relationships 1.4 Sustain positive working relationships by all of the following: – working in teams – supporting others – being cooperative and flexible – providing clear and accurate information 1.5 Maintain effective working relationships with two of the following: – colleagues in their own working group – supervisors/managers – more senior professionals/scientists – colleagues outside their normal working group – persons external to their organisation 1.6 Meet organisational standards for appearance and behaviour			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
2 Maintain effective and efficient working relationships in the laboratory (continued)	2.1 Deal with disagreements in an amicable and constructive way, so that good relationships are maintained 2.2 Maintain communication with others, to ensure that they are kept informed about any work plans or activities which may affect them 2.3 Be aware of the limits of their skills, and seek assistance from others in a polite and courteous way without causing undue disruption to normal work activities 2.4 Review their personal performance and development, with the appropriate people, at regular intervals 2.5 Review personal development objectives and targets, to include one of the following: – dual or multi-skilling – training on new equipment/technology – understanding of company working practices, procedures, plans and policies – increased responsibility – other specific requirements			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	2.6 Record details of work done, and communicate the details to the appropriate people, using: – verbal report Plus one method from the following: – written or typed report – specific company documentation – computer-based record – electronic mail			
3 Know how to maintain effective and efficient working relationships in the laboratory	3.1 Describe the health and safety requirements of the area in which they are carrying out the laboratory activities 3.2 Describe the implications of not taking account of legislation, regulations, standards and guidelines when conducting laboratory activities 3.3 Describe the standard operating procedures, as set down in local laboratory operating manuals 3.4 Describe the principles of Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP) applied in the workplace 3.5 Describe the purpose of the speciality of the department in which they are employed, and how it fits into the other specialities of the larger organisation			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	3.6 Describe the interactions which take place between the department and other specialities in the same organisation 3.7 Describe the interactions which take place between the speciality in which they are employed and others in the same speciality elsewhere 3.8 Explain how their work activities affect others within the department, organisation and the community 3.9 Describe the lines of communication and responsibilities in their department, and their links with the rest of the organisation 3.10 Describe the limits of their own authority and to whom they should report if they have problems that they cannot resolve			
4 Know how to maintain effective and efficient working relationships in the laboratory (continued)	4.1 Describe the lines of accountability within the department 4.2 Describe the general function and purpose of all the relevant laboratories 4.3 Describe the reasons why good working relationships are important 4.4 Explain how to create and maintain good working relationships 4.5 Describe the methods of working effectively with others			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	4.6 Describe the problems that can affect relationships in the workplace 4.7 Describe the procedures for dealing with disagreements within the workplace 4.8 Describe the departmental performance review process, and their role in this process 4.9 Describe the reasons why effective communication is important, and the methods used for communicating effectively			

Learner name: _____ Date: _____

Learner signature: _____ Date: _____

Assessor signature: _____ Date: _____

Internal verifier signature: _____ Date: _____
(*if sampled*)

Unit 3: Providing leadership for a laboratory team

Unit reference number: J/601/8173

Level: 3

Credit value: 16

Guided learning hours: 66

Unit summary

This unit covers the skills and knowledge needed to prove the competences required to provide leadership to members of a laboratory team, in accordance with approved procedures. The learner is required to motivate and support them to achieve the objectives of the team and their personal work objectives. They will be required to work to the relevant standard operating procedures, legislation and organisational policy, and to follow Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP). They will also be required to present records and details of their work to the appropriate people.

The learner will be required to plan the work of their team, and to set and agree individual objectives. They will help them solve technical problems, monitor their progress against the objectives they set, and provide feedback and guidance for improvements in their performance

The learner's responsibilities will require them to comply with health and safety requirements, and organisational policy and procedures, for the laboratory work that is undertaken. They will be required to report any problems with the laboratory procedures that they cannot personally resolve, or that are outside their permitted authority, to the relevant people. They will be expected to work to verbal/written instructions and standard operating procedures, with a minimum of supervision, taking personal responsibility for their own actions and for the quality and accuracy of the work that they carry out.

The learner's underpinning knowledge will be sufficient to provide a sound basis for their work, and will enable them to adopt an informed approach to team leading/building procedures. They will have an understanding of the necessary leadership skills, in adequate depth to provide a sound background for carrying out the laboratory activities to the required specification.

The learner will understand the safety precautions required when carrying out the laboratory activities for scientific operations and processes. They will be required to demonstrate safe working practices throughout, and will understand their responsibility for taking the necessary safeguards to protect themselves and others in the workplace.

Assessment requirements

Assessment requirements are set down in Annexe C: Assessment strategy.

Assessment methodology

This unit is assessed in the workplace. Learners can enter the types of evidence they are presenting for assessment and the submission date against each assessment criterion. Alternatively, centre documentation should be used to record this information.

Learning outcomes and assessment criteria

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
1 Provide leadership for a laboratory team	1.1 Ensure that their work is carried out in accordance with standard operating procedures 1.2 Wear the appropriate personal protection equipment (PPE) when handling laboratory items or materials 1.3 Use three of the following types of protective clothing and equipment, as appropriate for the specimens being handled: – laboratory coat – face mask – gloves – safety glasses – other (please specify) 1.4 Set out and positively communicate the purpose and objectives of their laboratory team			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	1.5 Carry out all of the following leadership activities: – evaluate the team knowledge and skills – obtain and give information to achieve team goals and objectives – plan tasks and objectives for the team to accomplish set goals – represent the team at meetings and in communications with senior colleagues and customers – improve the knowledge, skills and attitude of the team 1.6 Involve team members in planning how their laboratory team will achieve its objectives 1.7 Ensure that each member of their laboratory team has personal work objectives and understands how achieving these will contribute to achievement of the team's objectives			
2 Provide leadership for a laboratory team (continued)	2.1 Encourage and support their laboratory team members to achieve their personal work objectives and those of the team, and provide recognition when objectives have been achieved 2.2 Steer their laboratory team successfully through difficulties and challenges, including conflict within the team 2.3 Encourage and recognise creativity and innovation within their laboratory team			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	2.4 Give their laboratory team members support and advice when needed 2.5 Monitor activities and progress against objectives across their laboratory team, and encourage responsibility in individuals for their own actions 2.6 Communicate the required information about the work of their laboratory team, to authorised people, in accordance with departmental and organisational procedures 2.7 Record and communicate to the appropriate people, using all of the following: – verbal report – written or typed report – company documentation – computer-based record – electronic mail – graphs/charts			
3 Know how to provide leadership for a laboratory team	3.1 Describe the health and safety requirements of the area in which they are carrying out the laboratory activities 3.2 Describe the implications of not taking account of legislation, regulations, standards and guidelines when conducting laboratory activities			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	3.3 Describe the principles of Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP) applied in the workplace 3.4 Describe the organisational requirements for maintaining the security of the workplace (e.g., workplace access and laboratory sample containment) 3.5 Describe the lines of communication and responsibilities in their department, and the links with the rest of the organisation 3.6 Describe the limits of their own authority and to whom they should report if they have problems that they cannot resolve 3.7 Describe the different ways of communicating effectively with members of a team 3.8 Explain how to set objectives which are SMART (Specific, Measurable, Achievable, Realistic and Time-bound) 3.9 Explain how to plan the achievement of team objectives, and the importance of involving team members in this process			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
4 Know how to provide leadership for a laboratory team (continued)	4.1 Describe the importance of showing team members how their personal work objectives contribute to achievement of team objectives 4.2 Explain how to allocate work objectives and delegate responsibility to individuals in their laboratory team 4.3 Explain how to select and successfully apply a limited range of methods for motivating, supporting and encouraging team members and recognising their achievements 4.4 Describe the types of difficulty and challenge that may arise (including conflict within the team), and ways of identifying and overcoming them 4.5 Describe the importance of encouraging others to take the lead, and ways in which this can be achieved 4.6 Describe the benefits of, and how to encourage and recognise, creativity and innovation within a team 4.7 Describe the laboratory team members, their purpose, objectives and plans for them 4.8 Describe the types of support and technical advice that their laboratory team are likely to need, and how to respond to these needs			

Learner name: _____ Date: _____

Learner signature: _____ Date: _____

Assessor signature: _____ Date: _____

Internal verifier signature: _____ Date: _____
(*if sampled*)

Unit 4: Encouraging problem solving and innovation in a laboratory team

Unit reference number: F/601/8172

Level: 3

Credit value: 16

Guided learning hours: 66

Unit summary

This unit covers the skills and knowledge needed to prove the competences required to encourage and support the identification and practical implementation of ideas from their laboratory team, in accordance with approved procedures. The learner is required to motivate and support them to achieve the objectives of the team and their personal work objectives. They will be required to work to the relevant standard operating procedures, legislation and organisational policy, and to follow Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP). They will also be required to present records and details of their laboratory work to the appropriate people.

The learner will be required to think creatively with their team, and to set and agree individual objectives. They will help them solve technical problems, monitor their progress the objectives they set, and provide feedback and guidance on their innovative ideas.

The learner's responsibilities will require them to comply with health and safety requirements and organisational policy and procedures for the laboratory work that is undertaken. They will be required to report any problems with the laboratory procedures that they cannot personally resolve, or that are outside their permitted authority, to the relevant people. They will be expected to work to verbal/written instructions and standard operating procedures, with a minimum of supervision, taking personal responsibility for their own actions and for the quality and accuracy of the work that they carry out.

The learner's underpinning knowledge will be sufficient to provide a sound basis for their work, and will enable them to adopt an informed approach to the introduction of new ideas. They will have an understanding of the required leadership skills, in adequate depth to provide a sound background for carrying out the laboratory activities to the required specification.

The learner will understand the safety precautions required when carrying out the laboratory activities for scientific operations and processes. They will be required to demonstrate safe working practices throughout, and will understand their responsibility for taking the necessary safeguards to themselves and others in the workplace

Assessment requirements

Assessment requirements are set down in Annexe C: Assessment strategy.

Assessment methodology

This unit is assessed in the workplace. Learners can enter the types of evidence they are presenting for assessment and the submission date against each assessment criterion. Alternatively, centre documentation should be used to record this information.

Learning outcomes and assessment criteria

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
1 Encourage problem solving and innovation in a laboratory team	1.1 Ensure that their work is carried out in accordance with standard operating procedures 1.2 Wear the appropriate personal protection equipment (PPE) when handling specimens/samples 1.3 Use three of the following types of protective clothing and equipment, as appropriate for the specimens being handled: – laboratory coat – face mask – gloves – safety glasses – other (please specify) 1.4 Motivate members of their laboratory team to identify ideas for new products/services and process improvements 1.5 Encourage ideas for all of the following: – new laboratory products and/or services – improvements to existing laboratory products and/or services – improvements to existing laboratory practices, procedures, systems and ways of working 1.6 Respond enthusiastically to ideas identified by members of their laboratory team, and provide constructive feedback			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	1.7 Encourage members of their laboratory team to share, discuss and work together in developing initial ideas 1.8 Encourage problem solving and innovation, using three of the following: – force-field analysis – cause-effect analysis – five 'whys' analysis – mind-mapping – focus groups – brainstorming – flowcharting analysis – fault-tree analysis – de Bono's thinking tools – other (please specify) 1.9 Identify and pursue opportunities to work with other laboratory teams to generate and develop ideas 1.10 Discuss and agree with members of their laboratory team those ideas which should be developed further, how they should be developed and the required resources			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
2 Encourage problem solving and innovation in a laboratory team (continued)	2.1 Provide ongoing support, encouragement and resources to members of their laboratory team who are developing and testing ideas, and help to remove any obstacles 2.2 Agree the practical implementation of ideas, based on the identified benefits, risks and required resources, when they have the authority to do so 2.3 Support members of their laboratory team in submitting formal proposals and plans for the practical implementation of ideas to other people for approval 2.4 Oversee the practical implementation of ideas by their laboratory team, and monitor and report on progress 2.5 Encourage and develop the creativity of members of their laboratory team 2.6 Encourage members of their laboratory team to take acceptable risks in pursuing innovation 2.7 Ensure that the originators and developers of any ideas which are successfully implemented receive recognition for their achievement 2.8 Communicate the required information about the work of their laboratory team to authorised people, in accordance with departmental and organisational procedures			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	2.9 Record and communicate details of work done, to the appropriate people, using: – verbal report Plus one method from the following: – written or typed report – specific company documentation – computer-based record – electronic mail			
3 Know how to encourage problem solving and innovation in a laboratory team	3.1 Describe the health and safety requirements of the area in which they are carrying out the laboratory activities 3.2 Describe the implications of not taking account of legislation, regulations, standards and guidelines when conducting laboratory activities 3.3 Describe the principles of Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP) applied in the workplace 3.4 Describe the organisational requirements for maintaining the security of the workplace (e.g., workplace access and laboratory sample containment) 3.5 Describe the lines of communication and responsibilities in their department, and the links with the rest of the organisation			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	3.6 Describe the limits of their own authority and to whom they should report if they have problems that they cannot resolve 3.7 Describe the organisational policy and strategy for innovation 3.8 Describe the organisational guidelines and procedures for developing and implementing new ideas 3.9 Describe the benefits of innovation to their team, the overall organisation and its customers 3.10 Explain how to make time available for identifying and developing ideas 3.11 Explain how to motivate people to generate and develop ideas			
4 Know how to encourage problem solving and innovation in a laboratory team (continued)	4.1 Explain how to provide constructive feedback on ideas to individuals 4.2 Describe the importance of good communication to innovation, and how to encourage it across their team 4.3 Describe the potential obstacles to creativity, and how they can be minimised 4.4 Describe the importance of giving feedback on initial ideas 4.5 Explain how initial ideas might be further developed and tested			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	4.6 Explain how to recognise and manage risk in innovation 4.7 Explain how to develop formal proposals and plans for the practical implementation of an idea, and how to support others in doing this 4.8 Explain how to develop creativity in themselves and others 4.9 Describe the resources required for creativity and innovation, particularly time 4.10 Explain how to encourage their laboratory team to learn from mistakes associated with new ideas 4.11 Explain how to recognise the achievements of the originators/developers of ideas which have been successfully implemented			

Learner name: _____ Date: _____

Learner signature: _____ Date: _____

Assessor signature: _____ Date: _____

Internal verifier signature: _____ Date: _____
(*if sampled*)

Unit 5: Managing budgets for laboratory projects

Unit reference number: L/601/8174

Level: 3

Credit value: 8

Guided learning hours: 33

Unit summary

This unit covers the skills and knowledge needed to prove the competences required to manage project budgets in the laboratory, in accordance with approved procedures and practices. Prior to undertaking the laboratory activity, the learner will be required to carry out all the necessary preparations, within the scope of their responsibility. This may include preparing the work area and ensuring that it is in a safe condition for the intended activities, and ensuring that any materials, equipment and other resources required are available and are in a safe and usable condition. They will be required to work to the relevant standard operating procedures, legislation and organisational policy, and to follow Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP). They will also be required to present records and details of their laboratory work to the appropriate people.

The learner's responsibilities will include ownership of, and responsibility for a budget for a laboratory team and activity. It will involve preparing, submitting and agreeing a budget for a set operating period. It also involves monitoring actual performance against the agreed budget, and taking necessary action in response to identified variances and any unforeseen developments.

The learner's responsibilities will require them to comply with organisational policy and procedures for the laboratory projects undertaken, and to report any problems with the activities, materials or equipment that they cannot personally resolve, or that are outside their permitted authority, to the relevant people. They will work with minimal supervision, whilst taking responsibility for their own actions and for the quality and accuracy of the work that they carry out.

The learner's underpinning knowledge will be sufficient to provide a sound basis for their work, and will enable them to adopt an informed approach to budgeting procedures. They will have an understanding of the budgeting process and its application, and will know about the process used, in adequate depth to provide a sound background for carrying out the laboratory activities to the required specification.

The learner will understand the safety precautions required when carrying out laboratory activities. They will be required to demonstrate safe working practices throughout, and will understand the responsibility they owe to themselves and others in the workplace.

Assessment requirements

Assessment requirements are set down in Annexe C: Assessment strategy.

Assessment methodology

This unit is assessed in the workplace. Learners can enter the types of evidence they are presenting for assessment and the submission date against each assessment criterion. Alternatively, centre documentation should be used to record this information.

Learning outcomes and assessment criteria

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
1 Manage budgets for laboratory projects	1.1 Ensure that their work is carried out in accordance with standard operating procedures 1.2 Work safely at all times, complying with health and safety and other relevant regulations and guidelines 1.3 Evaluate available information and consult with others to prepare a realistic budget for the respective area or activity of work. 1.4 Manage budgets for all of the following: – accrued v actual project expenditure – project cashflow – project team costs – project equipment costs – project resource costs – other (please specify) 1.5 Submit the proposed budget to the relevant people in the organisation, for approval and to assist the overall financial planning process 1.6 Discuss and, if appropriate, negotiate the proposed budget with the relevant people in the organisation, and agree the final budget 1.7 Use the agreed budget to actively monitor and control performance for the respective area or activity of work			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	1.8 Agree budgets with two of the following: – colleagues in their own working group – supervisors/managers – more senior professionals/scientists – colleagues outside their normal working group – persons external to their organisation			
2 Manage budgets for laboratory projects (continued)	2.1 Identify the causes of any significant variances between what was budgeted and what actually happened, and take prompt corrective action, obtaining agreement from the relevant people if required 2.2 Propose revisions to the budget, if necessary, in response to variances and/or significant or unforeseen developments, and discuss and agree the revisions with the relevant people in the organisation 2.3 Provide ongoing information on performance against the budget to relevant people in their organisation 2.4 Advise the relevant people as soon as possible if they have identified evidence of potentially fraudulent activities 2.5 Gather information from implementation of the budget to assist in the preparation of future budgets			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	2.6 Communicate the required information about the work done, to authorised people, in accordance with departmental and organisational procedures 2.7 Record and communicate details of work done, to the appropriate people, using: – verbal report Plus one method from the following: – written or typed report – specific company documentation – computer-based record – electronic mail			
3 Know how to manage budgets for laboratory projects	3.1 Describe the health and safety requirements of the area in which they are carrying out the laboratory activities 3.2 Describe the standard operating procedures, as set down in local laboratory operating manuals 3.3 Describe the principles of Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP) applied in the workplace 3.4 Describe the factors, processes and trends likely to affect the setting of budgets in their industry/sector 3.5 Describe the lines of communication and responsibilities in their department, and their links with the rest of the organisation			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	3.6 Describe the limits of their own authority and to whom they should report if they have problems that they cannot resolve 3.7 Describe the purposes of budgetary systems 3.8 Explain where to get, and how to evaluate, the available information in order to be able to prepare a realistic budget 3.9 Describe the importance of spending time and consulting with others in preparing a budget			
4 Know how to manage budgets for laboratory projects (continued)	4.1 Explain how to discuss, negotiate and confirm a budget with people who control the finances, and the key factors that should be covered 4.2 Explain how to use a budget to actively monitor and control performance for a defined area or activity of work 4.3 Describe the main causes of variances, and how to identify them 4.4 Explain what different types of corrective action could be taken to address identified variances 4.5 Explain how unforeseen developments can affect a budget, and how to deal with them 4.6 Describe the importance of agreeing revisions to the budget and of communicating the changes 4.7 Describe the importance of providing regular information on performance against the budget to other people			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	4.8 Describe the types of fraudulent activities, and how to identify them 4.9 Describe the importance of using the implementation of the budget to identify information and lessons for the preparation of future budgets			

Learner name: _____ Date:_____

Learner signature: _____ Date:_____

Assessor signature: _____ Date:_____

Internal verifier signature: _____ Date:_____
(*if sampled*)

Unit 6: Analysing laboratory samples using High Performance Liquid Chromatography (HPLC)

Unit reference number: R/601/8175

Level: 3

Credit value: 16

Guided learning hours: 66

Unit summary

This unit covers the skills and knowledge needed to prove the competences required to carry out laboratory sample analysis using high performance liquid chromatography (HPLC) analysers, in accordance with approved procedures. The learner is required to confirm that the HPLC analyser is ready for the analysis to be performed and that the required reagents are available. In operating the analyser, they will be expected to follow the correct procedures for calling the analyser-operating program, entering operating parameters for analysis, dealing with error messages and executing the program activities safely and correctly. They will be required to work to the relevant standard operating procedures, legislation and organisational policy, and to follow Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP). They will also be required to present records and details of their laboratory work to the appropriate people.

The learner will be required to set up and operate the HPLC analyser in line with safe working practices and approved procedures, to monitor the analysis operations and, where necessary, make the required adjustments, in order to ensure that the output analysis is to the required quality and accuracy. Meeting laboratory targets will be an important issue, and their laboratory records must show consistent and satisfactory performance.

The learner's responsibilities will require them to comply with standard operating procedures for the HPLC work activities undertaken, and to report any problems that they cannot personally resolve, or that are outside their permitted authority, to the relevant people. They will be expected to work to instructions, with a minimum of supervision, either on their own or as part of a team, taking personal responsibility for their own actions and for the quality and accuracy of the work that they carry out.

The learner's underpinning knowledge will be sufficient to provide a sound basis for their work, and will enable them to adopt an informed approach to applying HPLC analyser procedures. They will have an understanding of the HPLC analysis process and its application, and will know about the analyser, samples and reagents used, in adequate depth to provide a sound background for carrying out the laboratory activities to the required specification.

The learner will understand the safety precautions required when carrying out the laboratory activities for scientific operations and processes. They will be required to demonstrate safe working practices throughout, and will understand their responsibility for taking the necessary safeguards to protect themselves and others in the workplace.

