GUIDANCE TO CANDIDATES AND TRAINERS

for

ADVANCED SPECIALIST DIPLOMA

in

NON-GYNAECOLOGICAL CYTOLOGY

Institute of Biomedical Science
12 Coldbath Square
London
EC1R 5HL

Tel: 020 7713 0214 ext 142
Email: examinations@ibms.org

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For the purposes of this diploma, this qualification covers:

- Urine
- Respiratory exfoliative specimens
- Serous cavity effusions (including peritoneal washings)

For the avoidance of doubt the qualification does not cover breast cyst fluid and nipple discharges or fine needle aspiration cytology. In addition the respiratory exfoliative specimens do not include EBUS or FNA cytology.

ADVANCED SPECIALIST DIPLOMA in NON-GYNAECOLOGICAL CYTOLOGY

INTRODUCTION

The Institute's Advanced Specialist Diploma (ASD) in Non-Gynaecological Cytology provides evidence of the attainment of both the necessary scientific and clinical knowledge underpinning the assessment of non-gynaecological cytology specimens. Possession of this diploma will enable you to apply for an appropriate post.

The Institute's professional qualification structure (below) indicates the position of an Advanced Specialist Diploma.

Qualification	Membership Class	Additional qualifications
Advanced Specialist Diploma	Fellow	
⇧ Higher Specialist Diploma	Member	Diplomas of Expert Practice Certificates of Expert Practice
⇧ Specialist Diploma	Licentiate	
⇧ Certificate of Competence		
⇧ BSc (Hons) Biomedical Science		

AIMS

1. To develop the professional knowledge and skills of a candidate beyond a Higher Specialist Diploma (HSD) to the highest level of professional practice

2. To enable successful candidates to undertake a role that involves the acquisition, preparation, assessment and reporting of selected non-gynaecological cytology specimens, including those where a clinically significant diagnosis is made

3. To enable successful candidates to offer expert professional advice on non-gynaecological cytology specimen reporting

4. To enable successful candidates to participate in training of biomedical scientists and specialist trainee medical staff in the reporting of normal and abnormal non-gynaecological cytology

LEARNING OUTCOMES

Individuals awarded the Advanced Specialist Diploma in Non-Gynaecological Cytology will be able to:

1. Demonstrate expert professional skills and advanced knowledge beyond those required of biomedical scientists working at the level of a Diploma of Expert Practice (DEP) in Non-Gynaecological Cytology

2. Demonstrate full understanding of the physiological and pathological processes associated with serous cavities, respiratory and urinary tract

3. Use highly specialised knowledge and skills to describe and report non-gynaecological cytology specimens received in the cytology laboratory.

4. Independently prepare, critically evaluate and interpret non-gynaecological cytology samples initiating ancillary tests and/or issuing reports as appropriate

5. Evaluate, reflect and comment on previous or current clinical/pathological findings as an integral part of case management

6. Demonstrate the ability to operate autonomously whilst recognising the limits of their own competence, seeking advice from consultant colleagues when needed

7. Engage in critical dialogue and work collaboratively with other healthcare professionals to provide a high quality service

8. Continue to develop their own area of practice by keeping up-to-date their professional knowledge and skills

9. Participate in, organize, present at and/or lead multidisciplinary team (MDT) meetings

10. Demonstrate the knowledge and skills to supervise and participate in the training of biomedical scientists and specialist trainee medical staff in non-gynaecological cytology

ELIGIBILITY CRITERIA

The assessment and reporting of non-gynaecological cytology specimens constitutes an expert role for biomedical scientists with the requirement to undertake additional duties and responsibilities as part of their professional practice.

The following requirements MUST be achieved at the stage of application:

1. Fellow of the IBMS
2. Current HCPC Registration
3. Must hold the IBMS Diploma in Expert practice in Non-Gynaecological Cytology and /or the Diploma of Interpretative and Diagnostic Cytology.
4. More than seven years post registration experience in non-gynaecological cytology with substantial experience (at least four years) in pre-reporting for consultant pathologists and reporting negative samples

5. More than three years at a senior level involvement with preparation, quality management, EQA and IQC of the relevant categories of non -gynaecological specimens.
6. A single named consultant pathologist trainer who has overall responsibility for mentoring, guiding and monitoring the progress of the Biomedical Scientist

CONSULTANT PATHOLOGIST SUPERVISOR

All biomedical scientists undertaking training for the Advanced Specialist Diploma (ASD) in Non-Gynaecological Cytology must have a named consultant pathologist supervisor to oversee and have responsibility for the training process. This is essential to ensure the biomedical scientist in training has the necessary support, exposure to material and training to enable the acquisition of the advanced skills and knowledge to obtain the diploma and fulfill subsequent professional roles.

