

Document Code: QMS-AND-UM-4	
Document Title: Andrology Diagnostic User Manual Liverpool Womens Hospital	
Version No: 3	
Date of issue: 16.07.2015	Date of review: 16.07.2016
<i>Hewitt Fertility Centre</i>	
Owner: K Schnauffer	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

Andrology Laboratory  
Hewitt Fertility Centre  
Liverpool Women's Hospital  
Crown Street  
Liverpool  
L8 7SS

Tel: 0151 702 4214  
Fax: 0151 702 4152

The Andrology Laboratory is under the direction and management of Dr Stephen Troup (Scientific Director) (ISO 15189:2012 4.1.14) and Ms Karen Schnauffer (Consultant Embryologist), respectively. The Andrology Laboratory is supervised by Mrs Stephanie Brooks (Andrology Supervisor) and staffed by trained Andrologists, Mrs Judith Cunningham, Mr Paul Mallanaphy and Ms Amanda Hall, Andrology Practitioners Miss Laurie Wishman, Mr Andrew Allan and supported by Mrs Cheryl Thomas (Medical Laboratory Assistant) and Miss Jennifer Edge (Scientific Administrative Assistant).

We are under the supervision in regards to Quality management by Mrs Sharon Fensome-Rimmer who directs the service with regards to maintenance of our Quality management system. (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 of the Liverpool Womens Hospital. From the main entrance of the hospital proceed to the left and using lifts 3 & 4 go to the 2<sup>nd</sup> 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 Andrology Laboratory at Liverpool Womens 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. HOW TO REQUEST A SEMEN ANALYSIS

(ISO 15189:2012 5.4.3)

#### 5.1 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 on the Hewitt centre who has been trained to give patients the correct labelled sample pots and paperwork. Using the IDEAS system, locate the next available 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.

#### 5.2 Referrals from GOPD Liverpool Women's Hospital

Using the green folder, next available slot is located and the patients ID label (and partners) are firmly fixed onto the appropriate location. The patients Consultant is recorded also. This date and time are agreed with the patient and written in the appropriate slot on the patient information leaflet. This is then taken periodically by Andrology staff to update IDEAS and Meditech

#### 5.3 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 1). It is essential that this form is completed in full and is legible.

The 'Semen Analysis Request Form' should be faxed to 0151 702 4152.

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On receipt of this form the Andrology Laboratory will arrange an appointment by sending the patient a pack containing the following:

- i. covering letter (see Appendix 2)
- ii labelled semen collection pot(s)
- iii. labelled 'Semen Analysis' form (Appendix 3 & 4) including a date and time of their appointment
- iv. labelled 'Record of Semen Production' form (Appendix 5)
- v. Patient Information Leaflet (Appendix 6)

When the patient makes contact with the Andrology Laboratory a convenient appointment should be made.

NB. Non-routine appointments must be arranged by contacting the Andrology Laboratory.

## 6. INSTRUCTIONS FOR PRODUCTION OF SEMEN SAMPLES

(ISO 15189:2012 5.4.4.2)

Instructions for the production of semen samples are detailed in leaflet entitled 'Instructions for the production of semen samples' [see Appendix 2]. The date of the appointment should also be entered on this form.

Patients should be advised to follow the instructions in this leaflet in order to optimise the semen sample that they produce.

Patients should be provided with a suitable sample collection vessel and plastic transportation bag.

**Patients should be advised to only use the collection vessel provided.**

The following instructions are contained within this leaflet:

The patient should

- i. not ejaculate for between 2 and 7 days prior to their appointment
- ii. only use the pot provided to collect their sample
- iii. clearly label the pot with their name, date and time of sample production and the number of days since they last ejaculated
- iv. empty their bladder before producing the semen sample
- v. produce the sample by masturbation and not by 'withdrawing' after intercourse
- vi. not use a condom to collect the sample as condoms can adversely affect sperm\*
- vii. attempt to collect ALL of the sample into the pot and advise a member of the Andrology staff if any of the sample is not collected
- viii. \* If the patient is unable to produce a semen sample by masturbation, then special condoms (a 'Male Factor Pack') are available by prior arrangement with the Andrology Laboratory.

