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Document Title: Andrology Diagnostic User Manual Liverpool Women's Hospital		
Date of issue: 20.05.2022	Date of review: 20.05.2024	
Owner: R Gregoire	Author: S Brooks	

Liverpool Women's Hospital




DIAGNOSTIC ANDROLOGY SERVICES

USER MANUAL

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1 INTRODUCTION

This manual describes the policies, procedures and repertoire of the Andrology Laboratory, The Hewitt Fertility Centre at Liverpool Women's Hospital. This department is manned by dedicated staff on a full time basis. We work towards the standards outlined by WHO 2010 Examination and processing of human semen and ISO 15189:2012 Medical laboratories – Requirements for quality and competence.

2 CONTACT DETAILS

The postal address of the Andrology Laboratory is

The Lewis-Jones Andrology Laboratory
Hewitt Fertility Centre
Liverpool Women's Hospital
Crown Street
Liverpool
L8 7SS
Tel: 0151 702 4214
Email: lwft.andrology@nhs.net


The Andrology Laboratory is under the management of Dr Rachel Gregoire (Scientific Director) (ISO 15189:2012 4.1.14) as Person Responsible for Hewitt Fertility Centre (HFEA 0007). The Laboratory is staffed by 2 Clinical Andrologists, 2 Biomedical Andrologists, 1 Trainee Biomedical Andrologist and 2 STP Trainees. It is supported by a Medical Laboratory Assistant and a Scientific Administrative Assistant. Quality management is under the supervision of Ms Stephanie Brooks (ISO 15189:2012 4.12.7, 4.2).

This, in conjunction with the team above includes meeting the needs of our users (ISO 15189:2012 4.1.2.2, 4.4, 4.14.3), Service level agreements & third party agreements ((ISO 15189:2012 4.4), complaints (ISO 15189:2012 4.8), assessment of user feedback (ISO 15189:2012 4.14.3), review input (ISO 15189:2012 4.15), training of staff and competency assessment (ISO 15189:2012 5.1.5, 5.1.6), maintenance of facilities (ISO 15189:2012 5.2), Equipment maintenance (ISO 15189:2012 5.3), reagents and consumables (ISO 15189:2012 5.3.2), pre-examination processes (ISO 15189:2012 5.4), examination processes (ISO 15189:2012 5.5), ensuring quality of examination of results (ISO 15189:2012 5.6), post examination processes, (ISO 15189:2012 5.7), reporting of results (ISO 15189:2012 5.8). This list is not exhaustive and may include additional items.

3 LOCATION

(ISO 15189:2012 5.4.2 A)

The Lewis-Jones Andrology Laboratory is located on the 2nd floor of the Liverpool Women's Hospital. From the main entrance of the hospital proceed to the left and using lifts 3 & 4 go to the 2nd floor. On exiting the lift turn to the right and the Andrology Laboratory entrance is located on the left.

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4 OPENING TIMES

(ISO 15189:2012 5.4.2 C)

The Lewis-Jones Andrology Laboratory at Liverpool Women's hospital is open 0830-1630 Monday to Friday (although usually closed on Bank Holidays). There is a telephone service and answer-machine in operation when the laboratory is closed, on 0151-702-4214. This service can be used regarding appointments which need to be cancelled or changed. There is no out-of-hours service, unless exceptional circumstances prevail.

5 PROTECTION OF PATIENT INFORMATION

The information that you give to us regarding your patients is protected by Liverpool Women's NHS Foundation Trust policies. The following link will direct you to more information if required:
<https://www.liverpoolwomens.nhs.uk/about-us/our-aims-vision-values/>

6 HOW TO REQUEST A SEMEN ANALYSIS

(ISO 15189:2012 5.4.3)

6.1 Referrals from clinics at the Hewitt Fertility Centre, Liverpool Women's Hospital

Appointments can be made for patients already on the IDEAS system immediately by any staff member of the Hewitt Fertility Centre who has been trained to give patients the correct labelled sample pots and paperwork. Using the IDEAS system, locate the next available appointment on the Seminology diary (Green list) then insert the patients details into the available slot. In the details section it must be indicated where the results are to go back to, the patients Consultant and if the patient is NHS or self-funding (PP). This date and time are agreed with the patient and written in the appropriate slot on the patient information leaflet. Patients are given the appropriate paperwork and collection pot by the member of staff making the appointment.

