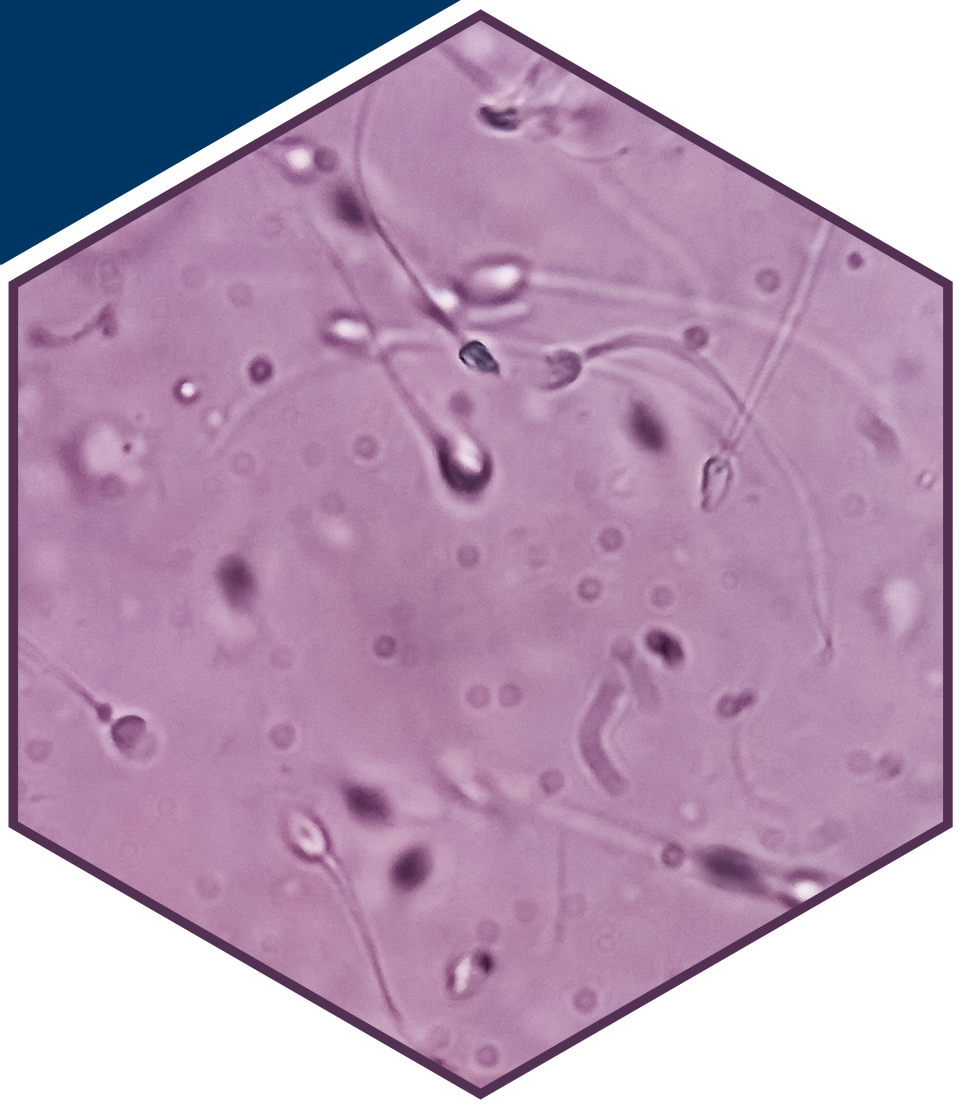
ANDROLOGY DIGITAL SPECIALIST PORTFOLIO MODULES



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Andrology Digital Specialist Portfolio Modules

- Quality - See separate document for LOs
- General Andrology Laboratory Procedures
- Fundamentals of Male Infertility
- Examination of Samples for Diagnostic Semen Analysis (DSA)
- Reporting Diagnostic Semen Analysis
- Post Vasectomy Semen Analysis (PVSA)
- Examination of Potential Retrograde Ejaculation Samples

Please note
All learning outcomes (LOs) are met through two pieces of evidence, Q&A as agreed with a training officer and an additional piece of work as selected by the candidate.