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## 7. 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.

## 8. 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 2010 Examination and processing of human semen, 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>Presence of acellular debris</b>	A qualitative assessment of the amount of acellular debris present in the ejaculate. Reported as 0, +, ++ or +++
<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 progressive, non-progressive or immotile



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<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 minimal agglutination and 4 being the majority of sperm are agglutinated)
<b>Sperm viability</b>	Percentage of viable sperm (only measured if sperm motility <90%)

## 10. EXAMINATION OF POST-VASECTOMY SAMPLES

The guidelines issued by the British Andrology Society for the examination of post-vasectomy semen samples are followed throughout (P Hancock & E McLaughlin for the British Andrology Society, 2002, J.Clin.Path., p812-816)

All samples in which very low numbers of sperm are observed, or samples in which no sperm are observed on initial microscopic examination will be subjected to 'centrifugation concentration' and further examination. By concentrating the sample the sensitivity of the analysis, in terms of the ability to observe sperm is increased 10-50 fold. It is also then possible to examine the entire ejaculate.

The Andrology Laboratory will report any observations including the presence of very low numbers of immotile sperm. When greater than 50 non-motile sperm seen on wet prep a concentration will be performed to assist the clinician on 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).

## 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.

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## 12. REPORTING OF RESULTS

(ISO 15189:2012 5.8)

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

There are normal reference ranges stated on the bottom of this report.

VERBAL RESULTS WILL NOT BE GIVEN OUT UNDER ANY CIRCUMSTANCES

## 13. TURNAROUND TIME

The Andrology Laboratory endeavours to return results within 2 weeks 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 Stephen Troup, Scientific Director	0151 702 4173
Dr Iwan Lewis-Jones, Consultant Clinical Andrologist	0151 702 4215
Andrology Laboratory	0151 702 4214

Or by e-mail enquiry to [stephen.troup@lwh.nhs.uk](mailto:stephen.troup@lwh.nhs.uk)/ [Karen.schnauffer@lwh.nhs.uk](mailto:Karen.schnauffer@lwh.nhs.uk)

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

## 15. MEASUREMENT OF UNCERTAINTY

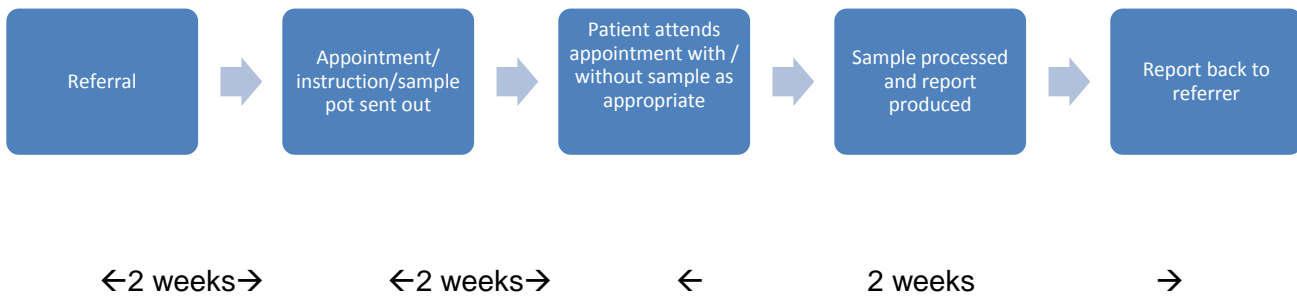
(ISO 15189:2012 5.5.1.3, 5.5.1.4, 5.5.3)

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 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 that you consider when interpreting the results that we provide.



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## 16. PROCEDURE 'FLOW-DIAGRAM' WITH APPROXIMATE TIMESCALES



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Attach Patient Label:	Attach Patient Label:
Male name:	Female name:
Date of Birth:	Date of Birth:
Mobile Tel. no.	Mobile Tel. No.
Address:	Address:
NHS No.	NHS No.

