



Document Code: QMS-AND-UM-4	Version No: 6	 The Hewitt Fertility Centre
Document Title: Andrology Diagnostic User Manual Liverpool Women's Hospital		
Date of issue: 15.05.2020	Date of review: 15.05.2022	
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.andrologylab@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 Biomedical Andrologists, 1 Trainee Biomedical Andrologist and 3 STP Trainees. Supported by a Medical Laboratory Assistant and a Scientific Administrative Assistant. Quality management is under the supervision of Mrs 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.

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

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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 NHS trust policies. The following links will direct you for more information if required.

<https://www.liverpoolwomens.nhs.uk/media/2817/pl001-information-governance-and-information-security.pdf>

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

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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

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 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 one hour of production and not exposed to extremes of temperatures.

9 ACCEPTANCE/ REJECTION CRITERIA

- Samples brought to the Andrology laboratory without full patient details SHOULD BE REJECTED.
- Samples received in non-designated containers SHOULD BE REJECTED.
- Samples received more than 60 minutes after production SHOULD BE REJECTED.

However, it will be at the discretion of the Senior Biomedical Andrologist to determine if a sample not meeting criteria is to be analysed.

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

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10 ROUTINE TESTS PROVIDED

(ISO 15189:2012 5.4.2 D)

The Andrology Laboratory provides a range of diagnostic Andrology tests.

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

A routine semen analysis will typically assess the following seminal parameters:

SEMINAL PARAMETER	COMMENTS
Liquefaction	A qualitative assessment of how liquefied the ejaculate has become. Measured at least 30 minutes post-ejaculation.
pH	The pH of the ejaculate. Measured at least 30 minutes post-ejaculation.
Appearance	A qualitative assessment of the visual appearance of the ejaculate. E.g. Normal, opaque etc.
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 as millions round cells per ml of ejaculate
Presence of acellular debris	A qualitative assessment of the amount of acellular debris present in the ejaculate. Reported as 0, +, ++ or +++
Ejaculate volume	The volume of the ejaculate measured in millilitres (ml)
Sperm concentration	Millions sperm per ml of ejaculate (millions/ml)
Sperm morphology	Percentage of sperm with 'normal' morphology (%)
Sperm motility	The motility of at least 200 sperm is assessed (at 37°C) and expressed as the percentage showing progressive or non-progressive motility or immotility
Presence of agglutination	A qualitative assessment of the numbers of sperm 'sticking' to each other. Reported as 0, +, ++ or +++.
Sperm viability	Percentage of viable sperm (only measured if sperm motility <90%)
Post-vasectomy semen analysis	An inspection of whether viable sperm is within a semen sample 12 weeks post procedure

11 EXAMINATION OF POST-VASECTOMY SAMPLES

The Andrology Laboratory follow the guidelines 2016 Laboratory Guidelines for Post Vasectomy 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>).

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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 10ul, a concentration will be performed to assist clinicians in giving 'special clearance'.

It is left to the clinical judgement of the referring clinician to deem whether patients are 'fertile' or 'infertile' on the basis of semen analysis results. Although clinical advice will gladly be provided upon request (see 'Provision of Clinical Advice' below).

12 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 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

13 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, to the referring clinician (See Appendix for sample report).

Verbal results will not be given out under any circumstances.

14 TURNAROUND TIME

The Andrology Laboratory endeavours to return results within 2 weeks of patient attendance.

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15 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, Consultant Clinical Andrologist	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	Senior Biomedical Andrologist
lwf.andrology@nhs.net	General enquiries

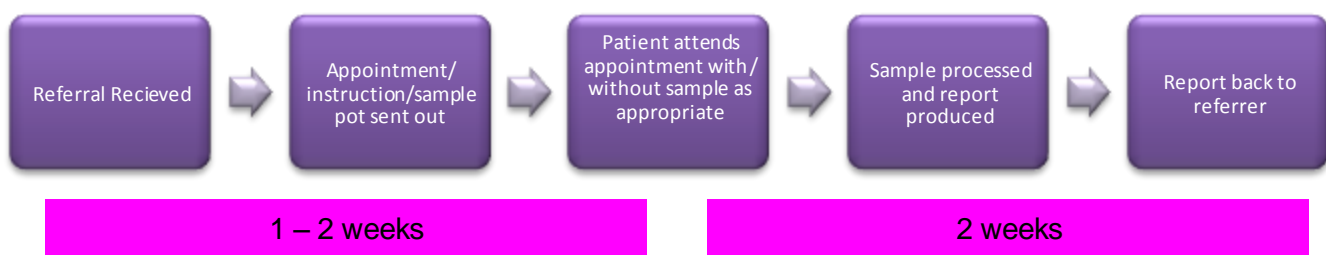
Complaints should be directed to the Quality Manager or Scientific Director at the Hewitt Fertility Centre, Liverpool Women's Hospital, Crown Street, Liverpool L8 7SS. (ISO 15189:2012 4.8),

16 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 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. Therefore we have produced a document SCI-POL-1 (See appendix) Measurement of uncertainty in semen analysis, that we ask that you read. It includes a section at the back with bullet points that we ask you to consider when interpreting the results that we provide.


17 PROCEDURE 'FLOW-DIAGRAM' WITH APPROXIMATE TIMESCALES



18 APPENDIX

The following forms are available to download at (<https://www.thehewittfertilitycentre.org.uk/useful-information/for-gps-and-other-clinicians/>)

- I. Semen Analysis Request Form
- II. Patient information leaflet

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III. Sample report example

IV. Measurement of uncertainty Hewitt Fertility Centre document (SCI-POL-1)