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Document Title: Andrology Laboratory User Manual Leighton Hospital		
Date of issue: 15.05.2020	Date of review: 15.05.2022	
Owner: R. Gregoire	Author: S Brooks	

**Patrick Murphy Unit, Leighton Hospital**


# **DIAGNOSTIC ANDROLOGY SERVICES**

## **USER MANUAL**



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## 1 INTRODUCTION

This manual describes the policies, procedures and repertoire of the Andrology Laboratory, situated within Ward 25, at Leighton Hospital. This department is manned part-time and is therefore under the direction and facilitated administratively by the Hewitt Fertility Centre at the Liverpool Women's Hospital. We work towards the standards outlined by WHO 2010 Examination and Processing of Human Semen, ISO16190:2003 Medical Laboratories Requirement for Safety and ISO 15189:2012 Medical laboratories – Requirements for quality and competence.


## 2 CONTACT DETAILS

The postal address of the Andrology Laboratory is:

Andrology Laboratory  
Ward 25  
Leighton Hospital  
Middlewich Road  
Crewe  
CW1 4QJ  
Tel: 01270 612212  
Fax: 01270 273497

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 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.

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### **3 LOCATION (ISO 15189:2012 5.4.2 A)**

The Andrology Laboratory is situated on the 2<sup>nd</sup> floor (Ward 25) of Leighton Hospital. From the main entrance of the hospital proceed through the Ante-natal Clinic entrance and take the stairs to the 2<sup>nd</sup> floor. Follow signs to Ward 25.

### **4 OPENING TIMES**

**(ISO 15189:2012 5.4.2 C)**

The Andrology Laboratory at Leighton hospital is open 0900 - 1600 on Fridays.

### **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)**

GP referrals are actioned when a request is made from the GP to the administration staff of Ward 25 using the request form in appendix 2.

Appointments are made following referral from a GP to the Ward 25 or following a request from the Fertility Clinic at the Ward 25, where the patient books an appointment at the appointments desk.

Appointments can be also made by telephoning the department on 01270 612212 or 01270 612293. These telephone numbers are also used to cancel or change existing appointments. There is no out-of-hours service, unless exceptional circumstances prevail.

### **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 (Leighton)' 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)

If the patient is producing the sample 'off-site' he 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 Andrology Laboratory **WITHIN ONE HOUR** of production.

## 9 ROUTINE TESTS PROVIDED

(ISO 15189:2012 5.4.2 D)

The Andrology Laboratory provides a range of diagnostic Andrology tests and follows recommendations made by the World Health Organisation (WHO Laboratory manual for the examination of human semen and sperm-cervical mucus interaction, Fifth Edition, 2010), the British Andrology Society, Association of Biomedical Andrologists and the Association of Clinical Embryologists.

A routine semen analysis will assess the following seminal parameters:

SEMINAL PARAMETER	COMMENTS
<b>Liquefaction</b>	A qualitative assessment of how liquefied the ejaculate has become. Measured at least 30 minutes post-ejaculation.
<b>pH</b>	The pH of the ejaculate. Measured at least 30 minutes post-ejaculation.
<b>Appearance</b>	A qualitative assessment of the visual appearance of the ejaculate. eg Normal, opaque etc
<b>Presence of round cells</b>	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
<b>Ejaculate volume</b>	The volume of the ejaculate measured in millilitres (ml)
<b>Sperm concentration</b>	Millions sperm per ml of ejaculate (millions/ml)
<b>Sperm morphology</b>	Percentage of sperm with 'normal' morphology (%)
<b>Sperm motility</b>	The motility of at least 200 sperm is assessed (at 37°C) and expressed as the percentage showing grade progressive, non-progressive or immotile.
<b>Presence of agglutination</b>	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 the majority)
<b>Sperm viability</b>	Percentage of viable sperm (only measured if sperm motility <10%)

## 10 ACCEPTANCE/ REJECTION CRITERIA

Samples brought to the Andrology laboratory without full patient details SHOULD BE REJECTED. It will be at the discretion of the Senior Biomedical Andrologist to determine if the sample is to be analysed.

Samples received in non-designated containers SHOULD BE REJECTED, as the volume for this sample will be measured volumetrically and the container will not have been toxicity tested.

Samples received more than 60 minutes after production SHOULD NOT BE REJECTED. It will be at the discretion of the Senior Biomedical Andrologist to determine if the sample is to be analysed.

## 11 EXAMINATION OF POST-VASECTOMY SAMPLES


The guidelines issued by the British Andrology Society for the examination of post-vasectomy semen samples are followed throughout. 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 Urological Surgeons (P Hancock, BJ Woodward, A Muneer, JC Kirkman-Brown 2016) 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 patients 'fertile' or 'infertile' on the basis of semen analysis results, although clinical advice will gladly be provided on 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.

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## 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.

VERBAL RESULTS WILL NOT BE GIVEN OUT UNDER ANY CIRCUMSTANCES

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

## 14 TURNAROUND TIME

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

## 15 PROVISION OF CLINICAL ADVICE

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](mailto:rachel.gregoire@lwh.nhs.uk)  
[stephanie.brooks@lwh.nhs.uk](mailto:stephanie.brooks@lwh.nhs.uk)  
[lwft@andrologylab@nhs.net](mailto:lwft@andrologylab@nhs.net)

Scientific Director  
Senior Biomedical Andrologist/ Quality Manager  
General Enquiries

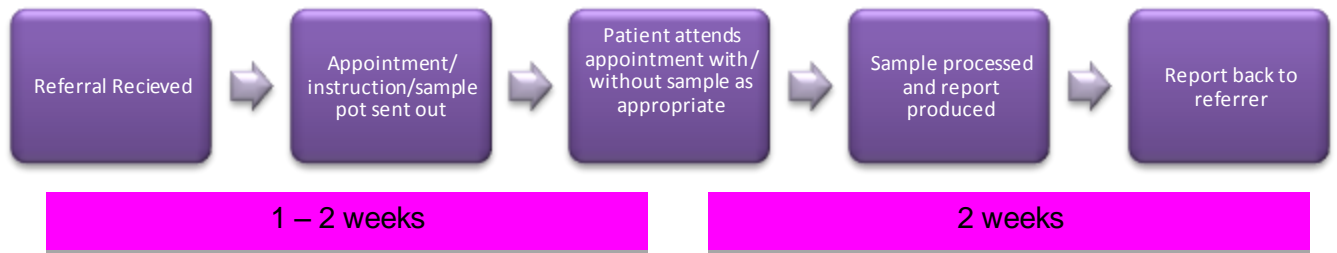
Complaints should be directed to the Quality Manager or Scientific Director at the Hewitt Fertility Centre, Liverpool Women's Hospital, Crown Street, Liverpool L8 7SS. (ISO 15189:2012 4.8),

## 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 Measurement of uncertainty in Semen analysis 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.

## 17 PROCEDURE 'FLOW-DIAGRAM' WITH APPROXIMATE TIMESCALES



## 18 APPENDIX

The following forms are available to download at <https://www.thehewittfertilitycentre.org.uk/media/1550/andrology-user-manual-leighton-hospital.pdf>

- I. Semen Analysis Request Form
- II. Patient information leaflet
- III. Sample report example
- IV. Measurement of uncertainty Hewitt Fertility Centre document (SCI-POL-1)