



HIGHER SPECIALIST DIPLOMA

Study Guide and Indicative Syllabus

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INTRODUCTION

The Higher Specialist Diploma (HSD) is a Masters level professional qualification that enables biomedical and clinical scientists to demonstrate depth of knowledge of a chosen specialism within the wider professional context, which is required for senior roles. For this reason the qualification will be beneficial to those who are in, or aspire to hold, Band 7 job roles. It also enables successful candidates, if they do not already hold it, to apply for Fellow (FIBMS) status of the IBMS.

This study guide is an indication of the main areas covered by the Higher Specialist Diploma (HSD) examination. This is supplemented by further information and guidance documents that are available on the HSD pages of the IBMS website. This document contains an indicative syllabus aimed at guiding the candidate to the appropriate topics and should be 'added to' by the candidate to reflect updates in practice and resources available.

The study time for this examination could be made up of general reading, laboratory practice, involvement in case studies and managerial issues, presentations, essay writing, attendance at events, other relevant professional development activities, and reflective practice relating to the generic study guide and the chosen specialty. Candidates are strongly advised to seek a mentor who can help with their training and learning activities in preparation for the HSD. The diploma may be awarded in the following subjects:

- Cellular Pathology
- Clinical Chemistry
- Cytopathology
- Haematology
- Immunology
- Leadership and Management
- Medical Microbiology
- Transfusion Science
- Virology

Eligibility Criteria

To undertake the HSD applicants must be Health and Care Professions Council (HCPC) registered and have paid Institute membership at Member (MIBMS) or Fellow (FIBMS) grade. This must be maintained for the duration of this qualification.

Learning Outcomes

The HSD is designed to be at M-Level. The award of the HSD shows that you have demonstrated:

- A comprehensive understanding of a specific field of biomedical science
- The ability to analyse and interpret information critically in order to address practice-based situations
- Skills in leadership and communication within the healthcare environment
- Critical reflection of personal professional practice
- Knowledge and understanding of current issues and developments within healthcare and how they impact on professional practice

Assessment Structure

The assessment of the Higher Specialist Diploma consists of two parts:

- Part A – Portfolio of Experiential Learning
- Part B – Written Examinations

Part A - Portfolio of Experiential Learning

Entry into the written examination is dependent upon obtaining a pass grade for the portfolio of experiential learning. The portfolio is a compilation of documentary evidence which should be at M-level that is gained during the preparation of the HSD examination.

The IBMS recognises the difficulties experienced by candidates preparing for an examination without the support of a formal taught course. To help provide a focus for training, there is an evidence requirement around which the candidate can structure their preparation and demonstrate experiential learning in readiness for the examination. This will be contained in a portfolio that must be submitted to the IBMS for assessment prior to entry into the written examination.

As post-graduate study is based on continuing professional development (CPD) and supported by reflective practice, candidates must also be able to demonstrate that they can modify personal professional activity, critically evaluate scientific information sources and methodologies and demonstrate they possess the capacity to carry out such activities autonomously.

Preparation for the HSD examination is guided by this Study Guide and Indicative Syllabus which indicates the necessary knowledge, skills and competences in order to satisfy the above mentioned learning outcomes. The following must be included in the portfolio that is submitted to the IBMS for assessment:

- Personal Professional Profile
- Case Study and Managerial Report
- Two Essays
- Copy of Oral Presentation Power Point, Accompanying Notes and Feedback
- Reflective Statement

Personal Professional Profile

This should be 500 words (+/- 10%) and is designed to help you focus on the aspects of your practice that have been developed (or are being developed) towards higher specialist practice. It is therefore a description of relevant experience, your current job, roles and responsibilities, the nature and range of duties undertaken, what you have learned and how you are developing your practice as a professional biomedical scientist.

Personal profiles should summarise work experience following achievement of specialist practitioner status and admittance to the IBMS class of Member (MIBMS) or Fellow (FIBMS).

Clinical Case Study and Managerial Report

As those undertaking the HSD are in or aiming for roles where they will have managerial responsibilities candidates in **all** scientific disciplines are required to do one Clinical Case Study **and** One Managerial Report. Those undertaking the HSD in Leadership and Management must submit **two** managerial reports.

Each Case Study/Managerial Report must be **1,500 words (+/- 10%)**. It is essential that you **do not** include something from your departmental archive, or one in which you were **not** involved, instead they must be ones where you have had a clear and significant level of personal involvement and they should be typical of your workload, not exceptional.

Whether clinical or management, the work submitted must demonstrate your professional ability and a systematic approach to show:

- personal insight and wider understanding of the issue/condition
- current knowledge
- relevance to the current environment and your scope of practice

They should also show that you:

- systematically applied professional knowledge and understanding to determine action based on best-practice
- used self-direction to solve the problem(s) and/or issue(s)
- exercised personal autonomy in relation to your scope of practice but did, if necessary, liaise with others
- communicated findings to colleagues

The inclusion of illustrations, tables, images and references is strongly encouraged where appropriate. Information with tables, legends for figures and diagrams and the reference list at the end of the clinical case study and managerial report are not included in the word count but citations within them are included in the word count.

There must be personal reflection that includes a description of what went well and what went badly, what you learnt from your involvement in the case and, as appropriate, how it will, or did, inform future changes to your own, and if applicable the wider laboratory practice. When writing the clinical case study or managerial report personal pronouns should be avoided apart from when writing your reflection.

Clinical Case Studies

The clinical case study must include details of the initial clinical presentation, previous medical history, tests you performed and/or referred depending on your scope of practice, differential diagnoses based on the evidence you gathered, appropriate ancillary tests, management, treatment and follow-up.

Details of presenting symptoms and any additional relevant clinical history, including previous results, should be used to introduce the case. The clinical symptoms may be expanded upon and the possible need for further investigations should be critically

discussed to demonstrate that you have considered aetiology and pathogenesis of the disease.

The way the specimen is handled when it arrives in the laboratory should be discussed. The possible or probable outcomes for the patient should be discussed to include options for follow-up treatment. Discussion should include what could have happened if an error in analysis had been made.

You may wish to use the headings of pre-analysis, analysis, post-analysis and reflection to help structure their clinical case study.

Managerial Report

The managerial report must include details of the fundamental issue(s), your decision-making process for the initial investigation and subsequent action taken, outcomes and any follow-up. Examples of what could be submitted as a managerial report include the introduction of new equipment/tests, the implementation of audit outcomes, responding to inspection findings, investigation in response to error(s)/incident(s)/complaint(s), re-training of staff and reconfiguration/ amalgamation of services.

