



Title:	Diagnostic Andrology and Post Vasectomy Semen Analysis User Guide and Handbook.		
Reference:	844	Version:	4
Active date:	10/05/2023	Pages:	Page 1 of 14
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1 INTRODUCTION

This Andrology User Guide describes the relevant information, policies and procedures of the Regional Diagnostic Andrology Service offered at the Leicester Fertility Centre. The Andrology Laboratory at University Hospitals of Leicester NHS Trust is located within the Leicester Fertility Centre / Assisted Conception Unit, on the ground floor of the Kensington Building at the Leicester Royal Infirmary. The laboratory provides semen analysis for referring Clinicians and Healthcare Practitioners from the Leicestershire and Rutland area.

Diagnostic Semen Analysis: A Diagnostic Semen Analysis may be the first investigation requested from a Healthcare Practitioner for individuals and couples having difficulty conceiving. The Andrology Laboratory assesses semen and sperm parameters to provide diagnostic information regarding a patient's sperm function and therefore potential causes of infertility.

Post Vasectomy Semen Analysis (PVSA): A PVSA is performed to confirm the absence of spermatozoa from semen (indicative of a successful vasectomy operation) and is the postoperative management of the patient (given as the limit of quantification for the assessment method employed). A vasectomy (male sterilisation) is a surgical procedure to cut or seal the vas deferens from the testicles that transport sperm to permanently prevent pregnancy. There are strict pre-examination criteria for the examination for a PVSA. The minimum time requirement between the operation and analysis is <u>18 weeks</u>, and the minimum number of emissions within this period is <u>20 ejaculates</u>. Samples should arrive at the laboratory within 1 hour of production.

Retrograde Ejaculation: Retrograde ejaculation is a rarer type of ejaculation problem. It happens when semen travels backwards into the bladder instead of through the urethra. The main symptoms of retrograde ejaculation include: (a) producing no semen, or only a small amount, during ejaculation, and (b) producing cloudy urine (because of the semen in it) when you first go to the toilet after having sex. The laboratory will analyse the urine of patients following ejaculation (the sensation of ejaculation) for the presence of sperm and their motility.

The laboratory operates an appointment only, clinic based service which analyses in excess of 1500 samples per annum. At present the ratio of Diagnostic Semen Analyses and Post Vasectomy Semen Analyses is 55:1 (based on in-house non verified activity data for 01/04/21–31/03/22). Patients will be provided; sample production instructions, a request/referral form from, wide-mouthed metal lidded specimen pot and clear plastic bag from their healthcare provider, or a 24-hour urine container for retrogrades. Patient will then be asked to follow the instructions to arrange an appointment to attend and 'drop-off' the sample at the Leicester Fertility Centre reception. All samples are to be produced off-site and delivered within 1 hour of production, however in exceptional circumstances samples may be produced on site if they are unable to deliver to the laboratory within the 1 hour time interval.

The Andrology Laboratory has fully trained and competent scientists who are proficient in performing a diagnostic semen analysis in line with World Health Organisation (WHO) and associated professional body guidance. PVSA samples are analysed in accordance with The Association of Biomedical Andrologists, British Andrology Society and British Society of Urological Surgeons 2016 Guidelines for Post Vasectomy





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Semen Analysis. The laboratory participates in the UK National External Quality Assurance (EQA) Services (UKNEQAS) for Reproductive Science for Andrology and performs and monitors Internal Quality Control (IQC). The Andrology Laboratory is accredited to ISO:9001:2015 and is looking to become accredited to ISO:15189:2012 or ISO:23162:2021.

This Diagnostic Andrology and Post Vasectomy Semen Analysis User Guide and Handbook has been produced to ensure that healthcare providers and users have a comprehensive understanding about the service provided. The Andrology Laboratory offers the above tests on both a National Health Service (NHS) and Private basis. Private patients should contact the Leicester Fertility Centre directly.