A statement of work and reflective statement on each module will be required which will include sign off by the trainer stating that the candidate works in accordance with laboratory procedures, the competence for which should be evidenced in-house and is not part of the portfolio submission.

Indicative Content outlines background knowledge that may be required to meet the LOs and/or knowledge and competences expected to be demonstrated across multiple modules. Knowledge of areas highlighted in the indicative content may be examined during the viva.

Module Title	General Andrology Laboratory Procedures
Module code	11047
Rationale/ Aims	Candidates will gain the knowledge and skills to use equipment needed in the andrology laboratory correctly. Candidates will gain the knowledge and skills to work safely within a laboratory environment and understand how to mitigate risks. Candidates will gain knowledge of the procedural risks involved in semen and urine analysis. Candidates will gain knowledge relating to andrology laboratory validation, verification and change control.
Learning outcomes	1. Discuss the difference between verification and validation in andrology laboratories and their application, and demonstrate how these are undertaken with an example from candidate's practice for each type. 2. Describe the use of bright field and phase contrast microscopy in andrology and demonstrate their set up and use. Identify issues that may arise and resolution. 3. Describe the types of pipettes used within andrology and discuss how can you ensure that the pipettes are correctly used and functioning as expected. 4. Describe the use of centrifugation in andrology and the importance of speed/deceleration settings. 5. Describe the use of acceptance testing and toxicity testing in andrology - to include equipment, reagents and consumables. 6. Discuss with examples the importance of temperature monitoring within the andrology laboratory. 7. Identify the health and safety risks associated with semen and urine analysis (include the consideration of reagents, consumables and samples). Discuss steps in place to mitigate these risks within your laboratory. 8. Discuss the benefits and considerations of on-site sample production facilities and what would need to be considered for this provision.
Indicative Content	Candidates require knowledge, understanding of: Validation and verification within andrology. The theory of application of air displacement and positive displacement pipettes and their associated calibration schedule. The principles behind determination of g force and demonstrate the ability to calculate g/rpm to carry out centrifugation at appropriate setting. Health and Safety risks within the andrology laboratory and to ensure that can work with the current Health and Safety guidelines to mitigate these risks (including unfixed samples).

	On-site sample production requirements to ensure an appropriate environment and ensuring patient dignity. The benefit of providing this service when considering reduction of uncertainty and adherence to pre-examination criteria. Candidates must be able to: Set up, use and trouble shoot the centrifuge including maintenance, safety, and calibration. Set up, use, and troubleshoot microscopes set up for bright field and phase contrast microscopy. Able to troubleshoot any potential issues that arise. Use air displacement and positive displacement pipettes with the appropriate levels of precision and accuracy and highlight if pipettes are not performing properly. Acceptance test equipment, reagents and consumables including sperm toxicity testing. Carry out daily checks required within the laboratory. Carry out routine disinfection processes with the laboratory and to deal with spillages. Retain and store andrology samples and documentation.

Module Title	Fundamentals of Male Infertility
Module code	11045
Rationale/ Aims	Candidates will gain knowledge regarding the incidence of male infertility alongside potential causes. Candidates will gain an understanding of contributing factors within the field of Reproductive Science with a focus on male infertility. Candidates will gain knowledge that will support the interpretation of results.
Learning outcomes	1. Discuss, using appropriate data, the incidence of infertility in the general population and specifically in men. 2. Explain the biological basis of androgen synthesis, spermatogenesis and why these are important in fertility. 3. Identify and discuss risk factors for male infertility. 4. Discuss with examples causes of male infertility, with an emphasis on azoospermia, severe reduction in sperm concentration, severe motility problems and characteristic morphology abnormalities. 5. Discuss the impact of acute illness on sperm quality. 6. Discuss how patients' sperm quality can be improved and when this might not be possible. 7. Discuss the impact of infertility on health and wellbeing. 8. Discuss the pre-examination questions required for appropriate interpretation of diagnostic semen analysis results
Indicative Content	Candidates will require knowledge and understanding of: The impact viscosity and liquefaction have on sperm quality and conception. Male physiology, endocrinology and the male reproductive system. Incidence, prevalence and worldwide variation of infertility and specifically male infertility. Risk factors for male based fertility issues, to include: Cancer and subsequent treatments Genetic factors Co-morbidities (including endocrine disorders Medication and lifestyle Iatrogenic factors Ejaculatory and sexual dysfunction Acute illnesses Causes of azoospermia/severe reduction in sperm numbers. Causes of reduced sperm quality and how sperm quality can be improved. Recreational and prescribed drug use and the impact these have on fertility and wellbeing. Psychological impact of infertility on the couple and the man.

