



Leicester Fertility Centre

Diagnostic Andrology

&

Post Vasectomy Semen

Analysis

User guide

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Introduction

The Leicester Fertility Centre Assisted Conception Unit was established in 1988 and has provided the diagnostic andrology service since 2004.

The Leicester Fertility Centre is ISO 9001:2008 certified.

The International Standards Organisation (ISO) is an internationally recognised standard; as a mark of achievement in quality management, it demonstrates our commitment to quality and improvement of services. There are numerous benefits associated with a certified ISO quality management system, including improved service and quality and increased customer satisfaction levels.

The centre is licensed by the human Fertilisation and Embryology Authority (HFEA) and offers a complete range of licensed fertility treatments to include in vitro fertilisation (IVF), Intra Cytoplasmic Sperm Injection (ICSI), surgical retrieval of sperm, egg donation, egg sharing, donor insemination (DI) and intrauterine insemination (IUI). We have a large donor sperm bank providing a variety of choice for prospective parents and a large sperm-freezing programme for oncology patients.

The centre is located in purpose-designed, patient friendly facilities based on the ground floor of the Kensington Building at the Leicester Royal Infirmary and is part of the University Hospitals of Leicester NHS Trust. The ground floor location of the Centre allows for disabled access. As part of the University Hospitals of Leicester all necessary specialist back-up services can be provided.

Being a relatively small unit, we can offer a very personal treatment service. Patients get to know us very well indeed and find us very approachable.

The following languages are spoken by members of staff:

English
Arabic
Hindi
Urdu
Gujarati
Greek

We can also offer information leaflets in other languages as requested.

The regional diagnostic andrology service is based at the Leicester Fertility Centre; a professional team able to offer service users immediate clinical advice is available five days a week. Both NHS and private patients are treated.

The diagnostic andrology service offers preliminary diagnostic semen analysis investigations for the investigation of male fertility. Upon request the centre can also carry out tests for anti-sperm antibodies and vitality staining.

Referrals are received from Consultants within UHL and for General Practitioners from the Leicester and Leicestershire area for the following patients:

- Infertility (NHS and Private patients)
- Vasectomy reversals (NHS and Private patients)

- Retrograde analysis
- Oncology (NHS patients)

The centre provides a post vasectomy semen analysis service (PVSA) for organisations with whom it has a PVSA service level agreement. Listed below.

BPAS

Charnwood medical group

Dr Pulman (Long Lane Surgery)

Latham House

LLR Provider Company Ltd

North East Community Health Ltd

SPIRE Hospitals Leicester

UHL- Urology CMG UHL (including procedures carried out at Nuffield on behalf of UHL)

All samples should be produced and collected by the patient according to Leicester Fertility Centre protocol and Instructions for Patients, Doc 140 and Doc 829 and Doc 833.

The laboratory has approx. 1600 appointments per annum to cover the annual workload of routine diagnostic semen analysis and post-vasectomy samples. At present the ratio of diagnostic semen analysis to post vasectomy patients is undetermined but this will be monitored and feedback given in future versions of this handbook.

This guide includes pre-analytical process – analytical process – Post analytical process – Evaluation and QA.

Opening times

The andrology laboratory is open Monday to Friday 9-12 noon (except Bank Holidays). Appointments for semen analyses are available via the GP Choose and Book system which has replaced the drop off system.

Alternatively appointments for delivering samples can be made by calling the Leicester Fertility Centre on **0116 2585071**.

Out of hours cover is only provided for urgent sperm banking referrals

Contacting us

Our postal address is:

Leicester Fertility Centre

Ground Floor

Kensington Building

Leicester Royal Infirmary, Infirmary Square,

Leicester LE1 5WW

Tel 0116 2585071 or 0116 2585922 Fax 0116 2587688

Email: enquiries@leicesterfertilitycentre.org.uk

Patients with Special Needs

Please let us know if you have any special care needs. We endeavour to provide the best care possible in an environment suited to your needs. We can normally arrange most services quite quickly to ensure your experience is a positive one.