Post Vasectomy Semen Analysis (PVSA) services are only available for organisations with a **service level agreement**. The organisations are listed below:

- British Pregnancy Advisory Service (BPAS)
- Charnwood Medical Group
- Long Lane Surgery Dr Pulman
- Latham House Medical Practice
- Leicester, Leicestershire and Rutland (LLR)
 Provider Company Ltd
- North East Community Health Ltd
- SPIRE Hospitals Leicester
- University Hospitals of Leicester NHS Trust (UHL) - Urology CMG UHL (inclusive of Nuffield Hospital on behalf of UHL).

2 LOCATION AND OPENING HOURS

The Andrology Laboratory is located within the Leicester Fertility Centre, Leicester Royal Infirmary, Kensington Building (Ground Floor). The operational hours of the service are Monday – Wednesday 09:00 to 14:45 except for Bank Holidays. There is a telephone service and answer-machine in operation when the laboratory is closed. The telephone service and answer-machine telephone number is 0116 258 5922. This service can be used regarding appointments which need to be arranged, cancelled or changed.

3 CONTACT DETAILS

The Address is:
Andrology Laboratory
Leicester Fertility Centre / Assisted Conception Unit
Ground Floor,
Kensington Building
Leicester Royal Infirmary,
Infirmary Square,
Leicester
LE1 5WW

CONTACT	DETAILS	CONTACT DETAILS	
Appointment Booking	Reception – Leicester	Tel: 01162582522 Email: Andrology@uhl-tr.nhs.uk	
, appending	Fertility Centre	Email: LFCInfo@uhl-tr.nhs.uk	
General Enquiries	Andrology Laboratory -	Tel: 0116 258 5922	
·	Leicester Fertility Centre.	Email: Andrology@uhl-tr.nhs.uk	





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	Andrology Website	Website: https://www.leicesterfertilitycentre.org.uk/
		patients/andrology/
	Patient Information and	Tel: 08081 788337
	Liaison Service	Email pils.complaints.compliments@uhl-
Patient Compliments /	The Firs,	<u>tr.nhs.uk</u>
Complaints	C/O Glenfield Hospital,	
Complaints	Groby Road,	
	Leicester,	
	LE3 9QP	
	Laboratory Manager / Person Responsible	Contact via Andrology:
Emma Burrell		Tel: 0116 258 5922
		Email: Andrology@uhl-tr.nhs.uk
		Contact via Andrology:
Isla Ritchie	Quality Manager	Tel: 0116 258 5922
		Email: Andrology@uhl-tr.nhs.uk
		Contact via Andrology:
Amanda Derry	Andrologist	Tel: 0116 258 5922
		Email: Andrology@uhl-tr.nhs.uk

The Andrology Laboratory is under the direction and management of Emma Burrell (Laboratory Manager / HFEA Person Responsible). The Andrology Laboratory is staffed by a trained Andrologist (Amanda Derry) and support by trained/competent Clinical Scientists and Associate Laboratory Practitioners.

4 SERVICES PROVIDED

- Diagnostic Semen Analysis
- Post Vasectomy Semen Analysis
- Retrograde Ejaculation Analysis

5 REQUESTING AN ANALYSIS

The preferred method of requesting a semen analysis is by completing an appropriate referral form:

- (Microbiology Laboratory University Hospitals of Leicester Pathology Services).
- ICE Microbiology Laboratory Referral Form
- SPIRE Referral Form

Ensure referral/request forms contain the following information:

Type of Analysis Required:

This is the test type you wish to request. It must be chosen from the following set categories:

- Diagnostic Semen Analysis (SINF)
- Post Vasectomy Semen Analysis (PVSA)
- Retrograde Ejaculation Analysis





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Please clearly indicate which test type is required for the patient. If you require a retrograde analysis but also wish the laboratory to assess any semen that may be produced, please only select 'Retrograde Analysis' as the diagnostic semen analysis will automatically be performed if antegrade ejaculation occurs.

Referral Details

Male Patient Details: Full name, date of birth, address, contact number and NHS/Hospital number should be included for all referrals.

Referring Health Practitioner and GP Practice: This **MUST** be completed to enable results to be issued to the correct healthcare provider. Please provide the GP practice location code (if possible) to enable us to return the report to the correct requestor.

