Regional Andrology Service User Manual

For clinicians and patients

Please note - post-vasectomy samples are *not* accepted

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Please ensure that this is the most up to date version of the Regional Andrology Service user manual

This user manual and further information can be found on the RFC website
http://www.rfc.hscni.net/

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1. Introduction
(ISO 15189:2012)

The Regional Andrology Service (RAS) is located on the first floor of the Royal Jubilee Maternity Service (RJMS). It forms part of the Regional Fertility Centre (RFC), which is within the Belfast Health & Social Care Trust (BHSCT). The RAS's main function is to provide a diagnostic semen analysis service for men who are having difficulty achieving a pregnancy with their partner. Clinical referrals to the RAS are received from within the RFC itself, from Gynaecology and Fertility clinics, and from other clinicians and General Practitioners throughout the province.

2. Service Agreement
(ISO 15189: 2012 4.1.1.2)

Each request accepted by the RAS for semen analysis shall be deemed to be an agreement between the user and RAS (or other accredited laboratories as may be used by RAS to perform testing outside repertoire), to carry out the necessary testing and reporting function.

3. Protection of Personal Information
(ISO 15189: 2012 5.4.2 M, I)

All patient information is processed in accordance with the BHSCT Policy on the Data Protection Act 1998, which outlines the legal requirements for both the Trust and its staff to treat personal information confidentially, and ensure all information is held securely. The BHSCT is also compliant with General Data Protection Regulations (GDPR, 2016.)
All members of staff are fully trained in the importance of maintaining patient confidentiality and their records at all times.

Routinely, patient consent is not required within RAS for a diagnostic semen analysis.
On occasion, the lab may ask for your consent to use any excess waste sample for the following purposes:

- Staff training
- Testing of labware for toxicity
- Quality Control purposes to ensure the accuracy of results.

Excess waste sample will only be used **after** the full semen analysis is complete. No samples will be used for treatment purposes.

There is no obligation on you to participate and any decision to consent, or not, will not affect your test results.
Patient confidentiality will be maintained at all times.

4. Clinical Advice/Complaints
(ISO 15189:2012 4.8 and ISO 15189: 2012 5.4.2 F)

The RAS always aims to provide high quality services. Comment/Suggestion cards are available in the RAS waiting area & consultation room. If patients are unhappy with any aspect of the service, they should speak to any member of staff who will try to resolve the concern as soon as possible.

If the matter is not resolved, the Belfast Trust complaints procedure can be found at www.belfasttrust.hscni.net/contact/Complaints.htm, by emailing complaints@belfasttrust.hscni.net or by telephoning 028 95048000. The postal address is:

Complaints Department,
Belfast Health & Social Care Trust,
6th Floor,
McKinney House,
Musgrave Park Hospital,
Stockman's Lane,
Belfast,
BT9 7JB

5. Location
(ISO 15189:2012 5.4.2 A)

The Andrology Lab is located within the Royal Jubilee Maternity Service on the Royal Hospitals site.

The full postal address is:

Regional Andrology Service
Regional Fertility Centre
Royal Jubilee Maternity Service
Grosvenor Road
Belfast Health & Social Care Trust
Grosvenor Road
Belfast
BT12 6BA

Telephone: RAS 028 90633986
RFC 028 90635888 (Option 1)

Directions are as follows:

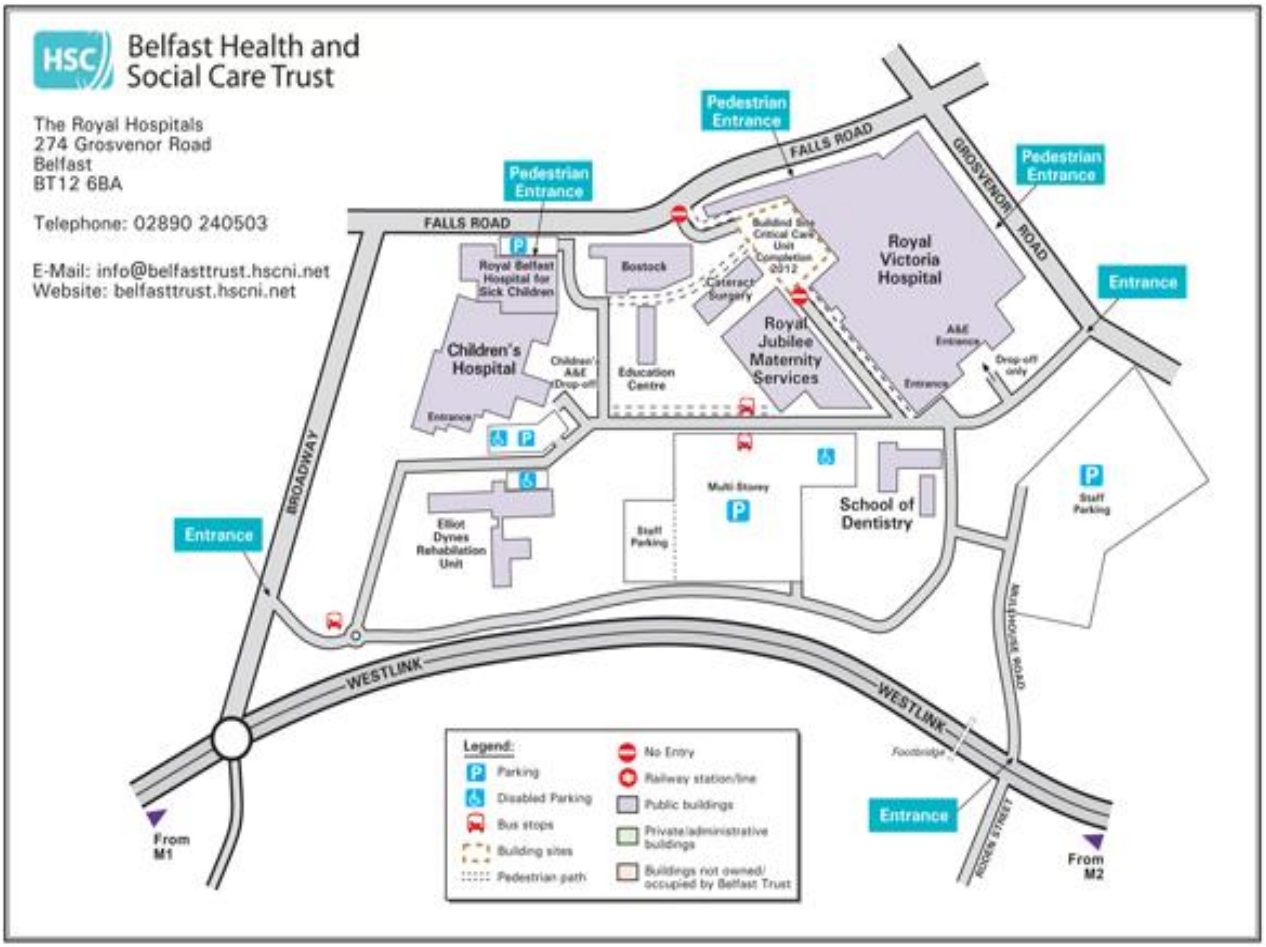
- Enter the Royal Jubilee Maternity Hospital through the main entrance & walk past reception.
- Turn left.
- The lifts and stairs are on the left hand side. Take either the lift/stairs to the 1st floor.
- On exiting on the 1st floor, turn left.
- The Andrology Laboratory entrance is signposted & will be found along the corridor on the right hand side.
- On arriving at the Andrology Lab, please knock on the reception window to speak to a member of staff

6. Opening Times
(ISO 15189:2012 5.4.2 C)

The Andrology laboratory is open from 7.30 am to 3.30 pm Monday to Friday. (It is closed on Bank Holidays). Appointments run from 8.00am to 11.45am Monday to Friday.

7. Car Parking

There are visitor's car parks providing on-site parking for a small charge. Please note that the car park can often be extremely busy and patients should leave additional time for parking. If the patient is more than 30 minutes late for their appointment it may need to be rebooked.