If English is not your first language and you feel you would benefit from an interpreter, this can be offered by prior arrangement. We can also offer information leaflets in other languages as requested.

Advisory service and Results

Please note we are unable to provide patients with results, these will be issued by the referring clinician. Results will be available on iLab or within 5 working days if a paper copy is issued. Clinical advice concerning a semen analysis can be given to clinicians between 9am and 3.00pm by contacting the Centre.

The laboratory staff may be able to answer your question. If they are unable to help they will pass it on to a member of the Fertility Centre medical team.

Specimen collection requirements

To produce a sample, patients must obtain the following from their requesting clinician:

- Wide mouthed sterile sample pot with a screw top lid (not a universal) provided by UHL Trust and be labelled with patients details
- Leak proof sample bag
- Request form with patient details, test required, clinical details and requesting physician
- Current sample production instructions (Diagnostic S/A Doc 140) and (PVSA Doc 829 & 833) These are available on our website: www.leicesterfertilitycentre.org.uk
- Samples must be labelled with a minimum of three unique identifiers, including patient first name, surname and date of birth.

Sample production

Samples should be produced at home and should be collected by dry masturbation only directly into the container provided. Lubrication should not be used. For diagnostic semen analysis and PVSA special clearance samples should reach the Laboratory within 1 hour of production, as close to body temperature as possible e.g. by placing in a pocket close to the body. For routine PVSA samples these may be accepted within 4 hours of production.

On Site Production:

If a patient wishes to produce a sample on site at the Leicester Fertility Centre, patients must ring the LFC reception and book the room.

Production with Silastic Condom:

If patient needs to produce a sample via intercourse then silastic non-toxic condoms can be purchased directly from the Leicester Fertility Centre reception. Condoms must be secured using the tie provided and placed into a labelled sample pot.

Specimen reception

On arrival at the Leicester Fertility Centre, patients will be asked to confirm that their name and date of birth is written on the sample pot.

The patient or their representative must complete a sample receipt form (Doc 144). Information requested will include:

- Name and Date of Birth
- GP name and address
- Number of previous samples
- Number of days of sexual abstinence
- If the sample was complete
- Method of production
- Reason for analysis
- If the patient has ever had HIV, Hepatitis B, Hepatitis C or Herpes virus
- Any recent travel to Zika affected countries
- Any medication or supplements taken within the last 3 months
- Whether they smoke or drink, and the quantities
- Date and time produced
- Time received

Acceptance criteria

Samples will only be tested if the acceptance criteria are met.

If a problem with the sample is noticed by the reception staff, the patient will be issued with a new sample pot, set of instructions, and asked to repeat the sample.

Samples will not be tested if;

- No referral form
- Sample is unlabelled
- Sample has leaked
- Less than three patient identifiers on the sample pot or request form. First name, surname and date of birth.
- Samples greater in excess of 1 hour old – dependant on assay request (>4 hours for initial PVSA)
- Samples not produced by masturbation (unless silastic condom is used)

If the sample is not tested, it will be given a unique laboratory accession number (LAN) and registered on the iLab computer system, with the reason why it was not accepted or tested. This goes back to the requestor who should ensure the patient repeats the sample.

Sample Analysis

Analysis involves the following steps:

- Measuring semen volume.
- Measuring semen pH.
- Assessing semen viscosity.
- Preparing a wet preparation for assessing microscopic appearance, sperm motility and sperm morphology.
- Preparing a stained slide for further morphology assessment
- Making a 1:20 dilution for assessing sperm concentration
- Assessing sperm concentration.
- Assessing sperm vitality (if required)
- Performing the mixed antiglobulin reaction (MAR) test (if required).