Other information:

- Infection control risk please indicate if there is a known infection risk. No further details are necessary.
- Clinical details this should be completed to give the laboratory an understanding of the issue and to ensure the correct referral has been undertaken. You may also wish to include reasons for repeat tests in this section.
- Add the date of the vasectomy if applicable. This is important for two reasons:
 - To ensure the appropriate time interval has been achieved to allow clearance (18 weeks and 20 ejaculates)
 - So that the laboratory can ascertain if the sample is within the appropriate time frame according to current guidelines.

The completed referral/request form should be given to the patient to bring with them to their appointments (which they will book following the 'Diagnostic Semen Analysis Instructions').

Please note there is NO facility to receive referrals by fax.

6 INSTRUCTIONS FOR PRODUCING A SEMEN SAMPLE

Instructions for the production of semen samples are detailed in the document entitled Andrology Semen Analysis Patient Instructions and Receipt Form: https://www.leicesterfertilitycentre.org.uk/patients/andrology/

These are available on our website:

https://www.leicesterfertilitycentre.org.uk/patients/andrology/

Patients should be advised to follow the instructions in this leaflet in order to optimise the semen sample that they produce, and to pre-arrange an appointment for sample 'drop-off' and document receipt completion.





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Patients should be provided with a suitable sample collection container (wide-mouthed metal lidded specimen pot) and plastic transportation bag.

6.1 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, as these do not contain spermicide. Condoms must be secured using the tie provided and placed into a labelled sample pot, leak proof sealable bag.

7 INSTRUCTIONS FOR TRANSPORTATION OF SEMEN SAMPLES

If the patient is producing the sample 'off-site' they should be instructed to not expose the sample to extremes of temperature, by carrying it in an inside pocket if possible. The patient should be instructed to deliver the sample to the Leicester Fertility Centre **WITHIN ONE HOUR** of production.

8 INSTRUCTIONS FOR PRODUCING A RETROGRADE EJACULATION SAMPLES

Instructions for the production of samples for Retrograde Ejaculation are detailed in the document entitled Andrology Retrograde Ejaculation Patient Instructions and Receipt Form: https://www.leicesterfertilitycentre.org.uk/patients/andrology/

Retrograde ejaculation can be a result of medication (e.g. for hypertension and depression), health problems (such as diabetes) and/or surgery. Patients will usually present with little or no semen and may have cloudy urine following ejaculation. Following an initial investigation by the referring clinician, retrograde ejaculation can be confirmed through examination of post-ejaculatory urine for the presence of spermatozoa. The post-ejaculatory urine analysis will help determine:

- If sperm is present in the ejaculate (if produced).
- If sperm is present in the urine present.
 - Where sperm is produced, if they are motile or immotile.

8.1 PRESCRIBING SODIUM BICARBONATE

Assessing the patients' medical history and prescribing Sodium Bicarbonate is the responsibility of the GP / referring medical practitioner. The Leicester Fertility Centre holds no responsibility.

Prior to referring the patient, the Andrology Diagnostic Semen Analysis Laboratory requests that the patients' medical history be reviewed by their GP / referring clinician and that they are prescribed **Sodium Bicarbonate (4000mg in total)** as this is required to reduce the acidity of





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the urine for sperm and enable us to assess motility if possible. If the urine has not been neutralised we will not be able to assess motility. If you feel it is appropriate, ask the patient to take **two Alka Seltzers** instead of prescribing them sodium bicarbonate. **You must ensure that you review medical history and advise the patient as appropriate.**

If sodium bicarbonate is prescribed or advised, they need to take this dissolved in 1 pint of water 30 minutes before the appointment time with the Leicester Fertility Centre. This will be the same for patients directed to use alka seltzers as an alternative.

Retrograde sample production must only take place on-site.

