APPLIED

WJEC Level 3 Diploma/Certificate in

MEDICAL SCIENCE

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DESIGNATED BY QUALIFICATIONS WALES

GUIDANCE FOR TEACHING

Teaching from 2016
For award from 2018

Contents

Unit 1 – Human Health and Disease

LO	AC	Specification statement	Comment
1	Understand biological principles		
	1.1	Describe the function of main classes of biological molecules in humans	
		Classes of biological molecules carbohydrates • monosaccharides, • disaccharides, • polysaccharides	Learners should be able to recognise examples of monosaccharides (formula – $C_n(H_2O)_n$) to include: • triose (glyceraldehyde) • pentose (ribose, deoxyribose) • hexose (α− and β−glucose, fructose, galactose). Learners should be able to recognise examples of disaccharides (formula - $C_{12}H_{22}O_{11}$) to include: • Sucrose (glucose-fructose) • maltose (α−glucose-α−glucose) • lactose (glucose-galactose). Learners should be able to recognise examples of polysaccharides to include: • glycogen, a polymer of α−glucose (branched structure), Learners should be able to link the properties and structures of these molecules to their functions.
		lipids • triglycerides, • phospholipids, • steroids	Learners should be able to recognise examples of: • triglycerides and phospholipids, and give the structural formula for glycerol and the general formula for saturated fatty acid. • Saturated fatty acids have only single carbon-to-carbon bonds. • Mono-unsaturated fatty acids have one carbon-to carbon double bond and poly-unsaturated fatty acids contain two or more carbon-to-carbon double bonds. Learners should understand how the functions of lipids and phospholipids in cells and organisms are related to their hydrophilic and hydrophobic properties. Learners should be able to recognise examples of steroids as four ring structures. Many hormones are steroids including oestrogen and testosterone, which are made from cholesterol. Cholesterol is a vital component of cell membranes. Other functions of lipids should include insulation, energy storage and protection.

		proteins and enzymes	Learners should be able to draw the general formula for amino acids. Proteins are polymers of amino acids of which there are twenty types which are coded for in proteins and which differ by the R group. Learners are not expected to recall names of amino acids but can be expected to identify them, given a structural formula and a suitable table showing R groups. Learners should be able to identify peptide, disulphide, ionic, hydrogen bonds and hydrophobic interactions between R groups at the various levels of protein structure. Learners should be familiar with different ways of representing protein structures, including ribbon diagrams and recognise regions of molecules as having a primary structure e.g. sequence of amino acids, a secondary structure e.g. α helices, β pleated sheets, a tertiary structure e.g. further folding of the polypeptide chain and a quaternary structure as more than one polypeptide chain bonded together. The bonding within a protein affects the three dimensional structure of the molecule and therefore affects its function within cells and organisms e.g. fibrous proteins (e.g. keratin) - a structural function and globular proteins (e.g. enzymes) - a metabolic function.
		• mechanisms of action (lock and key, induced fit) • factors affecting enzyme reactions (temperature, pH, substrate concentration, enzyme concentration, inhibitors)	Learners should understand the principle features of enzyme reactions to include: • the collision theory • the lock and key model • the induced fit model Learners should understand that high temperatures and pH (away from the optimum) alter the three dimensional structure of enzyme molecules. Bonds involved in the tertiary structure may be broken and hence the configuration of the active site is altered, reducing the ability to form enzyme-substrate complexes and hence the reaction rate. High temperatures and extreme changes in pH cause a permanent change in an enzyme's structure, this is called denaturation. Learners should be able to distinguish between competitive and non-competitive inhibition, including explaining the effect of increasing substrate concentration on both. Candidates should understand that inhibition can be reversible or irreversible.

		nucleotides • ATP	Learners should recognise the structure of ATP. Learners should understand that ATP is formed in an endergonic reaction. The energy required to combine ADP and inorganic phosphate (P_i) to form ATP (and water) comes from exergonic reactions, e.g. cell respiration. 30.6kJ mol^{-1} of energy is released when ATP is hydrolysed to ADP and phosphate. ATP may be called the 'universal energy currency' in organisms because it is a common energy source used in all living organisms. Candidates should be able to explain how the properties, structure and formation of ATP are linked to its role in cells.
		nucleic acids • DNA • RNA	Learners should know the structure of DNA and RNA. This should include structure, complementary base pairing, hydrogen bonding, and in DNA, the two polynucleotide strands are antiparallel. They should recognise similarities and differences between the two molecules. Learners should be able to differentiate between pyrimidine and purine bases when given structural formulae. Learners should know the structure of tRNA and be able to describe differences between mRNA, rRNA and tRNA.
	1.2	**Describe structure of human cells**	
		Human cellular structure • plasma membrane • nucleus • nucleolus • endoplasmic reticulum • golgi apparatus • mitochondria • nuclear envelope	Learners should be able to recognise the listed organelles on a diagram or electron micrograph of eukaryotic cells, and draw them onto a generalised diagram of a cell, understanding their relative size. The principal biochemical constituents of the cell membrane including: intrinsic and extrinsic proteins, glycoproteins, phospholipids and cholesterol. The polarity of protein molecules affects their position in the membrane. Intrinsic proteins include channel proteins and carrier proteins. The extracellular surfaces of the proteins can be glycosylated. Learners should be able to draw a simple diagram to illustrate the fluid mosaic model. Learners should understand that organelles work together to carry out functions within cells, e.g. in the synthesis and transport of biological molecules such as glycoproteins.

	1.3	**Explain transport systems in cells**	
		Movement into and out of cells • simple diffusion • osmosis • facilitated diffusion • active transport	Transport across cell membranes is affected by surface area, the concentration gradient, temperature, the size of the molecule, lipid solubility and thickness of the membrane. This then determines how different molecules are transported across the membrane. Facilitated diffusion (involving channel or carrier proteins, but not ATP) and active transport (carrier proteins with ATP) provide a mechanism to increase the rate of transport across the membrane for some molecules (e.g. polar molecules). Learners should understand the process of osmosis animal cells (no details of water potential required).
		• endo/exocytosis	Exocytosis and endocytosis provide a mechanism for bulk transport across a cell membrane and these processes change the surface area of cells as they occur.
	1.4	**Explain how cells process information**	
		DNA mechanisms • semi conservative replication	In DNA replication, DNA helicase breaks the hydrogen bonds between the bases in the helix, unwinding the DNA, exposing unpaired bases. DNA polymerase then forms bonds between adjacent nucleotides in the new strands of DNA being formed. Learners should be able to draw a representative diagram of the replication fork (with a small number of nucleotides).
		• transcription	DNA helicase breaks the hydrogen bonds between the bases in the helix, unwinding the DNA, exposing unpaired bases on the template strand. RNA polymerase links to the template strand of DNA, inserting mRNA nucleotides one at a time, according to the rules of complementary base pairing and forming bonds between them. Beyond the end of the gene there is a stop sequence, where RNA polymerase leaves DNA.
		• translation	Ribosomes have two attachment sites for tRNA (on the larger sub unit) and one attachment site for mRNA (on the smaller sub unit). Each tRNA molecule carries a specific amino acid. The Ribosome binds to the start codon on the mRNA. tRNA molecules bind to the ribosome through codon-anticodon interactions. A peptide bond is formed between the two amino acids. The ribosome moves along the mRNA one codon at a time. This continues until a stop codon is reached.

		• ‘one gene one protein’ hypothesis • triplet code	The genetic code is a linear, triplet, non-overlapping, degenerate, unambiguous, universal code for the production of polypeptides. Amino acids are coded for by triplets of bases in the DNA. The DNA is transcribed to produce codons in mRNA and then translated to produce a sequence of amino acids.

2	Understand function of human physiological systems		
	2.1	Describe structure of human physiological systems	
		Endocrine system • pancreas, • pituitary, • kidney	Learners should understand that the endocrine system is made up of a number of glands that secrete hormones directly into the bloodstream. Each hormone has a particular cell that is targets. Learners should know the locations of the pancreas, pituitary and kidneys. The Islets of Langerhans contain insulin and glucagon-producing cells in the pancreas. Separation of the pituitary into anterior and posterior lobes. Learners should recognise the main regions of a mammalian kidney and its blood supply and know the position of a nephron. Learners should be able to label a diagram of a nephron, including Bowman's capsule, proximal and distal convoluted tubules; loop of Henlé, vasa recta, collecting duct, afferent and efferent arterioles.
		Nervous system • CNS • PNS	Learners should be aware of the general structure of the CNS and PNS. Learners should be aware of the structure of a motor neurone. Learners should be able to draw a labelled diagram of a mammalian motor neurone; dendrites, cell body, nucleus, axon, myelin sheath of Schwann cells, nodes of Ranvier, axon endings/terminals, synaptic end bulbs. Learners should be able to describe the reflex arc.
		Musculoskeletal system • spinal column, • joints, • muscles	The spinal column is a series of small bones forming a flexible and supportive structure down the back. There are discs of cartilage found between the vertebrae to cushion them during locomotion. Learners are not expected to name regions of the vertebral column. Joints can be classified as fibrous joints (e.g. skull), cartilaginous joints(e.g. intervertebral discs holding vertebrae together), and synovial joints (e.g. knee). They should know the structure of the synovial joint to include ligaments, tendons, synovial membrane, synovial fluid, cartilage. Knowledge of muscle is limited to their action as antagonistic pairs. Knowledge of the structure of skeletal muscle is not required.

		Digestive system • mouth, • oesophagus, • stomach, • pancreas, • liver, • duodenum, • ileum, • colon	The structure, function and relative proportions of the layers of the gut wall (epithelium, mucosa, submucosa, muscle layers, serosa) in the different parts of the gut. Relative positions and sizes of various parts of the human gut and associated glands for digestion and absorption are required. This would include: mouth (buccal cavity, teeth, tongue, salivary glands), oesophagus, stomach, liver (secretes bile via the gall bladder and bile duct), duodenum, pancreas, ileum, colon, rectum and anus.
		Cardiovascular system blood vessels • arteries, • veins, • capillaries heart • coronary arteries, • chambers, • aorta, • pulmonary artery, • vena cava, • pulmonary vein, • cardiac muscle, • valves blood • plasma, • platelets, • red blood cells, • white blood cells, • blood group	Comparison of the structure of arteries, arterioles, capillaries, and venules and veins is required. Learners should be familiar with the internal and external structures of the mammalian heart. The terms tricuspid, bicuspid and semilunar should be used when describing valves. Learners should be able identify components of the blood. The terms thrombocyte, erythrocyte and leucocyte should be used. The two systems of blood grouping: • ABO • Rhesus

		Lymphatic system • vessels, • nodes	Learners should know that the lymphatic system is an extensive network of vessels. The spleen is the largest organ in the lymphatic system. Along the larger lymph vessels are sac-like structures called lymph nodes
		Respiratory system • lung, • trachea, • bronchi, • bronchioles, • alveoli, • pleural membranes, • ribs, • diaphragm	Learners should know the structure of the human respiratory system.
		Integumentary system • structure of skin	Learners should be able to recognise and describe the structure of the skin. Structures to include the hairs, hair follicles, sweat gland, sweat pore, sweat duct, erector muscle, sebaceous glands, sensory nerve endings, subcutaneous fat, capillaries.
		Immune system • white blood cells • antibodies • basic complement system	Learners should be able the recognise phagocytes and lymphocytes
	2.2	**Explain function of human physiological systems**	
		Endocrine System • purpose of system • role of the pancreas • action of insulin, action of glucagon	Learners should understand the purpose of the endocrine system. The role of the pancreas in the regulation of blood glucose, including the production of the hormone insulin by the beta cells of the Islets of Langerhans and glucagon by the alpha cells. Negative feedback as shown in the regulation of blood glucose levels. Learners should be aware of the terms glycogenolysis and glycogenesis.