Module Title	Examination of Samples for Diagnostic Semen Analysis (DSA)
Module code	11049
Rationale/ Aims	Candidates will gain the knowledge and skills to examine semen as part of infertility investigations. Candidates will gain understanding of sample requirements and the acceptance/rejection criteria. Candidates will be able to prepare semen samples for both macroscopic and microscopic examination and be able to undertake required parameters. Candidates will understand atypical findings in diagnostic semen analysis.
Learning outcomes	1. Discuss the importance of comprehensive instructions (patient information) for andrology patients to prevent sample rejection. Use examples from your practice and discuss any improvements that could be made. 2. Discuss how sample integrity is maintained for examination procedures including paperwork, labelling and checking procedures. Describe the pre-examination criteria that influence acceptance and rejection of samples. 3. Discuss preparation of samples for examination, including appropriate labelling and discuss hazards associated with handling these samples. 4. Demonstrate examination and identification of macroscopic aspects of DSA including volume, viscosity, liquefaction and pH. 5. Demonstrate microscopic examination of prepared slides to determine sperm motility (including agglutination and aggregation), concentration, morphology and vitality. Describe the requirements of the examinations required to ensure sample integrity is maintained, such as the use of heated stages. 6. Describe typical and atypical morphological appearance of spermatozoa in relation to guidelines used by the laboratory and discuss extended examination techniques associated with this. 7. Discuss the significance of incidental findings in semen analysis, such as haematospermia, non-sperm cells and bacteria. 8. Explain the process of assessing semen samples where no sperm appear to be present (suspected azoospermia). 9. Critically appraise the advanced tests/add-ons associated with DSA. 10. Discuss the implications of risk to patients if DSA is undertaken outside of recommended guidelines and critically review those relevant in semen analysis.

Indicative Content	Candidates require knowledge and understanding of: Clinical relevance of diagnostic semen analysis. Reagent and consumables acceptance testing including sperm toxicity testing. Acceptance and rejection of samples prior to examination and the implications of these decisions. Risks associated with assessing unfixed samples for examinations. Proficiency in equipment used for DSA including specialist phase-contrast microscopy, heated stages and positive displacement pipettes. The use of validated/verified examination procedures and an understanding of best practice guidelines, such as the World Health Organisation laboratory manual for the examination and processing of human semen. Assessments for macroscopic checks in semen analysis (volume, viscosity, liquefaction and pH). Relevant internal and external quality assurance procedures. Candidates must be able to undertake the following - Microscopically examine prepared slides to include: Assess grades of sperm motility in line with current guidelines. Detect and categorise agglutination and aggregation Preparing and assessing concentration of spermatozoa (including total sperm in the ejaculate) Preparation and assessment of sperm viability The morphological appearance of spermatozoa and considerations of advanced techniques associated with this, including Teratozoospermia Index (TZI). How to assess samples where no sperm are detected, and limitations associated with this. The relevance of detecting blood, non-sperm cells and bacteria in ejaculate. The use of different methods to undertake diagnostic semen analysis (all parameters) and the use of add-ons/advanced testing such as DNA fragmentation testing, anti-sperm antibodies, fructose, flow cytometry, CASA etc., Consideration between manual and automated methods. Implications of findings on patient pathways. Complete all the documentation in accordance with quality assurance and audit requirements.