Details of the issue(s), and relevant background information, should be used to introduce the study. If relevant the management culture and philosophy of the department or employer may be expanded upon and critically discussed to demonstrate that human, financial and service aspects of the matter have been considered.

The way the matter is handled when it initially arises, the extent and level to which individuals are personally involved and the process for gathering evidence and information should be discussed. Previous related experience may be referenced if relevant to the case and decision-making process.

The outcomes of the situation should be discussed, indicating whether a satisfactory resolution was achieved and the subsequent implications for individuals or the service. Include any options for follow-up action(s) or review that you feel would be necessary providing an explanation as to why. Discussion should include what could have happened if action had not been agreed.

You may wish to use the headings of issue, investigation, actions and outcomes and reflection to help structure the writing of the managerial report.

Identifiable Information

Information within the clinical case study and managerial report must conform to UK General Data Protection Regulation (UK GDPR) and must not contain any patient identifiable information such as the patient's name and/or NHS number. The names and job roles of colleagues that you worked and/or liaised with on the clinical case or managerial issue can be included if they have given you their permission to do so

The use of a marker pen to blank out confidential information out is insufficient, and its use is strongly discouraged. The inclusion of such information will be considered a breach of confidentiality. It is likely to lead to the portfolio being marked as a fail and the candidate not being able to resubmit to the following year. Depending on the precise nature of the offence it may also mean the candidate breaches the IBMS Code of Professional Practice which could result in disciplinary action.

Two Essays

The portfolio requires the submission of two appropriately referenced essays (each of 3000 words (+/- 10%)) based on titles published on the HSD section of the IBMS website. Any two of the four essay titles in the chosen discipline can be submitted. Essays must demonstrate that the learning outcomes have been met. Information with tables, legends for figures and diagrams and the reference list at the end of the essay are not included in the word count but citations within the essay are included.

In relation to the essays you must note that the IBMS will be using similarity detection software (Turnitin). This software will compare each essay with that submitted by other IBMS candidates and with millions of resources that have been published on the internet. It produces a report that highlights not only how much text is similar to other sources, but also where this material is located. The similarity score that the software produces requires the academic judgement of the examiners and the IBMS Head of Examinations to interpret whether this necessitates action.

Essays submitted as part of the HSD must reflect what you know and understand and therefore should largely be in your own words. Plagiarism, which does not only apply to written text, but also to figures, images, diagrams, tables etc., will likely result in an automatic failure and potentially a ban from future assessments, pending the outcome of the appeals procedure if invoked.

It would be poor academic practice for your essays to consist principally of several paraphrases or lots of ideas and thoughts from other authors, even if these are appropriately referenced and nor should you incorporate the views of others as if they were your own work. This is because it would show a lack of your understanding, views and opinions on the topic or issue.

Referencing for Case Studies, Managerial Reports and Essays

References should appear in either the Harvard or Vancouver format and must be used consistently in any document. More information on plagiarism and how to avoid it, how case studies, managerial reports and essays will be checked for plagiarism, similarity and poor academic practice and referencing in both the Harvard and Vancouver style of referencing can be found in the relevant 'How to' guides which can be found on the IBMS website.

Copy of Oral Presentation Power Point, Accompanying Notes and Feedback

Evidence of an oral presentation in the form of the slides presented and the accompanying notes must be included in the portfolio. The presentation **must not** be on the case study or managerial report submitted but can be on either a scientific/clinical issue or on a management subject. The presentation may have been delivered to a specialist or non-specialist audience or a combination of both. The evidence should demonstrate that the candidate has introduced the subject, dealt systematically with the issues and communicated the conclusions clearly to the audience.

Evidence should be provided on the feedback you gained from doing this presentation. This must include feedback from at least two senior colleagues, one of who must be your line manager. In addition, you should reflect on the success (or otherwise) of the presentation. A pro-forma has been provided for this feedback (see Appendix C).

Reflective Statement

Reflection is an important part of any learning activity. The portfolio must be supported by the inclusion of one reflective learning statement of 2,000 words **(+/- 10%)**.

In this statement you should articulate how you identified gaps in your knowledge, the action(s) you took to address these and the rationale behind your choice of action(s). The statement should highlight what you consider you have learnt from the CPD activities undertaken, the preparation/research done for completing the essays and any other relevant work and what you feel this means for your on-going professional practice.

The statement should also 'critique' what you could have done better, the advantages/disadvantages of your approach and what you would have done differently or advise others to do based on your experience. It should show your preparation for the HSD has contributed to your professional practice. The Clinical Case Study, Managerial Report(s) and Oral Presentation can be referenced but they should not form a significant part of this reflective statement as you will have already reflected on them with those specific sections of the portfolio.

For advice and guidance on writing your reflection for the case study, managerial report and the reflective learning statement please refer to the IBMS 'How to' Guide on Reflection document which can be found on the IBMS website.

CPD

You are expected to undertake a variety of CPD activities as part of their work in completing the HSD portfolio and preparation for the exam. The number of and specific mix of activities to be evidenced is not specified, as this will be different for each candidate and there is **no** requirement to provide a specific list of activities or supporting evidence within the portfolio submitted to the IBMS, but the CPD undertaken must be apparent in the reflective statement. The following are examples of the activities that candidates could consider evidencing in the reflective statement:

- Supervision of training (e.g. registration or specialist portfolios or DEP)

- Attending conferences/ events / IBMS Congress/ online courses etc.
- Presentation of papers or posters at events
- Acting as a tutor, lecturer, mentor or supervisor
- Professional appointments (e.g. IBMS, NQAAP, UKAS, etc.)
- Being an assessor, examiner or verifier for the IBMS or any other organisation
- Publications (book or journal)
- Setting and organising CPD activities (JBL, structured reading essays etc...)
- Discussion groups, journal clubs
- Instrument training
- Case-study meetings (attendance and presentation)
- Work-based tutor, training officer or project supervisor
- Local reviews or audits
- Involvement in PDPs or appraisals
- Analysing day-to-day events or practices
- Rotational or secondment training
- Other qualifications such as the IBMS Certificate of Expert Practice (CEP)

Role of Training Officer, Mentors and/or Supervisors

The level of input required by a training officer, mentor and/or supervisor is very different to the Registration or Specialist Portfolio. The HSD is a self-directed qualification and there is no requirement that those undertaking the qualification are given protected or study time to complete the requirements of the portfolio. Laboratory staff must however support those undertaking the HSD by giving them chances to increase their knowledge and depth and breadth of experience and by providing advice and guidance to them on complex issues.