8. RAS Staff

Laboratory Director:	Dr Ishola Agbaje *(ISO15189:2012 4.1.1.4)*
Scientific Director:	Dr D Lutton *(ISO15189:2012 4.1.1.4)*
Andrologists:	Dr Joan McKinney Ms Anne Havern Miss Emma McLean *(ISO15189:2012 4.1.2.5, 5.1)*
Senior Embryologists:	Mr Jim McNally Mr David Jennings (*ISO15189:2012 4.1.2.5, 5.1)*
Quality Co-Ordinator:	Mrs Joan Couhig *(ISO 15189:2012 4.1.2)*
Quality Systems Manager:	Mrs Louisa Taylor / Mrs Karen Marks *(ISO 15189:2012 4.1.2.7, 4.2)*

The above staff can be contacted by telephoning the RFC on 028 9063 5888.

9. How to Refer a Patient
(ISO 15189:2012 5.4.3)

Requests will only be accepted from registered medical practitioners.
Patients cannot 'self-refer'.

All GP referrals for Diagnostic Fertility Semen Analysis should be processed via the electronic CCG referral system. This mean that referrals are sent directly to the Regional Fertility Centre for processing. For guidance for this new CCG referral pathway refer to the NHS GP website.

RFC Consultants and other hospital departments may refer using the Semen Analysis request form (*FM-AN-RefSA 689*). This form can be obtained by downloading from the RFC website - http://www.rfc.hscni.net

It is essential that request forms are fully completed with the following information:

- **Full name**
- **Date of birth**
- **Gender**
- **Address**
- **Health & care number**
- **Hospital number (if known)**
- **Name & location of referrer**
- **Risk status**

Incomplete forms will be returned to the referrer. Full clinical and identifying information is essential to ensure the highest quality service.

It should be indicated in the relevant clinical information section on the request form if the patient has any special requirements. The Andrology suite is wheelchair accessible and sign language interpreters can be requested if prior notice is given.

If English is not the patient's first language and they would benefit from an interpreter, this should be indicated on the request form.

Patients who are **known or suspected carriers of Category 3 pathogens** (for example hepatitis B or C and HIV) must be clearly indicated on CCG referrals, or by circling the YES option on the High Risk section of the paper request form.
For a full list of Category 3 pathogens see the Belfast Trust Microbiology User Manual, located at http://www.belfasttrust.hscni.net/services/Laboratory-MortuaryServices.htm.
When the completed request form is received from external referrers, a letter will be sent to the patient providing information on how to book an appointment. When the appointment has been booked a confirmation letter will be sent. Specific instructions regarding the production of the sample will be included in this letter. Directions and a map to the RAS are also included in the appointment letter.

Patients attending the RFC in the Grove Wellbeing centre or Royal Hospital will book an appointment at reception and be provided with an appointment letter and instructions at that time.

Possible Clinical Indications: (This list is not exhaustive).
(ISO 15189:2012 5.4.3.E and 5.4.4.2.E)

- Previous Abnormal SA (1 or more parameter)
- Azoospermia
- Vasectomy Reversal
- Query Retrograde
- History of mumps
- History of Varicocele
- History of Testicular injury
- History of undescended testes
- History of testicular atrophy
- Sperm donation
- Previous / current steroid / supplement use
- Diagnosis of Cystic Fibrosis
- Diagnosis of Klinefelter's syndrome
- Transgender patient
- Previous SA at a different location
- Previous cytotoxic drugs
- Testosterone treatment
- Gonadotrophin treatment

10. Sample Production and what a patient needs to know in preparation for the test
(ISO 15189:2012 5.4.4.2 and ISO 15189:2012 5.4.2.F)

Semen samples should be produced in the discreet facilities available within the Andrology suite. This is because samples should be maintained at body temperature and analysed within one hour of production. A member of Andrology staff will guide patients to this facility. Adult literature is provided for those who wish to avail of it.

In exceptional circumstances only, samples may be produced off site but only by prior arrangement with the Andrology staff. In this situation, instructions will be provided individually to the patient together with an appropriate container.

A number of factors can affect the performance of the test and therefore it is important that the following are adhered to:

Patients should:

- Refrain from intercourse or masturbation for at least 2 days before their appointment but no longer than 7 days.
- Ensure good personal hygiene to avoid bacterial contamination.
- Produce the sample by masturbation **only**.
- Attempt to collect **ALL** the sample into the container provided, and advise a member of the Andrology staff if any of the sample is not collected.
- Use only the container provided by the RAS to collect their sample.
- Ensure that the container is clearly labelled with their name, address and date of birth.
- Tell the laboratory staff if they have been ill or had a viral infection e.g. flu, in the last three months. Also they should inform the laboratory staff if they have been, or are currently taking any medication.