9 ROUTINE TESTS PROVIDED

The Andrology Laboratory provides a standard range of diagnostic Andrology tests and follows recommendations made by the World Health Organisation (WHO Laboratory manual for the examination and processing of human semen, 5th Edition, 2010), (WHO laboratory manual for the examination of human semen and sperm - cervical mucus interaction. - 4th Edition, 1999), the British Andrology Society, Association of Biomedical Andrologists and the Association of Clinical Embryologists. Routine semen analyses will evaluate the following seminal parameters:

SEMINAL PARAMETERS	COMMENTS	Upper and Lower Reference Values
Liquefaction	A qualitative assessment of how liquefied the ejaculate has become. Measured at least 30 minutes post-ejaculation.	N/A
рН	The pH of the ejaculate. Measured at least 30 minutes post-ejaculation.	≥7.2
Appearance*	A qualitative assessment of the visual appearance of the ejaculate. Eg Normal, opaque etc.	N/A
Viscosity	A qualitative assessment of the semen viscosity. Reported as	





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	Reduced, Normal, Slightly	
	Increased and Greatly	
	Increased.	
	A quantitative assessment of	
	the number of non-sperm cells	
	in the ejaculate (NB no	
Presence of round cells	differentiation is made between	≤1x10 ⁶ /ml
	non-sperm round cells and	
	leucocytes). Reported as	
	million round cells per ml of	
	ejaculate	
	A qualitative assessment of the	
	amount of acellular debris	
Presence of acellular debris*	present in the ejaculate. If	N/A
	present, reported as +, ++ or	
	+++ if present.	
Ejaculate volume	The volume of the ejaculate	≥1.5
Ljaculate volume	measured in millilitres (ml)	21.5
Sperm concentration	Millions sperm per ml of	≥15
Openii concentration	ejaculate (millions/ml)	210
Sperm morphology	Percentage of sperm with	≥15
Sperm morphology	'normal' morphology (%)	210
	The motility of at least 200	
	sperm is assessed (at 37°C)	Progressive Motility: ≥32
	and expressed as the	Total Motility
Sperm motility	percentage (%) showing	(Progressive + Non-
	progressive, non-progressive	Progressive Motility): ≥40
	or immotile.	
	A qualitative assessment of the	
Presence of agglutination	numbers of sperm 'sticking' to	>50%





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	each other. Reported as a percentage.	
Sperm viability**	Percentage of viable sperm (only measured if sperm motility <10%).	≥58%
Anti-Sperm Antibody Testing*, ** (SpermMar IgG Direct Test)	A qualitative assessment of the semen to determine if Immunological infertility is present. Reported as a percentage.	≥40%

^{*}Reported in 'free-text' on report issued.

10 ACCEPTANCE/REJECTION CRITERIA

Semen samples should be brought directly to the Leicester Fertility Centre. Samples will only be tested if they meet the following criteria:

- If there are less than three patient identifiers present on the specimen collection pot, then the sample SHOULD BE REJECTED. It will be at the discretion of the Andrologist or Clinical Scientist to determine if the sample is to be analysed.
- Samples not received in designated containers SHOULD BE REJECTED.
- At present, samples received more than 60 minutes after production SHOULD BE REJECTED. However, it will be at the discretion of the Andrologist or Clinical Scientist to determine if the sample is to be analysed.
- Samples arriving will no request or referral form **WILL BE REJECTED.** Staff will check local electronic systems prior to making this decision.
- Samples that have leaked during transportation SHOULD BE REJECTED.
- Samples not produced by dry masturbation (no lubricant) WILL BE REJECTED unless produced by Withdrawal at Intercourse using a silastic condom (purchases through the clinic)
- PVSA ONLY: Samples that are not 'complete' SHOULD BE REJECTED.

Rejected samples will be reported at not tested and a reason provided.

11 EXAMINATION OF POST-VASECTOMY SAMPLES

The Andrology Laboratory follows the 2016 Laboratory Guidelines for Post Vasectomy Semen Analysis: Association of Biomedical Andrologists, the British Andrology Society and the British Association of Urology. The Andrology Laboratory will report any observations including the presence of very low numbers of immotile sperm. If greater than 200 non-motile sperm are seen on a 10ul slide preparation, a concentration will be performed to assist clinicians in giving 'special

^{**}Test only performed if clinically required.





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clearance'. 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. 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. It is left to the clinical judgement of the referring clinician to deem patients 'fertile' or 'infertile' on the basis of the semen analysis results, although clinical advice will gladly be provided on request. PVSA samples showing presence of sperm require a second sample for analysis. This is organised by the referring clinician.

