Document Code: QMS-AND-UM-2	
Document Title: Countess of Chester Seminology Laboratory User Manual	
Version No: 3	
Date of issue: 16.07.2015	Date of review:16.07.2016
Hewitt Fertility Centre	
Owner: K Schnauffer	Author: S Brooks

Countess of Chester Fertility Centre

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DIAGNOSTIC SEMINOLOGY SERVICES

USER MANUAL

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1. INTRODUCTION

This manual describes the policies, procedures and repertoire of the Seminology Laboratory, Countess of Chester Fertility and Assisted of Conception Unit. 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
Countess of Chester Fertility and Assisted Conception Unit
Countess of Chester Hospital NHS Foundation Trust
Countess of Chester Health Park
Liverpool Road
Chester
CH2 1UL

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 Unit is staffed by Embryology Trainees, Mrs Grace Haresnape and Miss Lauren Wallace and Miss Kyriaki Andreou, this is with the support of Clinical Scientists, Miss Hannah Marsden, Miss Rebecca Lunt, Mrs Natalie Scott and Mrs Lorraine Smullen who are all based at the Hewitt Fertility Centre.

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

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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 1st floor of Countess of Chester Hospital. From the Ante-natal Clinic entrance take the stairs or lift to the 1st floor. Follow signs to the Fertility and Assisted Conception Unit.

4. OPENING TIMES

(ISO 15189:2012 5.4.2 C)

The Seminology Laboratory at Chester Fertility Unit is open 0900 - 1300 Monday to Friday.

5. HOW TO REQUEST A SEMEN ANALYSIS

(ISO 15189:2012 5.4.3)

Appointments are made following referral from a GP by and contacting the Fertility Unit Secretary on 01244 336401 [Appendix 1]. Appointments are also made following a request from the Fertility Clinic at the Chester Fertility and Assisted Conception Unit directly with the Fertility Unit Secretary. This telephone number is 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 3]. 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.

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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 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. E.g. 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 acelluar 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 sperm.
Presence of agglutination	A qualitative assessment of the numbers of sperm 'sticking' to each other. Reported as 1, 2, 3 or 4 (1 being least agglutination, 4 majority of sperm stuck together.
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. Where greater than 50 non-motile sperm have been identified, a concentration will be performed to assist the clinician 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).

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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 (within 60 mins of production)
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/COMPLAINTS

Clinical advice on any aspect of the diagnostic (or therapeutic) services provided by the Andrology Laboratory can be obtained from

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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

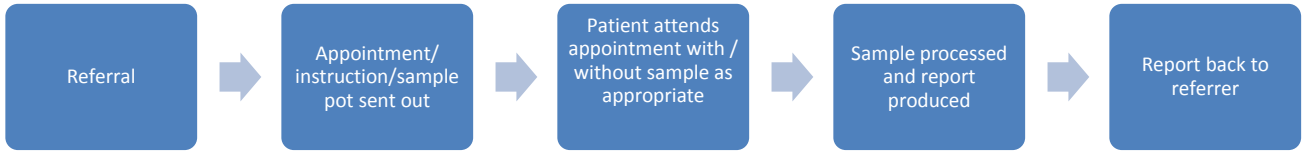
Complaints should be directed to the Quality Manager or Scientific Director at the Hewitt Fertility Centre, Liverpool Women's Hospital, Crown Street, Liverpool L8 7SS. (ISO 15189:2012 4.8),

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



←2 weeks→ ←2 weeks→ ← 2 weeks →

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Date of analysis:…… Lab code no.:……

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

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

Please circle appropriate clinic:

Chester HFC GP Vas Clinic 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 .....ºC (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

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Instructions for the production of semen samples

Your appointment is at the Andrology Laboratory at the Assisted conception Unit, Countess of Chester Hosptial 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
01244-366401

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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 Assisted Conception 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, 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 Assisted conception unit 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 Assisted conception 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_____