Patients should NOT:

- Use a condom to collect the sample as condoms can adversely affect sperm.
- Use lubricants when producing the semen sample as lubricants can have a detrimental effect on sperm.
- Expose the sample to extremes of temperature. If transporting the semen sample to the laboratory, it should be carried inside their jacket or trouser pocket to keep it close to body temperature. *(ISO 15189:2012 5.4.5 B)*
- Use containers other than those provided by the Andrology laboratory as they cannot be accepted and a new appointment will need to be booked.

If patients are unable to produce a semen sample by masturbation, then a special condom (a 'Male Factor Pack') is available by prior arrangement with the Andrology Laboratory.

11. Change of Appointment

If patients are unable to attend their appointment, they should contact the RFC by telephoning 02890635888 (option 1) to rearrange at a more convenient date & time. Please bear in mind that the laboratory is a regional centre and deals with many samples each day so if an appointment needs to be changed, an alternative may not be available immediately.

12. The Semen Analysis Test

(ISO 15189:2012 5.4.2 D)

A comprehensive semen analysis is carried out on samples examining a number of factors which all contribute towards a man's ability to conceive.

Seminal parameter	Comments
Ejaculate volume	The volume of the ejaculate measured in millilitres (ml).
Liquefaction & viscosity ***NB the liquefaction & viscosity tests are not subject to accreditation.***	A qualitative assessment of whether liquefaction is complete or incomplete and whether the sample has increased viscosity.
pH	The pH of the ejaculate.
Appearance	A qualitative assessment of the visual appearance of the ejaculate. E.g. Normal, blood streaked etc.
Presence of round cells	A quantitative assessment of the number of round cells in the ejaculate (N.B. no differentiation is made between round cells and leucocytes). Reported as millions per ml if greater than 1 million round cells/ml are observed.
Presence of debris	A qualitative assessment of the amount of debris present in the ejaculate. Reported as +, ++ or +++ if significant amounts of debris are observed.
Sperm concentration	Millions of sperm per ml of ejaculate (millions/ml).
Sperm motility	Sperm are graded on their ability to move in a progressive manner. The rapidly progressive sperm are generally the most fertile. The motility of at least 200 sperm is assessed (at 37°C) and expressed as a percentage showing rapidly

	progressive, slowly progressive, non-progressive or immotile.
Sperm morphology	The shape and size of the sperm are assessed using a stained smear. The proportion of sperm in the sample that have a normal appearance is calculated after 200 sperm per slide are counted, and expressed as percentage normal.
Presence of agglutination/Aggregation	A qualitative assessment of the numbers of sperm 'clumping' together, reported as a percentage. Agglutination refers to motile sperm clumping together while aggregation refers to immotile sperm clumping together. These can occur simultaneously.
Anti-sperm Antibodies ****NB the anti-sperm antibodies test is not subject to accreditation.***	The % of IgG antibodies present on sperm are quantified using a SpermMar direct testing kit. When this result is over 50% positive IgA antibodies are also quantified.
Trial Wash (For hospital use only) ****NB The trial wash is not subject to accreditation.***	Where appropriate, a trial wash is performed in which the sample is prepared and washed as it would be on the day of treatment. This helps the senior embryologist decide on the most suitable type of fertility treatment should this prove necessary.

Additional tests

Vitality stain (for RFC use only):
In cases where the total sample motility is less than 5%, a vital stain may be carried out. This enables the percentage of live sperm in the sample to be calculated, thus providing differentiation between sperm which are simply immotile, but alive, and those that are dead. This test is only carried out if deemed necessary by an Andrologist. NB. This test is not accredited.

Culture & sensitivities:
If the sample is bloodstained, or if it contains 1 million or more round cells/ml it will be referred to the BHSCT Microbiology lab for culture & sensitivities in order to detect any sign of infection. The results of this analysis will be sent independently to the referrer. The Andrologist is responsible for transportation of the sample to the BHSCT Microbiology Lab. This test is only carried out if deemed necessary by an Andrologist.