		• role of the kidney • action of ADH	The glomerulus, Bowman's capsule (including podocytes) and the afferent and efferent arterioles are involved in ultrafiltration of the blood and produce glomerular filtrate in the first stage in the production of urine. The adaptations of the structure of the proximal convoluted tubule (PCT) in relation to selective reabsorption. The process of selective reabsorption from the filtrate in the PCT to the peritubular capillaries. The loops of Henlé concentrate salts in the tissue fluid of the medulla and that causes an osmotic flow of water out of the collecting ducts and distal convoluted tubules. ADH secretion has a role in negative feedback restoring the normal osmotic concentration in the blood. This includes the role of : • detectors - osmoreceptors in the hypothalamus; • coordinator - posterior lobe of pituitary secreting ADH • effector - distal convoluted tubules and collecting ducts of the kidneys. • ADH enables more concentrated urine to be formed: • ADH makes the plasma membranes of the distal convoluted tubule cells and collecting duct cells • more permeable to water; • water is reabsorbed, by osmosis, from the filtrate into the surrounding tissue fluid (and hence blood capillaries) around the DCTs and collecting ducts;
		Nervous system • purpose of system • voluntary and involuntary responses	Learners should know the role of the nervous system. Sensory neurones carry messages from the peripheral sense organs to the CNS consisting of brain and spinal cord. The CNS processes information. Motor neurones convey instructions from the CNS to effector organs (muscles or glands.) They should also be able to describe the functions of; dendrites; cell body, nucleus, axon, myelin sheath, Schwann cell, nodes of Ranvier, axon endings/ terminals, synaptic end bulbs. Learners should have an overview of how a nerve impulse is transmitted along an axon. This should be limited the overall charge distribution (knowledge of action potentials, sodium-potassium pumps and voltage-gated Na^+ channels is not required). Leaners should know that the synapse ensures one-way flow of impulses. Learners should be able to label a diagram of a synapse and be able to explain the role of the following in synaptic transmission: pre and post-synaptic membranes, synaptic vesicles, neurotransmitters (e.g. acetylcholine), synaptic cleft, Ca^{2+} channels; receptors on post-synaptic membrane.

			They should be able to explain how the merging of impulses is prevented including: the effect of cholinesterase, active transport of Ca^{2+} out of the synaptic knob and reabsorption of neurotransmitter molecules. Learners should be able to describe the effects of chemicals on synaptic transmission.
		Musculoskeletal system • purpose of system • sliding filament theory	Learners should know the purpose of the musculoskeletal system in support and locomotion. Discs of cartilage are found between the vertebrae to cushion them during locomotion. Learners are not expected to name regions of the vertebral column. Knowledge of the sliding filament is limited to the presence of thick and thin filaments that slide over each other to allow contraction.
		Digestive system • purpose of system • chemical digestion • mechanical digestion • bile production • glucose metabolism • absorption	Learners should understand the purpose of the human digestive system. They should describe how the organs of the digestive system are involved in chemical and mechanical digestion. Many enzymes are required to carry out digestion of the different food substrates. The enzymes and other secretions produced in the various parts of the gut and their roles. These should include: • The roles of saliva and mucus. • The chemical digestion of starch and glycogen by salivary amylase and pancreatic amylase to maltose, which is hydrolysed further by maltase to alpha-glucose. • Chemical digestion of lactose (by lactase) and sucrose (by sucrase). • Sites of production of the carbohydrases; gut regions where they function, and usual pH levels. • Proteases called endopeptidases and exopeptidases hydrolyse peptide bonds to form peptides. • Pepsin is an endopeptidase secreted by gastric glands as inactive pepsinogen. Trypsin is an endopeptidase secreted by the pancreas as inactive trypsinogen. • These proteases are secreted as inactive enzymes and are subsequently activated (including the role of enterokinase and hydrochloric acid). • The sites of production of these peptidases; gut regions where they function, and usual pH levels. • The role of bile salts in emulsifying lipid globules. • Action of pancreatic lipase in the small intestine: hydrolysis of triglycerides to monoglycerides and fatty acids.

			Learners should know the role of the pancreas and liver in glucose regulation (see endocrine system) Learners need to understand the site and mechanism of final digestion and absorption of dipeptides, disaccharides, fatty acids and glycerol. No detail of the fates of absorbed nutrients is required.
		Cardiovascular system • purpose of system • control of heartbeat	Learners should understand the purpose of the cardiovascular system. Learners should be able to describe and explain the pressure changes in the heart and blood vessels during the circulation of the blood. They should understand how the structure of the blood vessels results in the delivery of blood to the tissues and its return to the heart, including the role of valves in maintaining unidirectional flow of blood in the heart and veins. Learners should understand the myogenic nature of cardiac muscle and the transfer of electrical impulses through the heart during a heartbeat. They should be able to describe how heartbeat is controlled and coordinated (link to unit 2 here) Learners should be able to describe and explain the pressure changes in the heart and blood vessels during the circulation of the blood. Learners should be able state how CO_2 and O_2 are transported in the blood (no details of oxygen-dissociation curves or chloride shift are required) .
		Lymphatic system • formation of tissue fluid • formation of lymph	Lymph is transported within a network of vessels. The spleen contains an emergency supply of blood and also white blood cells. Learners should be able to explain that at the arterial end of the capillary bed, hydrostatic pressure is higher than osmotic pressure and so water and small soluble molecules are forced through the capillary walls, forming tissue fluid between the cells. Proteins and cells in the plasma are too large to be forced out. Blood pressure falls along the capillary because of friction/ resistance of the walls and reduced volume of blood. At the venous end of the capillary bed, osmotic pressure of the blood is higher than the hydrostatic pressure and so most of the water from tissue fluid moves back into blood capillaries. The remainder of the tissue fluid is returned to the blood, via lymph vessels.

		Respiratory System • Purpose of system • control of breathing • role of pulmonary surfactant	Learners should understand the purpose of the respiratory system in humans. They should be able to describe the processes of inspiration and expiration, including the role of the intercostal muscles. Learners should understand how breathing rate is increased or decreased. Learners should know the role of pulmonary surfactant in lowering surface tension and preventing alveolar collapse at end-expiration.
		Integumentary system • purpose of system • thermoregulation	Learners should know the purpose of the skin to include thermoregulation, protection against foreign bodies, mechanical damage and solar radiation, energy storage and production of vitamin D. Roles of sweating, hairs, adipose layer, blood supply in thermoregulation. Role of the hypothalamus in monitoring of blood temperature.
		Immune System • purpose of system	Learners should know the purpose of the immune system. Natural barriers reduce the risk of infection: • the skin • blood clotting to seal wounds • inflammation to localise breaks in the barrier • phagocytosis to destroy invading microbes • ciliated mucous membranes that trap microbes in inhaled air • lysozyme in tears, saliva and stomach acid that kills bacteria. A specific immune response develops as a result of antigens being recognised as foreign to the body: Humoral response involves: • B lymphocytes have receptors for the detection of its specific antigen; • activation stimulates production of plasma cells, and memory cells; • memory cells remain in the circulation ready to divide if the same antigen is encountered again; • antibodies are proteins which are specific to the antigen with which they bind to form an antigen-antibody complex; • an antigen-antibody complex renders the antigen inactive which increases the rate of engulfment by phagocytes.

			Cell-mediated immune response involves: • detection of the corresponding specific antigen causes the production of T lymphocytes; • there are many subpopulations of T cells including: effector cells (T killer or cytotoxic T lymphocytes) which cause lysis of the target cells; helper T cells which cooperate with B lymphocytes to initiate an antibody response; memory cells which remain dormant until the host is next exposed to the antigens; • cell-mediated defences include the activation of phagocytes, antigen-specific killer / cytotoxic T lymphocytes; • activation of B cells involves the release of various chemicals called cytokines in response to an antigen. Learners should understand the differences between the primary and secondary immune responses.

3	**Understand how external factors impact on the body**		
	3.1	**Explain how lifestyle may affect major body systems**	
		Physiological effects • coronary heart disease • diabetes • nutrient deficiencies • obesity • alcohol/drug dependency • lung disease **Psychological effects** • stress • depression	Learners should understand the risk factors for the listed effects. Learners should understand the consequences of listed effects to include: Coronary heart disease – cardiac arrest, angina Nutrient deficiencies – scurvy, rickets and anaemia Obesity – link with arthritis, diabetes, CHD Alcohol/drug dependency and withdrawal Lung disease – restricted to asthma, emphysema, lung cancer, bronchitis Please note that this list is not exhaustive and different scenarios may be supplied in the pre-release article or exam questions.
	3.2	**Assess how lifestyle may impact health**	
		lifestyle examples • diet, alcohol, recreational drugs • smoking • exercise/physical activity • housing • type of employment	Learners should be able to assess how lifestyle affects health.
	3.3	**Explain how pathogens can affect body systems**	
		Pathogens • viruses • bacteria • protozoan • fungal • worms	Learners should describe the modes of infection and effect on body systems. Examples include: Viruses (e.g. HIV, HPV) Bacteria (e.g. Chlamydia, TB) Protozoan (toxoplasmosis) Fungal (Athlete's foot) Worms (tapeworm)

		• prions	Prions (CJD) Please note that this list is not exhaustive and different examples may be supplied in the pre-release article or exam questions.
	3.4	**Explain how non-infectious diseases affect body systems**	
		Non-infectious conditions • allergies • autoimmune diseases • cancer • Inherited diseases e.g. dominant, recessive and sex-linked	Learners should have an overview of the types of non-infectious conditions and are not expected to recall specific examples. Specific examples may described in pre-release articles or given as a context in exam questions.

4	**Be able to report on human health**		
	4.1	**Analyse data**	
		Qualitative • e.g. interviews, observation, diaries (link to unit 3) **Quantitative** • physiological methods (link to unit 2)	Learners should use knowledge and understanding gained in units 1, 2 and 3 to analyse qualitative and quantitative data.
	4.2	**Process data**	
		Graphical methods • scatter diagrams, line graphs, trend lines • bar charts	Learners should be able to select the most appropriate graphical method.
		Calculations • expressions in decimal and standard form • interchange ratios, fractions and percentages • find arithmetic means • make order of magnitude calculations • substitute numerical values into algebraic equations and solve them using appropriate units for physical quantities • translate information between graphical and numeric form	Learners should perform calculations in a medical context.

		• determine the slope of a linear graph	
		Significant figures • expresses information to appropriate number of significant figures	Learners should use anappropriate number of significant figures when performing calculations in a medical context.
	4.3	**Make evidence based conclusions**	
		Conclusions • comparison of data • linking of ideas • uncertainty in conclusions	
	4.4	**Report on health**	
		Language • spelling, grammar, structure	Learners should use appropriate spelling, grammar and structure when communicating in a medical context.
		Style • formal, informal • appropriateness for audience	Learners should use appropriate language style when communicating in a medical context.
		Audience • individual • technical, non-technical	Learners should be able to communicate in a technical and non-technical context.

Unit 2 – Physiological Measurement techniques

LO	AC	Specification statement	Comment
1	Understand the function of physiological measurement tests		
	1.1	Explain principles of physiological measurement tests	
		• cardiac physiology (e.g. electrocardiograms (ECG): ambulatory and stress, echocardiography, exercise tolerance testing, blood pressure) • respiratory physiology (e.g. respiratory rate, peak expiratory flow, spirometry, oximetry) • neurophysiology (e.g. nerve conduction studies, electromyography, electroencephalography, evoked potentials) • audiology (otoscopic examination, pure tone audiometry, tympanometry tuning fork tests) • GI physiology (endoscopy, measurement of muscle and sphincter function)	Learners should be aware of the range of physiological measurement techniques that are used. They should appreciate that some measurement techniques are simple such as the measurement of body temperature with a thermometer, whilst others require the use of specialist equipment, for example measuring how well the heart is functioning through the recording of an electrocardiograph. Learners should be able to explain the **principles** of the physiological measurement techniques, i.e. what the test is attempting to measure and how it does this. So in an ECG the aim is to measure heart function; this is achieved through the placing of electrodes on the skin, these electrodes detect tiny electrical changes on the skin that arise from electrical activity of the heart during each heart beat. Many physiological tests use a similar approach to the ECG, there is a sensor (transducer) that converts a non-electrical signal from inside the body into an electrical signal that can be recorded and analysed. **Cardiac physiology:** Learners should be able to explain the principles of blood pressure testing and ECGs. With blood pressure the learner needs to understand that the principle of the test is restricting blood flow, and then releasing this to give a measure of pressure: so with a blood pressure monitor the cuff inflates to cut off blood flow, then slowly releases, so that the sensor can accurately record when pressure returns. With ECG the principle is on the recording of electrical signals. Learners should understand the significance of the trace that is produced in terms of what each feature represents in terms of electrical activity of the heart

		• ophthalmic physiology (ophthalmic imaging, intra-ocular pressure measurements) • urodynamics (free flow rate, cystometry) • Vascular function (carotid, peripheral arterial, peripheral venous) **Principles:** • how does the test work	**Respiratory physiology**: Learners should be able to explain that peak expiratory flow testing is a measure of the rate that air can be exhaled by a person. This is recorded in litres per minute. Learners should understand that measuring this rate provides an indication of narrowing of the airways. Peak flow measurements work best as a comparison measure, i.e. before and after a treatment, to see if a patient's condition is worsening, or to see if a particular trigger is causing symptoms. Measurements can also be compared to expected values. Spirometery can provide a more detailed and accurate measure of lung function than peak flow measurements. A spirometer measures the amount of air that can be exhaled in one second and the total volume of air that can be exhaled in one forced breath. Spirometery shows if problems are obstructive or restrictive or a combination of both. **Neurophysiology:** Learners should be aware that an Electroencephalogram (EEG) is a recording of brain activity. The principle of the test is the same as with an ECG: sensors attached to the scalp pick up electrical signals which are then recorded and analysed. The EEG recording shows different types of brain waves. Different types of brain waves are evident on an EEG, learners would not be expected to explain these. The main use of EEG is to detect and investigate epilepsy. **Audiology:** Learners should understand that an otoscopy is an ear examination that involves looking into the ear with an instrument called an otoscope. This allows examination of the external auditory canal, from the outer ear to the ear drum. The otoscope is in effect a magnifying lens with a light source. With this technique the results are qualitative, and involve looking for any signs of abnormality, such as, inflammation, discharge, and presence of wax or other foreign body. Often an otoscope allows a doctor to release a small puff of air into the auditory canal, which allows observation of how much the ear drum moves with pressure. Tympanometry is often used alongside otoscopic examination, to help diagnose disorders that can lead to hearing loss. The test measures the movement of the tympanic membrane in response to changes in pressure. The tympanic membrane is a thin tissue that separates the middle and outer ear segments. The results of tympanometry are recorded on a graph called a tympanogram.

