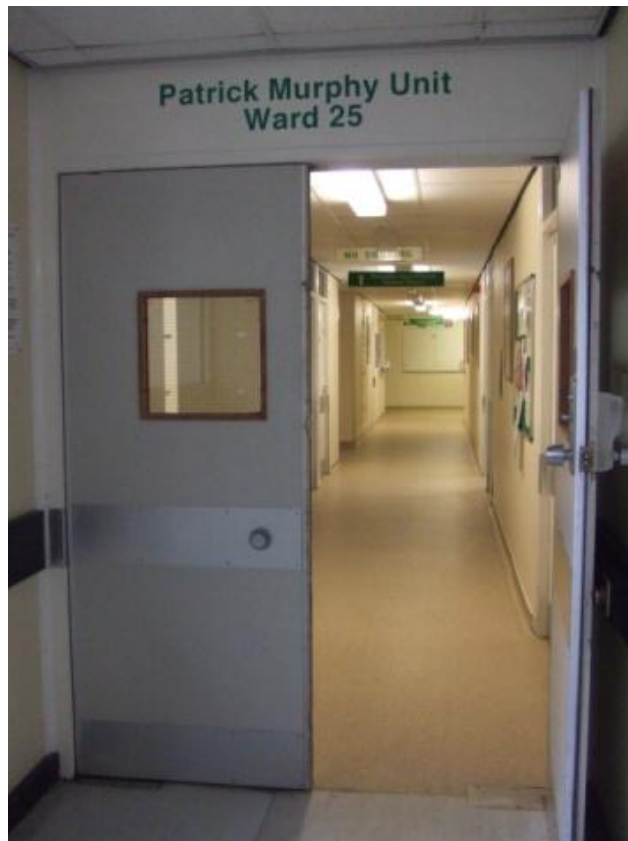


Patrick Murphy Unit, Leighton Hospital



DIAGNOSTIC SEMINOLOGY SERVICES

USER MANUAL

CONTENTS

CONTENTS	2
2. CONTACT DETAILS	3
3. LOCATION	4
4. OPENING TIMES.....	4
5. HOW TO REQUEST A SEMEN ANALYSIS	4
6. INSTRUCTIONS FOR PRODUCTION OF SEMEN SAMPLES	4
7. INSTRUCTIONS FOR TRANSPORTATION OF SEMEN SAMPLES	5
8. ROUTINE TESTS PROVIDED	5
10. EXAMINATION OF POST-VASECTOMY SAMPLES	6
11. INTERPRETIVE COMMENTS & TERMINOLOGY	6
12. REPORTING OF RESULTS.....	7
13. TURNAROUND TIME	7
14. PROVISION OF CLINICAL ADVICE	7
15. Measurement of Uncertainty	7
16. Procedure 'flow-diagram' with approximate timescales	8
17. REFERRAL PROFORMA.....	10
18. SEMEN ANALYSIS FORM.....	11
19. PATIENT INSTRUCTION LEAFLET.....	12
20. OFF-SITE PRODUCTION FORM.....	13-14

1. INTRODUCTION

This manual describes the policies, procedures and repertoire of the Seminology Laboratory, Patrick Murphy Unit, 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 and ISO 15189:2012 Medical laboratories – Requirements for quality and competence.

2. CONTACT DETAILS

The postal address of the Seminology Laboratory is:

Seminology Laboratory
 Patrick Murphy Unit
 Leighton Hospital
 Middlewich Road
 Crewe
 CW1 4QJ
 Tel: 01270 612212
 Fax: 01270 273497

The Seminology 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 Seminology Laboratory at the Patrick Murphy Unit is supervised by Mrs Stephanie Brooks and staffed by trained Andrology Practitioner Miss Laurie Wishman, Mr Andrew Allan and supported by Biomedical Andrologists, Mrs Judith Cunningham, Mr Paul Mallanaphy, and Ms Amanda Hall.

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.

3. LOCATION

(ISO 15189:2012 5.4.2 A)

The Seminology Laboratory is situated on the 2nd 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 2nd floor. Follow signs to the Patrick Murphy Unit (Ward 25).

4. OPENING TIMES

(ISO 15189:2012 5.4.2 C)

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

5. 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 Patrick Murphy Unit using the request form in appendix 2.