The laboratory must enable those undertaking the HSD to have a significant level of involvement in clinical cases and managerial issues of sufficient complexity that can be included in the portfolio. They must also give them the chance to deliver a presentation and as part of that there should be at least two senior colleagues (such as the training officer and/or laboratory manager) who provide feedback on the success or otherwise of the presentation. Those doing the HSD must also be given opportunities to undertake a variety of CPD activities as these will need to be reflected upon as part of the portfolio requirements.

The HSD portfolio is marked by IBMS examiners and therefore the training officer/supervisor/mentor **does not** need to review and/or sign-off the portfolio before it is submitted to the Institute by the candidate however it would be good practice for them to do so.

The laboratory will need to support the individual(s) when it comes to the exams themselves as these exams will be sat at their own place of work. Once someone has passed the portfolio, they will be expected to find an appropriate individual who will co-ordinate the invigilation of the exams. If there are multiple individuals from the same hospital undertaking the HSD exams these people can sit the exam together.

Submission and Marking of the Portfolio

The portfolio must be submitted for assessment by the deadline that is published on the HSD section of the IBMS website. The IBMS will endeavour to carry out all portfolio assessments within eight weeks of the submission deadline. They will be assessed by IBMS examiners against the Portfolio Assessment Indicators stated in Appendix D. Candidates are advised to refer to these as checklist before submitting their portfolio. Portfolios will be awarded a 'pass' or marked as 'refer' or 'fail'.

Pass

Candidates whose portfolio is marked as a pass will be notified of their eligibility to enter the examination. It is normal practice for candidates to enter the examination in the same year that their portfolio is judged to have passed but candidates may, on request, defer their first attempt at the examination until the following year. Passed portfolios are valid for up to two attempts of the HSD examination.

Refer

On review the examiners may decide that a portfolio has not yet met the required standards but is close to doing so. These portfolios will be marked as a 'refer'. In these circumstances, individuals will be notified of the shortcomings and will be given a further three to four weeks to address these issues. Once submitted the additional evidence will be assessed by the same examiners who reviewed the initial portfolio and at this point it will be either be awarded a 'pass' or 'fail'. If a candidate does not submit the additional evidence by the deadline stated by the IBMS Head of Examinations, this will result in an automatic fail. These candidates will be able to re-submit in the following year.

Fail

Candidates whose examination portfolio is deemed to have significant deficiencies and therefore not to have met the requirements of the qualification will be marked as a fail. These candidates will not be permitted at this stage to proceed to sit the examination.

Resubmission of Portfolios

Candidates who wish to resubmit their portfolio for assessment will be required to address the deficiencies identified by the assessors and submit the portfolio the following year by the stated deadline, accompanied by the portfolio re-assessment fee. In addition, candidates who re-submit their portfolio must ensure that the evidence presented within the revised portfolio is current to their practice at that time (i.e. should not normally exceed five years and reflects the training and experience gained in the period since the initial assessment of the portfolio).

After resubmission and reassessment any portfolios that are still deemed not to have met the requirements of the qualification will be again marked as a fail. These portfolios are not valid for a further re-submission and candidates must re-apply to undertake the qualification and must construct a new portfolio for assessment.

Part B – Written Examinations

The HSD written examination consists of four papers as follows:

Generic Essay Questions

Two hours - All candidates attempt the same questions no matter their HSD discipline. There is one pre-released mandatory question. Candidates are then expected to answer two further questions from a choice of four. The syllabus for this exam is shown in Appendix A.

Discipline Specific Short Answer Questions

One Hour - Questions that focus on problem solving / operational scenarios/ analysis of results or quality control issues. Candidates will be expected to answer four questions in an hour.

Discipline Specific Essay Questions

Two hours - Candidates will be expected to answer two from five questions in their chosen speciality.

Discipline Specific Case Studies

Two hours - Candidates are expected to answer three mandatory case studies one of which is pre-seen.

The IBMS has produced a document providing advice on exam tips and techniques. The document also explains the 'Command Verbs' used in the exam papers and what these mean in terms of what the examiners expect to see. This document can be found on the IBMS website.

Pre-Seen (Pre-Released) Questions

Candidates should use the period between the release of the pre-seen question for the generic paper and the pre-seen case study and the examination to prepare the answers for these questions. Candidates however should note that they are **NOT** permitted to take any prepared materials into the examination room itself and that the pre-released questions carry equal weight to the other questions in the examination.

Past Examination Papers

Candidates are strongly recommended to review the past papers that are available in the HSD section of the IBMS website. It should be noted that papers are only made available for the years' that there were candidates sitting that particular discipline.

Examination Arrangements

The HSD examinations are held over two consecutive days. The dates and venue(s) for these will be published on the IBMS website with the detailed itinerary being sent to candidates following a successful outcome in the portfolio assessment. Examinations are governed by the *Rules for Conducting Examinations*, a copy of which can be found on the IBMS website.

Deferrals and Withdrawals

Candidates who wish to **defer** entry to an examination must contact the IBMS a minimum of six weeks prior to the date of the examination will be entitled to a full transfer of their fees. A maximum of two deferrals is permitted. Candidates wishing to **withdraw** from an examination at any time will not be entitled to any reimbursement of the examination fee unless proven mitigating circumstances exist.

Candidate Support

The IBMS hosts Candidate Preparation events aimed at both those thinking of undertaking the HSD and those already registered on it. These events include presentations on the completion of the portfolio and examination techniques and workshops with examiners for the various disciplines where past examination papers are discussed so that delegates are aware of the demand of the qualification and examination. These events will be advertised on the IBMS website.

Special Needs

Candidates with special needs are required to notify the IBMS in writing at the time of their application. Any change in needs must be brought to the attention of the IBMS as soon as possible prior to the examination. The IBMS will make every endeavour to accommodate the needs of such candidates for example normally through the provision of extra time to undertake the examination, large print papers or IT equipment. Depending on the nature of additional support that is required it may be necessary for the candidate concerned to sit the exams at a different location and/or at a different time to the other HSD candidates.