			GI physiology: the principle of endoscopy is that it is a technique which allows a clinician to look inside the body. Learners should understand that unlike other physiological measurement techniques endoscopes are inserted directly into the body to investigate a particular organ or cavity. An endoscope is a long, thin, flexible tube that has a light source and a video camera at one end. Images from the examination are usually relayed to a television screen. Endoscopes can be inserted into the body through a natural opening, such as the mouth and down the throat, or through the anus. Alternatively, an endoscope can be inserted through a small surgical cut made in the skin (known as keyhole surgery). Learners should be aware of the most common types of endoscopes and what they are used to examine: colonoscopes—used to examine colon, gastroscopes, used to examine oesophagus and stomach, endoscopic retrograde cholangiopancreatography (ERCP), used to check for gallstones. **Ophthalmic tests:** many learners will be aware of ophthalmic tests that test for difficulties in vision, through the use of different lenses and a reading chart. Learners maybe less familiar with ophthalmic imaging, where recent advances in digital techniques have provided opportunities to improve physiological measurements in this area. Angiographic tests are used to measure the blood flow through the eye. A dye is injected into the arm and its progress through the vessels of the eye is recorded using a retinal camera. Other physiological measurement tests for ophthalmic physiology include: tonometery (eye pressure test) and visual field test. **Urodynamics**. Learners should understand that urodynamic testing is any measurement technique which investigates how well the bladder, sphincters and urethra are storing and releasing urine. Most urodynamic tests focus on the bladder's ability to hold urine and empty steadily and completely. Urodynamic tests can also show whether the bladder is having involuntary contractions that cause urine leakage. Learners should understand, that as with many systems of the body, Urodynamic tests range from simple observations to precise measurements using sophisticated instruments. Simple observations record the length of time it takes a person to produce a urinary stream, noting the volume of urine produced, and recording the ability or inability to stop the urine flow in midstream.

			For precise measurements, imaging equipment takes pictures of the bladder filling and emptying, pressure monitors record the pressures inside the bladder, and sensors record muscle and nerve activity. **Vascular function:** Diseases of blood vessels in places other than the heart or brain are called peripheral vascular disease. Most often, the cause is narrowing of the vessels due to a build-up of fatty plaque (atherosclerosis). Physiological measurements to test vascular function include precise blood pressure measurements on feet and arms. Other diagnosis is through imaging techniques. Learners do not need to understand the detailed procedures for all physiological measurement tests, only those for the tests that they will be undertaking (LO3). As indicated previously learners should be able to explain the **principles** of the physiological measurement techniques, i.e. what the test is attempting to measure and how it does this.
	1.2	**Explain significance of data obtained from physiological measurements**	
		Significance • normal range • outside normal range • indicators of disease/ disorders	Learners should be able to explain the significance of results obtained in relation to normal ranges, and possible indicators of disease or disorder. So low peak flow results maybe an indication of asthma, high blood pressure (hypertension) does not produce symptoms as such, but can increase a person's chances of having a stroke or heart attack. With an ECG learners should be able to consider the significance in terms of both rate and rhythm compared to expected norms. Learners should have an understanding of what each feature of the trace represents, i.e. the P wave represents depolarization of the atria, and the PR interval represents the time taken for the electrical impulse to travel from sinus node to AV node etc... Learners are not expected to be able to make accurate medical diagnoses or to know every possible disease/disorder that particular results could be indicative of.
		Examples • cardiovascular disease such as coronary heart disease, congenital heart disease, arrhythmias	Learners should be able to explain the significance of results with reference to overarching examples as noted in the content.

		• hearing impairment/loss • eye disease, vision disorders • conditions affecting the central and peripheral nervous system • conditions affecting upper and lower GI tract • conditions affecting bladder and lower urinary tract function • conditions affecting arteries and veins e.g. DVT	So after testing peak flow, learners might suggest that the low peak flow reading was a possible indication of asthma. When looking at an ECG trace learners might suggest that a heart rate below or above expected is caused by a disruption to the normal electrical impulses. Learners could suggest that this disruption could be as a result of damage to the heart tissue, or a congenital disorder or due to a lifestyle factor such as stress, smoking, alcohol etc.
	1.3	**Describe limitations of physiological measurement testing**	
		Limitations • precision & accuracy • artefacts • sensitivity • • measurement errors	Learners should consider the limitations of different measurement techniques. For example, with peak flow measurements, learners should explain that measurement errors can occur through patient error in using the equipment: not blowing as hard as they can or not putting their lips right round the mouthpiece. In the measurement of blood pressure with a cuff, it is possible to obtain inaccurate results if an incorrectly sized cuff is used. The position of the patient, or more accurately the patient's arm on which the cuff is placed also affects the reading. Patients who drink coffee, smoke tobacco or have exercised 30 minutes before the reading is taken may also provide false readings. Artefacts: This is when an error in the representation of results occurs as a result of the technique being used. For example in the recording of an ECG, it is possible to see "motion artefacts" if patients are shivering or have a disorder that causes tremor (such as Parkinson's or MS).

2	**Understand how to deal with patients**		
	2.1	**Explain importance of patient confidentiality**	
		Confidentiality • Codes of practice (e.g. NHS code of practice) • Protect information, inform, provide • Disclosure of information	Learners should understand that patient information is generally held under legal and ethical obligations of confidentiality. This means that information about a patient, including results should not be used or disclosed in a form that might identify a patient without his or her consent, apart from in respect of providing healthcare. So whilst patient information often needs to be shared between members of a care team and between different organisations involved in health care provision, it should not be disclosed for any other purpose than the provision of healthcare.
	2.2	**Describe conduct towards patients**	
		Conduct • Empathy • Tone • Use of language	Learners need to be aware that patients attending for physiological measurement tests maybe apprehensive and/or unwell. Learners need therefore, to be able to describe and apply appropriate interpersonal skills and communication style relevant to a given patient. Learners should describe why it is important to take account of patient's age, any sensory or motor impairment, mental health needs, effect of medication, or emotional state.
3	**Be able to carry out physiological measurement tests**		
	3.1	**Plan to perform physiological measurement tests**	
		Key aspects of plan • identify information to collect • procedures and equipment • location • timing • informing individuals Procedures and equipment • identifies procedures • informs technician of required equipment and times	Learners should plan a physiological measurement procedure.

		Informing patients • patients • other personnel affected (e.g facilities)	
	3.2	**Use physiological testing equipment**	
		Equipment **e.g.** • peak flow meter • equipment for hearing tests (e.g. otoscope, pure tone audiometer, tympanometer) • equipment for ophthalmic tests (e.g. visual acuity, field of vision and colour vision) • cardiovascular equipment (e.g. electrocardiogram-ECG, echocardiography (Echo) blood pressure monitor, pulse oximeter)	Learners should correctly and safely use a range of equipment available in the school/college laboratory. It may also be possible for learners to use equipment at an employer's premises, if organised by the school/college. Learners should use at least two pieces of equipment for the testing of two different physiological systems, for example blood pressure testing using a manual or automated monitor **and** peak flow meter.
	3.3	**Record results from physiological measurement tests**	
		Recording documentation • laboratory notebook • proforma • LMS/database	Learners should be able to record their experimental methods and results in different formats, e.g. using standard proformas or in a laboratory notebook. Learners should be aware that in a workplace setting results are often recorded onto a laboratory management system.
		Records made • information recorded • precision of recorded data • legible entries	Learners should record physiological measurement data.

4	**Be able to report on physiological measurement testing**		
	4.1	**Process data from physiological measurement tests**	
		Physiological measurement tests • primary data • secondary data **Process data** • graphical methods • calculations	In processing data learners should be aware of the difference between primary and secondary data. Learners could calculate means for readings they have taken for blood pressure, or peak flow. In processing data such as ECG traces learners should show how heart rate has been calculated and label traces to demonstrate they have an understanding of the significance of the various features of such a trace.
	4.2	**Make evidence based conclusions about the "health" of individuals**	
		Comparisons • comparison of data to expected norms, considering age, gender, ethnicity • comparison of data to previous test results: patient history **Physiological basis of findings** • link findings to expected physiology and possible pathology • any uncertainty in conclusions	Learners are not expected to recall expected normal ranges, they will be supplied with any relevant normal ranges during assessment, and they should understand that values that lie outside the normal range can be indicators of ill-health. In making evidence based conclusions, learners should understand that for many physiological measurement tests, it is comparison's to a patient's previous test results that will be important. For example using peak flow results for a patient with asthma will produce a low reading, but it is changes in these readings over time, or particular low readings as a result of exposure to a particular trigger substance that will be most useful. Learners could comment on results in relation to previous data, or if they do not have access to this they may comment on uncertainty in their conclusions.
	4.3	**Evaluate information from physiological measurement tests**	
		Evaluation • validity of data • presence of artefacts • variables affecting data	Rather than make general statements about limitations of data (1.3), learners should evaluate the data they actually have from the testing of patients. They should consider how valid data is considering any factors affecting the testing they undertook.

	4.4	Communicate in writing	
		Written communication • technical and scientific language • spelling, punctuation and grammar • clarity • relevance of included material • structure of communication **Audiences** • colleagues, patients **Style of language/format used** • scientific and technical • semi technical, non-technical • • illustrations	When using written communication to report on physiological measurement testing, learners should make use of appropriate scientific and technical language when considering the audience for the communication. So in writing a report to the head of department at the hospital, learners should be using terms such as hypertension, bradycardia, tachycardia etc. When communicating to patients the style of language would be significantly different to that used with colleagues.

Unit 3 – Medical Science Research Methods

LO	AC	Specification statement	Comment
1	Understand research methods		
	1.1	Describe variables affecting research	
		Variables • variables (independent variables, dependent variables) • extraneous variables	Learners should be able to define the different categories of variables listed and apply these terms. Learners must build upon the definitions and use these terms when identifying and describing the different variables that occur in actual research.
	1.2	Justify the research hypothesis	
		Hypothesis • null hypotheses • alternative hypotheses • one-tailed (directional) hypotheses • two-tailed (non-directional) hypotheses.	The key to this assessment criterion is that the learners write a meaningful hypothesis for research. Learners need to be able to define and distinguish between each of the terms listed. Learners are required to demonstrate their understanding of these terms by proposing a suitable hypothesis for an experiment/research. In order to do this they must be able to identify and write both a null hypothesis and alternative hypothesis. Learners also need to be able to identify/distinguish one-tailed and two-tailed hypothesis. Useful link: McLeod, S. A. (2014). Aims and Hypotheses, http://www.simplypsychology.org/aims-hypotheses.html
		Justification • relevance to research question	Learners should justify their research hypothesis by showing linking to the research question. This also requires a clear explanation of the choice of operational variables. Useful link: McLeod, S. A. (2008). Independent, Dependent and Extraneous Variables. Retrieved from www.simplypsychology.org/variables.html

	1.3	**Justify selection of sampling methods**	
		Sampling • target population and sample • random sampling • snowball sampling • opportunity sampling • self-selected sampling	Learners should be able to use the terms listed to describe different sampling techniques available together with potential advantages and disadvantages of each. The emphasis of the assessment criterion is upon selecting an appropriate sampling method for a particular research project under the limitations they may be constrained (e.g. cost). Learners should not only be able to explain the method they used but also explain their rejection of alternative approaches of sampling a population. Useful link: http://holah.co.uk/page/sampling/
	1.4	**Explain selection of research methods**	
		Research methods • quantitative methods (e.g. laboratory experimentation, epidemiological, closed questionnaires) • qualitative methods (e.g. participant observation, non-participant observation, structured interview, unstructured interview)	The key to this assessment criterion is that learners apply their understanding of the two approaches to research by selecting a suitable approach to collecting useful and relevant information towards a research question. Learners must be able to justify their selection. In order to achieve this, learners must be able to describe and distinguish between both quantitative and qualitative methods. They should know the difference in approach of the two types of methods, the type of information that they each generate and the limitations of each. In addition, learners should be familiar with the different methods used to collect qualitative and quantitative information. The examples listed are considered key research methods that learners should be familiar with, however they may make use of methods that are not listed for their research as part of the unit assessment, if they wish. The written examination for unit 6 will not require a knowledge of methods that are not listed.
		Justification • relevance to research question and hypothesis • type of information required	Learners should be able to explain the most suitable type of approach to answer a research question. The explanation must be in terms of the research question and hypothesis together with the type of information they are required/intend to generate.