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 recanalisation after clearance.

Factors advising Clearance and Special Clearance:

Clearance:

- Abstain from ejaculating prior to sample production (2-7 days).
- Ejaculated a minimum of 20 times since their operation.
- Had a minimum of 18 weeks post operation for first sample analysis.
- Sample must have been delivered/produced no more than 1 hour prior to examination within the laboratory.
- The complete sample is collected (the laboratory would reject incomplete samples).
- One sample can be examined where:
 - No sperm are detected

Special Clearance:

- Abstain from ejaculating prior to sample production (2-7 days).
- Ejaculated a minimum of 20 times since their operation on first sample.
- Had a minimum of 18 weeks post operation for first sample analysis.
- Sample must have been produced within an hour of examination.
- The complete sample is collected (the laboratory would reject incomplete samples).
- Minimum of two analysis to have been undertaken, each showing:
 - o <100, 000 sperm per ml
 - No motility detected
 - All criteria above met for EACH sample.

12 INTERPRETIVE COMMENTS & TERMINOLOGY

TERM	DEFINITION
Asthenozoospermia	Percentage of progressively (PR) motile spermatozoa below the lower reference limit.





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	No spermatozoa in the ejaculate (given as	
Azoospermia	the limit of quantification for the	
·	assessment method employed).	
	Spermatozoa absent from fresh	
Cryptozoospermia	preparations but observed in a	
	centrifuged pellet.	
	Concentration of spermatozoa and	
	percentages of progressively (PR) motile	
Normozoospermia	and morphologically normal spermatozoa,	
	equal to or above the lower reference	
	limits.	
Oligozoospermia	Concentration of spermatozoa below the	
Oligozoosperrilia	lower reference limit.	
	Percentage of morphologically normal	
Teratozoospermia	spermatozoa below the lower reference	
	limit	

13 REPORTING OF RESULTS

VERBAL RESULTS WILL NOT BE GIVEN OUT UNDER ANY CIRCUMSTANCES.

A semen infertility / semen analysis report form is generated using iLAB, which is later transcribed to ICE, where it can be viewed by the referring clinician. 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 medical team.

14 TURNAROUND TIME

The Andrology Laboratory endeavours to return results within 10 working days of patient attendance.

15 CONSENT FOR USE OF RESIDUAL SAMPLE AND CONFIDENTIALITY OF DATA

On the patient medical history questionnaire (part of the patient receipt form), there is a section asking whether the laboratory may use any residual sample left over after reporting for quality control and training. We have to maintain levels of quality by regularly assuring procedures are followed and to ensure that regardless of what scientist carries out the test, you can be confident of the results. Training is an important part of this procedure, and for new scientists working within the laboratory. All samples used for quality or training will not affect the patient's results in any way. We will not use the sample for anything else other than quality and training. The patient must answer 'YES' for us to use the sample and they must sign and date the bottom of the form. Staff can advise if there are difficulties in understanding what we may use the sample for.





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All patient data is protected by Trust confidentiality regulations which encompass the Data Protection Act. The laboratory acts in the best interest of the patient and will not tolerate deviation from these procedures. Further advice can be sought if required.

16 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. Clinicians and scientists are generally comfortable with the concept of uncertainty in relation to a blood test to determine (e.g., a hormone level), but of course, a semen analysis comprises a combination of different test results. As such it is important to consider the measurement of uncertainty in relation to semen analysis testing and the mechanisms that are in place to attempt to minimise uncertainty of measurement when assessing semen samples.

17 COMPLAINTS

The Leicester Fertility Centre aim to ensure that both patients and service users are satisfied 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.

17.1 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. Patient can also contact the PILS Team using the contact details provided in the document.





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18 PROCEDURE 'FLOW-DIAGRAM' WITH APPROXIMATE TIMESCALES

TWO - THREE WEEKS **TWO WEEKS** Patient provided Patient attends Report back to Patient to contact Sample appointment, referral, Leicester Fertility referring clinician processed, instructions, drops sample off Centre and book who provides report produced sealable bag and and completes and authorised. follow on care. an appointment. pot. paperwork.