**Details of referring Clinician** Please use Practice Stamp

Clinicians Name:

Practice address:

**Please tick appropriate boxes**

GOPD     Hewitt Centre     GP     Aintree     Ormskirk

This referral is NHS     PP    Date of appointment if known \_\_\_\_\_

Reason for referral:    Fertility     Sperm Freeze

(please tick)  
 Vasectomy     Vasectomy reversal

Date performed: \_\_\_\_\_    Date performed: \_\_\_\_\_

Other: \_\_\_\_\_

**Is this patient High risk (i.e. Virus positive)**

Yes (please give details) \_\_\_\_\_

**Additional information (i.e. History of violence/aggression)** \_\_\_\_\_

**Please post or fax this request form to:**  
 Andrology Laboratory  
 Hewitt Fertility Centre  
 Liverpool Women's Hospital  
 Crown Street  
 Liverpool  
 L8 7SS  
 Tel No. 0151-702-4214  
 Fax No. 0151-702-4152

**PLEASE FILL IN ALL DETAILS CORRECTLY  
 AND LEGIBLY AND YOUR PATIENT WILL BE  
 CONTACTED TO ARRANGE THEIR  
 APPOINTMENT.  
 INCOMPLETE OR ILLEGIBLE FORMS  
 WILL NOT BE PROCESSED**

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Dear Sir

## Re. Semen Analysis

Your doctor has asked us to contact you in order to arrange an appointment to attend for a semen analysis test.

Please find enclosed a pack containing your sample pot(s) and paperwork. On one of these forms it indicates the date and time of your appointment.

Please contact us on **0151 702 4214** to confirm this appointment or rearrange if not convenient. If you **fail** to confirm this appointment, you risk losing your appointment slot. If telephoning us to confirm your appointment please feel free to leave a message on the answer machine. We may contact you by telephone, if you do not want us to do that, please inform us of that when you call. Please note that all appointments are Monday to Friday, 8.30am – 2pm.

Please also find enclosed some instructions. It is important that you read these instructions and complete the paperwork. Your results will be available from your doctor within 14 days or from your Consultant at your next clinic appointment.

With kindest regards.  
Yours sincerely

Dr Stephen Troup  
Scientific Director

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Date of analysis:..... Lab code no.:.....

Male name .....DOB:.....Hospital no. ....

Female name .....DOB:.....Hospital no.....

Please circle appropriate clinic:

HFC OSI GOPD ACWH GP Vas Referring clinician:..... NHS / PP

Sample pot Lot No.....

Time of sample production ..... Analysis interval .....mins

Abstinence period.....(days) Appearance .....Viscosity : Viscous / Non-viscous

pH ..... Round Cells ..... x 10<sup>6</sup>/ml

Volume: ..... ml

- -0.3=

Weight-Weight before-0.3

Concentration:..... x 10<sup>6</sup>/ml (Performed by: )

Total sperm number ..... M/ejaculate

Morphology: ..... % (Performed by: )

Agglutination 1 2 3 4

Vitality .....% (Performed by: )

Motility at .....°C (Performed by

Grade A.....% (*progressive*)

Grade B.....% (*progressive*)

Grade C ..... % (*non-progressive*)

Grade D ..... % (*non-motile*)

Average speed.....M/sec

**Comments**

	Analyst	Date
<b>Analysed</b>		
<b>IDEAS</b>		
<b>2<sup>nd</sup> person verified</b>		
<b>Returned</b>		

**Reference ranges WHO 2010**

Volume	1.5 mls or more
pH	7.2 or more
Concentration	15 million sperm per ml or more
Total sperm number	39 Million sperm per ejaculate
Total motility (A, B & C)	40 % (38-42%)
Progressive motility (A&B)	32 % (31-34%)
Sperm Morphology	4% or more
Vitality	58 % (55-63%) only measured when 90% non-motile

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### Instructions for the production of semen samples

Your appointment is at the Andrology Laboratory on the 2<sup>nd</sup> floor of Liverpool Womens Hospital at the following date and time -