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

Appointments can be also made by telephoning the appointments 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.

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 an appropriate 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 Seminology 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 Seminology 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 Seminology Laboratory **WITHIN ONE HOUR** of production.

8. ROUTINE TESTS PROVIDED

(ISO 15189:2012 5.4.2 D)

The Seminology Laboratory provides a range of diagnostic seminology 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
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. Eg 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
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 grade progressive, non-progressive or immotile.
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 the majority)
Sperm viability	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 Seminology Laboratory will report any observations including the presence of very low numbers of immotile sperm. If greater than 50 non-motile sperm are seen in 10ul then a concentration will be performed. This will give an estimated number of sperm to assist in the 'special clearance' of patients.

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.

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.

VERBAL RESULTS WILL NOT BE GIVEN OUT UNDER ANY CIRCUMSTANCES

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

13. TURNAROUND TIME

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

14. PROVISION OF CLINICAL ADVICE

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
Mr Richard Russell, Consultant Clinical Andrologist	0151 702 4215
Andrology Laboratory	0151 702 4214

Or by e-mail enquiry to stephen.troup@lwh.nhs.uk

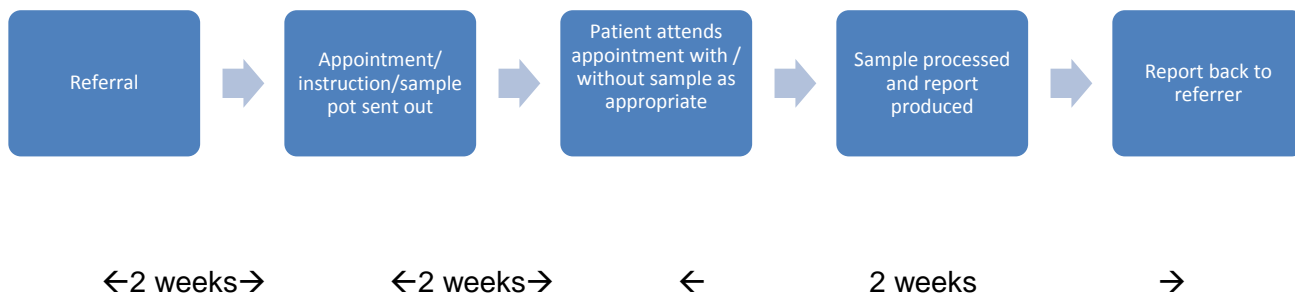
Complaints should be directed to the Quality Manager or Scientific Director at the Hewitt Fertility Centre, Liverpool Womens Hospital, Crown Street, Liverpool L8 7SS. (ISO 15189:2012 4.8),

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



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

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

NHS No.

NHS No.

Details of referring Clinician

Please use Practice Stamp

Clinicians Name:

Practice address:

Please tick appropriate boxes

Leighton Fertility Hewitt Centre GP

This referral is NHS PP Date of appointment if known _____

Reason for referral: Fertility Sperm Freeze

Vasectomy (please tick) Vasectomy reversal

Date performed: _____ Date performed: _____

Other: _____

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

Yes (please give details) _____
 No

Additional information (i.e. History of violence/aggression) _____

Seminology Laboratory
 Patrick Murphy Unit
 Leighton Hospital
 Middlewich Road
 Crewe
 CW1 4QJ
 Tel: 01270 273499
 Fax: 01270 273497

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.

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

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

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

Please circle appropriate clinic:

Leighton HFC GP Vas Referring clinician:..... NHS / PP

Sample pot Lot No.....

Time of sample production Analysis intervalmins

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

pH

Round Cells x 10⁶/ml

Volume: ml

- -0.3=
Weight-Weight before-0.3

Concentration:..... x 10⁶/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
Analysed		
IDEAS		
2nd person verified		
Returned		

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

Instructions for the production of semen samples

Your appointment is at the Andrology Laboratory on the Patrick Murphy Unit 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
01270 612212

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 Patrick Murphy Unit* (Please delete as appropriate)

If at home, 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, Hepatitis B or Hepatitis C Yes/ No

I confirm the following with regard to the semen sample that I have handed to staff at the Patrick Murphy Unit 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 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, 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 Patrick Murphy Unit 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: _____