

Document Code: QMS-AND-UM-5	
Document Title: Andrology Laboratory User Manual Hewitt Fertility Centre @ Knutsford	
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

Hewitt Centre @ Knutsford



DIAGNOSTIC ANDROLOGY SERVICES USER MANUAL

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1. INTRODUCTION

This manual describes the policies, procedures and repertoire of the Andrology Laboratory, at the Hewitt Fertility Centre @ Knutsford, This department is manned part-time and is therefore under the direction and facilitated administratively by the Andrology laboratory, 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 Andrology Laboratory is

4 The Pavillions,
Knutsford Business Park,
Mobberley Road,
Knutsford ,
WA16 8ZR.

OR

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 Andrology Practioners Miss Laurie Wishman, Mr Andrew Allan and supported by Biomedical Andrologists, Mrs Judith

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Cunningham, Mr Paul Mallanaphy and Ms Amanda Hall supported by Mrs Cheryl Thomas (Medical Laboratory Assistant) and Miss Jennifer Edge (Scientific Administrative assistant).

3. LOCATION

The Andrology Laboratory is situated on the ground floor of the Hewitt Fertility Centre @ Knutsford Patients are to announce themselves at the reception of the department where they will be directed by staff from there.

4. OPENING TIMES (ISO 15189:2012 5.4.2 A)

The Andrology Laboratory at Knutsford is open 08.30-12.30 Tuesdays. At the Liverpool Women's Hospital there is a telephone service and answer-machine in operation when the laboratory is closed, on 01565 635000. 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 within the Knutsford Facility

Semen analysis should be booked in using the Knutsford Andrology appointments diary on IDEAS and must include patients' consultant, self-funding or NHS and where to send the result back to.

5.2 Referrals from outside Hewitt Fertility Centre @ Knutsford

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 01565 635000

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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

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- 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 Laboratory manual for the examination and processing of human semen, 5th Edition, 2010), the British Andrology Society, Association of Biomedical Andrologists and the Association of Clinical Embryologists.

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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
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, 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 minimal and 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)

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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 Semiology Laboratory will report any observations including the presence of very low numbers of immotile sperm. If greater than 50 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).

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.

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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
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 / 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

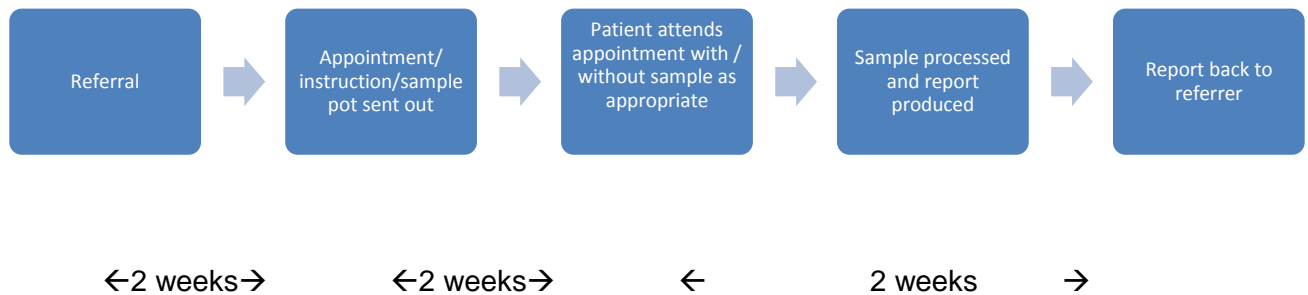
(ISO 15189:2012 5.5.1.3, 5.5.1.4, 5.5.3)

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

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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



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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.

<u>Details of referring Clinician</u>	Please use Practice Stamp
Clinicians Name:	
Practice address:	

Please tick appropriate boxes

Hewitt Centre GP Other _____

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) _____

No

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

Please post or fax this request form to:
 Andrology Laboratory
 4 The Pavillions
 Knutsford Business Park
 Mobberley Road
 Knutsford
 WA16 8ZR.
 Tel No. 01565 635000

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

Fax No. 01565 635003

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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 **01565 635000** 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 Tuesday 8.30 am– 12.00 noon. Alternative arrangements can be arranged upon request.

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.

Please note that your appointment is for the Andrology Laboratory, 4 The Pavillions, Knutsford Business Park, Mobberley Road, Knutsford , WA16 8ZR.

With kindest regards.

Yours sincerely

Dr Stephen Troup
Scientific Director

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

Male nameDOB:.....Hospital no.

Female nameDOB:.....Hospital no.

Please circle appropriate clinic:

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

Sample pot Lot No.....	
Time of sample production	Analysis intervalmins
Abstinence period.....(days) AppearanceViscosity : 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:)	Motility at°C (Performed by Grade A.....% (progressive) Grade B.....% (progressive) Grade C % (non-progressive) Grade D % (non-motile) Average speed.....M/sec
Agglutination 1 2 3 4 Vitality% (Performed by:)	

Comments	Analysed	Analyst	Date
	IDEAS		
	2 nd 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

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Instructions for the production of semen samples

Your appointment is at the Andrology Laboratory at Hewitt Fertility Centre @ Knutsford 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

01565 635000

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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)

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 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, 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: _____