6.2 Referrals from GOPD Liverpool Women's Hospital

Using the yellow folder located within the department, an available slot (using SCI-AND-FORM-30) is located and the patients ID label (and partners) are firmly fixed onto the appropriate location. The patient's Consultant is recorded also. This date and time are agreed with the patient and written on the 'Record Of Semen Production And Instructions (Liverpool) (SCI-AND-FORM-60)' form given to the patient. This is then taken the week prior by Andrology staff to update IDEAS and Meditech


6.3 Referrals from outside Liverpool Women's Hospital

Clinicians wishing to arrange an appointment for a semen analysis should complete a 'Semen Analysis Request Form' (See Appendix). It is essential that this form is completed in full and is legible.

The 'Semen Analysis Request Form' should be emailed to lwft.andrology@nhs.net (or posted to The Andrology Laboratory at The Liverpool Women's Hospital.)

On receipt of this form the Andrology Laboratory will arrange an appointment by sending the patient a pack via post containing;

- i. A covering letter
- ii. A semen collection pot
- iii. And a 'Record Of Semen Production And Instructions (Liverpool)' form, including the date and time of their appointment

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If the appointment originally given to them is unsuitable, the patient is able to rearrange the date and time of their appointment by contacting the laboratory on 0151-702-4214. Appointments can be changed to the Knutsford or Ormskirk sites if requested.

NB. Non-routine appointments such as sperm cryopreservation must be arranged by contacting the Andrology Laboratory directly on 0151-702-4214.

7 INSTRUCTIONS FOR PRODUCTION OF SEMEN SAMPLES

(ISO 15189:2012 5.4.4.2)

Instructions for the production of semen samples are detailed in the 'Record of Semen Production and Instructions (Liverpool)' form, contained in the pack sent to the patient via post.

Patients are advised to carefully follow the instructions on this form in order to optimise the semen sample that they produce.

Instructions should be read at least 2 days prior to their appointment as a minimum abstinence period of 2 days is required.

Patients should be advised to only use the collection vessel provided as these will have been toxicity tested on a batch by batch basis, the sterility of the sample container can be assured and a more accurate calculation of seminal volume can be made.

Patients should produce their sample by masturbation only. However, if this is not possible, non-spermicidal condoms can be provided by the laboratory on a case-by-case basis.

8 INSTRUCTIONS FOR THE TRANSPORTATION OF SEMEN SAMPLES

(ISO 15189:2012 5.4.2 H)

The patient has the option of producing their sample 'off-site' provided that the sample is delivered to the Andrology Laboratory within 50 MINUTES of production and not exposed to extremes of temperatures. This can be prevented by keeping the sample pot close to the body.


9 ROUTINE TESTS PROVIDED

(ISO 15189:2012 5.4.2 D)

The Andrology Laboratory provides a range of Andrology tests and follows recommendations made by the World Health Organisation (WHO Laboratory manual for The Examination and Processing of Human Semen, current edition), Laboratory Guidelines for Post Vasectomy Analysis 2016, The British Andrology Society and The Association of Reproductive and Clinical Scientists (ARCS).