Assessment requirements

Assessment requirements are set down in Annexe C: Assessment strategy.

Assessment methodology

This unit is assessed in the workplace. Learners can enter the types of evidence they are presenting for assessment and the submission date against each assessment criterion. Alternatively, centre documentation should be used to record this information.

Learning outcomes and assessment criteria

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
1 Analyse laboratory samples using High Performance Liquid Chromatography	1.1 Ensure that their work is carried out in accordance with standard operating procedures 1.2 Wear the appropriate personal protection equipment (PPE) when handling specimens 1.3 Wear three of the following types of protective clothing and equipment: – laboratory coat/overalls – face mask/respirator – gloves – safety glasses/safety goggles – mop cap – other (please specify) 1.4 Confirm that the equipment is calibrated, safe and ready for operation			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	1.5 Carry out all of the following High Pressure Liquid Chromatography (HPLC) operations: – confirm that the machine is ready for analysis – check that all safety equipment and guards are in place and functioning correctly – prepare reagents, mobile phase and machine operating program sequences – install the column and prime the system – ensure that specimens are in suitable containers/vials (e.g. not overfilled, poorly crimped or wrong septa) – ensure that machine settings are adjusted as and when required for the analysis – allow for suitable system equilibration by running method conditions and monitoring the baseline – ensure that all specimens are correctly loaded with respect to sequence requirements – check that the operating program sequence is at the correct start point, and that all the data handling is ready for data acquisition – operate the analyser, following the defined operating procedures, and apply safe working practices and procedures at all times			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	1.6 Follow the defined procedures for starting and running the operating system and/or data handling and control software 1.7 Run appropriate system parameter tests and confirm the system suitability for the analyses to be done 1.8 Deal promptly and effectively with error messages or equipment faults that are within their control, and report those that cannot be resolved			
2 Analyse laboratory samples using High Performance Liquid Chromatography (continued)	2.1 Load specimens for analysis and run program sequences correctly 2.2 Shut down the equipment to a safe condition on conclusion of the activities, using the compatible flushing and line storage procedures 2.3 Evaluate data in accordance with standard operating procedures and manufacturers' instructions			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	2.4 Conduct four of the following analyses: – single peak assay – multi-peak determination – sample agreement calculations (precise replication) – system suitability peak asymmetry plate count resolution by EP and USP calculations – global response factor – standard agreement calculation – bracket response factor – linear range standards 2.5 Communicate the required information about the work done, to authorised people, in accordance with departmental and organisational procedures 2.6 Record details of the analysis work, and communicate the details to the appropriate people, using: – verbal report Plus one method from the following: – written or typed report – specific company documentation – computer-based record – electronic mail			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
3 Know how to analyse laboratory samples using High Performance Liquid Chromatography	3.1 Describe the health and safety requirements of the area in which they are carrying out the laboratory activities 3.2 Describe the implications of not taking account of legislation, regulations, standards and guidelines when conducting laboratory activities 3.3 Describe the principles of Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP) applied in the workplace 3.4 Describe the importance of wearing protective clothing, gloves and eye protection when handling laboratory samples for analysis 3.5 Describe the laboratory sample reception, records database and tracking system 3.6 Describe the types of handling and sorting system used, and the procedures and practices used for transferring specimens/samples within the laboratory while undergoing processing 3.7 Describe the importance of using the correct identification, and any unique organisational or laboratory numbers for specimens/samples 3.8 Describe the organisational requirements for maintaining the security of the workplace (e.g. workplace access and laboratory sample containment)			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	3.9 Describe the lines of communication and responsibilities in their department, and the links with the rest of the organisation 3.10 Describe the limits of their own authority and to whom they should report if they have problems that they cannot resolve 3.11 Describe the minimum size/volume of laboratory sample required for the High Pressure Liquid Chromatography (HPLC) investigations conducted by the laboratory 3.12 Describe the range of samples analysed, containers used for HPLC analysis in the laboratory, and other essential resources needed for each investigation 3.13 Describe the importance of keeping the work area clean and tidy 3.14 Describe the main features of the HPLC analyser, and the accessories that can be used			
4 Know how to analyse laboratory samples using High Performance Liquid Chromatography (continued)	4.1 Describe the various HPLC analyser operations that can be performed, and the methods and equipment used 4.2 Explain how to record and prepare standard samples, reagents and mobile phases 4.3 Describe the manufacturer's instructions for changing consumables and maintenance items in the HPLC analyser			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	4.4 Explain how to interpret the analyser visual display and understand the various messages displayed 4.5 Describe the function of error messages, and what to do if an error message is displayed 4.6 Explain how to find the correct restart point in the program, if the HPLC has been stopped before completion of the program 4.7 Explain where to obtain the standard operating procedures, equipment procedures and job instructions required for the analysis to be conducted 4.8 Explain how to measure the efficiency of a column 4.9 Explain how to determine the symmetry of a peak (e.g. tailing) 4.10 Explain how to determine the separation and resolution of the column 4.11 Explain how to apply standard agreement, response factor, sample precision, standard linearity calculations 4.12 Describe the typical HPLC and column faults, and the actions to be taken if they occur 4.13 Describe the procedure to be followed if a broken or leaking sample is identified in the laboratory			

Learner name: _____ Date: _____

Learner signature: _____ Date: _____

Assessor signature: _____ Date: _____

Internal verifier signature: _____ Date: _____
(*if sampled*)

Unit 7: Analysing laboratory samples using Gas Chromatography (GC)

Unit reference number: Y/601/8176

Level: 3

Credit value: 8

Guided learning hours: 33

Unit summary

This unit covers the skills and knowledge needed to prove the competences required to carry out laboratory sample analysis using gas chromatography (GC) analysers, in accordance with approved procedures. The learner is required to confirm that the GC analyser is ready for the analysis to be performed, and that the required reagents and standards are available. In operating the analyser, they will be expected to following the correct procedures for calling the analyser operating program, entering operating parameters for analysis, dealing with error messages and executing the program safely and correctly. They will be required to work to the relevant standard operating procedures, legislation and organisational policy, and to follow Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP). They will also be required to present records and details of their laboratory work to the appropriate people.

The learner will be required to set up and operate the GC analyser in line with safe working practices and approved procedures, to monitor the analysis operations and, where necessary, to make the required adjustments in order to ensure that the output analysis is to the required quality and accuracy. Meeting laboratory targets will be an important issue, and their laboratory records must show consistent and satisfactory performance.

The learner's responsibilities will require them to comply with standard operating procedures for the GC work activities undertaken, and to report any problems that they cannot personally resolve, or that are outside their permitted authority, to the relevant people. They will be expected to work to instructions, with a minimum of supervision, either on their own or as part of a team, taking personal responsibility for their own actions and for the quality and accuracy of the work that they carry out.

The learner's underpinning knowledge will be sufficient to provide a sound basis for their work, and will enable them to adopt an informed approach to applying GC analyser procedures. They will have an understanding of the GC analysis process and its application, and will know about the analyser, the use of appropriate standards, samples and reagents, in adequate depth to provide a sound background for carrying out the laboratory activities to the required specification.

The learner will understand the safety precautions required when carrying out the laboratory activities for scientific operations and processes. They will be required to demonstrate safe working practices throughout, and will understand their responsibility for taking the necessary safeguards to protect themselves and others in the workplace.

Assessment requirements

Assessment requirements are set down in Annexe C: Assessment strategy.

Assessment methodology

This unit is assessed in the workplace. Learners can enter the types of evidence they are presenting for assessment and the submission date against each assessment criterion. Alternatively, centre documentation should be used to record this information.

Learning outcomes and assessment criteria

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
1 Analyse laboratory samples using Gas Chromatography	1.1 Ensure that their work is carried out in accordance with standard operating procedures 1.2 Wear the appropriate personal protection equipment (PPE) when handling specimens 1.3 Wear three of the following types of protective clothing and equipment: – laboratory coat/overalls – face mask/respirator – gloves – safety glasses/safety goggles – mop cap – other (please specify) 1.4 Confirm that the equipment is calibrated, safe and ready for operation			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	1.5 Carry out all of the following operations: – confirm that the machine is ready for analysis – check that all safety equipment and guards are in place and are functioning correctly – prepare reagents, mobile phase and machine operating program sequences – install the column and prime the system – ensure that specimens are in suitable containers/vials (e.g. not overfilled, poorly crimped or wrong septa) – ensure that machine settings are adjusted as and when required for the analysis – allow for suitable system equilibration by running method conditions and monitoring the baseline and standard peak height – ensure that all specimens are correctly loaded with respect to sequence requirements – check that the operating program sequence is at the correct start point, and that all the data handling is ready for data acquisition – operate the analyser, following the defined operating procedures, and apply safe working practices and procedures at all times			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	1.6 Follow the defined procedures for starting and running the operating system and/or data handling and control software 1.7 Run appropriate system parameter tests and confirm the system suitability for the analyses to be done			
2 Analyse laboratory samples using Gas Chromatography (continued)	2.1 Deal promptly and effectively with error messages or equipment faults that are within their control, and report those that cannot be resolved 2.2 Load standards and specimens for analysis and run program sequences correctly 2.3 Shut down the equipment to a safe condition on conclusion of the activities, using the compatible flushing and line storage procedures 2.4 Evaluate data in accordance with standard operating procedures and manufacturers' instructions			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	2.5 Carry out analyser maintenance involving eight of the following: – changing liners – changing injector septa – changing waste arm septa – changing rinse reservoir fluid – venting the pump – changing pump oil – changing syringes – changing ferrules – changing capillary columns – preparing and conditioning columns – packing columns 2.6 Communicate the required information about the work done, to authorised people, in accordance with departmental and organisational procedures			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	2.7 Record details of the preparation work and communicate to the appropriate people, using: – verbal report Plus one method from the following: – written or typed report – specific company documentation – computer-based record – electronic mail			
3 Know how to analyse laboratory samples using Gas Chromatography	3.1 Describe the health and safety requirements of the area in which they are carrying out the laboratory activities 3.2 Describe the implications of not taking account of legislation, regulations, standards and guidelines when conducting laboratory activities 3.3 Describe the principles of Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP) applied in the workplace 3.4 Describe the importance of wearing protective clothing, gloves and eye protection when handling laboratory samples for analysis 3.5 Describe the laboratory sample reception, records database and tracking system			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	3.6 Describe the types of handling and sorting system used, and the procedures and practices used for transferring specimens/samples within the laboratory while undergoing processing 3.7 Describe the importance of using the correct identification, and any unique organisational or laboratory numbers for specimens/samples 3.8 Describe the organisational requirements for maintaining the security of the workplace (e.g. workplace access and laboratory sample containment) 3.9 Describe the lines of communication and responsibilities in their department, and the links with the rest of the organisation 3.10 Describe the limits of their own authority and to whom they should report if they have problems that they cannot resolve 3.11 Describe the minimum size/volume of laboratory sample required for the gas chromatography (GC) investigations conducted by the laboratory 3.12 Describe the range of samples analysed, containers used for GC analysis in the laboratory and other essential resources needed for each investigation			
4 Know how to analyse laboratory samples using Gas Chromatography (continued)	4.1 Describe the importance of keeping the work area clean and tidy 4.2 Describe the main features of the GC analyser, and the accessories that can be used			

Learning outcomes	Assessment criteria		Evidence type	Portfolio reference	Date
	4.3	Describe the various GC analyser operations that can be performed, and the methods and equipment used			
	4.4	Describe the various sources of combustion and carrier gases, and the importance of ensuring consistency of supply and flow rate and checking for leaks			
	2,17	Explain how to record and prepare standard samples, reagents and mobile phases			
	4.5	Describe the manufacturer's instructions for changing consumables and maintenance items in the GC analyser			
	4.6	Explain how to interpret the analyser visual display and understand the various messages displayed			
	4.7	Describe the function of error messages, and what to do if an error message is displayed			
	4.8	Explain how to find the correct restart point in the program if the GC has been stopped before completion of the program			
	4.9	Explain where to obtain the standard operating procedures, equipment procedures and job instructions required for the analysis to be conducted			
	4.10	Describe the typical GC faults, and the actions to be taken if they occur			
	4.11	Describe the procedure to be followed if a broken or leaking sample is identified in the laboratory			

Learner name: _____ Date: _____

Learner signature: _____ Date: _____

Assessor signature: _____ Date: _____

Internal verifier signature: _____ Date: _____
(*if sampled*)

Unit 8: Analysing laboratory samples using Gas Chromatography-Mass Spectrometry (GCMS)

Unit reference number: D/601/8177

Level: 3

Credit value: 12

Guided learning hours: 50

Unit summary

This unit covers the skills and knowledge needed to prove the competences required to carry out laboratory sample analysis using gas chromatography-mass spectrometry (GCMS) analysers, in accordance with approved procedures. The learner is required to confirm that the GCMS analyser is ready for the analysis to be performed, and that the required reagents and standards are available. In operating the analyser, they will be expected to follow the correct procedures for calling the analyser operating program, entering operating parameters for analysis, dealing with error messages and executing the program safely and correctly. They will be required to work to the relevant standard operating procedures, legislation and organisational policy, and to follow Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP). They will also be required to present records and details of their laboratory work to the appropriate people.

The learner will be required to set up and operate the GCMS analyser in line with safe working practices and approved procedures, to monitor the analysis operations and, where necessary, make the required adjustments in order to ensure that the output analysis is to the required quality and accuracy. Meeting laboratory targets will be an important issue, and their laboratory records must show consistent and satisfactory performance.

The learner's responsibilities will require them to comply with standard operating procedures for the GCMS activities undertaken, and to report any problems that they cannot personally resolve, or that are outside their permitted authority, to the relevant people. They will be expected to work to instructions, with a minimum of supervision, either on their own or as part of a team, taking personal responsibility for their own actions and for the quality and accuracy of the work that they carry out.

The learner's underpinning knowledge will be sufficient to provide a sound basis for their work, and will enable them to adopt an informed approach to applying GCMS analyser procedures. They will have an understanding of the GCMS analysis process and its application, and will know about the analyser, the use of appropriate standards, samples and reagents, in adequate depth to provide a sound background for carrying out the laboratory activities to the required specification.

The learner will understand the safety precautions required when carrying out the laboratory activities for scientific operations and processes. They will be required to demonstrate safe working practices throughout, and will understand their responsibility for taking the necessary safeguards to protect themselves and others in the workplace.

Assessment requirements

Assessment requirements are set down in Annexe D: Assessment strategy.

Assessment methodology

This unit is assessed in the workplace. Learners can enter the types of evidence they are presenting for assessment and the submission date against each assessment criterion. Alternatively, centre documentation should be used to record this information.

Learning outcomes and assessment criteria

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
1 Analyse laboratory samples using Gas Chromatography-Mass Spectrometry	1.1 Ensure that their work is carried out in accordance with standard operating procedures 1.2 Wear the appropriate personal protection equipment (PPE) when handling specimens 1.3 Wear three of the following types of protective clothing and equipment: – laboratory coat/overalls – face mask/respirator – gloves – safety glasses/safety goggles – mop cap – other (please specify) 1.4 Confirm that the equipment is calibrated, safe and ready for operation			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	1.5 Carry out all of the following operations: – confirm that the machine is ready for analysis – check that all safety equipment and guards are in place and functioning correctly – prepare reagents, mobile phase and machine operating program sequences – install the column and prime the system – ensure that specimens are in suitable containers/vials (e.g. not overfilled, poorly crimped or wrong septa) – ensure that machine settings are adjusted as and when required for the analysis – allow for suitable system equilibration by running method conditions and monitoring the baseline and standard peak height – ensure that all specimens are correctly loaded with respect to sequence requirements – check that the operating program sequence is at the correct start point, and that all the data handling is ready for data acquisition – operate the analyser, following the defined operating procedures, and apply safe working practices and procedures at all times			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	1.6 Follow the defined procedures for starting and running the operating system and/or data handling and control software 1.7 Run appropriate system parameter tests and confirm the system suitability for the analyses to be done			
2 Analyse laboratory samples using Gas Chromatography-Mass Spectrometry (continued)	2.1 Deal promptly and effectively with error messages or equipment faults that are within their control, and report those that cannot be resolved 2.2 Load standards and specimens for analysis and run program sequences correctly 2.3 Shut down the equipment to a safe condition on conclusion of the activities, using the compatible flushing and line storage procedures 2.4 Evaluate data in accordance with standard operating procedures and manufacturers' instructions			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	2.5 Carry out analyser maintenance involving ten of the following: – changing liners – changing injector septa – changing waste arm septa – changing rinse reservoir fluid – venting the pump – changing pump oil – changing syringes – changing ferrules – changing capillary columns – preparing and conditioning columns – packing columns – changing electron multiplier and replacement horns – changing filaments – changing ion source – changing MS chemicals 2.6 Communicate the required information about the work done, to authorised people, in accordance with departmental and organisational procedures			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	2.7 Record details of the preparation work and communicate the details to the appropriate people, using: – verbal report Plus one method from the following: – written or typed report – specific company documentation – computer-based record – electronic mail			
3 Know how to analyse laboratory samples using Gas Chromatography-Mass Spectrometry	3.1 Describe the health and safety requirements of the area in which they are carrying out the laboratory activities 3.2 Describe the implications of not taking account of legislation, regulations, standards and guidelines when conducting laboratory activities 3.3 Describe the principles of Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP) applied in the workplace 3.4 Describe the importance of wearing protective clothing, gloves and eye protection when handling laboratory samples for analysis 3.5 Describe the laboratory sample reception, records database and tracking system			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	3.6 Describe the types of handling and sorting system used, and the procedures and practices used for transferring specimens/samples within the laboratory while undergoing processing 3.7 Describe the importance of using the correct identification, and any unique organisational or laboratory numbers for specimens/samples 3.8 Describe the organisational requirements for maintaining the security of the workplace (e.g. workplace access and laboratory sample containment) 3.9 Describe the lines of communication and responsibilities in their department, and the links with the rest of the organisation 3.10 Describe the limits of their own authority and to whom they should report if they have problems that they cannot resolve 3.11 Describe the minimum size/volume of laboratory sample required for the Gas Chromatography-Mass Spectrometry (GCMS) investigations conducted by the laboratory 3.12 Describe the range of samples analysed, containers used for GCMS analysis in the laboratory, and other essential resources needed for each investigation			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
4 Know how to analyse laboratory samples using Gas Chromatography-Mass Spectrometry (continued)	4.1 Describe the importance of keeping the work area clean and tidy 4.2 Describe the main features of the GCMS analyser, and the accessories that can be used 4.3 Describe the various GCMS analyser operations that can be performed, and the methods and equipment used 4.4 Describe the various sources of combustion and carrier gases, and the importance of ensuring consistency of supply and flow rate and checking for leaks 4.5 Explain how to record and prepare standard samples, reagents and mobile phases 4.6 Describe the manufacturer's instructions for changing consumables and maintenance items in the GCMS analyser 4.7 Explain how to interpret the analyser visual display and understand the various messages displayed 4.8 Describe the function of error messages, and what to do if an error message is displayed 4.9 Explain how to find the correct restart point in the program if the GCMS has been stopped before completion of the program			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	4.10 Explain where to obtain the standard operating procedures, equipment procedures and job instructions required for the analysis to be conducted 4.11 Describe the typical GCMS faults, and the actions to be taken if they occur 4.12 Describe the procedure to be followed if a broken or leaking sample is identified in the laboratory			

Learner name: _____ Date: _____

Learner signature: _____ Date: _____

Assessor signature: _____ Date: _____

Internal verifier signature: _____ Date: _____
(*if sampled*)

Unit 9: Analysing laboratory samples using Gas Chromatography-Thermal Conductivity (GCTC)

Unit reference number: H/601/8178

Level: 3

Credit value: 8

Guided learning hours: 33

Unit summary

This unit covers the skills and knowledge needed to prove the competences required to carry out laboratory sample analysis using gas chromatography-thermal conductivity (GCTC) analysers, in accordance with approved procedures. The learner is required to confirm that the GCTC analyser is ready for the analysis to be performed, and that the required reagents and standards are available. In operating the analyser, they will be expected to follow the correct procedures for calling the analyser operating program, entering operating parameters for analysis, dealing with error messages and executing the program safely and correctly. They will be required to work to the relevant standard operating procedures, legislation and organisational policy, and to follow Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP). They will also be required to present records and details of their laboratory work to the appropriate people.

They will be required to set up and operate the GCTC analyser in line with safe working practices and approved procedures, to monitor the analysis operations and, where necessary, make the required adjustments in order to ensure that the output analysis is to the required quality and accuracy. Meeting laboratory targets will be an important issue, and their laboratory records must show consistent and satisfactory performance.

Their responsibilities will require them to comply with standard operating procedures for the GCTC activities undertaken, and to report any problems that they cannot personally resolve, or that are outside their permitted authority, to the relevant people. They will be expected to work to instructions, with a minimum of supervision, either on their own or as part of a team, taking personal responsibility for their own actions and for the quality and accuracy of the work that they carry out.

Their underpinning knowledge will be sufficient to provide a sound basis for their work, and will enable them to adopt an informed approach to applying GCTC analyser procedures. They will have an understanding of the GCTC analysis process and its application, and will know about the analyser, the use of appropriate standards, samples and reagents, in adequate depth to provide a sound background for carrying out the laboratory activities to the required specification.

They will understand the safety precautions required when carrying out the laboratory activities for scientific operations and processes. They will be required to demonstrate safe working practices throughout, and will understand their responsibility for taking the necessary safeguards to protect yourself and others in the workplace.