The named consultant pathologist supervisor must be registered on the specialist register with the GMC, currently reporting non-gynaecological cytology (as defined previously), meet the minimum RCPath CPD requirements and participate in any appropriate National EQA Scheme if available. The consultant pathologist supervisor must:

1. Guide and direct the training process

2. Regularly review progress during the training period. These reviews must be documented and include the discussion of results, cytological/histological correlation and case reviews using 'double-headed' microscopy if available and appropriate

3. Set agreed learning plans with the biomedical scientist

4. Be able to arrange for the biomedical scientist to obtain training in all the required areas of healthcare professional practice

5. Inspect the portfolio prior to submission to the Institute to ensure it meets the requirements specified in the guidance to candidates

6. Sign the declaration in Appendix A to confirm that the candidate has undergone training, and in his/her opinion is competent and ready to sit the examination

The consultant pathologist supervisor and the biomedical scientist in training must comply with all relevant IBMS and RCPath guidelines and standards.

LABORATORY REQUIREMENTS

The laboratory where the training is undertaken must be a CPA (Clinical Pathology Accreditation (UK) Ltd) or UKAS (United Kingdom Accreditation Service) registered laboratory. The laboratory must also have Institute training approval. The laboratory manager must support the training of biomedical scientists in the reporting of non-gynaecological cytology specimens.

DELIVERY OF TRAINING

Although there is no training logbook for this diploma, training must be delivered in accordance with an agreed training programme that includes the following:

- The interpretation, diagnosis, classification and reporting of non-gynaecological cytology samples

- Histology as relevant to the appropriate non-gynaecological cytology specimens where available, including the types of specimens, their handling and reporting criteria and classifications

- Patient management in respect to the appropriate disease processes including treatment options, follow-up protocols, MDT meetings, quality assurance, clinical audit and professional guidance

- Involvement/exposure of the biomedical scientist in other aspects of diagnostic procedures including clinical assessment, imaging, sample collection and histopathology

Completion of training is evidenced by the compilation and submission of a portfolio that contains evidence of regular assessments of competence in reporting the specimen types covered by this qualification by the named consultant pathologist supervisor.

If the repertoire of the training laboratory is not comprehensive enough to allow exposure to the full spectrum of relevant pathology needed for this qualification, it is considered good practice for biomedical scientists to visit other laboratories to gain the necessary expertise. This may require the delivery of training by individuals other than the named consultant pathologist supervisor, who must also conduct appropriate assessments of competence as described below.

The aim of the overall programme of training for biomedical scientists in the reporting of non-gynaecological cytology samples is to develop expert knowledge and advanced skills and attitudes in non-gynaecological cytology.

ONGOING ASSESSMENT OF COMPETENCE

In-house assessments of competence must be an interactive continuous process between the supervising pathologist and the biomedical scientist that must include the use of formal discussion of results, case-based discussion or equivalent processes. Regular reviews of progress are essential for the setting of agreed learning plans and as part of an ongoing personal development plan.

PORTFOLIO OF EVIDENCE

The compilation of a portfolio is a means of clearly organising and recording achievements and should demonstrate a range of competencies, skills, experience and

an overall reflective approach to learning. This must also include a record of any formal assessments carried out during the training period.

It must be submitted to the Institute, as part of the evidence for completion of training in non- gynaecological cytology prior to the examination. In addition to the common requirements in the generic guidance, the portfolio must contain:

- a prospectively constructed shadow reporting log of at least 500 cases, using the template below. This must include at least 100 reports of each type (urine, respiratory, serious effusions) ensuring that an outcome (a clinical/ final diagnosis) is recorded for at least 50% of these cases. The log should reflect the normal workload of the candidate and include a mixture of negative, positive and equivocal results.

The log must be numbered and submitted as a word processed document.

Log Number	Date	Specimen/ Sample Number	Observations and Candidate Report Recommendations	Ancillary Tests Recommended By Candidate	Observations and Final Report	Ancillary Tests Requested	Discrepant Cases	Discussion Notes	Final Diagnosis/ Outcome
1									
2									

- **ten** different case studies that reflect the case-mix within non-cervical cytology encountered by the biomedical scientist during the training period. The significance of cytology within the context of the 'patient pathway' from initial clinical presentation through medical management and treatment should provide the framework for each case.