Date
------

Time
------

#### **Please read the following instructions carefully before producing your semen sample**

- Do not ejaculate for **2 – 7** days before your appointment.
- Produce your sample by masturbating into the pot provided.
- Samples can be produced at home or at the facilities available in the Andrology Laboratory. If producing at home, the sample must be delivered to the laboratory within one hour and at the date and time given above.
- Please complete the **‘Record of Sperm Production Form’**.
- Results will be given by the referring clinician at your follow up appointment.
- Do not produce your sample using a condom, lubricant, the withdrawal method or by any other means other than masturbation.
- Do not expose to extremes of temperature.
- If you are unable to ejaculate by masturbation, then special condoms designed specifically for the collection of semen samples are available, please ask.

**If you do not attend your appointment there may be a 6-8 week wait for a further appointment which may delay your attendance at clinic.**

If you are unsure about any of the above points, or are unable to attend this appointment then please contact the Andrology laboratory on  
**0151 - 702 – 4214**

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**SECTION I – TO BE COMPLETED BY MALE OR FEMALE PARTNER**

I confirm that the sample container is correctly labelled with my/my partners correct details including name, D.O.B. and address (if applicable).

Signature of patient/ partner confirming details on sample pot \_\_\_\_\_

Date \_\_\_\_\_

**Section 2 - Please complete this section if you are the man who has produced the sample**

Your name \_\_\_\_\_ Date of birth \_\_\_\_\_

Partner's name \_\_\_\_\_ Date of birth \_\_\_\_\_

Your address \_\_\_\_\_

Where was your sample produced *At home / At the Hewitt Fertility Centre (Please delete as appropriate)*

What time was your sample produced \_\_\_\_\_

How many days is it since you last ejaculated \_\_\_\_\_

Was any of the sample spilled during collection? Yes\* / No

Have you been ill during last 3 months? \_\_\_\_\_ (eg Flu)

**Do you have or have you ever been told that you have HIV, Hepatits B or Hepatitis C Yes/ No**

I confirm the following with regard to the semen sample that I have handed to staff at the Hewitt Fertility centre today:

- i. That the sample was produced by me
- ii. That the sample has not been tampered with since its production
- iii. That the sample was produced at the time specified above
- iv. I am happy for any surplus specimen to be used for teaching and/or quality assurance purposes

Signature of patient \_\_\_\_\_ Date \_\_\_\_\_

**\* If some of the sample was lost during collection please inform a member of the laboratory staff**

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**Section 3 – Please complete this section if you are delivering the sample on behalf of your partner**

Your name \_\_\_\_\_ Date of birth \_\_\_\_\_

Your partner's name \_\_\_\_\_ Date of birth \_\_\_\_\_

Your partners address \_\_\_\_\_  
 \_\_\_\_\_

What time did your partner produce the sample? \_\_\_\_\_

How many days is it since your partner last ejaculated \_\_\_\_\_

Did your partner spill any of the sample during collection? Yes\* / No

Has your partner been ill during last 3 months? \_\_\_\_\_ (please describe e.g. flu)

**Does your partner have or have they ever been told that they have HIV, Hepatits B or Hepatitis C Yes/ No**

Please confirm the following with regard to the semen sample that you have handed to staff at the Hewitt Fertility centre today:

- v. The sample was produced by my partner named above
- vi. The sample has not been tampered with since its production
- vii. That the sample was produced at the time specified above

Signature of person delivering sample \_\_\_\_\_ Date \_\_\_\_\_

**\* If some of the sample was lost during collection please inform a member of the laboratory staff**

**SECTION 4 – TO BE COMPLETED BY STAFF RECEIVING SAMPLE**

I confirm that the paperwork belonging to the patient named above was handed to me at the time specified below, and the patient's details have been verbally confirmed.

Signature of staff member receiving paperwork \_\_\_\_\_

Time sample received \_\_\_\_\_ Date: \_\_\_\_\_

I confirm that I have received the sample from the patient named above and that the sample was appropriately labelled.

Signature of staff member receiving sample \_\_\_\_\_

Time sample received \_\_\_\_\_ Date: \_\_\_\_\_