Assessment requirements

Assessment requirements are set down in Annexe C: Assessment strategy.

Assessment methodology

This unit is assessed in the workplace. Learners can enter the types of evidence they are presenting for assessment and the submission date against each assessment criterion. Alternatively, centre documentation should be used to record this information.

Learning outcomes and assessment criteria

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
1 Analyse laboratory samples using Gas Chromatography-Thermal Conductivity	1.1 Ensure that their work is carried out in accordance with standard operating procedures 1.2 Wear the appropriate personal protection equipment (PPE) when handling specimens 1.3 Wear three of the following types of protective clothing and equipment: – laboratory coat/overalls – face mask/respirator – gloves – safety glasses/safety goggles – mop cap – other (please specify) 1.4 Confirm that the equipment is calibrated, safe and ready for operation			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	1.5 Carry out all of the following operations: – confirm that the machine is ready for analysis – check that all safety equipment and guards are in place and are functioning correctly – prepare reagents, mobile phase and machine operating program sequences – check reference gas flow for thermal conductivity analysis – check thermal conductivity reference supply cylinder levels – install the column and prime the system – ensure that specimens are in suitable containers/vials (e.g. not overfilled, poorly crimped or wrong septa) – confirm the machine settings are adjusted as and when required for the analysis – allow for suitable system equilibration by running method conditions and monitoring the baseline and standard peak height – ensure that all specimens are correctly loaded with respect to sequence requirements – check that the operating program method and sequence is at the correct start point, and that all the data handling is ready for data acquisition – operate the analyser, following the defined operating procedures, and apply safe working practices and procedures at all times			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	1.6 Follow the defined procedures for starting and running the operating system and/or data handling and control software 1.7 Run appropriate system parameter tests and confirm the system suitability for the analyses to be done 1.8 Deal promptly and effectively with error messages or equipment faults that are within their control, and report those that cannot be resolved			
2 Analyse laboratory samples using Gas Chromatography-Thermal Conductivity (continued)	2.1 Load standards and specimens for analysis and run program sequences correctly 2.2 Shut down the equipment to a safe condition on conclusion of the activities, using the compatible flushing and line storage procedures 2.3 Evaluate data in accordance with standard operating procedures and manufacturers' instructions			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	2.4 Carry out analyser maintenance involving eight of the following: – changing liners – changing injector septa – changing waste arm septa – changing rinse reservoir fluid – venting the pump – changing pump oil – changing syringes – changing ferrules – changing capillary columns – preparing and conditioning columns – packing columns 2.5 Communicate the required information about the work done, to authorised people, in accordance with departmental and organisational procedures			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	2.6 Record details of preparation work, and communicate the details to the appropriate people, using: – verbal report Plus one method from the following: – written or typed report – specific company documentation – computer-based record – electronic mail			
3 Know how to analyse laboratory samples using Gas Chromatography-Thermal Conductivity	3.1 Describe the health and safety requirements of the area in which they are carrying out the laboratory activities 3.2 Describe the implications of not taking account of legislation, regulations, standards and guidelines when conducting laboratory activities 3.3 Describe the principles of Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP) applied in the workplace 3.4 Describe the importance of wearing protective clothing, gloves and eye protection when handling laboratory samples for analysis 3.5 Describe the laboratory sample reception, records database and tracking system			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	3.6 Describe the types of handling and sorting system used, and the procedures and practices used for transferring specimens/samples within the laboratory while undergoing processing 3.7 Describe the importance of using the correct identification, and any unique organisational or laboratory numbers for specimens/samples 3.8 Describe the organisational requirements for maintaining the security of the workplace (e.g. workplace access and laboratory sample containment) 3.9 Describe the lines of communication and responsibilities in their department, and the links with the rest of the organisation 3.10 Describe the limits of their own authority and to whom they should report if they have problems that they cannot resolve 3.11 Describe the minimum size/volume of laboratory sample required for the Gas Chromatography-Thermal Conductivity (GCTC) investigations conducted by the laboratory 3.12 Describe the range of samples analysed, containers used for GCTC analysis in the laboratory, and other essential resources needed for each investigation			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
4 Know how to analyse laboratory samples using Gas Chromatography-Thermal Conductivity (continued)	4.1 Describe the importance of keeping the work area clean and tidy 4.2 Describe the main features of the GCTC analyser, and the accessories that can be used 4.3 Describe the various GCTC analyser operations that can be performed, and the methods and equipment used 4.4 Describe the various sources of combustion and carrier gases, and the importance of ensuring consistency of supply and flow rate and checking for leaks 4.5 Explain how to record and prepare standard samples, reagents and mobile phases 4.6 Describe the manufacturer's instructions for changing consumables and maintenance items in the GCTC analyser 4.7 Explain how to interpret the analyser visual display and understand the various messages displayed 4.8 Describe the function of error messages, and what to do if an error message is displayed 4.9 Explain how to find the correct restart point in the program if the GCTC has been stopped before completion of the program.			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	4.10 Identify where to obtain the standard operating procedures, equipment procedures and job instructions required for the analysis to be conducted 4.11 Describe the typical GCTC faults, and the actions to be taken if they occur 4.12 Describe the procedure to be followed if a broken or leaking sample is identified in the laboratory			

Learner name: _____ Date: _____

Learner signature: _____ Date: _____

Assessor signature: _____ Date: _____

Internal verifier signature: _____ Date: _____
(*if sampled*)

Unit 10: Analysing DNA/RNA samples using Polymerase Chain Reaction (PCR) and Quantitative PCR (QPCR)

Unit reference number: K/601/8182

Level: 3

Credit value: 8

Guided learning hours: 33

Unit summary

This unit covers the skills and knowledge needed to prove the competences required to carry out laboratory sample analysis using Polymerase Chain Reaction and Quantitative PCR, in accordance with approved procedures. The learner is required to confirm that the required reagents are available and have been stored in the way indicated by the supplier. Before carrying out the analysis, they will be expected to follow the correct procedures for ensuring that a high standard of cleanliness is maintained with due regard for the risk of cross contamination of samples. They will be required to work to the relevant standard operating procedures, legislation and organisational policy, and to follow Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP). They will be expected to handle potentially dangerous chemicals in such a way that they are contained within designated areas whilst in use, and are disposed of in the correct way. They will also be required to present records and details of their laboratory work to the appropriate people.

The learner will be required to set up and operate the PCR thermal/light cycler, choosing the required program, in line with safe working practices and approved procedures, to monitor the analysis operations and, where necessary, to make the required adjustments in order to ensure that the output analysis is to the required quality and accuracy. Meeting laboratory targets will be an important issue, and their laboratory records must show consistent and satisfactory performance.

The learner's responsibilities will require them to comply with standard operating procedures for the PCR activities undertaken, and to report any problems that they cannot personally resolve, or that are outside their permitted authority, to the relevant people. They will be expected to work to instructions, with a minimum of supervision, either on their own or as part of a team, taking personal responsibility for their own actions and for the quality and accuracy of the work that they carry out.

The learner's underpinning knowledge will be sufficient to provide a sound basis for their work, and will enable them to adopt an informed approach to applying PCR, thermal/light cycler procedures. They will have an understanding of the PCR reaction and the reagents used, the use of fluorescent dyes in visualizing DNA and RNA, and in QPCR, and the interpretation of amplified DNA, in adequate depth to provide a sound

background for carrying out the laboratory activities to the required specification.

The learner will understand the safety precautions required when carrying out the preparation and disposal of hazardous chemicals, and will understand the nature of the risks involved with these chemicals. They will be required to demonstrate safe working practices throughout, and will understand their responsibility for taking the necessary safeguards to protect yourself and others in the workplace and outside.

Assessment requirements

Assessment requirements are set down in Annexe C: Assessment strategy.

Assessment methodology

This unit is assessed in the workplace. Learners can enter the types of evidence they are presenting for assessment and the submission date against each assessment criterion. Alternatively, centre documentation should be used to record this information.

Learning outcomes and assessment criteria

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
1 Analyse DNA/RNA samples using Polymerase Chain Reaction and Quantitative PCR	1.1 Ensure that their work is carried out in accordance with standard operating procedures 1.2 Wear the appropriate personal protection equipment (PPE) when handling specimens 1.3 Wear three of the following types of protective clothing and equipment: – laboratory coat/overalls – face mask/respirator – gloves – safety glasses/safety goggles – mop cap – other (please specify) 1.4 Confirm that the analyser and associated equipment are ready for operation			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	1.5 Carry out all of the following: – confirm that the machine is ready for analysis – check that all safety equipment and guards are in place and are functioning correctly – prepare reagents and reaction mixtures to the desired level of accuracy – load the thermal/light cycler, and select the correct operating program – ensure that all specimens are correctly loaded with respect to sequence requirements – check that the operating program method and sequence is at the correct start point, and that all the data handling is ready for data acquisition – operate the analyser, following the defined operating procedures, and apply safe working practices and procedures at all times 1.6 Ensure that reagents are stored correctly and are maintained at the correct temperature during use 1.7 Start and run the operating system, and select the appropriate program for the analysis to be done 1.8 Deal promptly and effectively with error messages or equipment faults and report those that cannot be resolved			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
2 Analyse DNA/RNA samples using Polymerase Chain Reaction and Quantitative PCR (continued)	2.1 Load specimens for analysis and run program sequences correctly 2.2 Ensure that correct positive and negative controls are included for each run of the thermal/light cycler 2.3 Record and evaluate data in accordance with standard operating procedures and the LIMS 2.4 Store reaction mixtures at the correct temperature, and dispose of spent materials in accordance with departmental health and safety procedures 2.5 Conduct all the following: – calibration of micro pipettes – storage of reagents – storage of samples – handling and disposal of dangerous chemicals – selecting and running the program – recording data in the LIMS 2.6 Communicate the required information about the work done, to authorised people, in accordance with departmental and organisational procedures			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	2.7 Record details of the analysis work, and communicate the details to the appropriate people, using: – verbal report Plus one method from the following: – written or typed report – specific company documentation – computer-based record – electronic mail			
3 Know how to analyse DNA/RNA samples using Polymerase Chain Reaction and Quantitative PCR	3.1 Describe the health and safety requirements of the area in which they are carrying out the analytical activities 3.2 Describe the implications of not taking account of legislation, regulations, standards and guidelines when conducting laboratory activities 3.3 Describe the principles of Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP) applied in the workplace 3.4 Describe the importance of wearing protective clothing, gloves and eye protection when handling laboratory samples for analysis 3.5 Describe the laboratory sample reception, records database and tracking system			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	3.6 Describe the types of handling and sorting system used, and the procedures and practices used for transferring specimens/samples within the laboratory whilst undergoing processing 3.7 Describe the importance of using the correct identification, and any unique organisational or laboratory numbers for specimens/samples 3.8 Describe the organisational requirements for maintaining the security of the workplace (e.g., workplace access and laboratory sample containment) 3.9 Describe the lines of communication and responsibilities in their department, and the links with the rest of the organisation 3.10 Describe the limits of their own authority and to whom they should report if they have problems that they cannot resolve 3.11 Describe the minimum size/volume of laboratory sample required for the PCR investigations conducted by the laboratory 3.12 Describe the range of samples analysed, containers used for sample storage and PCR analysis in the laboratory, and other essential resources needed for each investigation			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
4	Know how to analyse DNA/RNA samples using Polymerase Chain Reaction and Quantitative PCR (continued)	4.1	Describe the importance of keeping the work area clean and tidy, and of avoiding cross contamination of samples			
		4.2	Describe the main features of the PCR analyser, and the underlying action of the reagents involved in the reaction mixture			
		4.3	Describe the various PCR thermal cycler operations that can be performed, and the methods and reaction mixtures used			
		4.4	Describe the manufacturer's instructions for changing programs and maintenance items in the thermal cycler			
		4.5	Explain how to interpret the cycler visual display and understand the various messages displayed			
		4.6	Describe the function of error messages, and what to do if an error message is displayed			
		4.7	Explain how to find the correct restart point in the program if the cycler has been stopped before completion of the program			
		4.8	Explain where to obtain the standard operating procedures, equipment procedures and job instructions required for the procedure to be conducted			
		4.9	Describe the typical thermal cycler faults, and the actions to be taken if they occur			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	4.10 Describe the procedure to be followed when disposing of harmful chemicals and contaminated equipment 4.11 Describe the procedure to be followed if a broken or leaking sample is identified in the laboratory			

Learner name: _____ Date: _____

Learner signature: _____ Date: _____

Assessor signature: _____ Date: _____

Internal verifier signature: _____ Date: _____
(*if sampled*)

Unit 11: Amplifying DNA samples using Polymerase Chain Reaction (PCR)

Unit reference number: J/601/8187

Level: 3

Credit value: 8

Guided learning hours: 33

Unit summary

This unit covers the skills and knowledge needed to prove the competences required to carry out laboratory sample amplification using Polymerase Chain Reaction (PCR), in accordance with approved procedures. The learner is required to confirm that the necessary reagents are available and have been stored in the way indicated by the supplier. They will be expected to follow the correct procedures, whilst ensuring that a high standard of cleanliness is maintained with due regard for the risk of cross contamination of samples. The learner will be required to work to the relevant standard operating procedures, legislation and organisational policy, and to follow Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP). They will be expected to handle potentially dangerous chemicals, ensuring that they are contained within designated areas whilst in use and are disposed of in the correct way. They will be required to present records and details of their laboratory work to the appropriate people.

The learner will be required to set up and operate the PCR thermal cycler, choosing the required program, in line with safe working practices and approved procedures and, where necessary, to make the required adjustments in order to ensure that the output analysis is to the required quality and accuracy. Meeting laboratory targets will be an important issue, and their laboratory records must show consistent and satisfactory performance.

The learner's responsibilities will require them to comply with standard operating procedures for the PCR work activities undertaken, and to report any problems that they cannot personally resolve, or that are outside their permitted authority, to the relevant people. They will be expected to work to instructions with a minimum of supervision, either on their own or as part of a team, taking personal responsibility for their own actions and for the quality and accuracy of the work that they carry out.

The learner's underpinning knowledge will be sufficient to provide a sound basis for their work, and will enable them to adopt an informed approach to applying PCR and thermocycler procedures. They will have an understanding of the PCR reaction and the reagents used, in sufficient detail to provide a sound background for carrying out the laboratory activities to the required specification.

The learner will understand the safety precautions required when carrying out the preparation and disposal of dangerous chemicals, and they will be aware of the risks involved with these chemicals. They will be required to demonstrate safe working practices throughout, and will understand their responsibility for taking the necessary safeguards to protect themselves and others in the workplace and outside.

Assessment requirements

Assessment requirements are set down in Annexe C: Assessment strategy.

Assessment methodology

This unit is assessed in the workplace. Learners can enter the types of evidence they are presenting for assessment and the submission date against each assessment criterion. Alternatively, centre documentation should be used to record this information.

Learning outcomes and assessment criteria

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
1 Analyse DNA samples using Polymerase Chain Reaction	1.1 Ensure that their work is carried out in accordance with standard operating procedures 1.2 Wear the appropriate personal protection equipment (PPE) or have the appropriate safety controls in place when handling specimens 1.3 Wear three of the following types of protective clothing and equipment: – laboratory coat/overalls – face mask/respirator – gloves – safety glasses/safety goggles – mop cap – other (please specify) 1.4 Confirm that the equipment is clean, safe and ready for operation and that any ancillary equipment is calibrated			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	1.5 Carry out all of the following amplification operations: – use correctly stored reagents, and thaw on ice – set up reactions, and maintain on ice prior to transfer to the thermocycler – confirm that the thermocycler is ready for the amplification process – check that all safety equipment and guards are in place and are functioning correctly – prepare reagents and reaction mixtures, according to the scale required – add specimens to the reaction mixture, load the thermocycler and select the correct operating program – ensure that all specimens are correctly loaded with respect to sequence and requirements – check that the operating program sequence is at the correct start point and that all the data handling is ready for data acquisition – operate the PCR equipment, following the defined operating procedures, and apply safe working practices and procedures at all times – remove the amplified DNA and store correctly for the next operation			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	1.6 Ensure that reagents are stored, thawed and transferred to the thermocycler correctly 1.7 Correctly quantify the DNA concentration of each sample, by spectroscopic techniques (OD260nm)			
2 Analyse DNA samples using Polymerase Chain Reaction (continued)	2.1 Start and run the thermocycler, and identify the appropriate PCR amplification program 2.2 Deal promptly and effectively with error messages or equipment faults that are within their control and report those that cannot be resolved 2.3 Load the PCR thermal cycler with reactions containing the DNA, and run the amplification program correctly 2.4 Transfer the amplified DNA to the correct location for further processing 2.5 Complete all of the following activities: – calibrating of micro pipettes – storage of reagents – storage of samples – disposal of waste products – selecting PCR amplification 2.6 Communicate the required information about the work done, to authorised people, in accordance with departmental and organisational procedures			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	2.7 Record details of the work and communicate the details to the appropriate people, using: – verbal report Plus one method from the following: – written or typed report – specific company documentation – computer-based record – electronic mail			
3 Know how to analyse DNA samples using Polymerase Chain Reaction	3.1 Describe the health and safety requirements of the area in which they are carrying out the analytical activities 3.2 Describe the implications of not taking account of legislation, regulations, standards and guidelines when conducting laboratory activities 3.3 Describe the principles of Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP) applied in the workplace 3.4 Describe the importance of wearing protective clothing, gloves and eye protection when handling laboratory samples for analysis 3.5 Describe the laboratory sample reception, records database and tracking system			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	3.6 Describe the types of handling and sorting system used, and the procedures and practices used for transferring specimens/samples within the laboratory while undergoing processing 3.7 Describe the importance of using the correct identification, and any unique organisational or laboratory numbers for specimens/samples 3.8 Describe the organisational requirements for maintaining the security of the workplace (e.g., workplace access and laboratory sample containment) 3.9 Describe the lines of communication and responsibilities in their department, and the links with the rest of the organisation 3.10 Describe the limits of their own authority and to whom they should report if they have problems that they cannot resolve 3.11 Describe the minimum size/volume/DNA concentration of laboratory sample required for the PCR amplifications conducted by the laboratory			
4 Know how to analyse DNA samples using Polymerase Chain Reaction (continued)	4.1 Describe the range of samples amplified, the containers used for sample storage and PCR amplification in the laboratory, and other essential resources needed for each investigation 4.2 Describe the importance of keeping the work area clean and tidy, and of avoiding cross contamination of samples			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	4.3 Describe the main features of the PCR thermocycler, and the underlying action of the reagents involved in the reaction mixture 4.4 Describe the various PCR thermocycler operations that can be performed, and the methods and reaction mixtures used 4.5 Describe the manufacturer's instructions for changing programs and maintenance items in the thermocycler 4.6 Explain how to interpret a PCR's visual display, and how to understand the various messages displayed 4.7 Describe the function of error messages, and what to do if an error message is displayed 4.8 Explain where to obtain the standard operating procedures, equipment procedures and job instructions required for the process to be conducted 4.9 Describe the typical thermocycler faults, and the actions to be taken if they occur 4.10 Describe the procedure to be followed when disposing of harmful chemicals and contaminated equipment 4.10 Describe the procedure to be followed if a broken or leaking sample is identified in the laboratory			

Learner name: _____ Date: _____

Learner signature: _____ Date: _____

Assessor signature: _____ Date: _____

Internal verifier signature: _____ Date: _____
(*if sampled*)

Unit 12: Maintaining cell lines for laboratory activities using cryogenic storage

Unit reference number: J/601/8190

Level: 3

Credit value: 6

Guided learning hours: 25

Unit summary

This unit covers the skills and knowledge needed to prove the competences required to maintain cell lines in cryogenic storage, in accordance with approved procedures. The learner is required to confirm that the required media are available, and that they have been prepared and stored in the way indicated by the manufacturer. In carrying out these activities, they will be expected to follow the correct procedures, whilst ensuring that a high standard of cleanliness and accuracy is maintained, with due regard for the risk of cross contamination of samples.

The learner will be required to work to the relevant standard operating procedures, legislation and organisational policy, and to follow Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP). They will be expected to handle potentially dangerous materials and chemicals, ensuring that they are contained within designated areas whilst in use, and are disposed of in the correct way. They will be required to present records and details of their laboratory work to the appropriate people.

The learner will be required to set up and grow cell lines in continuous or monolayer culture, choosing the required support medium, in line with safe working practices and approved procedures. They will then be required to harvest the cells and to determine the cell density, using a microscope or cell counting apparatus. They will make the required adjustments to cell density to obtain the predetermined value to give optimum viability after cryopreservation, in order to ensure that the output is to the required quality and accuracy, and that the cells remain viable after long term preservation. Meeting laboratory targets will be an important issue, and their laboratory records must show consistent and satisfactory performance.

The learner's responsibilities will require them to comply with standard operating procedures for the cell culture work activities undertaken, and to report any problems that they cannot personally resolve, or that are outside their permitted authority, to the relevant people. They will be expected to work to instructions, with a minimum of supervision, either on their own or as part of a team, taking personal responsibility for their own actions and for the quality and accuracy of the work that they carry out.

The learner's underpinning knowledge will be sufficient to provide a sound basis for their work, and will enable them to adopt an informed approach to applying the appropriate procedures. They will have an understanding of the principles of cell culture and cryopreservation, the media and reagents used, and the factors affecting viability of cells during and after freezing, in adequate depth to provide a sound background for carrying out the laboratory activities to the required specification.