	1.5	**Evaluate how ethical issues affect research**	
		Ethical review • ethical review of research and methods	Learners should be aware of the ethical implications of proposed research. They should be aware that the participants in a study need to be protected with regard to their dignity, rights, safety and well-being.
		Evaluation in terms of: • social / scientific value • care and protection of research participants • confidentiality • informed consent • working with vulnerable individuals (including children)	Learners should be aware that areas which must be addressed before research is initiated include: informed consent; confidentiality; protection of participants including data protection; right to withdraw; potential benefits (social/scientific value) and potential harm. There is a standard proforma that learners can use to complete an ethical evaluation Learners should make use of this profoirma as part of their learning.
		Health review committees	Learners should be aware that research proposals are examined in the UK by Health Boards research ethics committee (a group of people appointed to review research proposals to assess formally if the research is ethical).
2	**Be able to collect data**		
	2.1	**Plan to collect data**	
		Procedures • quantitative • qualitative	The emphasis of the assessment criterion lies on the ability to plan to collect data. The assessment criterion requires that learners are able to plan to collect **both** qualitative and quantitative data.

		Plan • sequencing • timing	Learners need to be taught how to present a plan in a series of sequential steps with meaningful timescales set for each step. Distinguishing the level of performance of a learner will depend upon the detail, clarity and realism of proposed timing.
	2.2	**Produce documentation to collect data**	
		Documentation • documents e.g. questionnaires, interviewer documentation • clarity • suitability and relevance for purpose • completeness	
	2.3	**Obtain data**	
		Data • suitable • sufficient	

3	**Understand data analysis**		
	3.1	**Explain significance of terms used in data analysis**	
		Terms • type I errors, type II errors • demand characteristics • reliability (internal reliability, external reliability) • validity (internal validity, external validity) • bias (including researcher/observer bias) • confidence limits • significance levels • correlation (positive correlation, negative correlation, no correlation) • dispersion	This assessment criterion essentially requires that learners show their understanding by applying their learning to concrete cases when they analyse data. In order to do this, learners need to be familiar with the meaning and implications of each the terms listed in the bullet points of the assessment criterion.
	3.2	**Explain selection of statistical methods used to analyse data**	
		descriptive statistics • measures of central tendency (mode, median, mean) • measures of dispersion (variance, range, standard deviation)	The focus of assessment criterion 3.2 is on learners explaining why they have selected and used particular statistical methods, rather than using statistical methods (using statistical methods is assessed in AC4.2). Measures of central tendency to include mean, mode and median. Learners should be able to distinguish between the mode, median and mean. They should be able to recognise the best measure of central tendency in particular cases, e.g. where there is a symmetric / skewed distribution, normal continuous data, ordinal data etc. Learners also need to be aware that range is a single number representing the spread of data (difference between highest and lowest score), standard deviation and variance are a measure of the dispersion/spread from a mean. Standard deviation is the square root of the variance and is the more informative than variance since it is in the same units as the raw scores themselves.

		Inferential statistics • normal distribution curves, skewed distribution curves • probability • significance levels • parametric test • specific non-parametric inferential test (e.g. t-test, Chi-square, Mann-Whitney U test and Spearman's Rho)	Learners should be able to recognise that inferential statistics allow them to generalise their findings from the sample data to the larger population and help assess the strength of the relationship between the independent variables, and the dependent variables. The emphasis is on explaining which statistical method is best to analyse the data. Learners should recognise the characteristics of a normal distribution (symmetry at the mean value; the curve end points or "tails" meet the x-axis; the shape of the curve should be bell-shaped) and recognise skewed distributions. They should also recognise both positive and negative skewed distributions. They need to link the best methods of measuring central tendency to the type of distribution. Learners should be able to recognise that different statistical tests apply, and the one used depends upon what we are trying to show, the type of data, etc. Learners should be aware of the distinction between parametric and non-parametric tests (see AC4.1). Parametric tests can be used when data is normally distributed whereas non-parametric data applies to ordinal data (i.e. data that can be ranked) or nominal data (i.e. data that can be put into categories).
		Explanation • data type and methodology • sampling method and size	The explanation for their use of statistical methods must be in terms of data type (normally distributed, skewed distribution, ordinal, nominal data etc), methodology; sampling method and size.

4	**Be able to process data**		
	4.1	**Analyse data using statistical methods**	
		Statistical methods • mean, mode, median • measures of dispersion (variance, range, standard deviation) • normal distribution curves, skewed distribution curves • probability • significance levels • confidence limits • parametric test • specific non-parametric inferential test • correlation	The focus in this assessment criterion is about correctly using appropriate statistical methods to obtain meaningful information whereas assessment criterion 3.2 focusses on explaining why they use a particular method. Learners must have access to 'WJEC Statistical concepts' when they analyse data. They should also be permitted use of this information as part of their learning. Learners should have had a number of opportunities as part of their learning to analyse information that they have collected or has been given them. Data should always be set in a medical field.
		Application • appropriateness • accuracy	The performance bands also make it clear that a good response gives a detailed analysis of data. The 'detailedness' of an analysis will always depend upon each individual set of data learners are analysing and the question it should be answering.
	4.2	**Make conclusions from data**	
		conclusions based upon data / data analysis	It is important that learners are able to make meaningful conclusions backed by their data/data analysis. As part of their learning, learners should be continually made to think about the significance of their data analysis and the conclusions that it supports. Learners should also not be made to feel that a good response is only one that affirms an experimental hypothesis.

	4.3	**Evaluate procedures**	
		Evaluation In terms of • sufficiency, suitability, quality data produced (e.g. validity etc) • limitations of data • cost, time, effectiveness procedures	Learners should also be made to consider the limitations of research. Evaluations should be in terms of procedures (e.g. cost, time, effectiveness and suitability of procedures) and the limitations of data (sufficiency, suitability, quality data produced (e.g. validity etc).
	4.4	**Use mathematical notation**	
		Mathematical notation • ratios, percentages, fractions • symbols: =, <, <<, >>, >, ∝, ~ • significant figures	Learners need to make appropriate use of mathematical notation. They also need to use an appropriate number of significant figures in their work.

5	**Be able to communicate information**		
	5.1	**Present data visually**	

		Visual methods
		• tables
		• graphs
		  ○ line graph
		  ○ pie charts
		  ○ bar charts
		  ○ histograms
		  ○ scatter diagrams
			Learners need to be taught how to construct effective tables with suitable headings and units as appropriate.
			Learners also should select and use an appropriate method of presenting graphical information. Learners should use the most appropriate form of presentation. They should be able to: label the axis correctly; use an appropriate scale/range; use appropriate grid lines (electronic form); add a trend line, where relevant.
			It is acceptable to use electronic methods to construct line graphs/charts/scatter diagrams etc. (e.g. using spreadsheets such as Excel).

	5.2	**Communicate outcome of research**	
		Customer • individual (scientifically literate, basic scientific understanding) • groups (scientifically literate, basic scientific understanding)	Learners need to be able to communicate the outcome of research to individuals and groups. These maybe either scientifically literate or only have a basic GCSE understanding. A basic GCSE understanding can be taken to mean a C grade pass at GCSE. Scientifically literate means that the audience will be at GCE A level or higher.
		Information • clarity • language style • spelling, punctuation and grammar • language including technical and scientific • evidence based • relevance information to customer	Learners should be able to communicate the outcome of work through a report or a presentation. Learners should be taught how to prepare a PowerPoint presentation. This includes, what makes a good slide and how to prepare speakers notes. Where necessary, learners should also be taught to put detailed supporting information onto a handout rather than use a large amount of text on a slide.

Ethical Evaluation

Name:……..….. Date: ……

1. Social or scientific value; scientific design and conduct of the study Is the research question important and necessary? Is the research design and proposed statistical analysis able to answer the question?
Evaluation:

2. Recruitment arrangements and access to health information, and fair research participant selection Selection of research participants so that vulnerable individuals are not targeted for risky research and the rich and socially powerful not favoured for potentially beneficial research. The benefits and risks of research should be distributed fairly among all social groups and classes. How are research participants recruited?
Evaluation:

3. Favourable risk benefit ratio; anticipated benefits/risks for research participants (present and future) Minimisation of risks. Is there evidence of the consideration of any benefits/risk for individual research Are benefits/risk clearly identified for the research participant? Have steps been taken to minimise or eliminate the discomfort, and distress and enhancement of potential benefits?
Evaluation:

4 Care and protection of research participants * protecting privacy through confidentiality * informing participants of results of research *what will happen at the end of the study? Where and how (anonymised/coded) and for how long will data be stored? What purpose will be served by the data? Who will access?
Evaluation:

Unit 4 – Medicines and treatment of disease

LO	AC	Specification statement	Comment
1	Understand management of medicines		
	1.1	Explain factors to be considering when prescribing medicines	
		Factors • establishing an accurate diagnosis • patient history (other medicines that are already been taken) • overall benefit • side effects/risks • individual patient factors altering benefits/risks (e.g. age, impaired kidney function, pregnancy) • cost-effectiveness • patient choice	Learners should be made aware that health care professionals must consider a number of factors in prescribing medicine to patients. The most important consideration for a healthcare professional is that medicines should be prescribed only when they are necessary, and in all cases the benefit of administering the medicine should be considered in relation to the risk involved.
	1.2	Suggest strategies to improve adherence of patients taking prescriptions	
		Reasons for non-adherence • unintentional • intentional **Unintentiona**l • barriers outside patient control e.g. difficulty understanding instructions	Learners should understand that it is important for healthcare professionals to discuss treatment options carefully with a patient to ensure that the patient is content to take the medicine as prescribed. In particular; the patient should be helped to distinguish the adverse effects of the prescribed medicine from the effects of the medical disorder. When the beneficial effects of the medicine are likely to be delayed, the patient should be advised of this.

		Intentional • patient perception e.g. beliefs about drug effectiveness, side effects, media claims • patient motivation **Improving adherence** • e.g. patient education, consultation, involving patients in decision making, support	
	1.3	**Compare options for administering medicines**	
		Administration routes • oral, sublingual, rectal, topical e.g. eye drops, inhalation bronchodilators, parenteral e.g. intravenous, intramuscular, subcutaneous injection **Administration** • self-administration, health care specialist **Comparison** • patient preference, comfort • ease of administration • speed of action, duration of action • predictability of absorption, reproducible effects, side effects • need to bypass hepatic metabolism • target of action (e.g. local eye drops in treatment of glaucoma, paracetamol in pain relief) • cost	Learners should know what different routes of administration are available for medicines. They should understand the pros and cons of each type of route so that they can then compare the options. Whilst most medicines are given orally because of the convenience, there are specific reasons why other routes are also used, for example intravenous injection is used where a rapid effect is required, for continuous administration (infusion), for large volumes and for drugs that cause local tissue damage if given by other routes. Intravenous injection as well as intramuscular injection and subcutaneous injection can however cause pain or discomfort to the patient, and they usually require trained staff using aseptic technique to administer them. Specific drugs, for example insulin, are destroyed by digestive enzymes and affected by the acid present in the stomach, as a result these drugs cannot be given orally. Topical administration generally refers to a medicine being applied directly where its action is desired, for example eye drops (antibiotics) in the treatment of conjunctivitis. This type of administration reduces the effect of side effects, but irritation can occur at the site of administration and the dosage can be difficult to control. Generally oral administration carries the lowest cost.