Module Title	Reporting Diagnostic Semen Analysis (DSA)
Module code	11046
Rationale/ Aims	This module aims to reinforce candidates understanding of the infertility pathway and the implications of reporting. Candidates will gain the knowledge and skills to report diagnostic semen analysis results after examination. Candidates will understand the importance of using clinical information appropriately during the interpretation of semen analysis results and have a sound understanding of when escalation is necessary for further scientific or technical advice.
Learning outcomes	1. Discuss and explain the considerations of pre-examination, examination and post-examination aspects when reporting results. 2. Discuss clinical information required to interpret semen analysis results. 3. Demonstrate reporting of DSA and discuss the importance of clear, unambiguous reports to the service users. Include the use of reference ranges based on best practice guidelines. 4. Discuss when there may be a requirement to provide narrative within reports to support appropriate clinical interpretation or support management options. This should include when to consider a repeat. 5. Discuss circumstances when it might be required to escalate reports to an appropriate authority for clinical or scientific advice. Detail the possible outcome of the escalation process within your discussion. 6. Describe the reporting systems and pathways in your laboratory from sample request to sample reporting and discuss how you would troubleshoot issues. 7. Discuss the impact of results on the management of the patient and their partner if applicable. 8. Discuss the difference in referral pathways for different outcomes arising from diagnostic semen analysis that may be initiated from users of the service. 9. Describe the importance of multi-disciplinary teams for andrology patients and provide examples where this may be beneficial. 10. Discuss the risks associated with reporting of diagnostic semen analysis, limitations of the reference ranges (including sampling error and uncertainty) and define roles and responsibilities within the reporting pathway.
Indicative Content	Candidates require knowledge and understanding of: LIMS processes when reporting including adherence to authorities and responsibilities. The influence of pre-examination criteria, examination outcome and post examination processes on results and reflect these in the report.

	The importance of the health information provided by the patient or referring clinician when reporting results. The influence of specific health conditions and medications that impact fertility and sperm quality. Sampling error and measurement uncertainty when reporting from all aspects of the process. The potential for error within the examination process that may require caution to the users. Requirements for repeating semen analysis to prevent inappropriate clinical management and to comply with local, national or global guidance. The potential impact of the results on patient management and treatment, including the couple. Their scope of practice and when it may be necessary to escalate results for clinical review or defer to users of the service. The appropriate individuals for advanced advice (scientific and technical). Appropriate reporting comments, where applicable, on results to support the referring healthcare professional. Appropriate reference ranges.

Module Title	Post Vasectomy Semen Analysis (PVSA)
Module code	11044
Rationale/ Aims	Candidates will gain knowledge and the practical skills of examining and reporting post vasectomy semen samples. Candidates will gain understanding of sample requirements, the importance of macroscopic and microscopic examination and factors that influence the results of PVSA. Candidates will be able to report samples based on best practice guidelines and understand the implications of these reports on the patient pathway.
Learning outcomes	1. Explain what a vasectomy is, the clinical relevance and who can undertake this procedure. 2. Discuss patient pathways for a vasectomy, including the consent process, the relevance of adequate patient information and responsibilities within these pathways. 3. Discuss how sample integrity is maintained for examination procedures and the acceptance/rejection of samples based on best practice and risk. Discuss factors that may influence the outcome of PVSA. 4. Demonstrate macroscopic examinations of PVSA (such as volume, viscosity and liquefaction). Consider the implications associated with findings from these examinations. 5. Demonstrate microscopic examinations of prepared slide(s) to determine, for example, sperm motility and concentration. 6. Discuss methods of detection of spermatozoa including the relevance of a limit of detection. 7. Discuss the potential incidental findings and pitfalls for PVSA to include difficulties in microscopy, crystals, debris and non-sperm cells. 8. Demonstrate reporting findings from PVSA examinations and discuss the relevance of the results reported, including pre-examination processes. 9. Discuss the limitations of PVSA reporting including when escalation may be required. 10. Explain the difference between clearance and special clearance.
Indicative Content	Candidates require knowledge and understanding of: The principles of a vasectomy and the pathway (including patient consenting, counselling, operation and post procedure checks).