The learner will understand the safety precautions required when carrying out the preparation and disposal of dangerous materials and chemicals, and they will be aware of the risks involved with these materials, chemicals and associated equipment. They will be required to demonstrate safe working practices throughout, and will understand their responsibility for taking the necessary safeguards to protect yourself and others in the workplace and outside.

Assessment requirements

Assessment requirements are set down in Annexe C: Assessment strategy.

Assessment methodology

This unit is assessed in the workplace. Learners can enter the types of evidence they are presenting for assessment and the submission date against each assessment criterion. Alternatively, centre documentation should be used to record this information.

Learning outcomes and assessment criteria

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
1 Maintain cell lines for laboratory activities using cryogenic storage	1.1 Ensure that their work is carried out in accordance with standard operating procedures 1.2 Wear the appropriate personal protection equipment (PPE) when handling specimens and equipment 1.3 Wear three of the following types of protective clothing and equipment: – laboratory coat/overalls – face mask/respirator – gloves/cryogloves – safety glasses/goggles/visor – mop cap – other (please specify)			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	1.4 Carry out all of the following for cell cryopreservation: – confirm that the safety cabinet, cryopreservation device and storage unit are clean and ready for use – check that all safety equipment and guards are in place and are functioning correctly – prepare reagents and reaction mixtures to the desired level of accuracy, ensuring that sterility is maintained – Prepare the cell suspension at the correct cell density – load the cell suspension into ampoules, and seal correctly – ensure that all specimens are correctly labelled – operate the controlled freezing device until the correct temperature is reached – transfer frozen cultures to long term storage – check the viability of frozen cultures after storage at very low temperature 1.5 Harvest cells in logarithmic growth suitable for cryogenic storage			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	1.6 Count the cells in a cell suspension, ensuring that clumps of cells are broken up, and adjust the cell count to the pre-determined optimum for recovery after freezing 1.7 Prepare the freezing media and re-suspend cells in this medium 1.8 Put aliquots of cells into ampoules, and seal and label them appropriately			
2 Maintain cell lines for laboratory activities using cryogenic storage (continued)	2.1 Freeze cultures in ampoules, using a controlled freezing chamber, in the correct manner 2.2 Remove frozen cells to an appropriate long term cryopreservation chamber 2.3 Monitor the cryopreservation unit, as required, and replenish liquid nitrogen when required 2.4 Remove ampoules in cryopreservation chamber storage, to check viability of the cell line 2.5 Carry out all the following: – calibration of micro pipettes – storage of reagents – storage of samples – handling and disposal of dangerous chemicals – measuring cell density – selecting the freezing program – recording data			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	2.6 Communicate the required information about the work done, to authorised people, in accordance with departmental and organisational procedures 2.7 Record details of the work, and communicate the details to the appropriate people, using both of the following: – verbal report – laboratory notebook Plus one method from the following: – written or typed report – specific company documentation – computer-based record – electronic mail			
3 Know how to maintain cell lines for laboratory activities using cryogenic storage	3.1 Describe the health and safety requirements of the area in which they are carrying out the activities 3.2 Describe the implications of not taking account of legislation, regulations, standards and guidelines when conducting laboratory activities 3.3 Describe the principles of Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP) applied in the workplace.			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	3.4 Describe the importance of wearing protective clothing, gloves and eye protection when handling laboratory samples for analysis (including low temperature samples and liquid nitrogen) 3.5 Describe the laboratory sample reception, records database and tracking system 3.6 Describe the types of handling and sorting system used, and the procedures and practices used for transferring specimens/samples within the laboratory whilst undergoing processing 3.7 Describe the importance of using the correct identification, and any unique organisational or laboratory numbers for specimens/samples 3.8 Describe the organisational requirements for maintaining the security of the workplace (e.g. workplace access and laboratory sample containment) 3.9 Describe the lines of communication and responsibilities in their department, and the links with the rest of the organisation 3.10 Describe the limits of their own authority and to whom they should report if they have problems that they cannot resolve			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
4	Know how to maintain cell lines for laboratory activities using cryogenic storage (continued)	4.1	Describe the minimum number/size/volume of laboratory samples required for long term storage			
		4.2	Describe the range of cell lines and containers used for sample storage and analysis in the laboratory, and other essential resources needed for each investigation			
		4.3	Describe the importance of keeping the work area clean and tidy, and of avoiding cross contamination of samples			
		4.4	Describe the main features of the cryopreservation unit, and the underlying action of the reagents involved in freezing cells and reaction mixture			
		4.5	Describe the function of error messages on the controlled freezing station, and what to do if an error message is displayed			
		4.6	Explain how to find the correct restart point if the freezing run has been stopped before completion of the operation			
		4.7	Explain how to check that the freezing and storage of the cell line has been successful			
		4.8	Explain where to obtain the standard operating procedures, equipment procedures and job instructions required for the activities to be carried out			
		4.9	Describe the procedure to be followed when disposing of harmful materials, chemicals and contaminated equipment			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	4.10 Describe the procedure to be followed if a broken or leaking sample is identified in the laboratory			

Learner name: _____ Date: _____

Learner signature: _____ Date: _____

Assessor signature: _____ Date: _____

Internal verifier signature: _____ Date: _____
(*if sampled*)

Unit 13: Culturing/fermenting cells for laboratory activities using controlled fed batch or continuous culture fermentation

Unit reference number: Y/601/8193

Level: 3

Credit value: 12

Guided learning hours: 50

Unit summary

This unit covers the skills and knowledge needed to prove the competences required to carry out laboratory culturing/fermentation of cells using a batch, fed batch or continuous culture fermenter, in accordance with approved procedures. The learner is required to confirm that the required media, reagents and components are available and have been stored in the way indicated by the supplier. In carrying out these activities, they will be expected to follow the correct procedures, whilst ensuring that a high standard of cleanliness is maintained with due regard for the risk of cross contamination of samples. The learner will be required to work to the relevant standard operating procedures, legislation and organisational policy, and to follow Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP). They will be expected to handle potentially dangerous cultures, materials and chemicals, ensuring that they are contained within designated areas while in use and are disposed of in the correct way. They will be required to present records and details of their laboratory work to the appropriate people.

The learner will be required to set up and operate the fermenter, choosing the appropriate program, in line with safe working practices and approved procedures. They are also expected to monitor and analyse operations and, where necessary, make the required adjustments in order to ensure that the output analysis is to the required quality and accuracy. Meeting laboratory targets will be an important issue, and their laboratory records must show consistent and satisfactory performance.

The learner's responsibilities will require them to comply with standard operating procedures for the fermentation work activities undertaken, and to report any problems that they cannot personally resolve, or that are outside their permitted authority, to the relevant people. They will be expected to work to instructions with a minimum of supervision, either on their own or as part of a team, taking personal responsibility for their own actions and for the quality and accuracy of the work that they carry out.

The learner's underpinning knowledge will be sufficient to provide a sound basis for their work, and will enable them to adopt an informed approach to applying fermentation and process control procedures. They will have an

understanding of the fermentation reaction and the reagents used, in relation to control of temperature, pH, pO_2, agitation and foaming in the reaction vessel, in order to produce and accumulate an end product.

The learner will understand the safety precautions required when carrying out the preparation and disposal of dangerous materials and chemicals, and the will be aware of the risks involved in handling these substances. They will be required to demonstrate safe working practices throughout, and will understand their responsibility for taking the necessary safeguards to protect themselves and others in the workplace and outside.

Assessment requirements

Assessment requirements are set down in Annexe C: Assessment strategy.

Assessment methodology

This unit is assessed in the workplace. Learners can enter the types of evidence they are presenting for assessment and the submission date against each assessment criterion. Alternatively, centre documentation should be used to record this information.

Learning outcomes and assessment criteria

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
1 Culture/ferment cells for laboratory activities using controlled fed batch or continuous culture fermentation	1.1 Ensure that their work is carried out in accordance with standard operating procedures 1.2 Wear the appropriate personal protection equipment (PPE) when handling specimens and equipment, and apply safe working practices at all times 1.3 Wear three of the following types of protective clothing and equipment: – laboratory coat/overalls – face mask/respirator – gloves – safety glasses/safety goggles – mop cap – other (please specify)			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	1.4 Carry out all of the following fermentation operations: – confirm that the equipment is ready for the analysis – check that all safety equipment and guards are in place and are functioning correctly – prepare reagents and reaction mixtures to the desired level of accuracy – dismantle, autoclave and reassemble the fermenter on the control base – calibrate and prepare probes for pH and pO_2 – operate the fermenter program, and record and evaluate data during fermentation – use the equipment software to control the fermentation until the critical end point is reached – harvest the desired cells/components of the fermentation – disinfect the components of the fermenter, and clean the equipment ready for use again 1.5 Prepare the fermenter for fermentation, in accordance with established procedures 1.6 Inoculate the fermentation medium with a starter culture, and monitor the culture purity and growth rate during the growth stage			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	1.7 Monitor the fermentation using the software, making additions to the fermenter vessel as detailed in the relevant procedures, when necessary			
2 Culture/ferment cells for laboratory activities using controlled fed batch or continuous culture fermentation (continued)	2.1 Take samples to monitor the progress of cell growth and production of metabolites 2.2 Harvest the culture at the required growth phase/cell density/metabolite production 2.3 Dispose of spent materials in accordance with departmental health and safety procedures 2.4 Disinfect and clean the fermenter ready for next use, in accordance with the manufacturer's guidelines 2.5 Carry out all of the following: – calibration of micro pipettes – storage of reagents – storage of samples – handling and disposal of dangerous chemicals – selecting/running the program – using correct autoclave cycle – recording data 2.6 Communicate the required information about the work done, to authorised people, in accordance with departmental and organisational procedures			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	2.7 Record details of the work, and communicate the details to the appropriate people, using: – verbal report Plus one method from the following: – computer readout – written or typed report – specific company documentation – electronic mail			
3 Know how to culture/ferment cells for laboratory activities using controlled fed batch or continuous culture fermentation	3.1 Describe the health and safety requirements of the area in which they are carrying out the fermentation activities 3.2 Describe the implications of not taking account of legislation, regulations, standards and guidelines when conducting laboratory activities 3.3 Describe the principles of Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP) applied in the workplace 3.4 Describe the importance of wearing protective clothing, gloves and eye protection when handling laboratory samples for analysis 3.5 Describe the laboratory sample reception, records database and tracking system			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	3.6 Describe the types of handling and sorting system used, and the procedures and practices used for transferring specimens/samples within the laboratory whilst undergoing processing 3.7 Describe the importance of using the correct identification, and any unique organisational or laboratory numbers for specimens/samples 3.8 Describe the organisational requirements for maintaining the security of the workplace (e.g., workplace access and laboratory sample containment) 3.9 Describe the lines of communication and responsibilities in their department, and the links with the rest of the organisation 3.10 Describe the limits of their own authority and to whom they should report if they have problems that they cannot resolve 3.11 Describe the minimum size/volume/cell density of any starter culture required for the fermentation investigations conducted by the laboratory 3.12 Describe the range and condition of essential resources needed for each investigation 3.13 Describe the importance of keeping the work area clean and tidy, and of avoiding cross contamination of samples			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
4 Know how to culture/ferment cells for laboratory activities using controlled fed batch or continuous culture fermentation (continued)	4.1 Describe the main features of the fermenter, and the underlying action of the cells, media and reagents involved in the fermentation reaction vessel 4.2 Describe the various fermentation operations that can be performed, and the cells, methods and reaction mixtures used 4.3 Explain how to dismantle the fermenter, calibrate probes and sterilise components before commencing fermentation 4.4 Explain how to apply good aseptic techniques, and how to reassemble the sterilised fermenter prior to the culture fermentation activities 4.5 Describe the manufacturer's instructions for changing programs and maintenance items in the fermenter 4.6 Explain how to interpret the fermenter visual display, and how to understand the various messages displayed 4.7 Describe the function of error messages, and what to do if an error message is displayed 4.8 Explain how to find the correct restart point in the program if the fermentation has been stopped before completion of the program 4.9 Explain where to obtain the standard operating procedures, equipment procedures and job instructions required for the fermentation activities			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	4.10 Describe the typical fermentation faults, and the actions to be taken if they occur 4.11 Describe the procedure to be followed when disposing of harmful cultures and bi-products and contaminated equipment 4.12 Describe the procedure to be followed if a broken or leaking sample is identified in the laboratory			

Learner name: _____ Date:_____

Learner signature: _____ Date:_____

Assessor signature: _____ Date:_____

Internal verifier signature: _____ Date:_____
(*if sampled*)

Unit 14: Maintaining cell lines for laboratory activities using sub-culture

Unit reference number: D/601/8194

Level: 3

Credit value: 8

Guided learning hours: 33

Unit summary

This unit covers the skills and knowledge needed to prove the competences required to maintain cell lines by regular sub-culture, in accordance with approved procedures. The learner is required to confirm that the necessary media are available, and that they have been prepared and stored in the way indicated by the manufacturer. In carrying out these activities, they will be expected to follow the correct procedures, whilst ensuring that a high standard of cleanliness and accuracy is maintained with due regard for the risk of cross contamination of samples. The learner will be required to work to the relevant standard operating procedures, legislation and organisational policy, and to follow Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP). They will be expected to handle potentially dangerous materials and chemicals, ensuring that they are contained within designated areas whilst in use and are disposed of in the correct way. They will be required to present records and details of their laboratory work to the appropriate people.

They will be required to maintain cell lines in batch or continuous culturing, in either monolayer or suspension culture, choosing the required support medium, in line with safe working practices and approved procedures. They will add agents to break any adhesion bonds between cells, and will determine the cell density using a microscope and cell counting apparatus. They will make the required adjustments to cell density to obtain the predetermined value for further culture work, in order to ensure that the output is to the required quality and accuracy, and that the cells remain viable and continue to grow. Meeting laboratory targets will be an important issue, and their laboratory records must show consistent and satisfactory performance.

Their responsibilities will require them to comply with standard operating procedures for the cell culture work activities undertaken, and to report any problems that they cannot personally resolve, or that are outside their permitted authority, to the relevant people. They will be expected to work to instructions with a minimum of supervision, either on their own or as part of a team, taking personal responsibility for their own actions and for the quality and accuracy of the work that they carry out.

Their underpinning knowledge will be sufficient to provide a sound basis for their work, and will enable they to adopt an informed approach to

procedures. They will have an understanding of the principles of cell culture and sub-culture, the media and reagents used, the factors affecting viability, and likely sources and signs of contamination, in adequate depth to provide a sound background for carrying out the laboratory activities to the required specification.

They will understand the safety precautions required when carrying out the preparation and disposal of dangerous materials and chemicals, and they will be aware of the risks involved with these materials and chemicals, and with the associated equipment. They will be required to demonstrate safe working practices throughout, and will understand their responsibility for taking the necessary safeguards to protect yourself and others in the workplace and outside.

Assessment requirements

Assessment requirements are set down in Annexe D: Assessment strategy.

Assessment methodology

This unit is assessed in the workplace. Learners can enter the types of evidence they are presenting for assessment and the submission date against each assessment criterion. Alternatively, centre documentation should be used to record this information.

Learning outcomes and assessment criteria

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
1 Maintain cell lines for laboratory activities using sub-culture	1.1 Ensure that their work is carried out in accordance with standard operating procedures 1.2 Wear the appropriate personal protection equipment (PPE) when handling specimens 1.3 Wear three of the following types of protective clothing and equipment: – laboratory coat/overalls – face mask/respirator – gloves – safety glasses/safety goggles/safety visor – mop cap – other (please specify) 1.4 Apply safe working practices at all times			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	1.5 Carry out all of the following for cell scale-up activities: – confirm that the safety cabinet, media and equipment are clean and ready for use – check that all safety equipment and guards are in place and functioning correctly – prepare reagents and reaction mixtures to the desired level of accuracy ensuring sterility is maintained – prepare a cell suspension at the correct cell density – sub-culture the cell suspension into clean culture vessels and add fresh medium – incubate the cell cultures at the correct temperature, humidity and CO_2 concentration – check growth and sterility of cultures on a daily basis 1.6 Ensure that samples, media and reagents are stored correctly and are maintained at the correct temperature during use 1.7 Wash media from the cells, and add an appropriate agent to break cell adhesion, where necessary 1.8 Perform cell counts on a cell suspension, ensuring that clumps of cells are broken up and a suitable dilution is used, and adjust the cell count, where necessary, before division into sub-culture vessels			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
2 Maintain cell lines for laboratory activities using sub-culture (continued)	2.1 Deal promptly and effectively with equipment faults and report those that cannot be resolved 2.2 Prepare fresh growth media, and re-suspend cells in accordance with requirements 2.3 Measure out aliquots of the cells into fresh culture vessels, label them correctly and add more medium to achieve the final volume for the recommended vessel 2.4 Set incubation conditions, monitor cell growth and ensure that the cultures are free from contamination 2.5 Carry out all of the following: – calibration of micro pipettes – storage of reagents – storage of samples – handling and disposal of dangerous chemicals – measuring cell density – incubating cultures – recording data 2.6 Communicate the required information about the work done, to authorised people, in accordance with departmental and organisational procedures			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	2.7 Record details of the work, and communicate the details to the appropriate people, using both: – verbal report – laboratory note book Plus one method from the following: – written or typed report – specific company documentation – computer-based record – electronic mail			
3 Know how to maintain cell lines for laboratory activities using sub-culture	3.1 Describe the health and safety requirements of the area in which they are carrying out the activities 3.2 Describe the implications of not taking account of legislation, regulations, standards and guidelines when conducting laboratory activities 3.3 Describe the principles of Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP) applied in the workplace 3.4 Describe the importance of wearing protective clothing, gloves and eye protection when handling laboratory samples for analysis 3.5 Describe the laboratory sample reception, records database and tracking system			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	3.6 Describe the types of handling and sorting system used, and the procedures and practices used for transferring specimens/samples within the laboratory whilst undergoing processing 3.7 Describe the importance of using the correct identification, and any unique organisational or laboratory numbers for specimens/samples 3.8 Describe the organisational requirements for maintaining the security of the workplace (e.g. workplace access and laboratory sample containment)			
4 Know how to maintain cell lines for laboratory activities using sub-culture (continued)	4.1 Describe the lines of communication and responsibilities in their department, and the links with the rest of the organisation 4.2 Describe the limits of their own authority and to whom they should report if they have problems that they cannot resolve 4.3 Describe the minimum number/size/volume of samples required for laboratory experimentation 4.4 Describe the range of cell lines, the containers used for cell growth and sub-culture in the laboratory, and other essential resources needed for each activity 4.5 Describe the health and safety requirements for dealing with potentially dangerous cell lines			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	4.6 Describe the importance of keeping the work area clean and tidy, and of avoiding cross contamination of samples 4.7 Describe the main features of the cell line, and the underlying action of the media and reagents involved in cell adhesion and disruption, and the growth of cells in culture 4.8 Explain where to obtain the standard operating procedures, equipment procedures and job instructions required for the activities being undertaken 4.9 Describe the procedure to be followed when disposing of harmful materials and chemicals and contaminated equipment 4.10 Describe the procedure to be followed if a broken or leaking sample is identified in the laboratory			

Learner name: _____ Date: _____

Learner signature: _____ Date: _____

Assessor signature: _____ Date: _____

Internal verifier signature: _____ Date: _____
(*if sampled*)

Unit 15: Measuring, weighing and preparing compounds and solutions for laboratory use

Unit reference number: H/601/8195

Level: 3

Credit value: 16

Guided learning hours: 66

Unit summary

This unit covers the skills and knowledge needed to prove the competences required to measure, weigh and prepare compounds and solutions for laboratory investigations. Prior to undertaking the laboratory activity, and in accordance with approved procedures and practices, the learner will be required to carry out all the necessary preparations, within the scope of their responsibility. This may include preparing the work area and ensuring that it is in a safe condition to carry out the intended activities, and ensuring that any materials, equipment or other resources required are available and are in a safe and usable condition. The learner will be required to work to the relevant standard operating procedures, legislation and organisational policy, and to follow Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP). The learner will also be required to present records and details of their laboratory work to the appropriate people.

On completion of the laboratory activity, the learner will be required to return their immediate work area to an acceptable condition before undertaking further work. This may involve putting processed paperwork in the correct location, returning and/or storing any materials and equipment in the correct area, identifying any waste and arranging for its disposal, and reporting any defects or damage to the materials and equipment used.

The learner's responsibilities will require them to comply with organisational policy and procedures for the measuring, weighing and preparations undertaken, and to report any problems with the activities, materials or equipment that they cannot personally resolve or that are outside their permitted authority, to the relevant people. The learner will work with a minimum of supervision, either on their own or as part of a team, whilst taking responsibility for their own actions and for the quality and accuracy of the work that they carry out.

The learner's underpinning knowledge will provide a good understanding of their work, and will provide an informed approach to measuring, weighing and preparing compounds and solutions in a laboratory environment. The learner will understand the importance of doing this work efficiently and effectively, and will know what to consider when preparing and tidying up the work area before and after the measuring, weighing and preparation activities. The learner will also know how to deal with problems, and how to

achieve their work objectives and targets, in adequate depth to provide a sound basis for carrying out the activities safely and correctly.

The learner will understand the safety precautions required when carrying out laboratory activities. The learner will be required to demonstrate safe working practices throughout, and will understand the responsibility they owe to themselves and others in the workplace.

Assessment requirements

Assessment requirements are set down in Annexe C: Assessment strategy.