Mitigating Circumstances

Any mitigating circumstances, which may affect examination performance or attendance, must be put in writing, at the earliest opportunity, to the IBMS, with the inclusion of any supporting evidence, e.g. doctor's certificate. Once written evidence is received, the matter will be brought to the attention of the appropriate examination board for consideration. This board will consider whether any adjustments should be made to the marks given to the candidate concerned because of these mitigating circumstances.

The examination board will not accept any claim for any mitigating circumstances that are received after the release of the examination results. Candidates who are unable to attend the examination for a reason deemed acceptable by the examination board may defer entry to the following year without financial penalty.

Marking Process and Release of Results

All examination papers will be marked by two examiners, referring to a third, independent, examiner if appropriate. All four papers carry an equal weighting. The overall pass mark 50% with no paper scoring below 40%. Candidates can pass with papers that score than between 40-50% provided they meet the required overall average. Candidates will be informed of their results in writing following ratification by the examination board.

Appendix E shows the marking criteria for the written examinations which is used by the examiners when developing the marking criteria for the generic paper, essay paper and case study papers.

Banking of Results of Papers

Candidates that fail to reach the overall pass mark will automatically 'bank' the papers in which they scored >50%. They will have to re-sit any papers where they score <50%. For the re-sit the marks that the candidate achieves on the re-sit papers will be the marks that count towards the overall qualification. This does not dispute the fact that 40-49% is a pass mark for the paper but rather it is stating that a pass mark in that range is not acceptable for banking.

The portfolio is valid for two attempts at the exam so banked marks will only be available for one re-sit. If the 50% overall mark is not achieved at this point (i.e. after two attempts at the exam) the candidate must submit a new portfolio and re-sit the entire examination.

Appeals

Any candidate who wishes to appeal against the outcome of the examination must contact the Head of Examinations within a maximum period of 30 days following publication of the results. The IBMS does not allow appeals against the academic judgement of examiners.

Application Form

Application forms are available on the IBMS web site. The completed application together with the correct fee must be returned to the IBMS via email to examinations@ibms.org. Fees can be paid by credit or debit card, or through the provision of a purchase order.

Enquiries

All enquiries relating to this qualification must be addressed to:

Head of Examinations

Institute of Biomedical Science

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London EC1R 5HL

Tel: 020 7713 0214 ext 142

E-mail: examinations@ibms.org

Appendix A

Generic Syllabus for all Disciplines

GENERIC STUDY GUIDE - INDICATIVE SYLLABUS

This describes what all candidates, no matter the discipline that they are undertaking the HSD in should know. This will be examined by the generic exam paper. Candidates should be able to demonstrate knowledge, understanding, application and relevance principally within their own discipline, but also showing awareness of the situation in other disciplines, of the following areas:

Academic Qualifications

- BSc and MSc
- Accredited and Non-Accredited Degrees
- Apprenticeships

Institute Professional Qualifications and Examinations

- Specialist Diploma
- Certificate of Expert Practice (CEP) - Distance Learning (On-line Courses)
- Diploma of Expert Practice (DEP)
- Higher Specialist Diploma (HSD)
- Advanced Specialist Diploma (ASD)

Voluntary and Statutory Regulation

- Registration and Regulation Bodies (e.g. Health and Care Professions Council (HCPC), Science Council, Academy of Healthcare Science)
- IBMS Registration Portfolio
- Standards of Proficiency

Principles and Practice of Training and Development

- Training Needs Analysis (TNA)
- Training Plans and Programmes
- Roles and Responsibilities of individuals and Training Officers
- Appraisals and Personal Development Plans (PDPs)
- Continuing Professional Development (CPD)
- Competency Assessment and Evidence / Demonstration of continuing competence
- Personnel Policies / Equality and Diversity / Relevant Legislation
- Career and Development Opportunities
- Good Professional Practice Documents

Laboratory Information Management Systems (LIMS)

- Data Protection / GDPR
- Document Control
- Confidentiality

Obtaining and Maintaining Accreditation

- UKAS - Compliance
- ISO Standards
- Professional and Regulatory Bodies
- Test implementation, acceptance testing and test validation

Audit

- Types of audit (vertical, horizontal, clinical, service, personal)
- Audit Cycle
- Audit Processes

Quality Management

- Internal Quality Control (IQC)
- Internal and National External Quality Assessment Schemes (I/NEQAS)
- Quality Management Systems
- Quality Plan and Objectives
- Measurement of Uncertainty
- Error logging / Incident Management / Events (Adverse, Serious and Never)
- Key Performance Indicators (KPIs) - Turnaround Times (TATs)
- Validation and Verification
- Implications for Clinical governance
- Roles and Responsibilities of individuals and designated Quality Managers
- Root Cause Analysis (RCAs) - corrective and preventive actions
- Standard Operating Procedures

Health and Safety

- Risk Assessment
- COSHH / RIDDOR - Other relevant legislation
- Risk Management
- Roles and Responsibilities of individuals and designated safety officers
- Incident Reporting

Service Configuration and Delivery

- Pathology Delivery Models and Networks
- AI and New Technologies
- Integrated Systems
- Forward Planning
- Managed Service Contracts
- Staff / Workforce Planning
- Training Requirements
- Change Management
- Budget Management
- Impact of Government Health Service Reforms on Healthcare Delivery

Appendix B

Discipline Specific Syllabuses

CELLULAR PATHOLOGY INDICATIVE SYLLABUS

An in-depth understanding of current knowledge and understanding of the following:
Normal and pathological tissue recognition of:

- Cardiovascular system
- Endocrine system
- Gastrointestinal system
- Immune system
- Liver
- Reproductive system
- Skin
- Soft tissue and bone
- Urinary system

Organ systems

- Physiology of the main organ systems
- Pathology of the main body systems
 - Incidence
 - Aetiology
 - Pathogenesis
 - Pathology
 - Sequalae
 - Outcome

Microscopy

- Principles and relevance to diagnosis
- Fluorescence
- Bright field
 - Köhler illumination
 - Oil immersion
 - Polarising microscopy

Disease classification

- Inflammation, fibrosis and malignancy
- SNOP/SNOMED
 - Topography
 - Morphology
 - Disease
 - Procedure

Audit

- Multidisciplinary team meetings
- Cancer registry

Immunohistochemistry/Immunocytochemistry

- Rationale of methodology

- Antibody knowledge
 - Staining patterns
 - Clinical value
 - Limitations and interferences
- Use of panels
- Detection systems
- Chromogens
- Antigen retrieval
- Immuno-therapeutics
- Immunofluorescence
- Automation