  Details about possible differential diagnoses should be included to show understanding of the clinical/pathological context of the cases. These cases must correlate clinical details and/or patient imaging with subsequent histological and cytological diagnosis. These case studies **must include at least one** from each of the following categories:

- urine malignancy
- lung malignancy
- abnormal serous cavity effusion

- a record of training programmes, CPD or courses attended in non-gynaecological cytology

- a record of multidisciplinary team meetings (MDT) attended. (These should show communication with relevant clinicians and pro-active involvement in MDTs such as the contribution made to the management plan of the patient)

- details of any seconded experience

- details of in-house assessments and audits of personal practice against local or nationally published performance targets (one clinical and one service audit as a minimum)

- reflection on the whole learning process

- evidence of regular case review of at least 50 of the cases from the shadow reporting log, using the template below, with the supervising pathologist(s) that should demonstrate critical evaluation of the assessment and reporting of non-gynaecological cytology specimens by the biomedical scientist.

  The case review will also show evidence of knowledge and understanding of the patient's diagnosis and the possible impact on their subsequent treatment and outcome. This should form part of the evidence for continuing audit of the biomedical scientist in training

Case Number	Date	Specimen/ Slide Number	Original Report Recommended	Final Report Recommendations	Discrepant cases	Discussion Notes	Final Diagnosis/ Outcome

Evidence in the portfolio should be accompanied by a written commentary indicating how and why particular evidence was included and its relationship to the training objectives. It may include digital microscopy images, flow diagrams and hand-outs from power-point presentations to accompany the written work.

CASE STUDIES

The **ten** different case studies reports will be appropriate to the complexity of the specimen and be at least 1000 ± 10% words in length. They should be prepared using aspects of the following format to bring a whole case history together supplemented by comments on options available to clinicians as the case progresses. Each case study must also include:

- clinical history
- correlation of any clinical/imaging/ findings with the cytological specimen
- correlation of the relevance of the macroscopic and microscopic descriptions, and ancillary tests to final diagnosis and subsequent patient management
- details of any interpretive report issued
- details of possible differential diagnoses (if applicable) where they show a critical understanding of the clinical/pathological context
- the timeline from surgery/reception to the final MDT outcome
- knowledge and reasoned argument of sufficient depth and clarity
- adequate and appropriate references to key sources of information

The following sections provide further guideline to content of a case study:

PRE-ANALYSIS

Details of any symptoms and additional relevant clinical history should be used to introduce the case. The medical history should be critically discussed.

ANALYSIS

The way the sample is handled when it arrives in the cytopathology laboratory

should be discussed. Previous and current diagnostic investigations should be reviewed and discussed, together with the results of these procedures.

POST ANALYSIS

The outcomes for the patient should be discussed to include treatment, and the relationship of that treatment to the final diagnosis. This should include a record of any MDT discussions and the outcomes.

COMPLETION OF TRAINING

Once the named consultant pathologist supervisor is satisfied that the training is complete, the candidate may contact the Institute for an examination application form. The candidate will be notified when the application has been accepted and will then be required to submit a completed portfolio by a specified date. Progression to the examination for the Advanced Specialist Diploma in Non-Gynaecological Cytology is dependent upon the satisfactory assessment of the portfolio. Success in the examination will be recognised by the awarding of the Advanced Specialist Diploma in Non-Gynaecological Cytology.

END POINT ASSESMENT

1. Successful portfolio assessment
2. Written examination including case-based scenarios
3. Practical microscopy examination

ASSESSMENT OF THE PORTFOLIO

Once submitted, the portfolio will be independently assessed by two members of the Conjoint Examination Board, using the following categories.

- Case log

- Case review
- Case studies
- Formative assessments
- Audit
- Tutorials and training sessions
- General overview of portfolio

There are a total of 28 standards across the above categories that must be met in order to achieve a pass and progress to the end point assessment.

Note: All evidence submitted as part of the portfolio must conform to the Data Protection Act (2003).

All evidence which is submitted as part of the portfolio that may identify an individual must be made anonymous, but in such a way that allows identification to be re-established subsequently if appropriate.

- The use of a marker pen to blank out this information is often insufficient and its use is discouraged
- The use of correction fluid or tape is not permitted

Portfolios that contain evidence that allows identification of a patient will be automatically referred and may not be resubmitted until the following year

ASSESSMENT STANDARDS

The portfolios will be assessed using the following standards:

Case log

1. The log is clearly laid out and accessible and in the prescribed format.

2. The log must reflect a variety of cases in order to assess candidates' scope of professional practice

3. The mix of cases is in accordance with the qualification being studied for

Case review

4. There is evidence that regular case reviews have taken place

5. The reviews are clearly laid out, accessible and in the prescribed format

6. There is a clear indication of the purpose of case review and that this has been undertaken by the candidate and the consultant pathologist supervisor

7. It is clear from the evidence presented that the candidate has an understanding of the impact of laboratory tests on diagnosis, treatment, monitoring and prognosis of patients

8. The reviews show clearly that points of interest have been used as a positive learning experience

9. Evidence of MDT discussion of cases reported by the biomedical scientist in training together with the minutes and outcomes included. Attendance at MDTs must be regular enough to ensure appropriate discussions take place and during training will require the biomedical scientist to attend at least six per year meetings, where relevant cytology cases reported by them are discussed.