Assessment methodology

This unit is assessed in the workplace. Learners can enter the types of evidence they are presenting for assessment and the submission date against each assessment criterion. Alternatively, centre documentation should be used to record this information.

Learning outcomes and assessment criteria

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
1 Measure, weigh and prepare compounds and solutions for laboratory use	1.1 Ensure that their work is carried out in accordance with standard operating procedures 1.2 Wear the appropriate personal protection equipment (PPE) when handling materials 1.3 Use three of the following types of protective clothing and equipment: – laboratory coat – face mask – gloves – safety glasses – other (please specify) 1.4 Use laboratory scales for accurately weighing out materials, using metric/imperial measures 1.5 Carry out weighing activities using balances (scales), using two of the following accuracies: – grams – milligrams – micrograms			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	1.6 Measure out aliquots of solutions, using four of the following: – automated pipettes – graduated/bulb pipettes – syringes – graduated cylinders/beakers/tubes – burettes – volumetric flasks – other (please specify) 1.7 Accurately measure pH and conductivity of solutions in the laboratory, using correctly calibrated meters 1.8 Measure out aliquots of liquids into tubes and microtrays for laboratory use and analysis			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
2 Measure, weigh and prepare compounds and solutions for laboratory use (continued)	2.1 Measure liquids and solids for laboratory use and analysis 2.2 Measure pH and/or conductivity, using two of the following: – handheld pH meter – bench top pH meter – combined pH/conductivity meter – conductivity meter – other (please specify) 2.3 Calibrate or check the calibration for two of the following: – pH meter – balance – conductivity meter – pipettes – other(please specify)			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	2.4 Calculate the concentrations of solutions, the amounts and volumes required, using four of the following: – moles per litre – grams per litre – parts per million – mass percent – other (please specify) 2.5 Make up known volumes of solutions to a specified concentration, using both of the following: – by measuring and dissolving the correct amount of solute in the correct volume of diluent/solvent – by dilution from a concentrated stock solution 2.6 Weigh and prepare three of the following types of compound or solution: – powders/granulations that do not readily lose or gain weight (moisture or solvent) – solids that readily lose or gain weight (moisture or solvent) – liquid samples (by difference) – liquid samples (direct)			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	2.7 Communicate the required information about the work done, to authorised people, in accordance with departmental and organisational procedures. 2.8 Record details of work done, and communicate the details to the appropriate people, using: – verbal report Plus one method from the following: – written or typed report (e.g. laboratory notebook) – specific company documentation – computer-based record – electronic mail			
3 Know how to measure, weigh and prepare compounds and solutions for laboratory use	3.1 Describe the health and safety requirements of the area in which they are carrying out the laboratory activities 3.2 Describe the implications of not taking account of legislation, regulations, standards and guidelines when conducting laboratory activities 3.3 Describe the principles of Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP) applied in the workplace			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	3.4 Describe the importance of wearing protective clothing, gloves and eye protection when handling specimens/samples 3.5 Describe the importance of correct identification, and any unique organisational or laboratory numbers 3.6 Describe the lines of communication and responsibilities in their department, and their links with the rest of the organisation 3.7 Describe the limits of their own authority and to whom they should report if they have problems that they cannot resolve 3.8 Explain how to calculate mass/mole calculations in metric and/or imperial measures 3.9 Explain how to select the appropriate balance and scale for less than 100mg, 100mg to 5g, and 5g and above 3.10 Explain how to check that a pipette is clean, dry, free of chips and ready for use			
4 Know how to measure, weigh and prepare compounds and solutions for laboratory use (continued)	4.1 Explain how to check the calibration on a pipette 4.2 Explain how to calibrate and check the calibration on a pH meter 4.3 Explain how to calibrate and check the calibration on a balance 4.4 Explain how to calibrate and check the calibration on a conductivity meter			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	4.5 Explain how to measure and weigh solids and liquids for laboratory use 4.6 Explain how to convert between different units of concentration (such as moles/litre, grams/litre, percent mass per volume and parts per million) 4.7 Explain how to calculate dilution factors and dilution volumes to make solutions from concentrated stock solutions 4.8 Describe the pH scale as a logarithmic scale for the measurement of the acidity of aqueous solutions, and the importance of pH to biological systems and processes 4.9 Explain how to choose the appropriate measuring equipment for the scale, accuracy and precision required for the task 4.10 Explain how to clean and maintain the pipettes, balances, pH meter probes and conductivity meter probes			

Learner name: _____ Date: _____

Learner signature: _____ Date: _____

Assessor signature: _____ Date: _____

Internal verifier signature: _____ Date: _____

(*if sampled*)

Unit 16: Separating samples for laboratory activities using centrifugation

Unit reference number: K/601/8196

Level: 3

Credit value: 3

Guided learning hours: 16

Unit summary

This unit covers the skills and knowledge needed to prove the competences required to carry out laboratory centrifugation, using low speed bench-top centrifuges and high speed refrigerated ultracentrifuges, in accordance with approved procedures. The learner is required to confirm that the necessary rotors and adaptors are available, and that they have been cleaned and stored in the way indicated by the supplier. In carrying out these activities, they will be expected to follow the correct procedures, whilst ensuring that a high standard of cleanliness and accuracy is maintained, with due regard for the risk of production of aerosols and damage to the instrument due to poor laboratory cleanliness and care. The learner will be required to work to the relevant standard operation procedures, legislation and organisational policy, and to follow Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP). They will be expected to handle potentially dangerous materials, ensuring that they are contained within designated areas while in use and that they are disposed of in the correct way. They will be required to present records and details of their laboratory work to the appropriate people.

The learner will be required to set up and operate the centrifuges, choosing the required rotors, buckets and accessories, in line with safe working practices and approved procedures, so that the instrument is safe and the output analysis is to the required quality and accuracy. Meeting laboratory targets will be an important issue, and their laboratory records must show consistent and satisfactory performance.

The learner's responsibilities will require them to comply with standard operating procedures for the centrifugation work activities undertaken, and to report any problems that they cannot personally resolve, or that are outside their permitted authority, to the relevant people. They will be expected to work to instructions with a minimum of supervision, either on their own or as part of a team, taking personal responsibility for their own actions and for the quality and accuracy of the work that they carry out.

The learner's underpinning knowledge will be sufficient to provide a sound basis for their work, and will enable them to adopt an informed approach to procedures. They will have an understanding of the principles of centrifugation, the use and limitations of the sample vessels, how to load and balance tubes and load the instrument. They will also know about the

rotors, adaptors and accessories used, and the use of centrifugation as an end product or as a preparative technique for further analysis, in adequate depth to provide a sound background for carrying out the laboratory activities to the required specification. They will have an understanding of measurement of speed in revolutions per minute (rpm), and the conversion to relative centrifugal force.

The learner will understand the safety precautions required when carrying out the preparation and disposal of dangerous chemicals, and the risks involved with these chemicals. They will also understand the safety requirements of the equipment, particularly with the production of aerosols and with the effects of corrosive materials on the long term safety and integrity of centrifuge rotors. They will be required to demonstrate safe working practices throughout, and will understand their responsibility for taking the necessary safeguards to protect themselves and others in the workplace and outside.

Assessment requirements

Assessment requirements are set down in Annexe C: Assessment strategy.

Assessment methodology

This unit is assessed in the workplace. Learners can enter the types of evidence they are presenting for assessment and the submission date against each assessment criterion. Alternatively, centre documentation should be used to record this information.

Learning outcomes and assessment criteria

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
1 Separate samples for laboratory activities using centrifugation	1.1 Ensure that their work is carried out in accordance with standard operating procedures 1.2 Wear the appropriate personal protection equipment (PPE) when handling specimens 1.3 Wear two of the following types of protective clothing and equipment: – laboratory coat/overalls – gloves – safety glasses/safety goggles/safety visor – mop cap – other (please specify) 1.4 Set up the equipment and ensure that it is ready for the centrifuging activities to be carried out			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	1.5 In carrying out their activities, ensure all of the following: – the centrifuge is clean and ready for use – all safety equipment and guards are in place and are functioning correctly – the rotors, buckets and centrifuge vessels are compatible with the centrifuge operation – all specimens are correctly labelled – lids are tight and samples are loaded diametrically and evenly – the run parameters on the centrifuge are compatible with the rotor, buckets, adaptors and vessels used – samples have no leaks or spills when removed from the centrifuge 1.6 Carry out all of the following: – load the rotor, and add buckets and adaptors – load and balance sample tubes – set the run parameters – handle spills and leakages – remove and clean rotors, buckets and adaptors – store rotors – record data			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	1.7 Separate samples for laboratory activities, using both of the following: – low speed bench-top centrifuges – high speed refrigerated ultracentrifuges 1.8 Operate the centrifuge controls safely and correctly, in line with operational procedures			
2 Separate samples for laboratory activities using centrifugation (continued)	2.1 Centrifuge samples to the required quality and within the specified dimensional accuracy 2.2 Carry out quality checks when removing samples from the centrifuge 2.3 Deal promptly and effectively with problems within their control and report those that cannot be solved 2.4 Shut down the equipment to a safe condition on conclusion of the centrifuging activities 2.5 Conduct all the following maintenance activities on the centrifuge: – remove and clean buckets and adaptors – remove the rotors and clean with the manufacturer's recommended cleaner – remove rotors and clean and lubricate rotor pins – report any signs of wear, damage or corrosion 2.6 Communicate the required information about the work done, to authorised people, in accordance with departmental and organisational procedures			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	2.7 Record details of work done, and communicate the details to the appropriate people, using: – verbal report Plus one method from the following: – written or typed report – specific company documentation – computer-based record – electronic mail			
3 Know how to separate samples for laboratory activities using centrifugation	3.1 Describe the health and safety requirements of the area in which they are carrying out the centrifuging activities 3.2 Describe the implications of not taking account of legislation, regulations, standards and guidelines when conducting laboratory activities 3.3 Describe the principles of Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP) applied in the workplace 3.4 Describe the importance of wearing protective clothing, gloves and eye protection when handling laboratory samples for analysis 3.5 Describe the laboratory sample reception, records database and tracking system			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	3.6 Describe the types of handling and sorting system used, and the procedures and practices used for transferring specimens/samples within the laboratory whilst undergoing processing 3.7 Describe the importance of using the correct identification, and any unique organisational or laboratory numbers for specimens/samples 3.8 Describe the organisational requirements for maintaining the security of the workplace (e.g. workplace access and laboratory sample containment) 3.9 Describe the lines of communication and responsibilities in their department, and the links with the rest of the organisation 3.10 Describe the limits of their own authority and to whom they should report if they have problems that they cannot resolve 3.11 Describe the minimum and maximum size/volume of laboratory sample required for the centrifugation operations conducted by the laboratory			
4 Know how to separate samples for laboratory activities using centrifugation (continued)	4.1 Describe the range of samples analysed, the containers used for sample storage and analysis in the laboratory, and other essential resources needed for each investigation 4.2 Describe the importance of keeping the work area clean and tidy, and of avoiding cross contamination of samples			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	4.3 Describe the main features of the centrifuge, and its uses and limitations 4.4 Describe the relationship between revolutions per minute (RPM) and relative centrifugal force (RCF [g]), and the calculations to interconvert these values 4.5 Describe the function of error messages, and what to do if an error message is displayed 4.6 Explain where to obtain the standard operating procedures, equipment procedures and job instructions required for the centrifugation to be conducted 4.7 Describe the typical centrifugation faults and problems, and the actions to be taken if they occur 4.8 Describe the routine cleaning and storage procedure for the centrifuge, rotor and adaptors 4.9 Describe the procedure to be followed when disposing of breakages of contaminated equipment or spills of harmful chemicals and materials 4.10 Describe the procedure to be followed if a broken or leaking sample is identified in the centrifuge			

Learner name: _____ Date: _____

Learner signature: _____ Date: _____

Assessor signature: _____ Date: _____

Internal verifier signature: _____ Date: _____
(*if sampled*)

Unit 17: Analysing laboratory samples using light microscopy

Unit reference number: M/601/8197

Level: 3

Credit value: 6

Guided learning hours: 25

Unit summary

This unit covers the skills and knowledge needed to prove the competences required to carry out laboratory sample analysis using a light microscope, in accordance with approved procedures. The learner is required to confirm that the required reagents are available, and has been stored in the way indicated by the supplier, and that the microscope is set up and used in line with the manufacturer's recommendations and the standard operating procedure. In carrying out these activities, they will be expected to follow the correct protocols for ensuring that a high standard of cleanliness and accuracy is maintained, with due regard for the risk of cross contamination of samples, the introduction of aberrations, and damage to the instrument resulting from misuse or poor maintenance.

The learner will be required to work to the relevant standard operating procedures, legislation and organisational policy, and to follow Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP). They will be expected to handle potentially dangerous biological materials and chemicals, ensuring that they are contained within designated areas whilst in use and that they are disposed of in the correct way. They will be required to present records and details of their laboratory work to the appropriate people.

The learner will be required to prepare biological materials for viewing, and to set up and operate the microscope, choosing the appropriate microscope configuration, and attaching any additional accessories to view and record samples, as applicable. They will also be required to make the necessary adjustments, in line with safe working practices and approved procedures and, when necessary, to produce a permanent record of the image by photography or LIMS, in order to ensure that the output analysis is to the required quality and accuracy. Meeting laboratory targets will be an important issue, and their laboratory records must show consistent and satisfactory performance.

The learner's responsibilities will require them to comply with standard operating procedures for the microscopy work activities undertaken, and to report any problems that they cannot personally resolve, or that are outside their permitted authority, to the relevant people. They will be expected to work to instructions with a minimum of supervision, either on their own or as part of a team, taking personal responsibility for their own actions and for the quality and accuracy of the work that they carry out.

The learner will be expected to maintain the microscope in working order and to follow simple procedures to replace used or worn out components and reagents, as required.

The learner's underpinning knowledge will be sufficient to provide a sound basis for their work, and will enable them to adopt an informed approach to applying the appropriate procedures. They will choose the correct program to record and interpret the images viewed, as an end product or as a preparative technique for further analysis. They will have an understanding of the principles of light microscopy, the set-up, use and care of lenses used, and the different methods of specimen illumination, in adequate depth to provide a sound background for carrying out the laboratory activities to the required specification.

The learner will understand the safety precautions required when carrying out the preparation and disposal of biological material. They will also understand the safety precautions required when using dangerous chemicals, and the risks involved with these chemicals and with the equipment. They will be required to demonstrate safe working practices throughout, and will understand their responsibility for taking the necessary safeguards to protect themselves and others in the workplace and outside.

Assessment requirements

Assessment requirements are set down in Annexe C: Assessment strategy.

Assessment methodology

This unit is assessed in the workplace. Learners can enter the types of evidence they are presenting for assessment and the submission date against each assessment criterion. Alternatively, centre documentation should be used to record this information.

Learning outcomes and assessment criteria

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
1 Analyse laboratory samples using light microscopy	1.1 Ensure that their work is carried out in accordance with standard operating procedures 1.2 Wear the appropriate personal protection equipment (PPE) when handling specimens 1.3 Use three of the following types of protective clothing and equipment: – laboratory coat/overalls – face mask/respirator – gloves – safety glasses/safety goggles/safety visor – mop cap – other (please specify) 1.4 Apply safe working practices at all times			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	1.5 Carry out all of the following for light microscopy: – confirm that the microscope and allied equipment is clean and ready for use – check that all safety equipment and guards are in place and are functioning correctly – prepare reagents and reaction mixtures to the desired level of accuracy – prepare biological specimens for viewing, by staining or addition of specific dyes – mount specimens onto the microscope, and select the correct operating parameters for the microscope – ensure that all specimens are correctly labelled with respect to their origin and subsequent treatment – set up and operate the microscope, following the defined operating procedures; choose the required program and apply safe working practices and procedures at all times – focus the specimen, using the required lens to give greatest resolution of the sample, and record data as a drawing, photograph or in a LIMS, in accordance with departmental procedures – dispose of or store used material and contaminated PPE, in accordance with safe departmental operating procedures			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	1.6 Follow the defined procedure for preparation of biological/compound material 1.7 Carry out all of the following: – calibration of micro pipettes – storage of reagents – storage of samples – handling and disposal of dangerous chemicals – setting up and cleaning the equipment – preparing and staining biological samples – recording data – maintaining equipment between uses			
2 Analyse laboratory samples using light microscopy (continued)	2.1 Load samples for analysis on to the microscope carefully, using low power, ensuring that the field of view is focused carefully without damage to the sample or objective lenses 2.2 Use standard size markers and selective stains or probes to measure, quantify and identify samples 2.3 Measure, quantify and identify samples, using three of the following: – staining procedures – counting chamber – counting fluorescents – other dyes			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	2.4 Store preparative samples in the correct location for storage, further preparation or analysis 2.5 Communicate the required information about the work done to authorised people, in accordance with departmental and organisational procedures 2.6 Record details of the work, and communicate the details to the appropriate people, using: – verbal report Plus one method from the following: – written or typed report – specific company documentation – computer-based record – electronic mail			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
3 Know how to analyse laboratory samples using light microscopy	3.1 Describe the health and safety requirements of the area in which they are carrying out the analytical activities 3.2 Describe the implications of not taking account of legislation, regulations, standards and guidelines when conducting laboratory activities 3.3 Describe the principles of Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP) applied in the workplace 3.4 Describe the importance of wearing protective clothing, gloves and eye protection when handling and preparing laboratory samples for analysis 3.5 Describe the laboratory sample reception, records database and tracking system 3.6 Describe the types of handling and sorting system used, and the procedures and practices used for transferring specimens/samples within the laboratory while undergoing processing 3.7 Describe the importance of using the correct identification, and any unique organisational or laboratory numbers for specimens/samples 3.8 Describe the organisational requirements for maintaining the security of the workplace (e.g. workplace access and laboratory sample containment)			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	3.9 Describe the lines of communication and responsibilities in their department, and the links with the rest of the organisation 3.10 Describe the limits of their own authority and to whom they should report if they have problems that they cannot resolve 3.11 Describe the minimum size/volume of laboratory sample required for the microscope slide preparation and investigations conducted by the laboratory 3.12 Describe the range of samples analysed, the containers used for sample storage and analysis in the laboratory, and other essential resources needed for each investigation			
4 Know how to analyse laboratory samples using light microscopy (continued)	4.1 Describe the importance of keeping the work area clean and tidy, and of avoiding cross contamination of samples 4.2 Describe the main features of the light microscope; how to calculate and record magnification, and the difference between magnification and resolution 4.3 Describe the underlying action of the reagents, stains and dyes involved in the process of sample preparation, and the expected outcome of each treatment			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	4.4 Describe the various types of microscope available in the laboratory, the operations that can be performed with each and the accompanying sample preparation 4.5 Describe the cleaning and maintenance of microscopes after use, and the harmful effects of using incorrect cleaning materials 4.6 Describe the common errors that may occur in sample preparation, and how to overcome or avoid those errors 4.7 Explain where to obtain the standard operating procedures, equipment procedures and job instructions required for the work to be carried out 4.8 Describe the typical microscope faults and maintenance procedures, and the actions to be taken if faults occur 4.9 Describe the procedure to be followed when disposing of harmful chemicals and contaminated equipment 4.10 Describe the procedure to be followed if a broken or leaking sample is identified in the laboratory 4.11 Describe the types of staining process used, and the range of dyes available			

Learner name: _____ Date: _____

Learner signature: _____ Date: _____

Assessor signature: _____ Date: _____

Internal verifier signature: _____ Date: _____
(*if sampled*)

Unit 18: Analysing laboratory samples using ultraviolet-visible spectrophotometer (UV-Vis)

Unit reference number: T/601/8198

Level: 3

Credit value: 8

Guided learning hours: 33

Unit summary

This unit covers the skills and knowledge needed to prove the competences required to carry out laboratory sample analysis using UV-Vis spectrophotometry analysers, in accordance with approved procedures. The learner is required to confirm that the UV-Vis analyser is ready for the analysis to be performed and that the required consumables are available. In operating the analyser, they will be expected to follow the correct procedures for calling the analyser operating program, entering operating parameters for analysis, dealing with error messages and executing the program activities safely and correctly. They will be required to work to the relevant standard operating procedures, legislation and organisational policy, and to follow Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP). They will also be required to present records and details of their laboratory work to the appropriate people.

The learner will be required to set up and operate the UV-Vis analyser, in line with safe working practices and approved procedures, to monitor the analysis operations and, where necessary, make the required adjustments in order to ensure that the output analysis is to the required quality and accuracy. Meeting laboratory targets will be an important issue, and their laboratory records must show consistent and satisfactory performance.

The learner's responsibilities will require them to comply with standard operating procedures for the UV-Vis work activities undertaken, and to report any problems that they cannot personally resolve, or that are outside their permitted authority, to the relevant people. They will be expected to work to instructions with a minimum of supervision, either on their own or as part of a team, taking personal responsibility for their own actions and for the quality and accuracy of the work that they carry out.

The learner's underpinning knowledge will be sufficient to provide a sound basis for their work, and will enable them to adopt an informed approach to applying UV-Vis analyser procedures. They will have an understanding of the UV-Vis analysis process and its application, and will know about the analyser, samples and reagents used, in adequate depth to provide a sound background for carrying out the laboratory activities to the required specification.

The learner will understand the safety precautions required when carrying out the laboratory activities for scientific operations and processes. They will be required to demonstrate safe working practices throughout, and will understand their responsibility for taking the necessary safeguards to protect themselves and others in the workplace.