Staining /Demonstration methods

- Health and Safety
- Principles and Quality Control Issues/ Problems associated with method
- H & Es
- Special stains
 - Amyloid
 - Carbohydrates
 - Connective tissue
 - Infective agents
 - Epithelial, muscle filament, lymphoid, cell cycle and neuroendocrine markers

Staining and slide preparation

- Automated and Manual staining
- Tissue processing and embedding
- Health and Safety
- Principles and Quality Control Issues/ Problems associated with method

Sampling and processing techniques

- Fixation
- Prioritisation/triage
- Dissection/sampling
- Embedding
- Processing Methods
- Health and Safety

Laboratory equipment

- Tissue processors
- Embedding centres
- Microtomes
- Staining machines
- Immunostaining machines

Imaging / photography

- Macrophotos

- Microphotos
- Digital pathology, image capture and analysis

Candidates are expected to have an awareness of the following:

- Patient management
- Clinical interpretation
- Molecular diagnosis
- Electron microscopy
- Neuropathology
- Paediatric pathology

Awareness and developing practice

- Screening
- Cancer targets

RECOMMENDED TEXTBOOKS, JOURNALS AND WEBSITES

Candidates are encouraged to expand their knowledge and understanding on the subject through further reading. Up-to-date recommendations on textbooks, journals and websites can be found on the IBMS website.

CLINICAL CHEMISTRY INDICATIVE SYLLABUS

Candidates should be able to demonstrate in-depth knowledge, understanding and application of the following:

- Normal physiological and biochemical parameters, understanding the variation caused by age, pregnancy and disease states
- Appropriate introduction and use of analytical techniques and the clinical governance issues associated with them
- Analytical procedures and instrumentation
- Sources of peri-analytical variation and errors and procedures to manage them
- Test requesting and samples
- Interpretation of biochemical data
- Point-of-care testing, analysis and governance
- Quality management schemes
- Selection of appropriate technique or method for laboratory investigation
- Principles and practice of determining normal, abnormal and target values
- Understanding the disease processes

- The function of the major organs and systems:
 - Cardiovascular system
 - Endocrine system
 - Gastrointestinal tract
 - Kidney and renal function
 - Liver and hepatic function
 - Nervous system
 - Skeletal system

- Fluid and electrolyte disorder
- Endocrine disorders
- Carbohydrates including structure, function and regulation of carbohydrate metabolism, regulation of blood glucose and disorders of carbohydrate metabolism
- Lipids and Lipoproteins
- Proteins and amino acids

- Biochemical genetics including molecular and genetic basis of inherited diseases, clinical features and biochemical changes in genetic disorders and screening tests

- Biochemistry of malignancy including genetic, cellular and biochemical changes and biomarkers used in screening, diagnosis, prognosis and monitoring

- Toxicology
 - Therapeutic drug monitoring (TDM)
 - Identification of drugs of abuse
 - Chemical poisons
 - Occupational exposure to toxins

- Biochemistry of pregnancy including physiological and biochemical changes, reference ranges in pregnancy, screening and foetal monitoring
- Biochemistry of nutrition and micronutrients
- Paediatric biochemistry including reference ranges of neonates, infants and children, biochemical effects of prematurity, disorders affecting children and the newborn
- Biochemistry of the elderly including physiological and biochemical changes, reference ranges and impaired function of major organs and systems

Awareness of areas of knowledge/practice related to clinical biochemistry

- Molecular techniques
- Normal ranges and predictive values of pathology tests used to support clinical biochemistry investigations

RECOMMENDED TEXTBOOKS, JOURNALS AND WEBSITES

Candidates are encouraged to expand their knowledge and understanding on the subject through further reading. Up-to-date recommendations on textbooks, journals and websites can be found on the IBMS website.

CYTOPATHOLOGY INDICATIVE SYLLABUS

General Cytopathology

An in-depth understanding of current knowledge and practice relating to:

- sampling techniques
- transport and storage of cytology specimens
- preparation and routine staining techniques
- cell morphology
- disease classification
- pathology of main body systems
- normal cytology and cytopathology of body systems
- use of immunohistochemistry
- interpretation of the cytological diagnosis in clinical management of the patient
- role of multidisciplinary teams
- quality management systems.
- awareness of research and developing practice
- new diagnostic technologies

Cervical Cytology

An in-depth understanding of current knowledge and practice relating to:

- anatomy and physiology of the female genital tract
- purpose, aims and organisation of the NHS cervical screening programme
- sampling and preparation techniques
- morphology
- disease classification
- pathology of the female genital tract
- role of quality assurance.
- role of MDTs in the diagnosis and management of cervical disease
- application of IT systems in cervical cytology
- quality management systems and multidisciplinary teams
- new screening technologies
- transport and storage of liquid-based cytology samples.
- accreditation standards and legislation relevant to cervical cytology

Awareness of research and developing practice

- Molecular technologies
- Vaccination

RECOMMENDED TEXTBOOKS, JOURNALS AND WEBSITES

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HAEMATOLOGY INDICATIVE SYLLABUS

A complete and thorough understanding of general haematology including:

- methodologies used in routine and specialist biomedical science laboratories
- primary investigations of blood and its components
- diagnosis of haematological malignancy
- diagnostic pathways and treatment options
- haematological results in health and disease
- current trends in the diagnosis, laboratory techniques, treatment and clinical practice, including BCSH guidelines.

Knowledge of the above must encompass the following areas:

- Red cell haematology
- White cell haematology
- Platelet haematology
- Blood coagulation
- Haemostasis and thrombosis
- Haemoglobinopathies, enzymopathies and red cell membrane defects
- Haematinics
- Anaemias
- Disease classification
- Patient management
- Clinical interpretation
- Image analysis and morphology
- Methodologies/technology (including limitations)

Areas of science related to haematology

Cross-over knowledge with other biomedical science disciplines, particularly genetics, transfusion science, immunology and clinical biochemistry, is expected, but not in depth. The successful candidate will demonstrate a basic knowledge of the importance of good liver, renal and gastrointestinal function to haematology.

Candidates may be expected to interpret standard routine biochemistry and microbiology results but are not expected to have an in-depth knowledge of these tests, only where they impact on haematology.