	The pre-examination criteria for PVSA (timeframe for first analysis, ejaculation number and sample requirements). The importance of validation, verification and acceptance of examination procedures and reagents/consumables. Sample acceptance and rejection criteria based on best practice guidelines. Assessment of semen for macroscopic checks in PVSA. Assessment of microscopic examination in PVSA, to include: • Sperm motility in line with current guidelines • Sperm concentration in line with current guidelines Candidates must also have knowledge and understanding of: The relevance of incidental findings such as non-sperm cells (round cells) crystals, debris and the difficulties of microscopy. Different methods to quantify sperm concentration (which may be dependent on findings). The morphological appearance of spermatozoa. The implications of sperm detection, motility and impact on clinical pathways relevant to PVSA. Reporting criteria, including an understanding of the relevance of measurement uncertainty. Escalation when outside an individual's scope of practice or in line with reporting procedures. Relevant internal and external quality assurance procedures. Implications of a failed vasectomy on the health services. Candidates must be able to: Complete all the documentation in accordance with quality assurance and audit requirements whilst considering the wider legal implications. Be proficient in equipment used in PVSA including specialist phase-contrast microscopy and positive displacement pipettes.

Module Title	Examination of Potential Retrograde Ejaculation Samples
Module code	11048
Rationale/ Aims	Candidates will gain the knowledge and skills to examine urine as part of investigations for retrograde ejaculation. Candidates will gain knowledge of sample acceptance, microscopic and macroscopic examination and understanding of the clinical importance of results. Candidates will be able to report retrograde samples.
Learning outcomes	1. Explain what retrograde ejaculation is and discuss the causes of this condition to include medication-induced, psychological factors, disorders/disease and surgery. 2. Discuss the pre-examination considerations for patients referred for retrograde ejaculation and the impact these may have on the results. 3. Discuss the acceptance/rejection criteria of retrograde samples. 4. Demonstrate examination and identification of macroscopic aspects of retrograde ejaculation samples (urinalysis) including appearance, volume and pH. 5. Demonstrate microscopic examination of samples to determine, for example, sperm motility and concentration. 6. Discuss difficulties associated with urinalysis. 7. Demonstrate reporting findings from retrograde ejaculate examinations. 8. Discuss the reporting considerations of retrograde ejaculation, including influencing factors (pre-examination, examination and post examination). Discuss the limitations of reporting retrograde samples and discuss when escalation may be required for clinical advice. 9. Discuss the clinical relevance of the results reported alongside the potential limitations. Explain the impact of the results on patient management. 10. Discuss the quality assurance of urinalysis specifically.
Indicative Content	Candidates require knowledge and understanding of: The causes, including medication, surgery, neurological and psychological aspects. Clinical relevance of retrograde ejaculation and potential management options available to the patient and a couple. Reagent and consumables acceptance testing specific for retrograde ejaculation. Actions to undertake if antegrade ejaculation is produced. Impact of findings technically (limitations and difficulties such as patient preparation) including limitations when using guidelines.

	Reporting of retrograde samples and limitations associated with these samples. The implications of findings on patient pathways and management options. Relevant internal and external quality assurance procedures. Understands the health and safety considerations with bodily fluids and how these can be mitigated. Candidates must be able to: Assess macroscopic checks in urinalysis (appearance, volume and pH). Microscopically examine urine on prepared slides to include: • Assessing and quantifying grades of motility in line with current guidelines • Preparing and assessing concentration of spermatozoa • Preparing and assessing morphology of spermatozoa (if applicable) • Preparation and assessment of sperm viability (if applicable) Effectively use equipment for urinalysis. Escalate or seek advice when appropriate.

About this version

Document title: IBMS Digital Specialist Portfolio Andrology Modules

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Version: Version 1

Date active: October 2024

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