Assessment requirements

Assessment requirements are set down in Annexe C: Assessment strategy.

Assessment methodology

This unit is assessed in the workplace. Learners can enter the types of evidence they are presenting for assessment and the submission date against each assessment criterion. Alternatively, centre documentation should be used to record this information.

Learning outcomes and assessment criteria

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
1 Analyse laboratory samples using ultraviolet-visible spectrophotometer	1.1 Ensure that their work is carried out in accordance with standard operating procedures 1.2 Wear the appropriate personal protection equipment (PPE) when handling specimens 1.3 Use three of the following types of protective clothing and equipment: – laboratory coat/overalls – face mask/respirator – gloves – safety glasses/safety goggles – mop cap – other (please specify) 1.4 Confirm that the equipment is calibrated, safe and ready for operation			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	1.5 Carry out all of the following ultraviolet-visible spectrophotometer (UV-Vis) operations: – confirm that the instrument is set up and ready for analysis – check that all safety equipment and guards are in place and are functioning correctly – set the machine operating program and sequences – ensure that machine settings are adjusted as and when required for the analysis being carried out – allow for suitable system equilibration, by running method conditions and monitoring the baseline – ensure that all specimens are correctly loaded with respect to the sequence requirements – check that the operating program and sequence is at the correct start point, and that all the data handling is ready for data acquisition – operate the analyser, following the defined operating procedures, and apply safe working practices and procedures at all times 1.6 Follow the defined procedures for starting and running the operating system and/or data handling and control software			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	1.7 Set all of the following: – wavelength scan – photometric mode – slit width – scan range – scan speed – data interval – data filename 1.8 Run appropriate system parameter tests and confirm the system suitability for the analyses to be done			
2 Analyse laboratory samples using ultraviolet-visible spectrophotometer (continued)	2.1 Deal promptly and effectively with error messages or equipment faults that are within their control, and report those that cannot be resolved 2.2 Load specimens for analysis and run program sequences correctly 2.3 Perform all of the following types of scan: – fixed wavelength – time scan – wavelength scan 2.4 Shut down the equipment to a safe condition on conclusion of the activities, using the compatible flushing and line storage procedures			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	2.5 Evaluate data in accordance with standard operating procedures and manufacturers' instructions 2.6 Communicate the required information about the work done, to authorised people, in accordance with departmental and organisational procedures 2.7 Record details of the work, and communicate the details to the appropriate people, using: – verbal report Plus one method from the following: – written or typed report – specific company documentation – computer-based record – electronic mail			
3 Know how to analyse laboratory samples using ultraviolet-visible spectrophotometer	3.1 Describe the health and safety requirements of the area in which they are carrying out the laboratory activities 3.2 Describe the implications of not taking account of legislation, regulations, standards and guidelines when conducting laboratory activities 3.3 Describe the principles of Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP) applied in the workplace			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	3.4 Describe the importance of wearing protective clothing, gloves and eye protection when handling laboratory samples for analysis 3.5 Describe the laboratory sample reception, records database and tracking system 3.6 Describe the types of handling and sorting system used, and the procedures and practices used for transferring specimens/samples within the laboratory whilst undergoing processing 3.7 Describe the importance of using the correct identification, and any unique organisational or laboratory numbers for specimens/samples 3.8 Describe the organisational requirements for maintaining the security of the workplace (e.g. workplace access and laboratory sample containment) 3.9 Describe the lines of communication and responsibilities in their department, and the links with the rest of the organisation 3.10 Describe the limits of their own authority and to whom they should report if they have problems that they cannot resolve 3.11 Describe the minimum size/volume of laboratory sample required for the investigations conducted by the laboratory			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
4 Know how to analyse laboratory samples using ultraviolet-visible spectrophotometer (continued)	4.1 Describe the range of samples analysed using UV-Vis analysis in the laboratory, and other essential resources needed for each investigation 4.2 Describe the importance of keeping the work area clean and tidy 4.3 Describe the main features of the UV-Vis analyser, and the accessories that can be used 4.4 Describe the various UV-Vis analyser operations that can be performed, and the methods and equipment used 4.5 Describe the manufacturer's instructions for changing consumables and maintenance items in the UV-Vis analyser 4.6 Explain how to interpret the analyser visual display, and how to understand the various messages displayed 4.7 Describe the function of error messages, and what to do if an error message is displayed 4.8 Explain how to find the correct restart point in the program if the UV-Vis has been stopped before completion of the program 4.9 Explain where to obtain the standard operating procedures, equipment procedures and job instructions required for the analysis to be carried out			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	4.10 Describe the typical UV-Vis faults, and the actions to be taken if they occur 4.11 Describe the procedure to be followed if a broken or leaking sample is identified in the laboratory			

Learner name: _____ Date: _____

Learner signature: _____ Date: _____

Assessor signature: _____ Date: _____

Internal verifier signature: _____ Date: _____
(*if sampled*)

Unit 19: Analysing laboratory samples using Circular Dichroism (CD)

Unit reference number: H/601/8200

Level: 3

Credit value: 16

Guided learning hours: 66

Unit summary

This unit covers the skills and knowledge needed to prove the competences required to carry out laboratory sample analysis using circular dichroism (CD) spectrophotometer analysers, in accordance with approved procedures. The learner is required to confirm that the CD equipment is equilibrated and calibrated for the analysis to be performed, and that the required consumables are available. In operating the analyser, they will be expected to follow the correct procedures for calling the analyser operating program, entering operating parameters for analysis, dealing with error messages and executing the program safely and correctly. They will be required to work to the relevant standard operating procedures, legislation and organisational policy, and to follow Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP). They will also be required to present records and details of their laboratory work to the appropriate people.

They will be required to set up and operate the CD analyser, in line with safe working practices and approved procedures, to monitor the analysis operations and, where necessary, to make the required adjustments in order to ensure that the output analysis is to the required quality and accuracy. Meeting laboratory targets will be an important issue, and their laboratory records must show consistent and satisfactory performance.

Their responsibilities will require them to comply with standard operating procedures for the CD work activities undertaken, and to report any problems that they cannot personally resolve, or that are outside their permitted authority, to the relevant people. They will be expected to work to instructions with a minimum of supervision, either on their own or as part of a team, taking personal responsibility for their own actions and for the quality and accuracy of the work that they carry out.

Their underpinning knowledge will be sufficient to provide a sound basis for their work, and will enable them to adopt an informed approach to applying CD analyser procedures. They will have an understanding of the CD analysis process and its application, and will know about the analyser, samples and reagents used, in adequate depth to provide a sound background for carrying out the laboratory activities to the required specification.

They will understand the safety precautions required when carrying out the laboratory activities for scientific operations and processes. They will be required to demonstrate safe working practices throughout, and will

understand their responsibility for taking the necessary safeguards to protect themselves and others in the workplace.

Assessment requirements

Assessment requirements are set down in Annexe C: Assessment strategy.

Assessment methodology

This unit is assessed in the workplace. Learners can enter the types of evidence they are presenting for assessment and the submission date against each assessment criterion. Alternatively, centre documentation should be used to record this information.

Learning outcomes and assessment criteria

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
1 Analyse laboratory samples using Circular Dichroism (CD)	1.1 Ensure that their work is carried out in accordance with standard operating procedures 1.2 Work safely at all times, complying with health and safety and other relevant regulations and guidelines 1.3 Wear the appropriate personal protection equipment (PPE) when handling specimens 1.4 Wear three of the following types of protective clothing and equipment: – laboratory coat/overalls – face mask/respirator – gloves – safety glasses/safety goggles – mop cap – other (please specify) 1.5 Confirm that the equipment is equilibrated, calibrated, safe and ready for operation			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	1.6 Carry out all of the following circular dichroism (CD) operations: – confirm that the machine is ready for the analysis – check that all safety equipment and guards are in place and are functioning correctly – purge the equipment, and turn on the lamps ready for the analysis – ensure that the equipment is calibrated for the analysis to be done – prepare reagents, samples and machine operating methods – acquire data, using appropriate settings – analyse the data, and make out a report 1.7 Follow the defined procedures for starting and running the operating system and/or data handling and control software 1.8 Run appropriate system parameter tests and confirm the system suitability for the analyses to be done			
2 Analyse laboratory samples using Circular Dichroism (CD) (continued)	2.1 Deal promptly and effectively with error messages or equipment faults that are within their control, and report those that cannot be resolved 2.2 Load specimens for analysis and run program sequences correctly			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	2.3 Carry out all of the following during the analysis: – wavelength and intensity calibration – performance assessment based on CD and HT voltage signals – convert raw data signals to absorbance and molar CD, where necessary – overlay spectra for comparison, or use objective spectra comparison techniques 2.4 Shut down the equipment to a safe condition on conclusion of the activities, using the compatible flushing and line storage procedures 2.5 Evaluate data in accordance with standard operating procedures and manufacturers' instructions 2.6 Communicate the required information about the work done, to authorised people, in accordance with departmental and organisational procedures			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	2.7 Record details of the work, and communicate the details to the appropriate people, using: – verbal report Plus one method from the following: – written or typed report (e.g. laboratory notebook) – specific company documentation – computer-based record – electronic mail			
3 Know how to analyse laboratory samples using ultraviolet-visible spectrophotometer	3.1 Describe the health and safety requirements of the area in which they are carrying out the laboratory activities 3.2 Describe the implications of not taking account of legislation, regulations, standards and guidelines when conducting laboratory activities 3.3 Describe the principles of Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP) applied in the workplace 3.4 Describe the importance of wearing protective clothing, gloves and eye protection when handling laboratory samples for analysis 3.5 Describe the laboratory sample reception, records database and tracking system			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	3.6 Describe the types of handling and sorting system used, and the procedures and practices used for transferring specimens/samples within the laboratory while undergoing processing 3.7 Describe the importance of using the correct identification, and any unique organisational or laboratory numbers for specimens/samples 3.8 Describe the organisational requirements for maintaining the security of the workplace (e.g. workplace access and laboratory sample containment) 3.9 Describe the lines of communication and responsibilities in their department, and the links with the rest of the organisation 3.10 Describe the limits of their own authority and to whom they should report if they have problems that they cannot resolve 3.11 Describe the main features of CD analysis (such as optics, lamp and cumulative operation time, nitrogen gas supply, sample compartment, sample holders [cells]) 3.12 Explain how to prepare the equipment by purging with N_2 (including safety considerations in handling nitrogen gas cylinders, stabilisation of lamp and electronics)			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	3.13 Explain how to calibrate the CD equipment for wavelength and intensity (e.g. using Nd and Ho glass filters, where intensity calibration is conducted using 0.06% ammonium d-10-camphosulphonate (ACS) solution) 3.14 Describe performance evaluation at a specified wavelength (e.g. 0.06% ACS solution can be used for the performance evaluation at 290.4 ± 0.5 nm for the majority of CD spectropolarimeters)			
4 Know how to analyse laboratory samples using ultraviolet-visible spectrophotometer (continued)	4.1 Describe performance evaluation using the HT voltage (e.g. ACS solution to monitor degradation of instrument optics) 4.2 Describe the importance of an appropriate path length sample cell to overcome problems due to solvent absorbance 4.3 Explain how to determine the true path length of the sample cell, compared to the nominal path length 4.4 Explain how to prepare samples (including the range of volumes and concentration of the samples to be analysed in appropriate sample holders [cells]) 4.5 Explain how to record and prepare samples, reagents and buffers (including introduction of buffer or sample to CD cell without introducing air bubbles)			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	4.6 Explain how to modify CD data acquisition parameters in order to acquire a high quality CD spectrum (e.g. sensitivity, wavelength range, data pitch, scan mode, scan speed, response, bandwidth, accumulation, data mode) 4.7 Explain how to acquire data in a logical sequence (e.g. the baseline and experimental data should be collected using the same cell, obtaining an absorbance spectrum for the sample before measuring the CD) 4.8 Explain how to clean sample cells between measurements with appropriate cleaning agents (e.g. deionised water, 2% Hellmanex, ethanol, acetone, drying with nitrogen gas) 4.9 Explain how to clean sample cells with severe contamination (e.g. soaking in nitric acid (70%) overnight) 4.10 Describe the precautionary safety steps when handling nitric acid 4.11 Explain how to process data and analyse it (e.g. converting HT and mDeg signals to absorbance and molar CD) 4.12 Explain how to assess data quality, for signal to noise or saturation 4.13 Explain how to calculate secondary structural content of a protein using algorithms from manufacturers or on the web			

Learner name: _____ Date: _____

Learner signature: _____ Date: _____

Assessor signature: _____ Date: _____

Internal verifier signature: _____ Date: _____
(*if sampled*)

Unit 20: Analysing laboratory samples using Fourier-transform infrared (FT-IR) spectroscopy

Unit reference number: K/601/8201

Level: 3

Credit value: 8

Guided learning hours: 33

Unit summary

This unit covers the skills and knowledge needed to prove the competences required to carry out laboratory sample analysis using Fourier-transform infrared (FT-IR) spectroscopy analysers, in accordance with approved procedures. The learner is required to confirm that the FT-IR equipment is equilibrated and calibrated for the analysis to be performed, and that the required consumables are available. In operating the analyser, they will be expected to following the correct procedures for calling the analyser operating program, entering operating parameters for analysis, dealing with error messages and executing the program activities safely and correctly. They will be required to work to the relevant standard operating procedures, legislation and organisational policy, and to follow Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP). They will also be required to present records and details of their laboratory work to the appropriate people.

The learner will be required to set up and operate the FT-IR analyser in line with safe working practices and approved procedures, to monitor the analysis operations and, where necessary, make the required adjustments in order to ensure that the output analysis is to the required quality and accuracy. Meeting laboratory targets will be an important issue, and their laboratory records must show consistent and satisfactory performance.

The learner's responsibilities will require them to comply with standard operating procedures for the FT-IR work activities undertaken, and to report any problems that they cannot personally resolve, or that are outside their permitted authority, to the relevant people. They will be expected to work to instructions with a minimum of supervision, either on their own or as part of a team, taking personal responsibility for their own actions and for the quality and accuracy of the work that they carry out.

The learner's underpinning knowledge will be sufficient to provide a sound basis for their work, and will enable them to adopt an informed approach to applying FT-IR analyser procedures. They will have an understanding of the FT-IR analysis process and its application, and will know about the analyser, samples and reagents used, in adequate depth to provide a sound background for carrying out the laboratory activities to the required specification.

The learner will understand the safety precautions required when carrying out the laboratory activities for scientific operations and processes. They will be required to demonstrate safe working practices throughout, and will understand their responsibility for taking the necessary safeguards to protect themselves and others in the workplace.

Assessment requirements

Assessment requirements are set down in Annexe C: Assessment strategy.

Assessment methodology

This unit is assessed in the workplace. Learners can enter the types of evidence they are presenting for assessment and the submission date against each assessment criterion. Alternatively, centre documentation should be used to record this information.

Learning outcomes and assessment criteria

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
1 Analyse laboratory samples using Fourier-transform infrared (FT-IR) spectroscopy	1.1 Ensure that their work is carried out in accordance with standard operating procedures 1.2 Work safely at all times, complying with health and safety and other relevant regulations and guidelines 1.3 Wear the appropriate personal protection equipment (PPE) when handling specimens 1.4 Wear three of the following types of protective clothing and equipment: – laboratory coat/overalls – face mask/respirator – gloves – safety glasses/safety goggles – mop cap – other (please specify) 1.5 Confirm that the equipment is equilibrated, calibrated, safe and ready for operation			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	1.6 Carry out all of the following operations: – turn on the equipment, cool with liquid nitrogen where necessary, and purge with nitrogen gas – validate the equipment – prepare reagents, samples and machine operating methods – acquire data, using appropriate settings – analyse the data and make out a report 1.7 Follow the defined procedures for starting and running the operating system and/or data handling and control software 1.8 Run appropriate system parameter tests and confirm the system suitability for the analyses to be done			
2 Analyse laboratory samples using Fourier-transform infrared (FT-IR) spectroscopy (continued)	2.1 Deal promptly and effectively with error messages or equipment faults that are within their control, and report those that cannot be resolved 2.2 Load samples for analysis and run program sequences correctly			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	2.3 Carry out all of the following: – measure samples in a logical sequence (background, blank, samples) – performance assessment (e.g. using manufacturer's recommendations) – process data by an appropriate method – overlay spectra for comparison, and critically assess quality of the data 2.4 Shut down the equipment to a safe condition on conclusion of the activities, using the compatible flushing and line storage procedures 2.5 Evaluate data in accordance with standard operating procedures and manufacturers' instructions 2.6 Communicate the required information about the work done, to authorised people, in accordance with departmental and organisational procedures			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	2.7 Record details of work done, and communicate the details to the appropriate people, using: – verbal report Plus one method from the following: – written or typed report (e.g. laboratory notebook) – specific company documentation – computer-based record – electronic mail			
3 Know how to analyse laboratory samples using Fourier-transform infrared (FT-IR) spectroscopy	3.1 Describe the health and safety requirements of the area in which they are carrying out the laboratory activities 3.2 Describe the implications of not taking account of legislation, regulations, standards and guidelines when conducting laboratory activities 3.3 Describe the principles of Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP) applied in the workplace 3.4 Describe the importance of wearing protective clothing, gloves and eye protection when handling laboratory samples for analysis 3.5 Describe the laboratory sample reception, records database and tracking system			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	3.6 Describe the types of handling and sorting system used, and the procedures and practices used for transferring specimens/samples within the laboratory while undergoing processing 3.7 Describe the importance of using the correct identification, and any unique organisational or laboratory numbers for specimens/samples 3.8 Describe the organisational requirements for maintaining the security of the workplace (e.g. workplace access and laboratory sample containment) 3.9 Describe the lines of communication and responsibilities in their department, and the links with the rest of the organisation 3.10 Describe the limits of their own authority and to whom they should report if they have problems that they cannot resolve 3.11 Describe the main features of FT-IR analysis (such as source, sample compartment, detector, liquid nitrogen supply, water bath) 3.12 Explain how to equilibrate the equipment (e.g. purging with nitrogen gas)			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
4 Know how to analyse laboratory samples using Fourier-transform infrared (FT-IR) spectroscopy (continued)	4.1 Explain how to validate the instrument (e.g. using software from the manufacturer) 4.2 Explain how to create a logical sequence for analysis (including background, blank and sample measurements, the range of weights, volumes and concentration of samples that can be analysed in appropriate sample holders) 4.3 Explain how to prepare samples for different types of analysis mode (transmission or attenuated total reflectance [ATR]), the range of liquid or solid sample preparation techniques used, and the appropriate solvents 4.4 Explain how to assemble and demount cells reproducibly; the choice of window material based on sample solubility, chemical compatibility, and the range needed 4.5 Explain how to fill sample cells without introducing air bubbles or aggregates 4.6 Explain how to modify the FT-IR data acquisition parameters in order to acquire a high quality FT-IR spectrum (e.g. resolution, scanner velocity, number of scans, phase resolution) 4.7 Explain how to acquire sample data in a logical sequence, acquiring a blank spectrum under the same conditions as the sample (e.g. temperature, number of scans, resolution)			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	4.8 Explain how to clean sample cells or ATR accessories between samples (e.g. using 2% Hellmanex and checking test spectra for sample carryover) 4.9 Explain how to process and analyse the data (e.g. subtraction of water signal where necessary, selection of a spectral range where the water absorbance does not overlap with that of the solute and has intensity comparable with that in the range of interest) 4.10 Describe the methods for processing data (e.g. by calculating the second derivative, to remove broad underlying contours in the spectra due to water) 4.11 Explain how to extract information from the spectra (e.g. to determine the secondary structural content of protein), and how to identify compounds from spectral libraries			

Learner name: _____ Date: _____

Learner signature: _____ Date: _____

Assessor signature: _____ Date: _____

Internal verifier signature: _____ Date: _____
(*if sampled*)

Unit 21: Analysing laboratory samples using Chromatography

Unit reference number: M/601/8202

Level: 3

Credit value: 9

Guided learning hours: 43

Unit summary

This unit covers the skills and knowledge needed to prove the competences required to carry out laboratory sample analysis using chromatography, in accordance with approved procedures. The learner is required to confirm that the equipment is ready for the analysis to be performed and that the required consumables are available. In operating the equipment, they will be expected to follow the correct procedures, and to work safely and correctly. They will be required to work to the relevant standard operating procedures, legislation and organisational policy, and to follow Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP). They will also be required to present records and details of their laboratory work to the appropriate people.

The learner will be required to set up and use the chromatography equipment in line with safe working practices and approved procedures, to monitor the analysis operations and, where necessary, to make the required adjustments in order to ensure that the output is to the required quality and accuracy. Meeting laboratory targets will be an important issue, and their laboratory records must show consistent and satisfactory performance.

The learner's responsibilities will require them to comply with standard operating procedures for the chromatography work activities undertaken, and to report any problems that they cannot personally resolve, or that are outside their permitted authority, to the relevant people. They will be expected to work to instructions with a minimum of supervision, either on their own or as part of a team, taking personal responsibility for their own actions and for the quality and accuracy of the work that they carry out.

The learner's underpinning knowledge will be sufficient to provide a sound basis for their work, and will enable them to adopt an informed approach to applying chromatography analysis procedures. They will have an understanding of the chromatography analysis process and its application, and will know about the equipment, samples and reagents used, in adequate depth to provide a sound background for carrying out the laboratory activities to the required specification.