Retrograde analysis:
In rare cases, semen passes into the bladder at ejaculation and little or no ejaculate will be present. The retrograde sample (post-orgasmic urine sample) can be assessed for the presence of sperm.
Referring clinicians should state clearly on the referral form if this test is required.

13. Reporting of Results
(ISO 15189:2012 5.8)

The 'Semen Analysis Report Form' is generated using the RFC IDEAs database.
This report will be posted to the referring doctor or the named individual (e.g. Secretary) at the address that is detailed on the referral form.

Patients who are attending the RFC will receive their semen analysis result at their next review appointment with their RFC doctor. This can be up to 12 weeks from the date of the semen analysis appointment.

Andrology and Embryology staff are unable to provide results over the phone, by e-mail or fax due to issues of confidentiality and data protection.

Telephoning should be avoided wherever possible. This is because non-urgent telephone calls can create an unnecessary delay in processing samples.

Interpretative comments and reference ranges are incorporated into the results reports. The department is happy to assist clinicians in the interpretation of test results if required. For advice and interpretation please contact a Senior Embryologist on either 028 90633986 or 028 90632237.

14. Interpretive Comments and Terminology:

(ISO 15189:2012 5.8.2)

Term	Definition
Azoospermia	No sperm present in this sample
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% progressive motility
Teratozoospermia	<4% normal forms

In addition, other self-explanatory interpretative comments, or a combination of the above terms may be added.

15. Sample Rejection/Rebooking Appointments

(ISO 15189:2012 5.4.2 J)

Sometimes it is necessary to reject a sample and/or rebook the appointment. This may be because:

- The first part of the sample was lost by the patient at the time of production.
- The patient did not abstain from sexual activity for 2-7 days before the test.
- The patient was unable to ejaculate on the day of the test.
- Patient arrived with a semen sample in a container which had not been provided and tested by the Andrology laboratory.
- If the sample has been tampered with.
- The patient was more than 30 minutes late for their appointment and other patients may be disadvantaged by this.
- Other reasons.

16. Repeat Tests
(ISO 15189:2012 4.7)

It may be necessary to repeat a test for various reasons.
If required, a repeat test is considered necessary to enable the staff to provide direction to the referrer. This may include advice on the most suitable type of fertility treatment should this prove necessary. The repeat test will either be arranged directly by the Embryologist, or a letter will be sent to the referrer stating that a re-referral is required. If considered necessary, directions will be provided on how soon the repeat test should be performed. This will be dependent on the individual patient circumstances. Following an illness, the advice may be to wait for a defined period of time to allow for semen production to fully recover.

If the patient is attending the RFC for treatment and it has been over 1 year since the last semen analysis if may be necessary to arrange a repeat test.

17. Turnaround Time
(ISO 15189: 2012 5.4.2 D)

Patients who have been referred by outside centres (GP, Gynae, or specialist clinics) for a semen analysis will have their results issued to their referring doctor. This will be approximately 2 weeks after their semen analysis. The turnaround times are closely monitored.

Patients who are currently attending the RFC, or who have been referred to the RFC for fertility investigations will receive their semen analysis results at their next review with a RFC consultant. This can take up to 12 weeks from the receipt of referral, (please note that waiting times for review can vary.)

The maximum turnaround time from receipt of referral to posting out of Semen Analysis report (or availability of report to RFC clinicians) is 40 working days.

18. Limitation of Examination Procedures
(ISO 15189:2012 5.4.2 K)

- The Andrology Lab and production rooms are clinical environments. Taking people out of their normal context, into an artificial environment may not reflect their natural behaviour.
- The patient may provide incorrect information, for example, abstinence period or medications.
- The patient may not disclose if they have spilt their sample, may disclose the spillage of the incorrect portion of the sample, or be unsure which portion of the sample was spilt.
- The patients may tamper with the sample (e.g. add water) and not report this.
- The patient may produce their sample by a method other than masturbation, for example, coitus interruptus. This sample may contain other cells unrelated to the ejaculate.
- Analysis can be difficult if there are high levels of debris/round cells/erythrocytes.
- The patient may have produced their sample off site, using a home sample or Male Factor Pak. This may expose the sample to non-optimal temperatures before arrival to the lab, which may affect sperm motility.
- A Home sample or Male Factor Pak being delivered to the lab later than one hour after production may result in motility being affected.
- The patient may have taken, or be taking medications which may affect sperm quality.