Tests include;

- Diagnostic semen analyses
- Sperm cryopreservation
- Sperm DNA fragmentation - Self funded only.
- Microbial Culture and Sensitivity testing
- Extraction of sperm through operating procedures – e.g. testicular biopsies
- Counselling services
- Access to a consultant male fertility specialist

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9.1 Diagnostic semen analysis

The following parameters are measured and included on the report:

PARAMETER	COMMENTS
Appearance	A qualitative assessment of the visual appearance of the ejaculate e.g normal, opaque etc.
Viscosity	A qualitative assessment of the consistency of the ejaculate e.g. viscous or non-viscous.
Presence of round cells	A quantitative assessment of the number of non-sperm cells in the ejaculate (NB. No differentiation is made between non-sperm round cells and leucocytes). Reported in millions of round cells per ml of ejaculate.
Sample volume	The volume of the ejaculate (ml).
pH	The pH of the ejaculate is measured to assess the function of the seminal vesicles. Measured at least 30 minutes post-ejaculation following liquefaction.
Sperm concentration	Number of sperm per ml of ejaculate (millions/ml).
Total sperm number	Total number of sperm in the whole ejaculate (millions).
Sperm motility	The assessment of the motility of at least 200 sperm (at 37°C) expressed as the percentage showing progressive motility, non-progressive motility or immotility.
Sperm vitality	Percentage of viable (live) sperm. Only measured if sperm motility <10%.
Presence of agglutination	A qualitative assessment of the numbers of sperm 'sticking' to each other. Reported as 1, 2, 3 or 4 (1 being little agglutination, 4 being a large proportion of the sperm agglutinated).
Sperm morphology	Percentage of sperm with 'normal' morphology.


9.2 Post-vasectomy semen analysis

The Andrology Laboratory follow the guidelines 2016 Laboratory guidelines for postvasectomy semen analysis: Association of Biomedical Andrologists, the British Andrology Society and the British Association of Urological Surgeons (P Hancock, BJ Woodward, A Muneer, JC Kirkman-Brown 2016, <http://jcp.bmj.com/content/early/2016/04/15/jclinpath-2016-203731>).

A post-vasectomy semen analysis will report any observations made. If motile sperm are present in the ejaculate, analysis will continue as per 9.1 above. If a low number of immotile sperm are observed, this number will be included in the report. If greater than 200 non-motile sperm are seen in a 10µl wet preparation slide, a concentration assessment will be performed to assist clinicians in giving 'special clearance'. It is left to the clinical judgement of the referring clinician to decide whether this should be granted. Clinical advice can be provided on request (see 'Provision of Clinical Advice' below). If no sperm are identified, the centrifugation method will be used and the pellet will be examined to assess the presence of sperm.

10 ACCEPTANCE/ REJECTION CRITERIA

The Senior Biomedical Andrologist will be consulted and professional judgement will be used at all times when deciding whether to accept or reject a sample. The type of sample (diagnostic semen analysis or post-vasectomy semen analysis) will also be considered.

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Patients who attend the laboratory without prior referral will not be accepted under any circumstances.

All semen collection pots must be clearly labelled with the patient's full name and DOB. Any samples brought to andrology laboratory without full patient details on may be rejected.

If the patient has produced their semen sample into a non-laboratory issued container it may not be rejected but the patient should be informed that it may be necessary to repeat the analysis.

If the patient's sample has spilt or leaked into the specimen bag, professional judgement will be used when deciding whether to accept or reject the sample. The patient should be informed that it may be necessary to repeat the analysis.

If the patient has the incorrect abstinence period the sample may not be rejected but the patient should be informed that it may be necessary to repeat the analysis.

If the patient delivers the sample to the andrology laboratory more than 50 minutes after production the sample may not be rejected but the patient should be informed that it may be necessary to repeat the analysis.

11 INTERPRETIVE COMMENTS & TERMINOLOGY

Term	Definition
Aspermia	No sample produced on ejaculation
Azoospermia	No sperm present in ejaculate
Cryptozoospermia	No sperm observed on initial examination but very low numbers observed following centrifugation concentration and examination of entire ejaculate
Oligozoospermia	<15 million sperm per ml of ejaculate
Asthenozoospermia	<32% grade A motility or <40% grade A + grade B motility
Teratozoospermia	<4% normal forms
Haemospermia	Presence of blood in the ejaculate
Incomplete sample collection	Patient has failed to collect entire ejaculate

In addition, other self-explanatory interpretative comments may be added.