It is strongly recommended that the evidence of these meetings should cover the three areas being assessed within the qualification. Candidates who are unable to provide evidence for one of these areas must provide an explanation.

Case Studies

10. Studies are neat, well laid out and of appropriate length including timeframe from sample taking to final MDT outcome

11. Details of any previous medical history, clinical presentation, including correlation with the findings of any other investigations performed, should be included in each study

12. Where appropriate, differential diagnoses should be discussed and the reasons for the final diagnosis included

13. Details of appropriate ancillary tests, management, treatment and follow-up are presented in each case study

14. Illustrations or images when used, are relevant and of high quality

15. The case mix, should include at least one from each category and must reflect the defined categories for this qualification as encountered by the biomedical scientist during the training period

Formative Assessments

16. It must be clear from the evidence presented that systematic and periodic review of the candidate's performance throughout the training period has been undertaken by the consultant pathologist supervisor

17. It must be evident from the details presented how the candidate's practice has evolved over the course of the training period by the inclusion of incident logs and competence assessments

Audit

18. There is evidence that the candidate understands the principles of quality assurance and audit appropriate to clinical practice and patient outcomes within non-gynaecological cytology

19. It is clear from the evidence presented that the candidate has gathered data relevant to his or her own practice

20. There is evidence of critical evaluation and implementation of audit outcomes where appropriate

Tutorials and training sessions

21. A record of training programmes, short courses, tutorials and in-house training sessions attended or delivered by the candidate has been included

22. Examples are accompanied by evidence of reflection on the learning outcomes

General overview

23. The portfolio is neat and tidy

24. There is a useful and accurate index

25. Sections are easily found and correctly labelled

26. The portfolio is written in English prose with the correct use of grammar and punctuation

27. There is no evidence of plagiarism. If evidence of plagiarism is found it may result in the rejection of the portfolio.

28. Evidence presented is high quality, relevant and shows appropriate reflection

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 written request, defer their first attempt at the examination until the following year.

Refer

On review the portfolio 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' (Unless governance issues are noted in which case the portfolio will be automatically marked as a 'fail') In these circumstances individuals will be notified by the Institute of the shortcomings and will be given a further four weeks to address these issues. The additional evidence must be submitted by the deadline stated by the Institute at which time it will be re-assessed. At this point the portfolio will be either be awarded a 'pass' or 'fail'.

If a candidate does not submit the additional evidence by the deadline stated by the Institute this will result in an automatic fail but 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. Feedback will be given to the candidates as appropriate to help identify areas of weakness.

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 up-to-date 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.

Written and Practical Microscopy Examinations

Candidates whose portfolio is judged to have met the necessary assessment standards will be able to proceed to the written and practical examinations.

Written Examination

The format of this paper is to cover the following areas:

- Morphology of the specimen types covered by this qualification
- Application of additional tests
- Quality assurance and audit
- Clinical applications of non-gynaecological cytology
- Patient pathways including diagnosis, management and training
- New developments

Please note that this is not an exhaustive list. Candidates will be expected to answer four out of six short-answer questions in 90 minutes.

Practical microscopy examination

There are two practical microscopy examinations which are set by the IBMS/RCPath Conjoint Board.

Short Cases

In this examination candidates will be expected to review 12 cases in 72 minutes. The slide(s) for each case will be rotated every six minutes and will not be returned to the candidate. For each case candidates are required to provide their diagnosis along with any confirmatory ancillary tests that should be undertake where this is appropriate.

Long Cases

In this examination candidates will be expected to review five cases in 100 minutes. The slide(s) for each case will be rotated every twenty minutes and will not be returned to the candidate. For each case the candidates answer should include:

- A clear morphological description
- Their diagnosis
- Clinical implications including an outline of the advice and recommendations that they would give for the patient pathway
- A description of any further investigations that should be undertaken should be included where appropriate

Candidates are expected to clearly identify each section of their answer.