- The patient may have been ill in the past 3 months, which may have affected sperm quality.
- Sperm concentration values below 10 million/ml are approximate.
- The semen sample may have insufficient volume to carry out the full range of tests.
- The semen sample may be highly viscous / mucoid which may make analysis difficult.

19. Uncertainty in Diagnostic Semen Analysis

(ISO 15189:2012 5.5.1.3, 5.5.1.4, 5.5.3)

Uncertainty in relation to laboratory testing simply means the existence of doubt or a level of error associated with a particular measurement. A degree of biological uncertainty exists when only a single semen sample is tested. Procedural uncertainty also exists from errors associated with specimen collection, to sample testing (method bias, sampling error and operator error) through to final reporting. Uncertainty values are available on request by contacting the RAS using the contact information on page 4.

Within the Regional Andrology Service, the following steps are taken to minimise uncertainty:

- Semen analysis methodologies are based on WHO recommendations.
- There is robust confirmation of the patient's identity and details on the specimen container(s), request and report forms are matched.
- Strict 'specimen acceptance criteria' are applied as detailed in section 15.
- The period of abstinence is defined (2-7 days). If the patient has not adhered to these guidelines the test will be rebooked.
- It is requested that all patients produce 'on site' to control the variation in sample collection and transportation. Home sample kits will be provided only in extenuating circumstances.
- The interval between production and analysis is defined (between 30 - 60 minutes) and semen analysis is commenced within an appropriate timeframe.
- There is traceability and toxicity testing of materials in significant contact with sperm.
- All laboratory equipment is appropriate and regularly serviced and maintained. Where necessary, calibration is carried out to ISO 15189 standards.
- Samples are well-mixed prior to analysis.
- Measurement of motility is carried out at 37°C.
- Sampling error is minimised by assessing large numbers of sperm wherever possible.
- Members of staff are fully trained and their competency is assessed at least once a year.
- Robust internal and external quality control measures are in place.
- A verification of report step is in place to ensure that the transcription from any hand written laboratory form is free from error.
- Results are checked and authorised by senior staff.

20. Lower Reference Limits

(ISO 15189:2012 5.5.2, 5.8.3

(5th centiles and their 95% confidence intervals) for semen characteristics
(*For professional use only)

Parameter	Lower reference limit
Semen volume (ml)	1.5 (1.4-1.7)
Total sperm number (10^6 per ejaculate)	39 (33-46)
Sperm concentration (10^6 per ml)	15 (12-16)
Progressive motility (PR, %)	32 (31-34)
Vitality (live spermatozoa, %)	58 (55-63)

Sperm morphology (normal forms, %)	4 (3.0-4.0)
pH	≥7.2
MAR test (motile spermatozoa with bound beads, %)	<50

(Adapted from WHO Manual, 5th Edition 2010)

The reference distributions shown provide a description of the semen characteristics of recent fathers, whose partner became pregnant within 12 months of stopping use of contraception.

Semen characteristics are highly variable, both within and among men, and are not the sole determinants of a couple's fertility; the ranges therefore provide only a guide to a man's fertility status.

Patients whose semen characteristics fall below the lower limits given here are not necessarily infertile; their semen characteristics are below the reference range for recent fathers, as are, by definition, those of 5% of the fertile men who provided data used in the calculation of the reference range.

A man's semen characteristics need to be interpreted in conjunction with clinical information.

21. Personal Protective Equipment

(ISO15189:2012 5.3)

Andrology staff adheres to strict safety procedures by using the required Personal Protective Equipment (PPE).

22. Accreditation Status

The RAS has a commitment to establish, maintain and comply with an effective quality management system based on the requirements of BS EN ISO 9001:2015 and ISO15189:2012. The RAS is a UKAS accredited testing laboratory No. 9655 accredited to ISO 15189:2012. RAS takes part in an external quality assurance scheme (UKNEQAS).