

Document Code: QMS-AND-UM-5	Version No: 6
Document Title: Andrology Laboratory User Manual Hewitt Fertility Centre @ Knutsford	
Date of issue: 15.05.2020	Date of review: 15.05.2022
Owner: R. Gregoire	Author: S Brooks

Hewitt Fertility 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 staffed part-time and is under the direction and administratively facilitated 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, 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

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

Email: lwft.andrologylab@nhs.net

The Andrology Laboratory is under the direction and management of Dr Rachel Gregoire (Scientific Director) (ISO 15189:2012 4.1.14). 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 ground floor of the Hewitt Fertility Centre, Knutsford. Patients are to present 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 C)

The Andrology Laboratory at Knutsford is open 08.30-15.30 week days. 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. PROTECTION OF PATIENT INFORMATION

The information that you give to us regarding your patients is protected by NHS trust policies. <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)

6.1 Referrals from within the Knutsford Facility

Semen analyses 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.

6.2 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, SCI-AND-FORM-17). It is essential that this form is completed in full and is legible.

The 'Semen Analysis Request Form' should be faxed to 01565 635000 or emailed to lwft.andrologylab@nhs.net

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.

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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 (Knutsford)' 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 and processing of human semen, 5th 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 million 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 +++

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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 <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.

As such, samples received more than 60 minutes after production SHOULD NOT BE REJECTED. However, 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 Andrology Laboratory follows the 2016 Laboratory Guidelines for Postvasectomy 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, <http://jcp.bmj.com/content/early/2016/04/15/jclinpath-2016-203731>).

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.

For more detailed interpretation and significance of results reported in semen analysis, the Andrology Laboratory recommends reference to the following organisations and guidelines to which the laboratory follows;

- The World Health Organisation (WHO Laboratory manual for the examination and processing of human semen, Fifth Edition, 2010).
- The Association of Reproductive Clinical Scientists

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

14. TURNAROUND TIME

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

15. PROVISION OF CLINICAL ADVICE/COMPLAINTS

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
stephanie.brooks@lwh.nhs.uk
lwf.andrologylab@nhs.net

Scientific Director
Senior Biomedical Andrologist
General enquiries

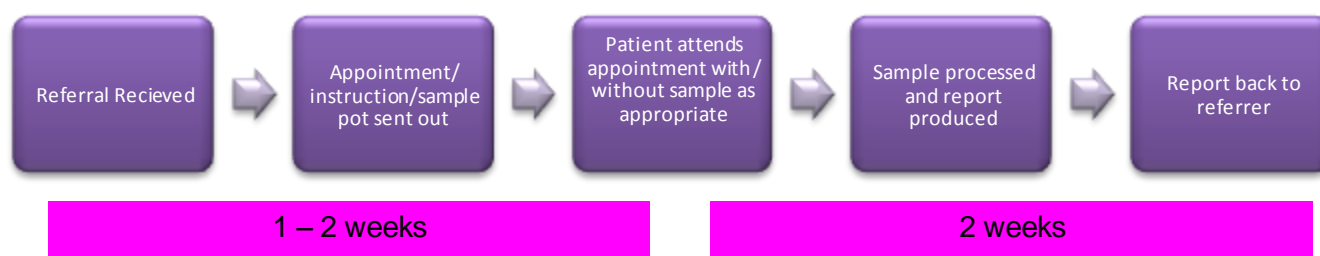
Complaints should be directed to the Quality Manager or Scientific Director at the Hewitt Fertility Centre, Liverpool Women's Hospital, Crown Street, Liverpool L8 7SS. (ISO 15189:2012 4.8),

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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 that you 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/useful-information/for-gps-and-other-dinicians/>

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