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)

3. LOCATION

(ISO 15189:2012 5.4.2 A)

The Andrology Laboratory is situated on the 2\textsuperscript{nd} 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\textsuperscript{nd} 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.
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.
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:

<table>
<thead>
<tr>
<th>SEMINAL PARAMETER</th>
<th>COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liquefaction</td>
<td>A qualitative assessment of how liquefied the ejaculate has become. Measured at least 30 minutes post-ejaculation.</td>
</tr>
<tr>
<td>pH</td>
<td>The pH of the ejaculate. Measured at least 30 minutes post-ejaculation.</td>
</tr>
<tr>
<td>Appearance</td>
<td>A qualitative assessment of the visual appearance of the ejaculate. Eg Normal, opaque etc</td>
</tr>
<tr>
<td>Presence of round cells</td>
<td>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</td>
</tr>
<tr>
<td>Presence of acellular debris</td>
<td>A qualitative assessment of the amount of acellular debris present in the ejaculate. Reported as 0, +, ++ or +++</td>
</tr>
<tr>
<td>Ejaculate volume</td>
<td>The volume of the ejaculate measured in millilitres (ml)</td>
</tr>
<tr>
<td>Sperm concentration</td>
<td>Millions sperm per ml of ejaculate (millions/ml)</td>
</tr>
<tr>
<td>Sperm morphology</td>
<td>Percentage of sperm with ‘normal’ morphology (%)</td>
</tr>
<tr>
<td>Sperm motility</td>
<td>The motility of at least 200 sperm is assessed (at 37°C) and expressed as the percentage showing progressive, non-progressive or immotile</td>
</tr>
</tbody>
</table>
10. EXAMINATION OF POST-VASECTIONY 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

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

In addition, other self-explanatory interpretative comments may be added.
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/ 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.
16. PROCEDURE ‘FLOW-DIAGRAM’ WITH APPROXIMATE TIMESCALES

Referral → Appointment/ instruction/sample pot sent out → Patient attends appointment with/ without sample as appropriate → Sample processed and report produced → Report back to referrer

←2 weeks→ ←2 weeks→ ← 2 weeks →
Attach Patient Label: Male name: Date of Birth: Mobile Tel. no. Address: NHS No.

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

Details of referring Clinician

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
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

Uncontrolled when photocopied. Do not use after review date.
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
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 10^6/ml

Volume: …………………….. ml

_________ - ______ - 0.3 = _____________

Weight-Weight before-0.3

Concentration:………………….. x 10^6/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

<table>
<thead>
<tr>
<th>Analyst</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Analysed</td>
<td></td>
</tr>
<tr>
<td>IDEAS</td>
<td></td>
</tr>
<tr>
<td>2nd person verified</td>
<td></td>
</tr>
<tr>
<td>Returned</td>
<td></td>
</tr>
</tbody>
</table>

Reference ranges WHO 2010

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume</td>
<td>1.5 mls or more</td>
</tr>
<tr>
<td>pH</td>
<td>7.2 or more</td>
</tr>
<tr>
<td>Concentration</td>
<td>15 million sperm per ml or more</td>
</tr>
<tr>
<td>Total sperm number</td>
<td>39 Million sperm per ejaculate</td>
</tr>
<tr>
<td>Total motility (A, B &amp; C)</td>
<td>40% (38-42%)</td>
</tr>
<tr>
<td>Progressive motility (A&amp;B)</td>
<td>32% (31-34%)</td>
</tr>
<tr>
<td>Sperm Morphology</td>
<td>4% or more</td>
</tr>
<tr>
<td>Vitality</td>
<td>58% (55-63%) only measured when 90% non-motile</td>
</tr>
</tbody>
</table>
Instructions for the production of semen samples

Your appointment is at the Andrology Laboratory on the 2nd 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
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
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 partner’s 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, Hepatitis 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:_________________________________________