Results interpretation

Nomenclature	Definition
Normozoospermia	All parameters are in normal range
Asthenozoospermia	Total Motility 40% (38-42) lower reference limit Progressive Motility 32% (31-34) lower reference limit
Oligozoospermia	Sperm concentration $15 \times 10^6/\text{ml}$ (12-16) lower reference limit
Teratozoospermia	Normal forms less than 15%
Olig-asthen-teratozoospermia	Signifies a disturbance in all 3 variables Combinations of only 2 prefixes may also be used
Azoospermia	No sperm seen in the ejaculate
Aspermia	No ejaculate
Cryptozoospermia	No sperm seen in initial sample, but some sperm seen in the centrifuged pellet
Globozoospermia	Sperm heads without any acrosome

Reference values (World Health Organisation, 2010)

Parameter	Lower reference limit
Semen volume (ml)	1.5 (1.4-1.7)
Total sperm number (10^6 per ejaculate)	39 (33-46)
Sperm concentration (10^6 per ml)	15 (12-16)
Total motility (PR+NP, %)	40 (38-42)
Progressive motility (PR, %)	32 (31-34)
Vitality (live sperm, %)	58 (55-63)
Other consensus threshold values	
pH	≥ 7.2
MAR test Anti-sperm antibodies (motile sperm with bound particles, %)	<50

PVSA Examination and Results

Samples are examined in accordance with the methods described within the 2016 best practice Laboratory guidelines for post vasectomy semen analysis: Association of Biomedical Andrologists, the British Andrology Society and the British Association of Urological Surgeons.

Special clearance cannot be provided if any motile sperm are observed and should only be given after assessment of two samples. The level for special clearance should be <100 000/mL non-motile sperm. However the final decision for clearance and advice regarding contraception will lie with the referring clinician. PVSA should take place a minimum of 18 weeks after surgery and after a minimum of 20 ejaculations.

The laboratory will routinely examine samples within 4 h of production if assessing for the presence of sperm. If non-motile sperm are observed, further samples must be examined within 1 h of production.

Assessment of a single sample is acceptable to confirm vasectomy success if all recommendations and laboratory methodology are met and no sperm are observed. Clearance can then be given.

The commissioners of this service are responsible both preoperatively and postoperatively for the counselling of patients and their partners regarding complications and the possibility of late re-canalisation after clearance.

Reference

2016 Laboratory guidelines for post vasectomy semen analysis: Association of Biomedical Andrologists, the British Andrology Society and the British Association of Urological Surgeons

PVSA samples showing presence of sperm require a second sample for analysis. This is organised by the referring clinician.

Special clearance is given to the patients by the referring clinician.

Repeat tests

If any sample parameters are abnormal (concentration, motility, morphology) a second repeat sample may be suggested. The patient should be requested to leave an appropriate time of sexual abstinence; the patient will also need a request form with this sample

If the patient has already had one abnormal result the patient can be referred to the Leicester Fertility Centre for NHS or self-funded treatment

Measurement of uncertainty

Any tests carried out within the laboratory are subject to a variety of factors that may influence the outcome of results. No measurement or test is perfect: imperfections or variability in the analytical processes give rise to measurement uncertainty.

To provide a measure of confidence in results produced by the laboratory it is necessary to identify all the factors that may interfere with the processes undertaken and assess their potential to influence uncertainty. Once identified, the factors that have capacity to cause significant variation must be reduced or controlled to an acceptable level, and a value for the uncertainty assigned where possible.

The process of generating a result can be broadly sub-divided into three key phases namely pre-examination, examination and post-examination. Sources of variation include operator and equipment.

Please contact for specific calculations associated with a result if required

Patient information leaflets

These are available on our website:

www.leicesterfertilitycentre.org.uk

Complaints

The Leicester Fertility Centre aim to ensure that patients are completely happy with the service offered and treatment received and that we maintain the highest standards of clinical and personal care.

We welcome both positive and negative comments, but if patients are dissatisfied with any aspect of care, they can speak to a member of staff, who will try to resolve the problem immediately.

Formal Complaints

- Formal complaints may be made verbally or in writing, including via e-mail.
- Letters of complaint addressed personally to clinicians, other hospital staff, wards or departments will be forwarded immediately to the PILS Team for acknowledgement and investigation