2	Understand how medicines work		
	2.1	Explain the molecular basis of the action of medicines	
		Drug-receptor interactions • agonists: full and partial • antagonists: competitive or irreversible • specificity: ability to combine with one particular receptor **Possible ways in which medicines work** • action on transmitter substances • action on hormones • action on membrane transport systems • action on enzymes	Medical pharmacology is the science of chemicals (medicines) that interact with the human body. These interactions are complex and learners are not expected to explain these interactions in great detail, but should be able to explain the molecular basis of the main types of action. Medicines that activate receptors and produce a response are agonists. Some medicines combine with a receptor but do not activate them, these are known as antagonists. In combining with the receptor these medicines reduce the chances of other substances combining with the receptor. Partial agonists bind to receptors and produce a response, but even at maximum receptor "occupancy" they only produce a limited response. As with other receptor and substance interactions, the reaction between a medicine and a receptor depends on the complementary fit of the two molecules at a binding site. The closer the fit and the greater the number of bonds, the stronger will be the forces between them and the higher affinity the medicine will have for the receptor. The ability of a medicine to combine with one particular type of receptor is called specificity. Many medicines act by either reducing or enhancing synaptic transmission. Medicines can affect the endocrine system by inhibiting or increasing hormone release, or through the interaction with hormone receptors. Some medicines inhibit transport mechanisms across the cell membrane through action at ion channels or through inhibiting active transport. Learners are not required to recall the molecular basis of action of specific medicines

	2.2	Explain how medicines affect body systems	
		Body systems • cardiovascular & respiratory; gastro-intestinal tract; endocrine system; kidneys and central nervous system **Cardiovascular & respiratory** • treatment of hypertension, angina, arrhythmias, asthma • e.g. beta-blockers, vasodilator drugs, centrally acting drugs, drugs acting at cholinergic synapses, drugs acting on sympathetic nervous system, calcium antagonists, opening/blocking ion channels **Gastro-intestinal tract** • treatment of indigestion, ulcers, constipation, diarrhoea, antacids and acid secretion reducers, medicines affecting motility and secretions • e.g. antacids: sodium bicarbonate, acid secretion reducers (cimetidine), mucosal strengthens (sucralfate), anti-diarrhoeal drugs **Endocrine system** • treatment of overactive/ underactive thyroid, diabetes • e.g. competitive inhibitors, replacement therapy, antidiabetic agents	Learners need to understand how medicines affect the particular body systems given in the content: cardiovascular & respiratory; gastro-intestinal tract; endocrine system; kidneys and central nervous system. Learners will need to be able to recall certain groups of medicines relevant to particular systems or organs, such as beta-blockers affecting the cardiovascular system or diuretics acting on the kidney. The level to which learners should be able to explain how medicines affect body systems is given in the examples below. Within each system learners should be able to explain how medicines affect that body system with reference to a particular disorder. In the cardiovascular system for example learners should be able to explain that drugs used in the treatment of hypertension, can act on arterioles causing dilation, can act on the heart to decrease heart rate and cardiac output, or could act on the kidney decreasing peripheral resistance. So beta blocker (also called beta adrenergic blocking agents) block the release of adrenaline and noradrenalin, this results in a slowing of heart rate and reduces the force at which blood is pumped around the body. In the gastrointestinal system, antacids are a well known and well used group of medicines; their mechanism of action is raising the pH of the stomach by neutralising gastric acid. Other drugs used to treat gastrointestinal system disorders (such as ulcers) include those that reduce acid secretion, by blocking the action of histamine on parietal cells (cells that secrete acid), these medicines are known as histamine antagonists and include the medicine Cimetidine. Antithyriod medicines, used to treat overactive thyroid disorders, include a group called Thionamids. These medicines prevent the synthesis of thyroid hormones by competitively inhibiting an enzyme catalysed reaction involved in the production of the hormones.

		Kidneys • treatment of oedema, in a range of disorders and diseases, e.g. congestive heart failure and hypertension • action on the kidney to increase urine flow; diuretics - thiazides, loop diuretics, potassium sparing **Central nervous system** • treatment of depression, insomnia, psychotic states e.g. schizophrenia, motor disorders, Parkinson's disease and epilepsy • control of pain and general anaesthetics • mechanisms of action through modifying synaptic transmission of central transmitter substances such as GABA, acetylcholine, dopamine, and serotonin	Diuretics are a group of medicines which act on the kidney to increase urine flow, most work by reducing the reabsorption of electrolytes in the kidney tubules. The increased electrolyte excretion is then accompanied by an increase in water excretion necessary to maintain osmotic balance. Diuretics are used in the treatment of a range of disorders including hypertension. The mechanism of action of medicines acting on the central nervous system is not always fully known, however virtually all medicines acting on the CNS produce their effects by modifying synaptic transmission. For example neuroleptic medicines used in the treatment of schizophrenia are antagonists at dopamine receptors; they therefore reduce the effect of dopamine in the brain, which appears to be beneficial in the treatment of schizophrenia. Whereas one of the main treatments for Parkinson's is a medicine called levodopa which is a dopamine agonist, as individuals with Parkinson have been shown to have greatly decreased levels of dopamine.
	2.3	**Explain how medicines affect causative agents of infectious disease**	
		Causative agents • bacterial infections • viral infections	Learners are not expected to cover the immunological aspects of bacterial and viral infections in any great detail. They should already have an understanding of how pathogens can affect body systems from unit 1 A.C 3.3. It is the mechanism of action of different medicines that learners need to explain. For bacterial infections there are three main types of medicines in terms of the mechanism of action, as outlined in the content. Sulphonamides were one of the first medicines found to be effective in the treatment of bacterial infections, and although not widely used today, they represent an important group of medicines in terms of their mechanism of action.

		Mechanisms • bacterial infections (medicines that inhibit nucleic acid synthesis: e.g. sulphonamides; medicines that inhibit cell wall synthesis e.g. penicillins; medicines that inhibit protein synthesis, e.g. chloramphenicol and erythromycin) • viral infections (medicines that stop a virus entering host cells, e.g. amantadine; medicines that inhibit nucleic acid synthesis, e.g. acyclovir)	Sulphonamides competitively inhibit an enzyme which prevents the production of folate which the bacteria require for the synthesis of DNA. Anti-viral medicine development has been difficult as viruses use the host's cells to replicate, so medicines are needed which interfere with the virus without harming the host's cells. Viruses also demonstrate variation so medicine development needs to try and take account of this. There are therefore two main groups of Anti-viral medicines: ones which try to prevent the virus entering a host cell, they may do this by binding to receptors on the cell surface which stops the virus binding to these receptors and entering the cell. The other group of medicines targets processes that synthesise virus components after a virus invades a cell. This includes medicines that inhibit nucleic acid synthesis within the virus
	2.4	**Explain why medicines may lose their effectiveness**	
		Loss of effectiveness • "loss" of receptors for drug-receptor interaction • drug "side effects" • antibiotic resistance	Learners need to be aware that medicines may lose their effectiveness, the mechanisms that cause this are not always fully understood. Medicines may lose their effectiveness due to the body's ability to adapt to the presence of the medicine, i.e. the body develops tolerance. This tolerance is the loss of sensitivity of the target cell to the medicine. There are a number of possible mechanisms related to this tolerance effect, one is a decrease in binding affinity between a medicine and receptor and also a decrease in the number of receptors.
	2.5	**Compare the effects of the interaction of medicines**	
		Interaction of medicines • polypharmacy (concurrent use of multiple medications by one individual) • interactions between more than one medication or drug-food interactions	Learners are not expected to be able to provide detailed examples of medicine interactions; they should however understand the general principles of possible interactions and be able to give some generic examples to demonstrate their understanding. Polypharmacy has previously been considered something to avoid. It is now recognised as having both positive and negative potential, depending on how medicines and care are managed.

		Positive effects • improves the effects of medicines (synergistic effect) e.g. use of codeine with paracetamol, combinations of drugs in the treatment of cancer • produces a new effect **Negative effects** • antagonistic effect, side effects, overdose	The interaction of medicines with each other or with certain foods is something which healthcare professionals need to be very aware of, especially with patients with different disorders that require different medicines. A well known example of medicine interaction would be combining “sleeping tablets” (benzodiazepines) and alcohol, less well known would be sleeping tablets and grapefruit. Grapefruit increases absorption and distribution of this particular medicine, so like alcohol has an additive (synergistic) effective which can lead to overdose.
	2.6	**Explain how factors affect the distribution of medicines in the body**	
		Distribution of medicine in body • movement of medicines to and from the blood and various tissues of the body • relative proportion of medicines in the tissues **Factors affecting distribution** • water-soluble drugs • fat-soluble drugs • ability to cross membranes • binding to proteins • accumulation in particular tissue types	Whilst learners need to be able to explain factors that affect the distribution of medicines in the body, they do not need to understand any detail of pharmacokinetics. Learners should understand that distribution around the body occurs when medicines reach the circulation. In order to act it must penetrate tissues, this absorption will be proportional to the lipid solubility of the medicine. Medicines are designed to try and maximise absorption. For medicines that are taken orally, food in the stomach, motility of the GIT and the medicines stability to enzymes and acid can all have an effect on absorption and therefore distribution.

	2.7	**Explain how adverse reactions to medicines can occur**	
		Adverse reactions • extension of the medicines intended action • action of medicine on more than one receptor/transmitter • production of toxic metabolites e.g. paracetamol • immunological responses	Learners should understand that the term “side effects” is widely used although the correct medical term would be adverse reactions or adverse events. Often health care professionals need to weigh up the benefit a particular patient will derive from a medicine against the likelihood of developing an adverse reaction. Learners are not expected to be able to provide detailed examples of adverse reactions to different medicines, they should however understand the general principles of possible adverse reactions and be able to give some generic examples to demonstrate their understanding. Sometimes the adverse reaction a patient reports is actually just an exaggeration of the medicine’s effects, for example a patient taking a medicine to reduce high blood pressure may feel dizzy or light-headed if the medicine reduces their blood pressure too much. Often adverse reactions are not predictable; there maybe two patients taking exactly the same medicine, but only one will exhibit an adverse reaction. Typically adverse reactions can be things such as rashes, sickness, headaches or more seriously kidney damage, impaired vision etc. Affected patients may be allergic or hypersensitive to the drug because of genetic differences in the way their body metabolises or responds to the medicine. The adverse effects of some medicines are known as they are related to the mechanism of action of the medicine. For example patients who regularly use aspirin can experience stomach irritation or bleeding, this is because aspirin is known to reduce the production of prostaglandins which help protect the stomach from the acid it produces.
	2.8	**Explain fate of medicines in the body**	
		Fate • metabolism: by liver, types of reaction	Learners need to understand that the liver is the primary organ involved in the process of metabolism of medicines within the body. Medicines are often not active until they have been metabolised by the liver. Medicines given orally are usually absorbed in the small intestine and enter the portal system to the liver where they are metabolised, this is called first-pass metabolism.

		• elimination and excretion: renal excretion, biliary excretion • importance of half-life	The waste products of medicines (and possibly even some active medicine) are generally excreted through the kidneys into the urine and/or through the GIT into the faeces. Whilst learners do not need to be able to perform any half life calculations they should appreciate the importance of this concept in the effectiveness of medicines. The half life is the time taken for the concentration of the medicine in the blood to fall by half its original value. Measurement of half life allows for other calculations to be undertaken which provide information on the effectiveness of the medicine and the required dosage that needs to be given.

3	**Understand principles of treatment of cancer**		
	3.1	**Describe what is meant by the term cancer**	
		Cancer • abnormal cell division alteration of cell cycle uncontrolled proliferation of cells • primary, secondary • difference between cancer cells and normal cells • types of cancer: carcinoma, sarcoma, leukaemia, lymphoma and melanoma	Learners need to know that although cancer comprises well over a 100 different diseases, all cancer cells share one important characteristic: they are abnormal cells in which the processes regulating normal cell division are disrupted.
	3.2	**Explain the genetic basis of cancer**	
		Genetic basis • genes are short pieces of DNA that carry specific genetic information • gene mutations (inherited, environmental) • risk factors for mutation **Genetics and cancer** • genetic changes (proto-oncogenes, tumour-suppressor genes and DNA-repair genes)	Learners need to understand the basis of the genetic code, so that they can explain the genetic basis of cancer (this is covered in unit 1). Learners need to understand that only a small number of the approximately 35,000 genes in the human genome have been associated with cancer. Alterations in the same gene often are associated with different forms of cancer. These malfunctioning genes can be broadly classified into three groups. The first group, called proto-oncogenes, produces protein products that normally enhance cell division or inhibit normal cell death. The mutated forms of these genes are called oncogenes. The second group, called tumor suppressors, makes proteins that normally prevent cell division or cause cell death. The third group contains DNA repair genes, which help prevent mutations that lead to cancer. Proto-oncogenes and tumor suppressor genes work much like the accelerator and brakes of a car, respectively. The normal speed of a car can be maintained by controlled use of both the accelerator and the brake. Similarly, controlled cell growth is maintained by regulation of proto-oncogenes, which accelerate growth, and tumor suppressor genes, which slow cell growth. Mutations that produce oncogenes accelerate growth while those that affect tumor suppressors prevent the normal inhibition of growth. In either case, uncontrolled cell growth occurs.