For more detailed interpretation and significance of results reported in a semen analysis, the Andrology Laboratory recommends reference to the following organisations and guidelines to which the laboratory follows;


- The World Health Organisation (WHO Laboratory manual for the examination and processing of human semen, Fifth Edition, 2010).
- The Association of Reproductive Clinical Scientists

12 REPORTING OF RESULTS

(ISO 15189:2012 5.8)

A 'Semen Analysis Report Form' is generated by the Hewitt Fertility Centre 'IDEAS' database and returned by post or email to the referring clinician.

VERBAL RESULTS WILL NOT BE GIVEN OUT UNDER ANY CIRCUMSTANCES

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13 TURNAROUND TIME

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

14 PROVISION OF CLINICAL ADVICE/COMPLAINTS

Clinical advice on any aspect of the diagnostic (or therapeutic) services provided by the Andrology Laboratory can be obtained from

Dr Rachel Gregoire, Scientific Director	0151 702 4173
Mr Richard Russell, Andrology Clinical Lead	0151 702 4215
The Andrology Laboratory	0151 702 4214

Or by e-mail enquiry to	
rachel.gregoire@lwh.nhs.uk	Scientific Director
stephanie.brooks@lwh.nhs.uk	Quality Manager
Rebecca.lunt@lwh.nhs.uk	Lead Clinical Embryologist
lwft@andrologylab@nhs.net	General Enquiries

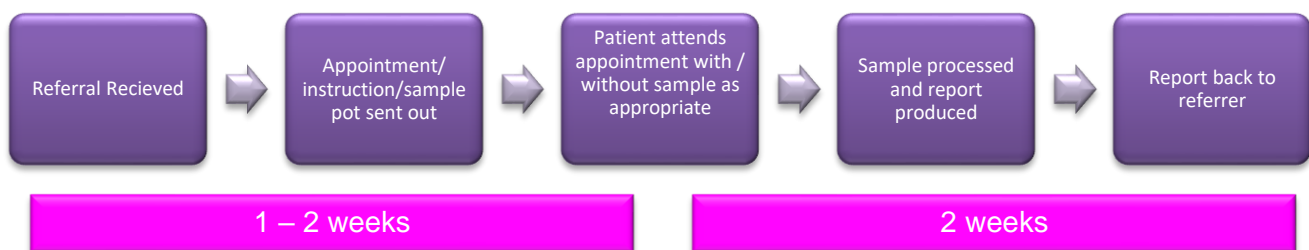
Complaints should be directed to the Quality Manager or Scientific Director at the Hewitt Fertility Centre, Liverpool Women's Hospital, Crown Street, Liverpool L8 7SS. (ISO 15189:2012 4.8),

15 MEASUREMENT OF UNCERTAINTY

(ISO 15189:2012 5.5.1.3, 5.5.1.4, 5.5.3)


Clinicians and scientists are generally comfortable with the concept of uncertainty in relation to a blood test to determine for example a hormone level, but 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. Therefore, we have produced a document SCI-POL-1 'Uncertainty measurement in semen analysis – information for users' that we ask that you read. It includes a section at the back with bullet points that you are asked to consider when interpreting the results that we provide.

16 PROCEDURE 'FLOW-DIAGRAM' WITH APPROXIMATE TIMESCALES



17 APPENDIX

The following forms are available to download at:
[For GPs and other Clinicians | The Hewitt Fertility Centre](#)

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- I. Semen Analysis Request Form
- II. Patient information leaflet
- III. User manuals all HFC Andrology laboratories
- IV. Sample report
- V. Measurement of uncertainty Hewitt Fertility Centre document (SCI-POL-1)