The learner will understand the safety precautions required when carrying out the laboratory activities for scientific operations and processes. They will be required to demonstrate safe working practices throughout, and will understand their responsibility for taking the necessary safeguards to protect themselves and others in the workplace.

Assessment requirements

Assessment requirements are set down in Annexe C: Assessment strategy.

Assessment methodology

This unit is assessed in the workplace. Learners can enter the types of evidence they are presenting for assessment and the submission date against each assessment criterion. Alternatively, centre documentation should be used to record this information.

Learning outcomes and assessment criteria

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
1 Analyse laboratory samples using Chromatography	1.1 Ensure that their work is carried out in accordance with standard operating procedures 1.2 Work safely at all times, complying with health and safety and other relevant regulations and guidelines 1.3 Wear the appropriate personal protection equipment (PPE) when handling specimens 1.4 Wear three of the following types of protective clothing and equipment: – laboratory coat/overalls – face mask/respirator – gloves – safety glasses/safety goggles – mop cap – other (please specify)			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	1.5 Carry out all of the following: – use the correct issue of job instructions and specifications – follow risk assessment procedures and COSHH regulations – prepare media for size of column, and wash it – assemble and check the column components – pour chromatography material into the column, seal the column and set the plunger – conduct a packing test, set the pressure limit and flow rate of the buffer solution – connect pipework to the column, and prepare for the loading and collection of fractions – run the program for loading, and monitor the system instruments – store fractions in sterile containers, and send samples for analysis – stop the processing, clean in place and dispose of waste – store containers with fractions in the correct location and quantities for further processing – store records of your activities, in accordance with appropriate procedures			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	1.6 Load the column by both of the following methods: – manual loading – automated loading 1.7 Fill the column with both of the following filter types: – uniform matrix – density gradient 1.8 Conduct a packing test, to include all of the following: – inject – asymmetry – height equivalent to a theoretical plate (HETP) 1.9 Prepare the filter unit and connect to the biomaterial source for processing, in accordance with established practices and procedures 1.10 Set the system pressure limit for all of the following: – media type – column type – system type			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
2 Analyse laboratory samples using Chromatography (continued)	2.1 Pump biomaterial through the filter unit, monitoring and adjusting flow-rate according to specification 2.2 Monitor all of the following system parameters: – pressure – flow-rate – fraction – collection – pH – uV – conductivity – temperature 2.3 Collect the filtered biomaterial in the correct aseptic containers and quantities 2.4 Collect fractions in all of the following: – sterile bags – sterile containers – sterile tubes 2.5 Perform a filter unit integrity test, in accordance with established practices and procedures 2.6 Dispose of waste in the correct manner and location, and tidy and clean the work area, in accordance with established procedures			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	2.7 Separate outputs into all of the following categories: – waste for autoclaving – waste for chemical cleaning – waste for flushing – biomaterial product 2.8 Communicate the required information about the work done, to authorised people, in accordance with departmental and organisational procedures 2.9 Record details of work done, and communicate the details to the appropriate people, using: – verbal report Plus one method from the following: – written or typed report – specific company documentation – computer-based record – electronic mail			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
3 Know how to analyse laboratory samples using Chromatography	3.1 Describe the health and safety requirements of the area in which you are carrying out the laboratory activities 3.2 Describe the implications of not taking account of legislation, regulations, standards and guidelines when conducting laboratory activities 3.3 Describe the principles of Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP) applied in the workplace 3.4 Describe the importance of wearing protective clothing, gloves and eye protection when handling laboratory samples for analysis 3.5 Describe the laboratory sample reception, records database and tracking system 3.6 Describe the types of handling and sorting system used, and the procedures and practices used for transferring specimens/samples within the laboratory while undergoing processing 3.7 Describe the importance of using the correct identification, and any unique organisational or laboratory numbers for specimens/samples 3.8 Describe the organisational requirements for maintaining the security of the workplace (e.g. workplace access and laboratory sample containment)			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	3.9 Describe the lines of communication and responsibilities in their department and the links with the rest of the organisation 3.10 Describe the limits of their own authority and to whom they should report if they have problems that they cannot resolve			
4 Know how to analyse laboratory samples using Chromatography (continued)	4.1 Describe the basic principle of purification using large-scale chromatography 4.2 Describe the procedures for loading, packing and setting plungers for optimal height in large-scale chromatography 4.3 Explain how to conduct packing tests (such as inject, asymmetry and HETP) 4.4 Explain how to set pressure limits and flow rates of buffer solution 4.5 Explain how to connect pipework to the system for processing 4.6 Explain how to monitor the system instrumentation 4.7 Explain how to store fractions and collect samples 4.8 Explain how to store, separate and dispose of waste in the correct manner			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	4.9 Describe the main differences between uniform and density gradient column materials 4.10 Explain how to store filled biomaterial containers for further processing			

Learner name: _____ Date: _____

Learner signature: _____ Date: _____

Assessor signature: _____ Date: _____

Internal verifier signature: _____ Date: _____
(*if sampled*)

Unit 22: Using and communicating laboratory information to authorised personnel

Unit reference number: T/601/8203

Level: 3

Credit value: 6

Guided learning hours: 25

Unit summary

This unit covers the skills and knowledge needed to prove the competences required to use and communicate laboratory information to authorised personnel, in accordance with approved procedures. The learner will be able to access data from the laboratory information management system (LIMS), from the appropriate files, as well as other laboratory paperwork, and they will need to communicate accurately the information to authorised personnel. They will be required to work to the relevant standard operating procedures, legislation and organisational policy, and to follow Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP). They will also be required to present records and details of their laboratory work to the appropriate people.

The learner's responsibilities will require them to access laboratory data on tests/samples, and to provide this to authorised personnel, in accordance with organisational procedures. They will be expected to work to instructions with a minimum of supervision, either on their own or as part of a team, taking personal responsibility for their own actions and for the quality and accuracy of the work that they carry out.

The learner's underpinning knowledge will be sufficient to provide an understanding of the data requirements for tests/samples and test requirements for the speciality that they work in. They will understand the importance of the Data Protection Act, and the need to maintain the security and integrity of the laboratory records.

The learner's underpinning knowledge will provide a good understanding of their work, and will provide an informed approach to accessing laboratory information and communicating this to authorised personnel, in a laboratory environment. They will understand the need to work efficiently and effectively, and will know what to consider when communicating laboratory information, including how to deal with problems, and how to achieve their work objectives and targets, in adequate depth to provide a sound basis for carrying out the activities safely and correctly.

The learner will understand the safety precautions required when carrying out the laboratory activities for scientific operations and processes. They will be required to demonstrate safe working practices throughout, and will

understand their responsibility for taking the necessary safeguards to protect themselves and others in the workplace.

Assessment requirements

Assessment requirements are set down in Annexe C: Assessment strategy.

Assessment methodology

This unit is assessed in the workplace. Learners can enter the types of evidence they are presenting for assessment and the submission date against each assessment criterion. Alternatively, centre documentation should be used to record this information.

Learning outcomes and assessment criteria

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
1 Use and communicate laboratory information to authorised personnel	1.1 Ensure that their work is carried out in accordance with standard operating procedures 1.2 Work safely at all times, complying with health and safety and other relevant regulations and guidelines 1.3 Ensure the integrity of the laboratory information management system (LIMS) by all of the following: – using the correct startup/shutdown procedures – following good practice for logging on/off – information is passed to authorised people only 1.4 Search and access data from the LIMS for three of the following: – test/sample information – process information – output quality information – cost/budget information – work delivery information – other (please specify) 1.5 Follow procedures correctly to ensure the security and confidentiality of laboratory information 1.6 Receive and record the information from customers, in the appropriate manner			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
2 Use and communicate laboratory information to authorised personnel (continued)	2.1 Forward messages and information to the appropriate people, in accordance with procedures 2.2 Communicate the required information about the work done, to authorised people, in accordance with departmental and organisational procedures 2.3 Communicate laboratory information to three of the following customers: – other department – clinician/scientist – team members – other laboratories – other (please specify) 2.4 Communicate four of the following types of information: – instructions – test results – progress report – work requirements – services available – other (please specify)			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	2.5 Record details of work done, and communicate the details to the appropriate people, using: – verbal report Plus one method from the following: – written or typed report – specific company documentation – computer-based record – electronic mail			
3 Know how to use and communicate laboratory information to authorised personnel	3.1 Describe the health and safety requirements of the area in which they are carrying out the laboratory activities 3.2 Describe the implications of not taking account of legislation, regulations, standards and guidelines when conducting laboratory activities 3.3 Describe the principles of Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP) applied in the workplace 3.4 Describe the standard operating procedures, as set down in the local laboratory operating manuals 3.5 Describe the data security requirements for different computer applications			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	3.6 Explain how to access and store data, in accordance with standard operating procedures and organisational practices 3.7 Explain why it is important to maintain accurate test/sample and departmental records 3.8 Describe the specific safety precautions to be taken when working with computer systems (to include such things as safety guidance relating to the use of visual display unit (VDU) equipment and workstation environment (such as lighting, seating, positioning of equipment), repetitive strain injury (RSI); the dangers of trailing leads and cables; how to spot faulty or dangerous electrical leads, plugs and connections) 3.9 Explain why it is important to maintain good housekeeping arrangements (such as putting disks, manuals and unwanted items of equipment into safe storage; leaving the work area in a safe and tidy condition) 3.10 Describe the laboratory sample reception, records database and tracking system 3.11 Describe the types of handling and sorting system used, and the procedures and practices used for transferring samples within the laboratory whilst undergoing processing 3.12 Describe the importance of using the correct identification, and any unique organisational or laboratory numbers for tests/samples			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	3.13 Describe the organisational requirements for maintaining the security of the workplace (e.g. workplace access and laboratory sample containment)			
4 Know how to use and communicate laboratory information to authorised personnel (continued)	4.1 Describe the lines of communication and responsibilities in their department, and the links with the rest of the organisation 4.2 Describe the limits of their own authority and to whom they should report if they have problems that they cannot resolve 4.3 Describe the basic set-up and operation of the laboratory records system and the peripheral devices that are used (such as mouse, keyboard, VDU, printer and barcode reader) 4.4 Describe the correct startup and shutdown procedures to be used for the computer system 4.5 Explain how to access the specific computer laboratory information management system (LIMS) database to be used, and the use of software manuals and related documents to aid efficient operation of the relevant laboratory records system 4.6 Explain how to deal with system problems (such as error messages received, peripherals which do not respond as expected, obvious faults with the equipment or connecting leads)			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	4.7 Explain how to access and communicate data effectively, and how to identify key information when recording and forwarding messages accurately 4.8 Explain where to obtain the information that they need to carry out their job, the form in which the information is expressed and why it should be up to date 4.9 Describe the different forms of communication available to them, and how they are used 4.10 Explain why it is important to communicate clearly and to give all of the information necessary to the audience 4.11 Describe the organisational and/or laboratory procedures for acknowledging and responding to incoming and outgoing information 4.12 Describe the organisational and/or laboratory procedures for recording laboratory information			

Learner name: _____ Date: _____

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Assessor signature: _____ Date: _____

Internal verifier signature: _____ Date: _____
(*if sampled*)

Unit 23: Analysing DNA using gel electrophoresis

Unit reference number: F/601/8205

Level: 3

Credit value: 8

Guided learning hours: 33

Unit summary

This unit covers the skills and knowledge needed to prove the competences required to carry out DNA sample analysis by gel electrophoresis, in accordance with approved procedures. The learner is required to confirm that the necessary reagents are available and have been stored in the way indicated by the supplier. They will be expected to follow the correct procedures, and to ensure that a high standard of cleanliness is maintained with due regard for the risk of cross contamination of samples. The learner will be required to work to the relevant standard operating procedures, legislation and organisational policy, and to follow Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP). They will be expected to handle potentially dangerous chemicals, ensuring that they are contained within designated areas whilst in use and are disposed of in the correct way. They will be required to present records and details of their laboratory work to the appropriate people.

The learner will be required to set up and run agarose gels by gel electrophoresis, to interpret the DNA data and, where necessary, to repeat the analysis to confirm or clarify the result. Conforming to the laboratory quality system will be an important aspect of their work and their laboratory records must reflect consistent experimental and data recording and reporting performance.

The learner's responsibilities will require them to comply with standard operating procedures for the gel electrophoresis work activities undertaken, and to report any problems that they cannot personally resolve, or that are outside their permitted authority, to the relevant people. They will be expected to work to instructions with a minimum of supervision, either on their own or as part of a team, taking personal responsibility for their own actions and for the quality and accuracy of the work that they carry out.

The learner's underpinning knowledge will be sufficient to provide a sound basis for their work, and will enable them to adopt an informed approach to applying DNA analysis procedures. They will have an understanding of the gel electrophoresis process and its application, and will know about the analysis, samples and reagents used, in adequate depth to provide a sound background for carrying out the laboratory activities to the required specification.

The learner will understand the safety precautions required when carrying out the laboratory activities for scientific operations and processes, and the

potential environmental impacts. They will be required to demonstrate safe working practices throughout, and will understand their responsibility for taking the necessary safeguards to protect themselves and others in the workplace.

Assessment requirements

Assessment requirements are set down in Annexe C: Assessment strategy.

Assessment methodology

This unit is assessed in the workplace. Learners can enter the types of evidence they are presenting for assessment and the submission date against each assessment criterion. Alternatively, centre documentation should be used to record this information.

Learning outcomes and assessment criteria

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
1 Analyse DNA using gel electrophoresis	1.1 Ensure that their work is carried out in accordance with standard operating procedures 1.2 Wear the appropriate personal protection equipment (PPE) or have the appropriate safety controls in place when handling specimens 1.3 Wear three of the following types of protective clothing and equipment: – laboratory coat/overalls – face mask/respirator – gloves – safety glasses/safety goggles – mop cap – other (please specify)			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	1.4 Carry out all of the following operations: – prepare agarose gels for analysis – load DNA samples onto an agarose gel for electrophoresis, and set the power supply at an appropriate level – visualise and record data (such as via digital camera), in accordance with departmental procedures – dispose of agarose gels safely, in accordance with departmental operating procedures and local requirements 1.5 Prepare the appropriate percentage agarose gel for the amplified DNA fragment. 1.6 Ensure that intercalating dyes (EtBR, SYBR green, etc) are added to the gel during setup, according to standard operating procedures			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	1.7 Carry out all following gel electrophoresis activities: – remove gel comb – submerge in running buffer – load the ladder(s) – prepare the sample and load the dye – load samples onto gel – connect to gel box and operate power supply – dispose of unwanted gel in hazardous waste			
2 Analyse DNA using gel electrophoresis (continued)	2.1 Load the DNA reference ladders and samples with the appropriate DNA visualisation dye, and run gels according to standard operating procedures 2.2 Perform gel electrophoresis analysis for one of the following categories: – large DNA fragments (5–10kb) – small DNA fragments (0.2 –1kb) 2.3 Visualise the gel using UV or white light, as appropriate, and according to standard operating procedures 2.4 Dispose of spent materials (gel and buffer systems) appropriately and according to local requirements			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	2.6 Evaluate the data, in accordance with standard operating procedures and laboratory instructions 2.7 Communicate the required information about the work done, to authorised people, in accordance with departmental and organisational procedures 2.8 Record details of the work, and communicate the details to the appropriate people, using: – verbal report Plus one method from the following: – written or typed report – specific company documentation – computer-based record – electronic mail			
3 Know how to analyse DNA using gel electrophoresis	3.1 Describe the health and safety requirements of the area in which they are carrying out the laboratory activities 3.2 Describe the implications of not taking account of legislation, regulations, standards and guidelines when conducting laboratory activities			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	3.3 Describe the principles of Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP) applied in the workplace 3.4 Describe the importance of wearing protective clothing, gloves and eye protection when handling laboratory samples for analysis 3.5 Describe the laboratory sample reception, records database and tracking system 3.6 Describe the types of handling and sorting system used, and the procedures and practices used for transferring specimens/samples within the laboratory whilst undergoing processing 3.7 Describe the importance of using the correct identification, and any unique organisational or laboratory numbers for specimens/samples 3.8 Describe the organisational requirements for maintaining the security of the workplace (e.g. workplace access and laboratory sample containment) 3.9 Describe the lines of communication and responsibilities in their department, and the links with the rest of the organisation			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	3.10 Describe the limits of their own authority and to whom they should report if they have problems that they cannot resolve 3.11 Describe the minimum size/volume/DNA concentration of laboratory sample required 3.12 Describe the range of samples analysed, the containers used for sample storage in the laboratory, and other essential resources needed for each investigation 3.13 Describe the importance of keeping the work area clean and tidy, and of avoiding cross contamination of samples 3.14 Describe the main types of gel solution used for analysis (such as gel percentage (between 0.2 and 2%) for large and small DNA fragments)			
4 Know how to analyse DNA using gel electrophoresis (continued)	4.1 Describe the different types of gel tank used (such as 8x10cm gel (minigels)) 4.2 Describe the typical DNA sample size to be loaded for a ladder to be visible under UV light 4.3 Describe the range of gel combs available, and the main factors to consider when selecting one for use (such as DNA sample size, number of teeth)			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	4.4 Explain how to transfer an appropriate amount of each sample to a fresh microfuge tube 4.5 Explain how to add an appropriate amount of loading buffer and DNA sample onto the gel 4.6 Explain how to load the gel tray with marker before and after loading the samples 4.7 Explain how to close the gel tank, switch on the power source and run the gel at the correct voltage and time 4.8 Describe the point at which to switch off the power supply (such as when the dye is $^2/_3$ to ¾ of the way down the gel) 4.9 Explain how to use a stain box to stain the gel ladder 4.10 Explain how to view and record data from the gel ladder (such as UV light and a digital camera) 4.11 Explain how DNA samples can be excised from gels when isolation is required 4.12 Explain how to construct and use a calibration curve for markers 4.13 Explain how to record and interpret results from gel electrophoresis			

Learner name: _____ Date: _____

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Assessor signature: _____ Date: _____

Internal verifier signature: _____ Date: _____
(*if sampled*)

Unit 24: Using statistical process control (SPC) for laboratory measurement processes

Unit reference number: K/601/8229

Level: 4

Credit value: 8

Guided learning hours: 42

Unit summary

This unit covers the skills and knowledge needed to prove the competences required to analyse laboratory data, and to apply the principles and processes of statistical process control (SPC), in accordance with approved procedures and practices. The learner will be expected to apply SPC, utilising statistical and graphical methods to represent the laboratory data. Typically, these would include run charts, tally charts, bar charts, histograms, box plots, Pareto diagrams, stem and leaf plots, and summary statistics. The competences include seeking authority and terms of reference from a senior scientist/project leader for the work to be undertaken. They will be required to work to the relevant standard operating procedures, legislation and organisational policy, and to follow Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP). They will be required to present their analysis of the data to the appropriate people.

The learner's responsibilities will require them to comply with organisational policy and procedures for analysing laboratory measurement processes, and to report any problems that they cannot personally resolve to the relevant authority. They will be expected to work unsupervised, either on their own or as part of a team, which they may lead or direct, taking full responsibility for their actions and, possibly, for the work of colleagues or subordinates.

The learner's underpinning knowledge will provide a good understanding of general and discipline-specific drug development principles and processes. They will understand the physical drug form principles and different modes of administration, data analysis methods, and patent, copyright and intellectual property issues, project planning and methodology for analysing laboratory measurements. They will be able to apply SPC with sufficient depth of understanding to enable them to show results to the required standard.

The learner will be fully aware of any health, safety and environmental requirements, and the appropriate legislative and regulatory frameworks, applicable to their area of responsibility. They will be required to ensure that safe working practices are maintained throughout, and will understand the responsibility they owe to themselves and others in the workplace.

Assessment requirements

Assessment requirements are set down in Annexe C: Assessment strategy.

Assessment methodology

This unit is assessed in the workplace. Learners can enter the types of evidence they are presenting for assessment and the submission date against each assessment criterion. Alternatively, centre documentation should be used to record this information.