	3.3	**Describe possible treatment options for cancer**	
		Treatment options • surgery • chemotherapy (cytotoxic drugs) • radiation therapy • combination therapy • • blood transfusion	Learners need to be aware that there are many types of cancer treatment. Treatment will often depend on the type of cancer and how advanced the cancer is within a person. There is a wealth of information that teachers and learners can access on cancer treatments. For example: http://www.cancerresearchuk.org/about-cancer/cancers-in-general/treatment/ http://www.macmillan.org.uk/information-and-support/treating http://www.nhs.uk/conditions/chemotherapy/Pages/Definition.aspx
	3.4	**Assess the potential impact of new treatments for cancer**	
		New treatments • targeted therapy • immunotherapy • photodynamic therapy **Impact** • potential benefits (e.g. improved life expectancy) • cost and impact on other services	Learners should be aware that significant progress has been made over the past few years in the treatment of both common and rare cancers, this has resulted from extensive research carried out across the scientific community. There are many news stories in scientific journals and general media which teachers and learners could use to further develop their understanding about the potential impact of these new treatment options.

4	**Be able to provide information about medicines**		
	4.1	**Communicate information to an audience**	
		Communication method • written information e.g. leaflet, website, media article • face-to-face • other e.g. radio, podcast • formal, informal • technical, non-technical **Communication** • clarity • style • level (accessibility, level of language for target audience) • structure **Audience** • patients • medical staff	When communicating information about medicines, learners should make us of appropriate scientific and technical language. If the audience is medical staff, learners should be using terms such as neurotransmitters, receptors, agonist etc. When communicating to patients the style of language would be significantly different to that used with medical staff.
	4.2	**Justify approach to communicate information**	
		Justification • audience addressed • issue(s) addressed • suitability of approach	Learners should justify their choice of communication method.

	4.3	Work as part of a team	
		Part of a team • flexible • reliable • takes responsibility • relationships contributes to team listens to view point's treats others in a respective and supportive manner makes constructive contributions	Learners should be able to work as part of a team.

Unit 5 – Clinical Laboratory Techniques

LO	AC	Specification statement	Comment
1	**Understand clinical testing**		
	1.1	**Explain principles of clinical tests**	
		• biochemical tests e.g. simple identification tests (for glucose, protein, sodium ions, potassium ions, calcium ions), • simple colorimetric assays,	Learners should be aware of Benedict's and biuret as simple, semi-quantitative tests for glucose and protein. Alternative tests may also be used (e.g. acidified potassium permanganate or Bradford). Flame tests for potassium ions, sodium ions and calcium ions. Learners should understand that the colorimeter may be used to give quantitative results from biochemical assays.
		• enzyme assays (kinetic and end point),	Learners should understand that enzyme assays are laboratory methods for measuring enzymatic activity. They measure either the consumption of substrate or formation of product over time. These assays may be continuous, where the assay gives a continuous reading of activity, or discontinuous, where samples are taken, the reaction stopped and then the concentration of substrates or products are determined.
		• chromatography (TLC, GLC, HPLC),	Chromatography is a term that encompasses a series of laboratory procedures that allow separation of mixtures. The mixture is dissolved in a fluid called a mobile phase, which carries it through a structure holding another material called a stationary phase. The constituents of the mixture travel at different speeds, causing them to separate. Thin layer chromatography (TLC) involves the use of a thin layer of silica gel, alumina or cellulose on a flat, inert substrate as a stationary phase. Gas liquid chromatography (GLC) is a technique in which the mobile phase is a gas. High pressure liquid chromatography (HPLC) is a technique where the mobile phase is a liquid and utilises a stationary phase of very small packing particles and relatively high pressure.
		• radioactive immunoassays (RIA),	Radioimmunoassay (RIA) is a very sensitive technique that can be used to measure low levels of antigens by use of antibodies.

			It is a commonly used technique and a relatively low-cost technique in clinical laboratories. In a RIA a known quantity of an antigen is made radioactive, and mixed with a known quantity of antibody and the two specifically bind together. A sample from a patient containing an unknown quantity of the same antigen is added. This causes the unlabelled antigen from the patient sample to compete with the labelled antigen for antibody binding sites. A higher concentration of unlabelled, patient antigen, displaces more labelled antigen from the antigen-antibody complex. Bound antigens are separated from unbound antigens and the radioactivity of the bound antigen remaining is measured by a gamma counter.
		• ELISA,	Enzyme- linked immunosorbent assay (ELISA) is a technique using antibodies and colour change to identify a concentration of an antigen in a mixture. Antigens from the sample are attached to a surface (usually a multi-well plate), time is then given for the antigen to adhere to the plate. A solution of a nonreacting protein (e.g. bovine serum albumin or powdered milk) is added to the plate to block any unbound sites to prevent non-specific binding of the antibody. A specific antibody is applied to the surface so that it can bind with the antigen. This antibody is linked to an enzyme, and then a substance containing the enzyme's substrate is added. The subsequent reaction produces a detectable signal, most commonly a colour change. The higher the concentration of antibody, the stronger the colour change, which can then be detected by a spectrometer. Direct or indirect (sandwich) ELISAs can be used (details of indirect ELISA are not required).
		• spectrophotometry,	Spectrophotometry is a method to measure how much a chemical substance absorbs or transmits light. There are two types of spectrophotometer, which are used according to the range of wavelength utilized. A UV-visible spectrophotometer uses light over the UV and visible range (185-700 nm) of the electromagnetic spectrum. An IR spectrophotometer uses light over the IR range (700-1500 nm).
		• nephelopmetry,	Nephelopmetry is a technique which is commonly used in clinical laboratories. It is based on the principle that a dilute suspension of small particles will scatter light (usually a laser) passed through it (rather than absorbing it). The amount of scatter is determined by collecting the light at an angle (usually 30 or 90 degrees).

		• turbidimetry	Turbidimetry is the process of measuring the loss of intensity of transmitted light due to the scattering effect of particles suspended in it. Light is passed through a filter creating a light of known wavelength which is then passed through a curvette containing a solution. Turbidimetry is commonly used to measure the number of cells in a solution.
		haematology tests e.g. red blood cell count, white blood cell count, haemoglobin, haematocrit, differential count, platelet number estimation	Haematology profile tests involve a full blood count to examine the components of blood. Specialised equipment is used in the clinical laboratory, and systems are often highly automated. A full blood count involves measuring the number of red blood cells, white blood cells and platelets per millilitre of blood; the size of red blood cells and calculates their mean size; calculates the proportion of blood made up from red blood cells (haematocrit); the amount of haemoglobin in red blood cells. Differential counts of white blood cells allow the numbers of different types of white blood cells to be calculated (eosinophils, basophils, lymphocytes, monocytes) to assess the body's ability to respond to infection. Platelet numbers can also be determined by automated system as a measure of the body's clotting ability
		histopathology techniques e.g. sample preparation, microscopy, immunohistochemistry	Histopathology refers to the microscopic examination of tissue in order to study disease. A detailed account of histopathology is given at the end of this section.
		microbiological techniques e.g. aseptic technique, serial dilution, staining, growth of bacterial populations	Microorganisms may be grown in the laboratory if supplied with suitable physical conditions, nutrients and water. Different species vary in their requirements and usually grow over a range of temperatures and pH values, with an optimum within the range. Nutrients are supplied in nutrient media and include: carbon compounds, usually organic compounds such as glucose; nitrogen, organic or inorganic; growth factors such as vitamins and mineral salts. Aseptic technique (also called sterile technique) is to prevent: • contamination of the environment by the microbes being handled • contamination of microbial cultures by unwanted microbes from the environment Equipment and media must be sterilised before use by appropriate methods including: • heat - examples being the use of an autoclave at a suitable temperature (121°C) for 15 minutes or heating an inoculating loop in a Bunsen flame • Irradiation - heat labile (stable) plastics

			Learners should understand: • the differences between total cell count and viable counts (knowledge of haemocytometers is required) • that for a viable count, a known volume of organism is added to agar plates, incubated and the colonies counted. It is assumed that one cell gives rise to one colony. This makes no allowance for clumping of cells in the initial inoculum so may lead to an underestimate of the numbers of the original plated cells. In both cases (total viable count and total cell count) the original culture usually requires dilution by e.g. ten-fold steps, serial dilution, in order to provide a final number within a countable range. Bacteria can be distinguished from each other by their size, shape, staining characteristics, and their metabolic, antigenic and genetic features. The shape of bacteria is due to their rigid cell wall which has a unique structure: it contains a 3D mesh of peptidoglycan (murein). Gram positive bacteria have cell walls with a thicker layer of peptidoglycan/murein (than Gram-negative bacteria), which retains the crystal violet/iodine complex within their cells when washed with alcohol - staining purple. On treatment with alcohol, the Gram negative cell walls lose their outer lipopolysaccharide membrane, and the thin inner peptidoglycan layer is left exposed, this means that the crystal violet/iodine complexes are washed from the gram-negative cell along with the outer membrane – they stain red with the counterstain safranin.
		genetic techniques e.g**.** use of restriction enzymes, gel electrophoresis, PCR, DNA sequencing	Polymerase Chain Reaction allows the quantity of DNA to amplified for analysis. Gel electrophoresis can then be used in the analysis of the DNA by producing a DNA profile. • The polymerase chain reaction (PCR) is used to amplify small sections of DNA rapidly. • PCR, is used to amplify the DNA by using a primer (single stranded DNA typically 6-25bp in length) which is complimentary to the start of the sequence. • PCR involves heating the DNA to 95^{o}C to separate the two strands. • The sample is then cooled to 50-60^{o}C to allow the primers to bind to the DNA strands (annealing). • Heating to 70^{o}C allows a thermally stable DNA polymerase (*Taq*) to add complimentary nucleotides (extension) by forming bonds in the sugar-phosphate backbone.

			• This cycle is repeated. After up to 40 cycles over a billion copies of the target sequence can be produced from just one piece of DNA. • Gel electrophoresis is a method of separating DNA fragments according to size. The gel is made from agarose (similar to agar), which contains pores in its matrix. • DNA samples are loaded into wells at one end and a voltage is applied across the gel. DNA is attracted to the positive electrode due to its negative charge on the phosphate group. Smaller fragments find it easier to migrate through the pores in the gel and so travel further than large fragments in the same time. • Fragment size can be estimated by running a DNA ladder (which contains fragments of known size) alongside. Learners should appreciate that DNA sequencing allows the order of bases to be deduced. No details of the procedure are required.
	1.2	**Explain factors that affect clinical test results**	
		Factors • sensitivity • specificity • interfering agents • human error	Learners should consider suitability and restrictions of individual biochemical tests in terms sensitivity, specificity, interfering agents and human error

2	**Be able to carry out clinical laboratory techniques**		
	2.1	**Plan tests**	
		Plan • identify information required • procedures and equipment • sequencing of activities • timing	Learners should be able to plan experiments in a clinical context.
	2.2	**Assess biological samples using clinical tests**	
		Biological samples • blood • plasma • urine	Learners are not expected to handle blood, plasma or urine samples but need to know how they are handled and analysed in the clinical laboratory. Simulated materials suitable for learners can be used but they should be given opportunities to use appropriate PPE
		Equipment • correct use	Learners should correctly and safely use a range of equipment available in the school/college laboratory
		Safe working practice • works in accordance with risk assessment and laboratory requirements • correctly uses PPE • maintains tidy working area	Learners should work safely in the laboratory as if they were working in a clinical setting.
	2.3	**Record results from tests**	
		Recording documentation • laboratory notebook • use of proformas	Learners should be able to record their experimental methods and results in different formats, e.g. using standard proformas or in a laboratory notebook.

		Records • key information recorded • correct format • data recorded to correct precision • entries legible	Learners should record appropriate clinical laboratory data.
3	**Be able to process data from clinical tests**		
	3.1	**Use graphs to process data**	
		Graphs • calibration curve • best-fit lines **Graphical methods** • by hand • using software (e.g. Excel/graphical packages)	Learners should use appropriate graphical methods to process clinical laboratory data.
	3.2	**Use numerical methods to process data**	
		Numerical methods • manipulation of algebraic expressions **Significant figures** • records data to appropriate number significant figures	Learners should use appropriate numerical methods to process clinical laboratory data.