RECOMMENDED TEXTBOOKS, JOURNALS AND WEBSITES

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IMMUNOLOGY INDICATIVE SYLLABUS

An in depth understanding of current Immunology knowledge and practice relating to:

- Structure and function of the human immune system
- Manual and automated immunology techniques / technologies
- Application of IT systems in immunology
- Accreditation standards and legislation
- National and international standards/guidelines
- Analytical values, detection limits, method ranges, method interference
- Reference ranges (age/sex)
- Specificity/sensitivity criteria
- Recognition of error
- Reflex testing and request management

Awareness of research and developing practice

- Molecular genotyping and other emerging technologies
- Luminex / bead-based technology
- Biological therapies

Awareness of areas of knowledge / practice related to immunology

The basis of specific immunity

- Immunogens, antigens and epitopes
- Types and structures of antigens, antigen processing and presentation
- Immunoglobulins (structure, function and antigen binding)
- Immunogenetics (polymorphisms, generation of diversity)
- Major histocompatibility complex (structure, function and regulation)
- T and B cell receptors (structure, function, diversity and the nature of antigen binding)
- T- and B-lymphocytes (ontogeny, phenotype, sub-populations, effector functions, receptor/ligand interactions and cell activation)

Immunopathology with reference to:

- Disease classification
- Patient management
- Clinical interpretation

Immunochemistry

- Paraproteins
- Complement
- Complement deficiencies
- The acute phase response and inflammation

Autoimmunity

- Antinuclear and related antibodies
- Dermatological disease

- Endocrine disease
- Gastrointestinal disorders
- Liver disease
- Neurological disease
- Renal disease
- Rheumatological Diseases

Immunodeficiency

Causes, clinical presentation, treatment and outcomes of following disease groups:

- Primary immune deficiency
- Primary antibody deficiency
- Secondary immunodeficiency
- Cytokine deficiencies
- Complement deficiencies

Allergy and Hypersensitivity

- Mechanisms of allergic inflammation
- Pathophysiology of type I hypersensitivity reactions: asthma, rhinitis, atopic dermatitis, anaphylaxis
- Food intolerance syndromes
- Skin prick testing / in vitro testing in the investigation of allergic disease
- Immune complex mediated hypersensitivity
- Delayed-type hypersensitivity
- Allergy and Anti-IgE immunotherapy

RECOMMENDED TEXTBOOKS, JOURNALS AND WEBSITES

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LABORATORY LEADERSHIP AND MANAGEMENT INDICATIVE SYLLABUS

An in-depth understanding of current knowledge and practice relating to:

Leadership and Management

- Understanding of leadership and management styles and qualities
- Principles of laboratory budget management and procurement
- Effective short, medium and long-term planning
- Effective team building and staff management
- Role of human resources in relation to staffing and employment issues
- Purpose and application of local disciplinary policy
- Methods for monitoring and assessment of ongoing performance
- Change management

Training and Development

- Purpose and requirements of registration with the HCPC
- Significance of learning objectives and assessment within the appraisal process
- Significance and purpose of CPD and reflective practice
- Purpose of competency assessment and the methods used to achieve this

Health and Safety

- Purpose and methods of COSHH and risk assessments
- Methods of waste and hazardous material disposal and the implications of non-compliance
- Relevant health, safety and security legislation and its application in the laboratory
- Role and responsibilities of the laboratory health and safety officer
- Significance of organisation and departmental health and safety policies in respect of staff, patient and visitor well-being
- Role of the organisation's occupational health service

Specimens

- Legal regulations and implications relating to the collection of samples
- Range and type of equipment and procedures used in the preparation and storage of specimens
- Relevant legislation, guidelines and regulations relating to storage, retention, packing, labelling, disposal and transport of specimens and retention of specimen results and records

Result Interpretation

- Normal and abnormal findings and their significance in relation to investigations performed
- Methods of data interpretation and review
- National and international standards/guidelines
- Analytical values, detection limits, method ranges, method interference
- Reference ranges (age/gender)
- Recognition of error

Protocols and Procedures

- Development, implementation and interpretation of policies and protocols
- Records and results maintenance
- The implications of national, international and legal directives

Quality Management

- The purpose and application of quality control, assurance systems and laboratory accreditation systems
- The purpose, construction and application of a quality manual
- Role of the quality manager
- Role of audit in quality control and risk management
- Significance and implications of clinical governance
- Application of the *IBMS Good Professional Practice For Biomedical Scientists*
- Principles, processes and purpose of different audits
- Storage and archiving of data and implications relating to patient results

Quality Assurance

- IQC / IQA / EQA: the differences and usefulness of each
- Accreditation
- Management of errors, incidents and non-conformances
- Quality improvement

Awareness of knowledge/practice related to laboratory management

- Current government strategy for the health service workforce
- Purpose and construction of an organisation's mission statement, policies, objectives and values, and how these relate to departmental strategic planning
- Influence and importance of analysing external factors and conditions when developing an organisational or departmental strategy
- How to produce reports and recommendations to assist in further action in relation to pathology in health and disease
- Organisational risk management and risk reduction strategies

Awareness of research and developing practice

- Developments in delivering learning, including IT-based learning systems
- Developing use of reflective practice and competency assessment styles in staff development

RECOMMENDED TEXTBOOKS, JOURNALS AND WEBSITES

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MEDICAL MICROBIOLOGY INDICATIVE SYLLABUS

An in-depth understating of current knowledge and practice relating to:

- medically important bacteria, fungi, parasites and viruses
- mycology
- disease classification
- patient management
- clinical interpretation
- isolation and identification techniques
- non-cultural detection methods and molecular diagnosis
- epidemiology
- infection prevention and control
- microscopy (operation and application)
- antimicrobial susceptibility testing
- serological diagnosis of diseases
- disinfection and sterilisation
- awareness of research and developing practice including evolving and emerging techniques

Infections of the systems the body to include (as appropriate):

- common causes
- pathogenic mechanisms
- microscopy
- diagnostic methodologies and techniques
- treatment strategies
- national vaccination strategies
- antimicrobial resistance patterns
- use of non-culture detection
- screening programmes
- notification procedures
- appropriate specimens etc.

relating to the following systems of the body:

- Central nervous system
- Gastrointestinal
- Genital tract
- Respiratory tract (Lower and Upper)
- Skin, bone, joint and soft tissue
- Systemic infections
- Urinary tract

RECOMMENDED TEXTBOOKS, JOURNALS AND WEBSITES

Candidates are encouraged to expand their knowledge and understanding on the subject through further reading. Up-to-date recommendations on textbooks, journals and websites can be found on the IBMS website.