Marking and Issuing of Results

All examination papers will be marked by at least two examiners, referring to a third or more, independent examiner(s) if appropriate. In order to pass a component of the examination, candidates will be required to achieve a minimum of 50% in each of the three examination components (the written examination and the two practical microscopy examinations). To pass the complete examination, all papers must be passed in a single sitting. Examination results will require ratification by the Institute's Conjoint Examination Board and will be sent to the candidates from the Institute no later than three weeks after the date of the examination.

Further attempts/Re-sits of written and practical examinations

Candidates who fail the examination will be provided with written feedback which, where possible, will include the identification of any areas of weakness.

After unsuccessful first and second attempts at written and practical examinations:

After failing the examination for a first or second time before attempting the examination for a second or third time a shadow reporting log must be submitted which should include a minimum of a further 250 cases with evidence supporting that the process of shadow reporting has been continued throughout the period between examination entries and has been inspected by the consultant pathologist supervisor prior to submission. The updated log must be submitted for assessment by the published portfolio submission deadline.

After unsuccessful third attempt at written and practical examinations:

After failing the examination for a third time before a fourth attempt candidates must submit a new portfolio, which must include a log of a minimum of 500 new cases that have been shadow reported since the third failure of the examination along with evidence of on-going training.

The portfolio and log must be submitted for assessment by the published portfolio submission deadline.

Please note: Candidates are only permitted to sit the examination a maximum of four times.

Appeals

Any candidate wishing to appeal against the outcome of the examination must contact the Head of Examinations stating the nature of the appeal. All appeals must be received, in writing, by the Institute within 40 days of the publication of results.

Mitigating circumstances

Any mitigating circumstances, which may affect examination performance or attendance, must be put in writing to the Institute, with the inclusion of any supporting

evidence, e.g. current doctor's certificate. Once written evidence is received the matter will be brought to the attention of the examination board for consideration. 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.

APPLICATION PROCESS

Application forms are available from the Institute's Office using the contact details below and may be requested by telephone or e-mail, or they may be downloaded from the Institute's web site. The completed application together with the correct fee must be returned to the Institute. Fees can be paid for through the provision of a personal cheque, credit or debit card payment or by a purchase order from your Hospital Trust. For information about fees, please refer to the Institute website or contact the Head of Examinations using the contact details below.

Incomplete, illegible or applications without fees will be returned for correction and resubmission before acceptance.

Confirmation of application

Once accepted, candidates will be sent a confirmation of candidacy and a reminder of the submission deadline for examination portfolios.

Enquiries

All enquiries relating to this Advanced Specialist Diploma must be addressed to:

Head of Examinations
Institute of Biomedical Science
12 Coldbath Square
London EC1R 5HL
Tel: 020 7713 0214 ext 142
E-mail: examinations@ibms.org

INDICATIVE READING LIST

This reading list has been compiled for those preparing for the IBMS Advanced Specialist Diploma in Non-Gynaecological Cytology. The reading list was updated when this version of the guidance was published in January 2016. It will be regularly reviewed, but if new editions of any texts have been published subsequently, please refer to these new editions.

Coleman W, Tsongalis G. (eds.) *Essential Concepts in Molecular Pathology*. Academic Press; 2010. ISBM-10: 0123744199

Dabbs DJ. *Diagnostic Immunohistochemistry: Theranostic and Genomic Applications.* 4th ed. Saunders; 2013. ISBN-10: 1455744611

Gray W, Kocjan G. *Diagnostic Cytopathology: Expert Consult: Online and Print.* 3rd ed. Churchill Livingstone; 2010. ISBN-10: 0702031542

Kocjan G, Gray W, Levine T, Kardum-Skelin I, Vielh P. *Diagnostic Cytopathology Essentials.* Churchill Livingstone; 2013. ISBN-10: 0702044504

Shambayati B. (ed.) *Fundamentals of Biomedical Science Series – Cytopathology*. OUP; 2011. ISBN-10: 019953392X

Sobin L, Gospodarowicz M, Wittekind C. (eds.) *TNM Classification of Malignant Tumours.* 7th edn. Wiley Blackwell; 2009. ISBN-10: 144332414

Journals

Acta Cytologica	British Medical Journal
British Journal of Obstetrics and Gynaecology	Cancer Cytopathology
Current Diagnostic Pathology	Cytopathology
Diagnostic Cytopathology	Journal of Clinical Pathology
Lancet	SCAN

Appendix A – Declaration

To be included as part of the portfolio:

Please print and complete this page.

I declare that …….. has satisfactorily completed a training programme and shadow reporting log, so meeting the requirements for entry, and is now ready to undertake the examination for the IBMS Advanced Specialist Diploma in Non-Gynaecological Cytology

Signed (consultant pathologist supervisor) ……..

Date ……