	3.3	**Interpret data from clinical tests**	
		Interpretation • identification of outliers • compares data with expected range • significance of data	Learners should interpret clinical laboratory data.
		Expected ranges • red blood cell count, white blood cell count, platelet count • blood glucose • plasma proteins • sodium ions, potassium ions, calcium ions	Learners will be supplied with normal ranges during assessment but should understand that values that lie outside the normal range are indicators of ill-health.
	3.4	**Communicate information to an audience**	
		Audience • scientifically literate audience • audience with basic scientific understanding **Information** • structure, clarity, style • language including technical and scientific • appropriate use of English • relevance information to audience	Learners should communicate outcomes of laboratory testing to an audience.

Histopathology (A .Wilson 2015)

Introduction

What is histology?

The microscopic study of tissues and cells, including their structure and function.

(Tissues range from tiny biopsies such as, bronchial, gastric & bladder up to whole organs such as breasts, colons & uterus)

What is histopathology?

This is concerned with the cause and effect of disease on structure of tissue and cells and analysing them microscopically

Importance of histopathology

- To differentiate between benign and malignant tumours (cancer)
- To establish type of cancer (i.e. carcinoma or lymphoma)
- To provide valuable information about tumour grade and stage (i.e. has it spread)
- To provide information for the treatment and prognosis of patients
- Also, to diagnose any non-tumour abnormality (i.e liver storage diseases, bacterial & fungal infections)
- To eliminate non pathological disorders

How do we do it?

All specimens in histology are received in a fixative (e.g formalin) to retain the architecture of the tissue and keep it as life like as possible. This is achieved by preventing autolysis and putrefaction. Fixation needs to be at least 24 hours and the volume of fixative to specimen needs to be X 10.

Each specimen will undergo the following processes:

1. Reception / registration:

All specimens that arrive in the laboratory will first be dealt with at specimen reception. Here the specimens are cross-matched with their forms to ensure that all the details are present and correct! They are then bar-coded and entered on to the computer system.

2. Dissection:

The specimens are described by the pathologists and cut up into cassette sized pieces ready for processing. There are two different sized cassettes used. A smaller size that is used routinely and larger cassettes for whole organ techniques (e.g whole prostate glands and larynx)

3. Processing:

At the end of each day the cassettes will be processed. This is carried out in enclosed automated processors. At this stage the tissues are infiltrated with graded alcohol's to remove water from the tissue, clearing agents and then impregnated with molten paraffin wax.

SHANDON TISSUE PROCESSOR

4. Embedding:

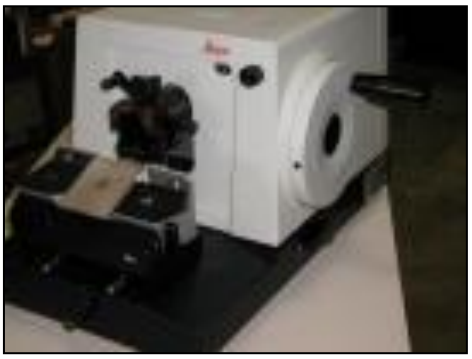
Each morning the tissue from the cassettes will be embedded in molten wax in metal moulds and allowed to solidify. The principle is to embed in a solid medium that is firm enough to support the tissue and give it enough rigidity to enable thin sections to be cut.

TISSUE TECH EMBEDDING CENTRE

5. Cutting:

With the use of rotary microtomes sections are cut 4 µm thick. These are then floated out onto a water bath to allow the wax to spread and remove any creases from the section. This should not be too hot otherwise the wax will melt and the sample will be lost. The sections are then picked up on glass slides and placed in a 60ºC oven for 30 minutes. This removes any excess water and helps the section adhere to the slide.

ROTARY MICROTOME



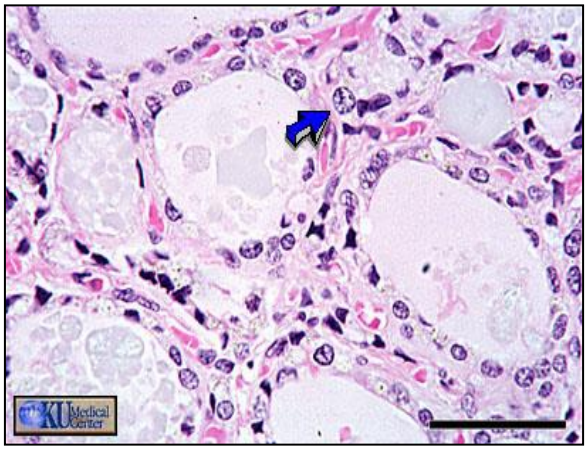
SECTION CUTTING

6. Staining and coverslipping:

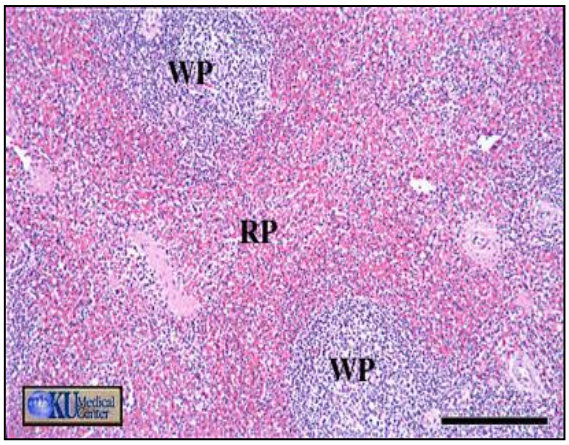
Every slide is stained with haematoxylin and eosin (H&E) on an automated stainer. The haematoxylin will stain the nuclear detail a blue /purple colour and the eosin stains red blood cells orange, collagen, reticulum & amyloid pink and muscle, elastic & fibrin bright red. Each slide is then covered with an acetate film (not glass!) on an automated coverslipper. THE END RESULT IS A STAINED SLIDE THAT IS A PERMANENT RECORD.

AUTOMATED STAINING MACHINE

AUTOMATED COVERSLIPPER



H&E of Thyroid

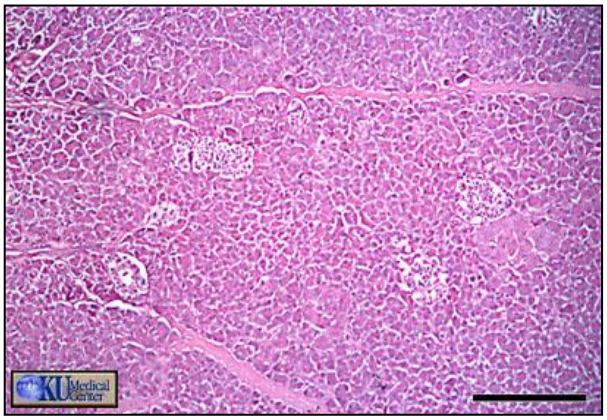


H&E of Spleen

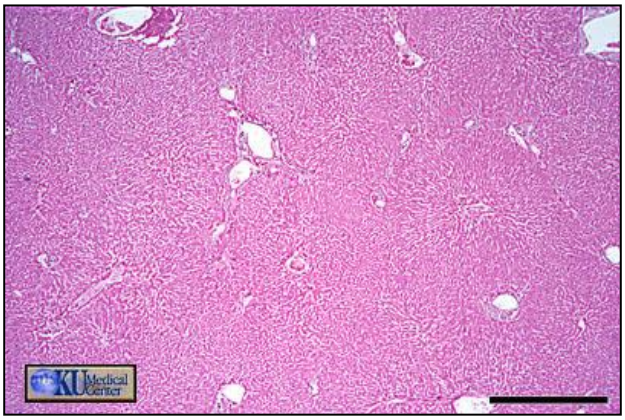
H&E of Colon

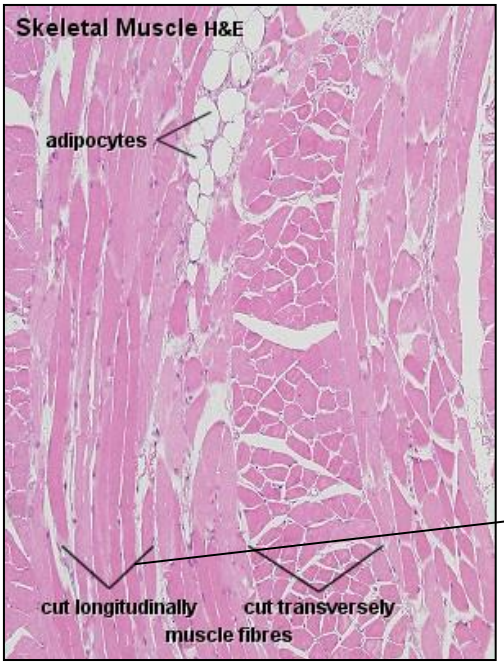
H&E of Skin

H&E of Pancreas

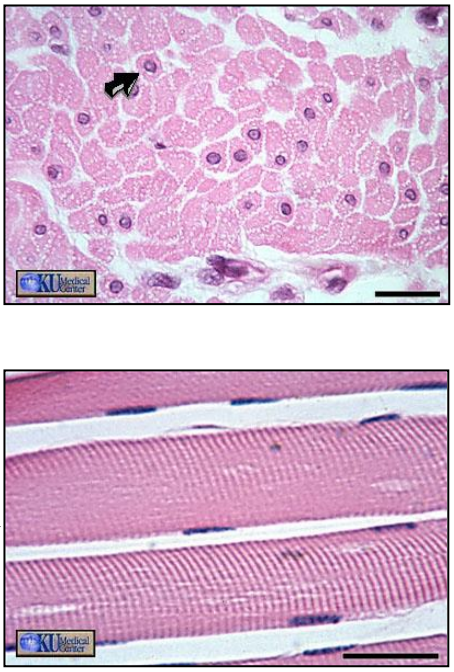


H&E of Liver





Skeletal Muscle



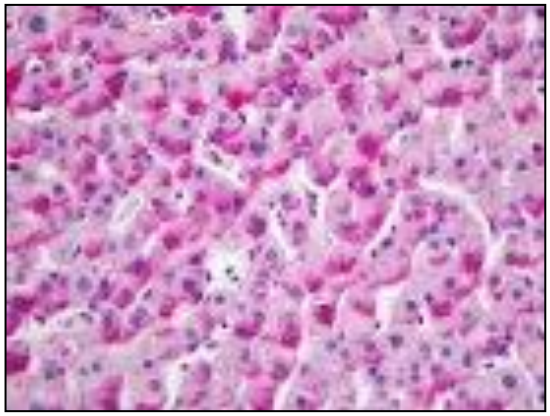
Smooth Muscle TS section

Specialist techniques

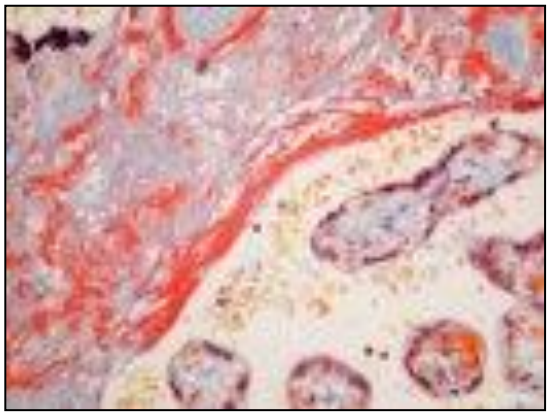
In addition to the routine H&E, the pathologist will sometimes require further staining techniques for a diagnosis.

Special stains

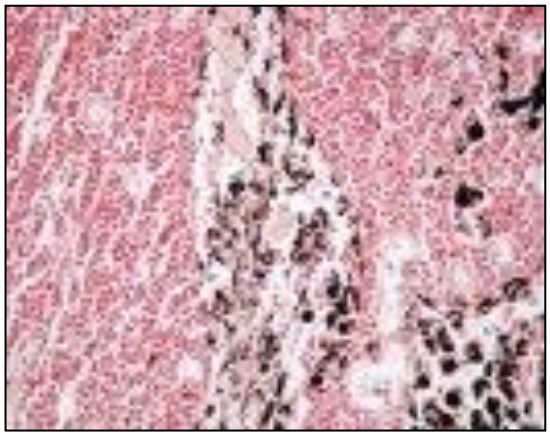
There are a vast amount of special stains available that are all carried out by hand by the biomedical scientists. They are used to demonstrate particular components that arise from disease processes. (i.e. the gram stain for bacteria, perls prussian blue for hemosiderin deposits, as seen in liver disease.)