Learning outcomes and assessment criteria

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
1 Use statistical process control for laboratory measurement processes	1.1 Ensure that their work is carried out in accordance with standard operating procedures 1.2 Work safely at all times, complying with health and safety and other relevant regulations and guidelines 1.3 Identify the appropriate analytical process to be studied using SPC 1.4 Establish the scope and purpose of the laboratory data to be analysed 1.5 Consult with relevant people, and gather all the necessary data for analysis 1.6 Apply the principles and processes of statistical process control to the laboratory measurement process			
2 Use statistical process control for laboratory measurement processes (continued)	2.1 Complete all of the following for analytical processes: – plan the analysis of laboratory measurement processes in a logical and structured way – assess the precision of a measurement system – determine if the system is stable with respect to a number of variables – quantify the amount of variation that exists within a particular sample – quantify the amount of variation from sample to sample			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	2.2 Utilise statistical and graphical methods to present the results of the analysis 2.3 Produce graphical analysis in three of the following formats: – run charts – tally charts – bar charts – histograms – box plots – Pareto diagrams – stem and leaf plots – multi-vari charts 2.4 Present the results of analysis to the appropriate people 2.5 Record details of the work done, and communicate the details to the appropriate people, using both: – verbal report Plus one method from the following: – written or typed report (e.g. laboratory notebook) – specific company documentation – computer-based record – electronic mail			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
3 Know how to use statistical process control for laboratory measurement processes	3.1 Describe the health and safety requirements of the area in which they are carrying out the laboratory activities 3.2 Describe the implications of not taking account of legislation, regulations, standards and guidelines when conducting laboratory activities 3.3 Describe the standard operating procedures, as set down in local laboratory operating manuals 3.4 Describe the principles of Good Laboratory Practice (GLP) and/or Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP) applied in the workplace 3.5 Describe the purpose or speciality of the department in which they are employed, and how it fits into the other specialities of the larger organisation 3.6 Describe the interactions which take place between the department and other specialities in the same organisation 3.7 Describe the interactions which take place between the speciality in which they are employed and others in the same speciality outside the organisation 3.8 Explain how their work activities affect others within the department, organisation and the community			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	3.9 Describe the lines of communication and responsibilities in their department, and their links with the rest of the organisation 3.10 Describe the limits of their own authority and to whom they should report if they have problems that they cannot resolve			
4 Know how to use statistical process control for laboratory measurement processes (continued)	4.1 Describe the organisation's requirements for recording and archiving reports 4.2 Explain how to apply statistical process control charts to measurement processes 4.3 Explain why accuracy and precision in measurement analysis is essential to ensure appropriate conclusions in experimental results 4.4 Describe the ways to define limits (such as limits of detection, determination, quantitation and quantification) 4.5 Explain how to use outlier tests and limits of detection correctly, and when not to use them 4.6 Explain how to recognise the action signal on the control chart 4.7 Explain how to set in-house specifications 4.8 Explain how to understand the influence of sample size (e.g. in control charts for grouped data, on statistical significance and power)			

Learning outcomes	Assessment criteria	Evidence type	Portfolio reference	Date
	4.9 Explain how to understand the strengths and weaknesses of data (e.g. the importance of using the standard operating procedure) 4.10 Explain how to use statistical techniques to assess experimental approaches with respect to specificity, sensitivity and linearity			

Learner name: _____ Date:_____

Learner signature: _____ Date:_____

Assessor signature: _____ Date:_____

Internal verifier signature: _____ Date:_____
(*if sampled*)

Further information

To get in touch with us visit our 'Contact us' pages:

- Edexcel, BTEC and Pearson Work Based Learning contact details: qualifications.pearson.com/en/support/contact-us.html
- books, software and online resources for UK schools and colleges: www.pearsonschoolsandfecolleges.co.uk

Key publications

- *Adjustments for candidates with disabilities and learning difficulties, Access and Arrangements and Reasonable Adjustments, General and Vocational qualifications* (Joint Council for Qualifications (JCQ))
- *Supplementary guidance for reasonable adjustments and special consideration in vocational internally assessed units* (Pearson)
- *General and Vocational qualifications, Suspected Malpractice in Examination and Assessments: Policies and Procedures* (JCQ)
- *Equality Policy* (Pearson)
- *Recognition of Prior Learning Policy and Process* (Pearson)
- *UK Information Manual* (Pearson)
- *Pearson Edexcel NVQs, SVQs and competence-based qualifications – Delivery Requirements and Quality Assurance Guidance* (Pearson)

All of these publications are available on our website: qualifications.pearson.com

Further information and publications on the delivery and quality assurance of NVQ/Competence-based qualifications are available at our website on the Delivering BTEC pages. Our publications catalogue lists all the material available to support our qualifications. To access the catalogue and order publications, please go to the resources page of our website.

Useful publications

Related information and publications include:

- Centre Handbook for Pearson NVQs and Competence-based Qualifications published annually
- functional skills publications – specifications, tutor support materials and question papers
- the current Pearson publications catalogue and update catalogue.

Pearson publications concerning the Quality Assurance System and the internal and standards verification of vocationally related programmes can be found on the Pearson website.

NB: Some of our publications are priced. There is also a charge for postage and packing. Please check the cost when you order.

How to obtain National Occupational Standards

To obtain the National Occupational Standards for Laboratory Science please go to:

SEMTA
www.semta.org.uk

Professional development and training

Pearson supports UK and international customers with training related to NVQ and BTEC qualifications. This support is available through a choice of training options offered in our published training directory or through customised training at your centre.

The support we offer focuses on a range of issues including:

- planning for the delivery of a new programme
- planning for assessment and grading
- developing effective assignments
- building your team and teamwork skills
- developing student-centred learning and teaching approaches
- building functional skills into your programme
- building effective and efficient quality assurance systems.

The national programme of training we offer can be viewed on our website (qualifications.pearson.com). You can request customised training through the website or by contacting one of our advisers in the Training from the Pearson team via Customer Services to discuss your training needs.

The training we provide:

- is active
- is designed to be supportive and thought provoking
- builds on best practice
- may be suitable for those seeking evidence for their continuing professional development.

Annexe A: Quality assurance

Key principles of quality assurance

- A centre delivering Pearson qualifications must be an Pearson recognised centre and must have approval for qualifications that it is offering.
- The centre agrees, as part of gaining recognition, to abide by specific terms and conditions relating to the effective delivery and quality assurance of assessment. The centre must abide by these conditions throughout the period of delivery.
- Pearson makes available to approved centres a range of materials and opportunities to exemplify the processes required for effective assessment and provide examples of effective standards. Approved centres must use the guidance on assessment to ensure that staff who are delivering Pearson qualifications are applying consistent standards.
- An approved centre must follow agreed protocols for: standardisation of assessors; planning, monitoring and recording of assessment processes; internal verification and recording of internal verification processes and dealing with special circumstances, appeals and malpractice.

Quality assurance processes

The approach to quality assured assessment is made through a partnership between a recognised centre and Pearson. Pearson is committed to ensuring that it follows best practice and employs appropriate technology to support quality assurance processes where practicable. The specific arrangements for working with centres will vary. Pearson seeks to ensure that the quality-assurance processes it uses do not inflict undue bureaucratic processes on centres, and works to support them in providing robust quality-assurance processes.

The learning outcomes and assessment criteria in each unit within this specification set out the standard to be achieved by each learner in order to gain each qualification. Pearson operates a quality-assurance process, designed to ensure that these standards are maintained by all assessors and verifiers.

For the purposes of quality assurance, all individual qualifications and units are considered as a whole. Centres offering these qualifications must be committed to ensuring the quality of the units and qualifications they offer, through effective standardisation of assessors and internal verification of assessor decisions. Centre quality assurance and assessment processes are monitored by Pearson.

The Pearson quality-assurance processes will involve:

- gaining centre recognition and qualification approval if a centre is not currently approved to offer Pearson qualifications
- annual visits to centres by Pearson for quality review and development of overarching processes and quality standards. Quality review and development visits will be conducted by an Pearson quality development reviewer
- annual visits by occupationally competent and qualified Pearson Standards Verifiers for sampling of internal verification and assessor decisions for the occupational sector
- the provision of support, advice and guidance towards the achievement of National Occupational Standards.

Centres are required to declare their commitment to ensuring quality and appropriate opportunities for learners that lead to valid and accurate assessment outcomes. In addition, centres will commit to undertaking defined training and online standardisation activities.

Annexe B: Centre certification and registration

Pearson Standards Verifiers will provide support, advice and guidance to centres to achieve Direct Claims Status (DCS). Pearson will maintain the integrity of Pearson NVQs through ensuring that the awarding of these qualifications is secure. Where there are quality issues identified in the delivery of programmes, Pearson will exercise the right to:

- direct centres to take action
- limit or suspend certification
- suspend registration.

The approach of Pearson in such circumstances is to work with the centre to overcome the problems identified. If additional training is required, Pearson will aim to secure the appropriate expertise to provide this.

What are the access arrangements and special considerations for the qualifications in this specification?

Centres are required to recruit learners to Pearson qualifications with integrity.

Appropriate steps should be taken to assess each applicant's potential and a professional judgement should be made about their ability to successfully complete the programme of study and achieve the qualification. This assessment will need to take account of the support available to the learner within the centre during their programme of study and any specific support that might be necessary to allow the learner to access the assessment for the qualification. Centres should consult Pearson's policy on learners with particular requirements.

Pearson's policy on access arrangements and special considerations for Pearson qualifications aims to enhance access to the qualifications for learners with disabilities and other difficulties (as defined by the 2010 Equality Act) without compromising the assessment of skills, knowledge, understanding or competence. Please refer to *Access Arrangements, Reasonable Adjustments and Special Consideration for General and Vocational Qualifications* for further details. qualifications.pearson.com

Annexe C: Assessment requirements/strategy

Introduction

Semta, the Sector Skills Council for the Science Engineering Manufacturing Technologies

Sector, has produced this QCF Unit Assessment Strategy to:

- assist Assessors, Internal Verifiers and External Verifiers
- encourage and promote consistent assessment of NVQ units
- promote cost effective assessment plans

This document also provides definitions for:

- the qualifications and experience required for Assessors and Verifiers
- the assessment environment and notes on simulation/replication.
- access to units

and requirements relating to:

- carrying out assessments
- performance evidence
- assessing knowledge and understanding

The importance and value in which employers and learners place on undertaking NVQ units will provide a key measure of [Semta's] success with this unit assessment strategy. Another key success factor will be [Semta's] partnership with the relevant Awarding Organisations.

Assessor Requirements to Demonstrate Effective Assessment Practice

Assessment must be carried out by competent Assessors that as a minimum must hold the Level 3 Award in Assessing Competence in the Work Environment. Current and operational Assessors that hold units D32 and/or D33 or A1 and/or A2 as appropriate to the assessment being carried out, will not be required to achieve the QCF Level 3 Award as they are still appropriate for the assessment requirements set out in this Unit Assessment Strategy. However, they will be expected to regularly review their skills, knowledge and understanding and where applicable undertake continuing professional development to ensure that they are carrying out workplace assessment to the most up to date National Occupational Standards (NOS)

Assessor Technical Requirements

Assessors must be able to demonstrate that they have verifiable, relevant and sufficient technical competence to evaluate and judge performance and knowledge evidence requirements as set out in the relevant QCF unit learning outcomes and associated assessment criteria.

This will be demonstrated either by holding a relevant technical qualification or by proven industrial experience of the technical areas to be assessed. The assessor's competence must, at the very least, be at the same level as that required of the learner(s) in the units being assessed.

Assessors must also be:

Fully conversant with the Awarding Organisation's assessment recording documentation used for the NVQ units against which the assessments and verification are to be carried out, other relevant documentation and system and procedures to support the QA process.

Verifier Requirements (internal and external)

Internal quality assurance (Internal Verification) must be carried out by competent Verifiers that as a minimum must hold the QCF Level 4 Award in the Internal Quality Assurance of Assessment Processes and Practices. Current and operational Internal Verifiers that hold internal verification units V1 or D34 will not be required to achieve the QCF Level 4 Award as they are still appropriate for the verification requirements set out in this Unit Assessment Strategy. Verifiers must be familiar with, and preferably hold, either the nationally recognised Assessor units D32 and/or D33 or A1 and/or A2 or the QCF Level 3 Award in Assessing Competence in the Work Environment.

External quality assurance (External Verification) must be carried out by competent External Verifiers that as a minimum must hold the QCF Level 4 Award in the External Quality Assurance of Assessment Processes and Practices**.** Current and operational External Verifiers that hold external verification units V2 or D35 will not be required to achieve the QCF Level 4 Award as they are still appropriate for the verification requirements set out in this Unit Assessment Strategy. Verifiers must be familiar with, and preferably hold, either the nationally recognised Assessor units D32 and/or D33 or A1 and/or A2 or the QCF Level 3 Award in Assessing Competence in the Work Environment.

External and Internal Verifiers will be expected to regularly review their skills, knowledge and understanding and where applicable undertake continuing professional development to ensure that they are carrying out workplace Quality Assurance (verification) of Assessment Processes and Practices to the most up to date National Occupational Standards (NOS).

Verifiers, both Internal and External, will also be expected to be fully conversant with the terminology used in the QCF NVQ units against which the assessments and verification are to be carried out, the appropriate Regulatory Body's systems and procedures and the relevant Awarding Organisation's documentation, systems and procedures within which the assessment and verification is taking place.

Specific technical requirements for internal and external verifiers

Internal and external verifiers of this qualification must be able to demonstrate that have verifiable, sufficient and relevant industrial experience, and must have a working knowledge of the processes, techniques and procedures that are used in the relevant sector/occupation.

The tables on the following page show the recommended levels of technical competence for assessors, internal verifiers, and external verifiers.

Technical Requirements for Assessors and Verifiers

Position	Prime activity requirements	Support activity requirements	Technical requirements (see notes)
Assessor	Assessment Skills	IV Systems	Technical competence in the areas covered by the QCF units being assessed
Internal Verifier	Verification Skills	Assessment Knowledge	Technical understanding of the areas covered by the qualifications
External Verifier	Verification skills	Assessment Understanding	Technical awareness of the areas covered by the qualifications

Notes

1 Technical competence is defined here as a combination of practical skills, knowledge, and the ability to apply both of these, in familiar and new situations, within a real working environment.

2 Technical understanding is defined here as having a good understanding of the technical activities being assessed, together with knowledge of relevant Health & Safety implications and requirements of the assessments.

3 Technical awareness is defined here as a general overview of the subject area, sufficient to ensure that assessment and portfolio evidence are reliable, and that relevant Health and Safety requirements have been complied with.

4 The competence required by the assessor, internal verifier and external verifier, in the occupational area being assessed, is likely to exist at three levels as indicated by the shaded zones in the following table.

Technical Competence / Required by:	An ability to discuss the general principles of the competences being assessed	An ability to describe the practical aspects of the competence being assessed	An ability to demonstrate the practical competences being assessed
Assessor			
Internal Verifier			
External Verifier			

Assessment Environment

The evidence put forward for this unit can only be regarded valid, reliable, sufficient and authentic if achieved and obtained in the working environment and be clearly attributable to the learner. However, in certain circumstances, simulation/replication of work activities may be acceptable.

- The use of high quality, realistic simulations, which impose pressures which are consistent with workplace expectations, should only be used in relation to the assessment of the following:-
  - rare or dangerous occurrences, such as those associated with health, safety and the environment issues, emergency scenarios and rare operations at work;
  - the response to faults and problems for which no opportunity has presented for the use of naturally occurring workplace evidence of learners competence;
  - aspects of working relationships and communications for which no opportunity has presented for the use of naturally occurring workplace evidence of learner's competence.
- Simulations will require prior approval from the specific Awarding Organisation and should be designed in relation to the following parameters: -
  - the environment in which simulations take place must be designed to match the characteristics of the working environment;
  - simulations which are designed to assess competence in dealing with emergencies, accidents and incidents must be verified as complying with relevant health, safety and environmental legislation by a competent health and safety/environmental control officer before being used;
  - simulated activities should place learners under the same pressures of time, access to resources and access to information as would be expected if the activity was real;
  - simulated activities should require learners to demonstrate their competence using real plant and equipment;

- simulated activities which require interaction with colleagues and contacts should require the learner to use the communication media that would be expected at the workplace;
- for health and safety reason simulations need not involve the use of genuine substances/materials. Any simulations which require the learner to handle or otherwise deal with materials substances/should ensure that the substitute take the same form as in the workplace

Simulations/replications should be designed in relation to a realistic work environment, having an acceptable level of appropriate equipment and operating to Good Laboratory Practice (GLP)/Good Control Laboratory Practice (GCLP) and/or Good Manufacturing Practice (GMP)/Current Good Manufacturing Practice (CGMP) standards. It may involve the use of inert substitutes for dangerous compounds or microbiological materials.

Access to Assessment

There are no entry qualifications or age limits required by learners to undertake the NVQ units unless this is a legal requirement of the process or the environment. Assessment is open to any learner who has the potential to achieve the assessment criteria set out in the units.

Aids or appliances, which are designed to alleviate disability, may be used during assessment, providing they do not compromise the standard required.

Carrying Out Assessment

The NVQ units were specifically developed to cover a wide range of activities. The evidence produced for the units will, therefore, depend on the learners choice of "bulleted items" listed in the unit assessment criteria.

Where the assessment criteria gives a choice of bulleted items (for example 'any three from five'), assessors should note that learners do not need to provide evidence of the other items to complete the unit (in this example, two) items, particularly where these additional items may relate to other activities or methods that are not part of the learners normal workplace activity or area of expertise.

Minimum Performance Evidence Requirements

Performance evidence must be the main form of evidence gathered. In order to demonstrate consistent, competent performance for a unit, performance evidence must be provided, and must be sufficient to show that the performance requirements of the unit have been carried out to the prescribed standards. It is possible that some of the scope items may be covered more than once. The assessor and learner need to devise an assessment plan to ensure that performance evidence is sufficient to cover all the specified scope items and which maximises the opportunities to gather evidence. Where applicable, performance evidence maybe used for more than one unit.

The most effective way of assessing competence, especially for the performance statements in relation to scope items, is through direct

observation of the learner. Assessors must make sure that the evidence provided reflects the learner's competence and not just the achievement of a training programme.

Evidence that has been produced from team activities, for example, cleaning equipment, is only valid when it clearly relates to the learners specific and individual contribution to the activity, and not to the general outcome(s).

Each example of performance evidence will often contain features that apply to more than one unit, and can be used as evidence in any unit where appropriate.

Performance evidence must be a combination of:

- outputs of the learner's work, such as items that have been processed or worked on, and documents produced as part of a work activity

together with:

- evidence of the way the learner carried out the activities such as witness testimonies, assessor observations or authenticated learner reports, records or photographs of the work/activity carried out, etc.

Competent performance is more than just carrying out a series of individual set tasks. Many of the units contain statements that require the learner to provide evidence that proves they are capable of combining the various features and techniques. Where this is the case, separate fragments of evidence would not provide this combination of features and techniques and will not, therefore, be acceptable as demonstrating competent performance.

If there is any doubt as to what constitutes valid, authentic and reliable evidence, the internal and/or external verifier should be consulted.

Assessing knowledge and understanding

Knowledge and understanding are key components of competent performance, but it is unlikely that performance evidence alone will provide enough evidence in this area. Where the learner's knowledge and understanding (and the handling of contingency situations) is not apparent from performance evidence, it must be assessed by other means and be supported by suitable evidence.

Knowledge and understanding can be demonstrated in a number of different ways. Semta expects oral questioning and practical demonstrations to be used, as these are considered the most appropriate for these units. Assessors should ask enough questions to make sure that the learner has an appropriate level of knowledge and understanding, as required by the unit.

Awarding Organisations may choose other methods, which must be supported by a suitable rationale

Evidence of knowledge and understanding will **not** be required for those bulleted items in the assessment criteria that have not been selected by the learner.

The achievement of the specific knowledge and understanding requirements of the units cannot simply be inferred by the results of tests or assignments

from other units, qualifications or training programmes. Where evidence is submitted from these sources, the assessor must, as with any assessment, make sure the evidence is valid, reliable, authentic, directly attributable to the learner, and meets the full knowledge and understanding requirements of the unit.

Where oral questioning is used the assessor must retain a record of the questions asked, together with the learner's answers.

Awarding Organisations may choose other methods, which must be supported by a suitable rationale.

Witness testimony

Where observation is used to obtain performance evidence, this must be carried out against the unit assessment criteria. Best practice would require that such observation is carried out by a qualified Assessor. If this is not practicable, then alternative sources of evidence may be used.

For example, the observation may be carried out against the assessment criteria by someone else that is in close contact with the learner. This could be a team leader, supervisor, mentor or line manager who may be regarded as a suitable witness to the learner's competency. However, the witness must be technically competent in the process or skills that they are providing testimony for, to at least the same level of expertise as that required of the learner. It will be the responsibility of the assessor to make sure that any witness testimonies accepted as evidence of the learner's competency are reliable, auditable and technically valid.

Quality Control of Assessment

General

There are two major points where an Awarding Organisation interacts with the Centre in relation to the External Quality Control of Assessment and these are:

- Approval - when a Centre take on new qualifications/units, the Awarding Organisation, normally through an External Verifier (EV) ensures that the Centre is suitably equipped and prepared to deliver the new units/qualification
- Monitoring - throughout the ongoing delivery of the qualification/units the Awarding Organisation, through EV monitoring and other mechanisms must maintain the quality and consistency of assessment of the units/qualification

Approval

In granting Approval, the Awarding Organisation, normally through its External Verifiers (EV) must ensure that the prospective Centre:

- Meets the requirements of the Qualification Regulator
- Has sufficient and appropriate physical and staff resources
- Meets relevant health and safety and/or equality and access requirements

- Has a robust plan for the delivery of the qualification/units

The Awarding Organisation may visit the Centre to view evidence or may undertake this via other means.

The Awarding Organisation must have a clear rationale for the method(s) deployed

Monitoring

The Awarding Organisation, through EV monitoring and other mechanisms must ensure:

- that a strategy is developed and deployed for the ongoing Awarding Organisation monitoring of the Centre. This strategy must be based on an active risk assessment of the Centre. In particular the strategy must identify the learner's, assessors and Internal Verifier sampling strategy to be deployed and the rationale behind this
- that the Centre's internal quality assurance processes are effective in learner's assessment
- that sanctions are applied to a Centre where necessary and that corrective actions are taken by the Centre and monitored by the Awarding Organisation/EV
- that reviews of Awarding Organisation's external auditing arrangements are undertaken

Awarding Organisations are required to provide to SEMTA, on request, details of the strategies, rationales and reviews detailed above.

Notes:

a) It is recognised that some Awarding Bodies provide supplementary guidance and documentation to centres to support the quality of assessment and verification practice of N/SVQs.

Annexe D: Additional requirement for qualifications that use the term 'NVQ' in a QCF qualification title

Please go to www.ofqual.gov.uk to access the document *'Operating rules for using the term 'NVQ' in a QCF qualification title'*.

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

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