TRANSFUSION SCIENCE INDICATIVE SYLLABUS

An in-depth understanding of current knowledge and practice relating to:

Blood Group Serology

- Blood group systems, genes and antigens
- Antibody identification
- Antigen prevalence
- Clinical significance of antibodies
- HLA, HPA and neutrophil antigens / antibodies
- Red cell membrane structure and function
- Immunological basis of antibody-mediated red cell and platelet destruction
- investigation and treatment of red cell-related autoimmune diseases
- Aetiology and clinical features of conditions requiring transfusion support

Hospital Blood Bank Practice

- Manual and automated immunohaematology techniques / technologies
- Specifications for immunohaematology reagents
- Pre-transfusion patient testing and procedures
- Bone marrow and stem cell transplant
- Patient blood group anomalies
- Haemolytic disease of the fetus and newborn and antenatal testing and procedures
- Estimation and management of feto-maternal haemorrhage
- Use of anti-D immunoglobulin
- Cell free foetal DNA testing
- Molecular testing
- Transfusion therapy in the management of acute and chronic conditions
- Normal ranges and predictive value of pathology tests used to inform transfusion support
- Selection and issue of blood and blood components
- Antigen frequency/sourcing compatible blood
- Management of major haemorrhage
- Management of transfusion reactions
- Transport and storage of blood and blood components
- Concessionary release of blood and blood components
- Hospital blood stock management
- Application of IT systems within transfusion medicine

Blood Donation and Testing

- Donor Screening and Testing
- Supply and demand
- Ethics of donor selection motivation and care
- Blood component preparation
- Transfusion transmitted infections

Patient Blood Management

- Positive patient identification
- Patient consent
- Appropriate use of blood and blood components
- Multidisciplinary teams - Hospital Transfusion Committees
- Alternatives to allogeneic blood
- Blood conservation
- Potential blood substitutes
- Emergency patient blood management – planning for shortages/major incidents

Quality and Regulation

- Quality Management Systems
- BCSH guidelines and UK guidelines for transfusion
- Blood Safety and Quality Regulations
- Medicines Health Regulatory Authority (MHRA)
- UK Transfusion Laboratory Collaborative (UKTLC)
- SaBTO
- NICE
- UKAS
- Haemovigilance reporting, investigation and management of serious adverse reaction and events - Serious Hazards of Transfusion (SHOT)
- Methods and management of traceability
- Recall procedures
- Validation and change control
- Internal Quality Control
- External Quality Assurance Schemes

Research and Development

- Cellular therapy
- Monoclonal therapies
- Trials: e.g. convalescent plasma
- Genomics

RECOMMENDED TEXTBOOKS, JOURNALS AND WEBSITES

Candidates are encouraged to expand their knowledge and understanding on the subject through further reading. Up-to-date recommendations on textbooks, journals and websites can be found on the IBMS website.

VIROLOGY INDICATIVE SYLLABUS

An in depth understanding of current knowledge and practice relating to:

Virus families and disease groups including:

- bloodborne viruses
- respiratory infections including fastidious bacteria
- neurological disease
- gastroenteritis and enterically transmitted viruses
- viral exanthems and systemic illness
- sexually transmitted diseases including syphilis and chlamydial infections
- ocular disease
- infections in pregnancy (pre and post-delivery)
- infections in the immunocompromised
- diseases of childhood and the young
- emerging and spreading viruses, haemorrhagic fevers and travel related and exotic viruses
- viruses and cancer.

Laboratory diagnosis and diagnostic methods including:

- diagnostic methods and principles
- automation and manual methods
- quality assurance and quality control
- asymptomatic screening (antenatal, occupational health)
- national guidelines and SOPs
- accreditation standards and legislation relevant to diagnostic virology
- evaluation and introduction of new diagnostic methods, reagents and kits
- point-of-care testing.

Use of appropriate test methods and interpretation of results including:

- recognition of inappropriate and discrepant results
- use of antivirals and viral load monitoring
- recommendation of appropriate samples
- management of disease contacts and outbreaks
- infection control

Pre- and post-exposure prophylaxis and vaccination

Antiviral treatment and resistance

Awareness of research and developing practice including:

- newly discovered viruses
- novel diagnostic methods
- changing best practice.

RECOMMENDED TEXTBOOKS, JOURNALS AND WEBSITES

Candidates are encouraged to expand their knowledge and understanding on the subject through further reading. Up-to-date recommendations on textbooks, journals and websites can be found on the IBMS website.

Appendix C

Pro-forma for Feedback on Oral Presentation



HSD Pro-Forma for Oral Presentation

Name of Presenter	
Date	
Title of Presentation	
Audience¹	

The Presenter

	Strongly Disagree	Disagree	Agree	Strongly Agree
Delivered the material in a clear and structured manner				
Delivered the presentation at the appropriate pace				
Was knowledgeable about the topic and any related issues				
Maintained my interest during the entire presentation				
Engaged with the audience				
Answered questions effectively				

The Presentation

	Strongly Disagree	Disagree	Agree	Strongly Agree
Was accurate				
Was informative				
The content was at the appropriate level for the audience				
Used visual aids effectively				
Fulfilled the aims set out at the start by the presenter				

¹ There should be a brief description of the number of attendees and the mix of staff grades who were at the presentation. The names of the attendees do not need to be provided.

Feedback to Presenter - This could include feedback on the suitability of the content, the presentation skills of the presenter and any areas for improvement.

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Name and Job Title of Assessor	
Signature	
Date	

Reflection by the HSD Candidate - This should include reflection by the candidate on their view of the success (or otherwise) of the presentation, the comments made by those who provided and any actions they plan to take ahead of any future presentations.

A large, empty rectangular box with a thin black border, intended for the candidate to write their reflection on the presentation.

Appendix D

Portfolio Assessment

Indicators

HSD Portfolio Assessment Indicators

The portfolio of experiential learning is assessed against the following criteria.

