

1 Purpose of Guidance

Guidance on the scope and direction of Andrology testing is required to:

Ensure that the assessment and accreditation process is applied fairly to all applicant laboratories.

Enable CPA officers to assess whether an Andrology assessor is required (*an andrologist or scientist who has documented CPD in reproductive medicine. It is desirable that assessors should also be a member of a suitable professional body that represents reproductive medicine/technologies*).

Enable applicant laboratories to understand what level of professional direction will be required to satisfy CPA standard B1

Enable applicant laboratories to understand how the requirements for CPA standard B1 should be met

Enable PAC members and CPA officers to make consistent decisions in relation to Andrology examinations carried out in applicant laboratories.

2 Background

Clinical and diagnostic Andrology services may be provided as part of a stand-alone Andrology laboratory, as part of an Assisted Conception Unit (ACU) or as part of the repertoire of any other pathology discipline. The Human Fertilisation & Embryology Authority (HFEA) is responsible for issuing licences to those laboratories offering assisted reproduction techniques and cryopreservation. In the terms of the Human Fertilisation & Embryology Act (1990) the licence is issued to the 'Person Responsible (PR)'. Many of these laboratories are part of clinical units and the 'PR' may be a clinician. The majority of semen analyses are carried out in pathology laboratories whose main focus of activity could be any of the other disciplines. These laboratories may offer a limited range of tests.

3 Definitions

In the absence of any currently available formal qualifications in Andrology the following groups of people are acceptable to give professional direction to the service.

Person Responsible is the person to whom HFEA issues a licence. The range of activity covered by the licence is clearly stated on the licence. This person may be a clinician, usually a consultant Gynaecologist.

Consultant Pathologist or Clinical Scientist specialising in reproductive medicine.

Consultant Pathologist In another discipline with an interest in Andrology. Such a person may have an active interest in Andrology or have delegated this service to a senior person who has been trained in Andrology & has documented evidence. Training may be by attendance at recognised courses (such as those run by the Association of Biomedical Andrologists – ABA) or at a specialist Andrology unit.

4 Andrology laboratories and assisted conception units

Provide a comprehensive range of Andrology testing and facilities for cryopreservation of spermatozoa and shall hold a licence to provide these services granted by Human Fertilisation & Embryology Authority (HFEA). Either a consultant pathologist or a clinical scientist of

equivalent status who specialises in reproductive medicine and/or andrology shall professionally direct these laboratories.

5 Andrology sections in other pathology disciplines

The service may provide a limited range of tests within another pathology discipline. The laboratories may be directed by a consultant of another pathology discipline with an active interest in Andrology (supported by CPD) or by a senior person who has been trained in Andrology (see 3 above).

6 Andrology testing that may be undertaken in the absence of a consultant specialising in reproductive medicine.

Sperm concentration
Sperm motility
Sperm morphology
Post vasectomy semen specimens
Seminal fructose
Sperm antibodies
Post coital test
Sperm viability
DNA fragmentation
Samples for retrograde ejaculation (both semen & urine)
Diagnostic sperm preparations (Not necessarily therapeutic & thus not come under the HFEA licence)

7 The following tests shall be referred to a centre holding an HFEA licence

CPA will provide general laboratory assessment but does not accredit the following procedures.

Cryopreservation and thawing gametes
Artificial insemination (partner) (AI)
Donor insemination (DI)
Intra Uterine Insemination (IUI)
In vitro fertilisation (IVF)
Intra-cytoplasmic sperm injection (ICSI)
Research on gametes or embryos
Any other tests or techniques that may be added to licensing requirements in the future

8 CPA assessment requirements

Those laboratories whose sole repertoire is reproductive medicine will require an assessor from a specialist Andrology unit

Assessor experience/qualifications for assessments

1. Laboratory offering Post Vasectomy service only:

Assessors could be from any discipline but they must have demonstrable knowledge of andrology & have that service within their own laboratory. (If the service includes motility/concentration evaluations in the event of a positive test, they may be considered as offering a full fertility service).

They must not act as an assessor if their own Andrology service has been referred.

2. Laboratory offering a full fertility service (may exclude or include post vas testing):

Ideally assessors should be andrologists. However, assessors from other disciplines would be acceptable but should have a background/track record of modern Andrology. Ideally they should be a member of one of the reproductive medicine professional bodies (ABA, ACE, BAS or BFS).

They must not act as an assessor if their own Andrology service has been referred.

If a full service is referred or cause concern, further inspections should be performed by a specialist andrologist.

3. Specialist Andrology Laboratory (may also be offering cryopreservation &/or assisted conception):

A specialist andrologist should be used.