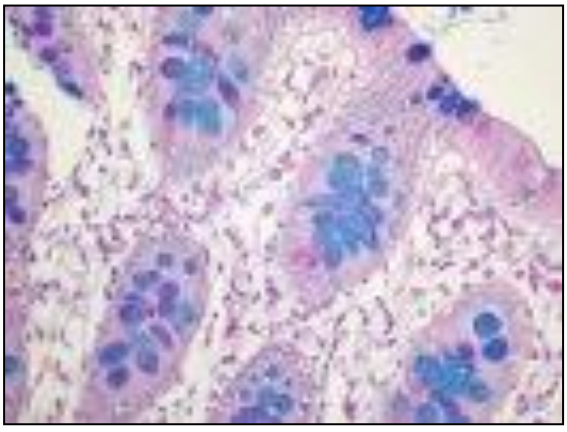
Periodic Acid Schiff (PAS) technique for Glycogen



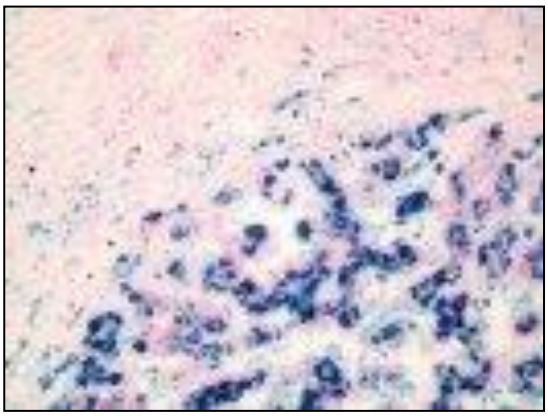
MSB for fibrin



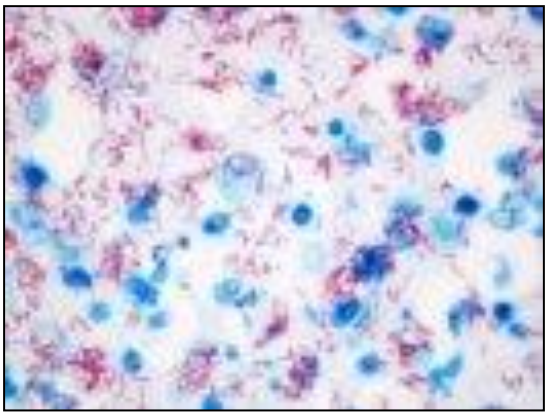
Massons Fontana for Melanin



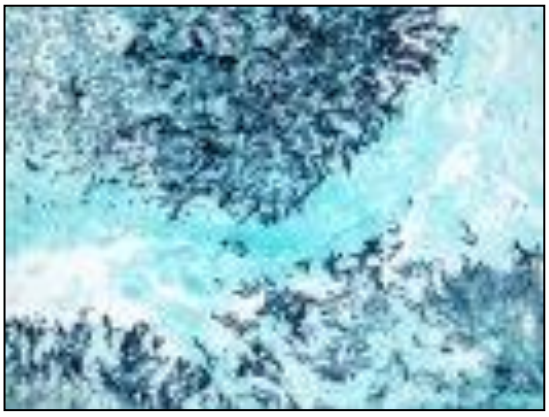
Alcian Blue/PAS for mucins



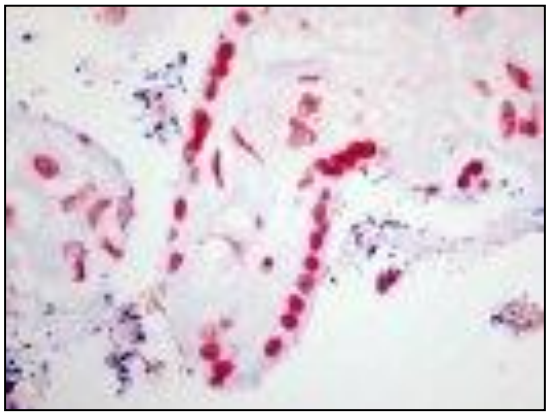
Perls Prussian Blue for Haemosiderin



Zeihl Neelson for TB



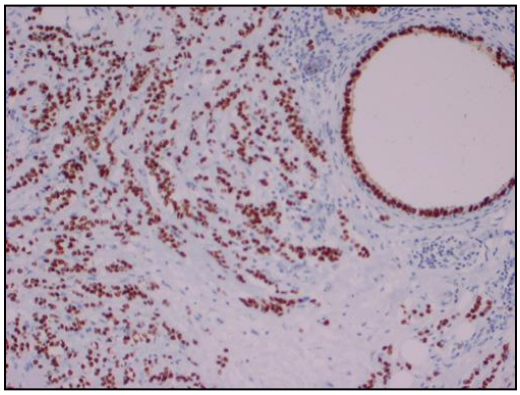
Grocott for Fungi



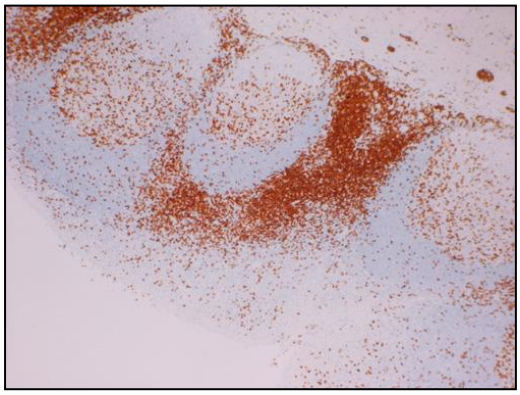
Gram Stain for Bacteria

Immunohistochemistry (or tumour markers) :

This is a rapidly growing area of histopathology. It utilises antibodies to demonstrate specific cells and is very important in differentiating between cancer types. It is all carried out on a modern immune-autostainer.



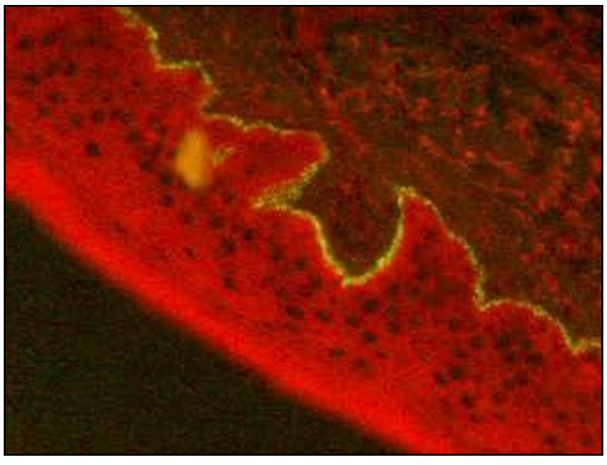
Oestrogen Receptor Status Marker



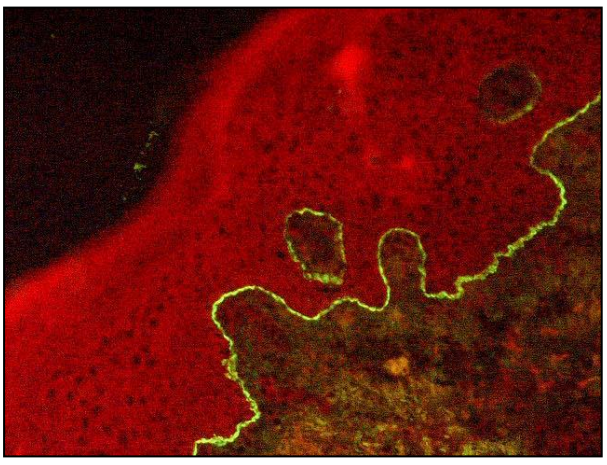
T-CELL Marker

Immunofluorescence:

This technique is used to diagnose many skin conditions, such as autoimmune skin conditions (e.g.bullous pemphigoid). The skin specimens are received fresh and rapidly frozen. The sections are cut using a cryostat and stained with antibodies that are labelled with a fluorescent dye. They are then viewed under a fluorescent microscope. These slides will only last a few days if kept in the fridge.



C3 Basement Membrane



IgG Linear Basement Membrane

Frozen sections:

This area allows for a rapid diagnosis. The lab will receive a fresh (not fixed!) piece of tissue from the patient while they are still on the operating table. This tissue is frozen rapidly (-70^{o}C) and cut using a cryostat. A rapid hand H&E is then carried out. Frozen sections are usually carried out when removing the parathyroid. This is because the parathyroid is very hard to locate and the surgeon needs to know that it has been removed before the operation is finished.

Large blocks

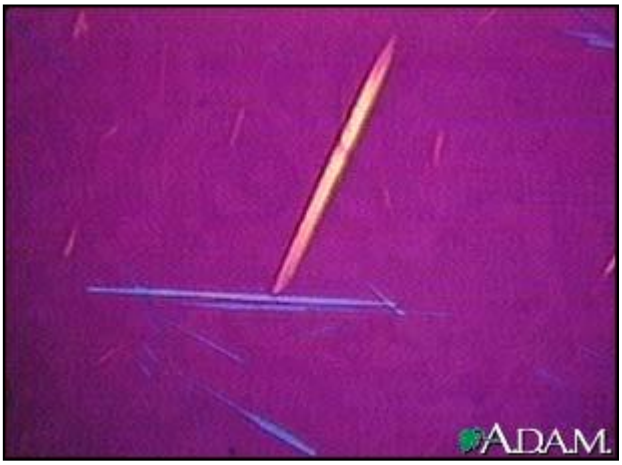
This technique is to provide haematoxylin and eosin stained sections of whole organs and large blocked specimens for microscopic examination.

The normal procedures are inadequate for such specimens and therefore a specialised technique has to be employed. This involves extended processing programme, use of specialised embedding moulds and microtomes.

Crystalography

This technique is concerned with the identification of crystalline deposits in joint fluids using polarised light and a quarter phase plate. E.g. uric acid in gout

Positive birefringence of GOUT crystals



Expected ranges for clinical markers

Test	Adult Male	Adult Female
Glucose (fasting)	4.5 - 6.1 mmol dm^{-3}	4.5 - 6.1 mmol dm^{-3}
Sodium ions	133 - 147 mmol dm^{-3}	133 - 147 mmol dm^{-3}
Potassium ions	3.5 – 5.0 mmol dm^{-3}	3.5 – 5.0 mmol dm^{-3}
Calcium ions	1.15 – 1.29 mmol dm^{-3}	1.15 – 1.29 mmol dm^{-3}
Zinc ions	10 – 17 µmol dm^{-3}	10 – 17 µmol dm^{-3}
RED BLOOD CELLS		
Haemoglobin	140 – 180 g dm^{-3}	115 – 160 g dm^{-3}
Red blood cell count	4.5 – 6.5 x 10^{12} dm^{-3}	3.8 – 5.8 x 10^{12} dm^{-3}
White blood cell count	4 – 11 x 10^{9} dm^{-3}	4 – 11 x 10^{9} dm^{-3}
Platelet count	150 – 400 x 10^{9} dm^{-3}	150 – 400 x 10^{9} dm^{-3}
SERUM PROTEINS		
Albumins	0.035 – 0.050 g dm^{-3}	0.035 – 0.050 g dm^{-3}
Globulins	0.020 – 0.025 g dm^{-3}	0.020 – 0.025 g dm^{-3}
Fibrinogen	0.0020 – 0.0045 g dm^{-3}	0.0020 – 0.0045 g dm^{-3}

Unit 6 – Medical Case Study

LO	Specification statement		Comment
1	**Understand physiological information presented within case studies**		
		Assessment criteria from unit 1	Please see guidance for unit 1.
2	**Understand how physiological measurement techniques can be used to support diagnosis and treatment**		
		Assessment criteria from unit 2	Please see guidance for unit 2. Physiological measurements play a very important role in the diagnosis and treatment of patients in a range of clinical settings. *In addition,* candidates should also be able to use the knowledge and understanding gained from **unit 2** to recommend ways in which physiological measurement techniques can be used in the particular case study situation. This will require candidates to draw on their knowledge of the principles and purpose of different physiological measurement tests, as well as their understanding of how tests are performed and the relevance of results that are generated.
3	**Understand how medical research can help support diagnosis and treatment**		
		Assessment criteria from unit 3	Please see guidance for unit 3.

4	**Understand ways in which medical treatments can be used to treat diseases and disorders**		
		Assessment criteria from unit 4	Please see guidance for unit 4. Knowing how specific interventions, in particular medicines, can be used is an essential requirement in the successful management and treatment of disorders and disease. *In addition,* candidates should be able to use the knowledge and understanding gained **from unit 4** to recommend ways in which medical treatments, including medicines can be used to treat diseases and disorders. This will require candidates to draw on their knowledge and understanding of how medicines are managed and how they work. Candidates will also need to use their knowledge and understanding of other treatments for specific disorders such as cancer.
5	**Understand ways in which clinical measurement techniques can be used to support diagnosis and treatment**		
		Assessment criteria from unit 5	Please see guidance for unit 5.