Personal Professional Profile

The profile is of the appropriate length (500 words, +/- 10%)

It is clear from the profile the relevant professional experience that the candidate has had and their current roles and responsibilities

Case Studies and Managerial Report (Each must meet these criteria)

Neat, well laid out and are of appropriate length (1500 words, +/- 10%)

Consistently and correctly referenced in Harvard or Vancouver style

Illustrations, images and figures when used are relevant and of high quality

Clearly demonstrates / describes how much involvement the candidate had

As appropriate it demonstrates that the candidate has:

- systematically applied professional knowledge and understanding to determine action based on best-practice
- used self-direction to solve the problem(s) or issue(s)
- exercised personal autonomy in relation to their scope of practice but has if necessary liaised with others
- communicated findings to colleagues

Candidate has reflected on what went and what badly, what they learnt from their involvement and as appropriate how it will, or did, inform changes to their own, and if applicable, the wider laboratory practice

Essays (Each essay must meet these criteria)

Essay is 3000 words, +/- 10%

Essay is referenced in Vancouver or Harvard style

There is no evidence of plagiarism, and the similarity score is acceptable

There is clarity in the presentation (such as layout and the use of paragraphs) and writing (including grammar, nomenclature, punctuation, spelling)

As appropriate for the essay title it demonstrates:

- a comprehensive understanding of a specific area of biomedical science
- knowledge and understanding of current issues and developments
- the use of relevant materials / sources

Oral Presentation

The candidate has provided copies of the slides that were presented and their accompanying notes

The slides and notes are clear, accurate and informative

Feedback has been provided from at least two colleagues

The candidate has reflected on the success or otherwise of the presentation

Reflective Statement

The statement is of the appropriate length (2000 words, $\pm 10\%$)

The candidate has explained how they identified gaps in their knowledge, what action they took action to address these and the rationale behind their choice of action(s)

There is evidence from the statement that the candidate has undertaken a range of CPD activities relevant to the preparation of the HSD

The candidate has explained how their preparation for the HSD has contributed to their professional practice

General Overview

The portfolio is presented to a professional standard

Appendix E

Marking Guidelines for

Examinations



Higher Specialist Diploma marking guidelines for examinations

Mark %	Grade (Masters level)	Description
90-100	Distinction	An answer with a clear and appropriate structure, showing very detailed understanding and critical analysis of the issues. Using suitable evidence, both the scientific and professional aspects of the topic are explored in depth. Critical discussion is deep and detailed throughout. The answer may provide an unusually insightful or even novel conclusion. Answer fully focussed on discipline specific science, technical details and / or service delivery issues – as appropriate to the question. Candidate demonstrates depth and breadth of knowledge, showing an awareness of policy, usual practice and current and future trends in this topic across pathology. This would include reflection on their department’s practice and comparison with national and even international developments where appropriate.
80-89	Distinction	An answer with a clear and appropriate structure, showing detailed understanding and critical analysis of the issues. Using suitable evidence, both the scientific and professional aspects of the topic are explored in some depth. Attempt at critical discussion is evident, although some possible observations or insights missed or not followed through completely. Answer clearly focussed on discipline specific science, technical details and / or service delivery issues - as appropriate to the question. Candidate demonstrates good knowledge of policy, usual practice and current trends in this topic across pathology and is able to bring them into discussion and to make suitable use of reflection their own department’s practice where appropriate.
70-79	Distinction	An answer with a clear and appropriate structure, showing understanding and critical analysis of the issues. Using suitable evidence, both the scientific and professional aspects of the topic are explored. Clear attempt at critical discussion is evident, though in places may be limited in depth or detail. Some opportunities to provide interesting conclusions or further observations missed. Answer mainly focussed on discipline specific science, technical details and / or service delivery issues - as appropriate to the question, but some details missing. Candidate demonstrates awareness of policy, usual practice and current trends in this topic across pathology and is able to use them to make comparisons with their own department’s practice where appropriate.
60-69	Merit	An answer which is well structured and shows understanding and analysis of the issues. Both the scientific and professional aspects of the topic are explored, with some evidence but lacking depth in some points. Some attempt at critical discussion has been made. Conclusions or further observations provided, with

		some discussion, but limited in scope. Answer focussed on discipline specific science, technical details and / or service delivery issues - as appropriate to the question, but some details missing. Candidate demonstrates good awareness of policy, usual practice and current trends in this topic across pathology but omits some pertinent details. There is some discussion about their department's practice.
50-59	Pass	An answer which is well structured and shows some understanding and analysis of the issues. Both the scientific and professional aspects of the topic are explored but lacking in required depth. Some attempt at critical discussion has been made but to a limited extent. Some conclusions or further observations provided but lacks adequate discussion and limited in scope. Answer focussed on discipline specific science, technical details and / or service delivery issues - as appropriate to the question, but missing detail and some irrelevant points made. Candidate demonstrates satisfactory awareness of policy, usual practice and current trends in this topic across pathology but omits some pertinent details. There is limited discussion about their department's practice.
40-49	Pass	An answer which contains some of the main points is quite well structured and shows some limited understanding of the issues. An attempt is made to explore the topic, but several points of either the scientific or professional (or both) aspects are missed. Limited discussion provided, generally lacking in depth, detail and critical analysis. If conclusion is given, it is a summary of the main text, rather than drawing insights or observations from the information provided in the answer. Answer generally addresses the question, but either omits key details, or strays in focus to provide irrelevant points. Candidates demonstrate some knowledge awareness of policy and trends in this topic across pathology but tends to stay focussed on their own department's practice, with limited awareness of how this compares with that of other laboratories.
35-39	Fail	An answer which contains some of the main points but misses out some important ones. It is not well structured and lacks depth and detail. A limited attempt is made to address the topic, but many obvious relevant points are missed with respect to the scientific and/or the professional aspects. Answer not focussed appropriately on the question through lack of detail or through providing irrelevant information. The meaning of the question has not been fully understood. Candidate does not show any knowledge of policies or usual practice or trends in this area.
30-35	Fail	An answer which does include a few points relevant to the question but lacks detail and is not focussed on the question. It is not well structured and most pertinent points have been missed out. The meaning of the question has not been understood at all. Any mention of policies or usual practice or trends in this area is incorrect or irrelevant and/ or shows poor knowledge and understanding.
20-29	Fail	An answer which does not address the question. Several relevant points may be made in passing, but there is no structure or detail and very little which pertains to the focus of the question. Candidate does not show any knowledge of policies or usual practice or trends in this area.
10-19	Fail	An answer which does not address the question. One or two relevant points may be made in passing, but there is no structure or detail and very little which pertains to the focus of the question. Candidate does not show any knowledge of policies or usual practice or trends in this area.
0-9	Fail	An answer which does not seriously address the question.