Lothian University Hospitals Division
Department of Women's Health

Reproductive Medicine Laboratory User Guide

Reproductive Medicine Laboratory
Edinburgh Fertility Centre
Royal Infirmary of Edinburgh
Little France Crescent
Edinburgh, EH16 4SA

Tel: 0131 242 2463
Email: loth.rmlenquiries@nhs.scot
Website: https://services.nhslothian.scot/edinburghfertilitycentre

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1 Overview

The Reproductive Medicine Laboratory (RML) is part of the Edinburgh Fertility Centre (EFC) based at the Royal Infirmary of Edinburgh. The centre is part of the Women and Children's Services Directorate within NHS Lothian. We provide a diagnostic and clinical service for patients residing in Lothian and Borders who are referred from General Practitioners and clinicians in those areas. Services provided include:

Diagnostic andrology

- Routine semen analysis:
  - As part of fertility investigation for couples wishing to conceive
  - Following a vasectomy reversal
  - Following treatments that can affect fertility (i.e. chemotherapy, radiotherapy, surgery)
- Retrograde urinalysis
  - This may be requested if there is the suggestion that semen is entering the bladder instead of exiting through the penis during orgasm.
- Post-vasectomy semen analysis
  - We perform a confirmatory test if the Pathology Department has seen sperm.

Clinical andrology

- Semen cryopreservation
- Sperm donation

2 Our Team

The RML team consists of Biomedical and Clinical Scientists who are registered with the Health & Care Professionals Council (HCPC) as well as support staff (e.g. secretarial/administrative). We are part of a wider team of specialist doctors, nurses, embryologists, counsellors and administration staff.

Medical Consultant and Clinical Lead (Person Responsible to the HFEA):	Dr Maya Chetty
Director of Women & Children's Services (HFEA Licence Holder):	Allister Short
Consultant Clinical Scientist (Embryology) and Head of Laboratory:	Dr Daniel Collins
Quality Manager:	Dave Wales

The RML retains professional links with the Department of Laboratory Medicine and Clinical Biochemistry (Compliance Manager for Laboratory Medicine and Clinical Manager in Biochemistry).

3 Contact Details

Reproductive Medicine Laboratory
Edinburgh Fertility Centre
Royal Infirmary of Edinburgh
51 Little France Crescent
Edinburgh, EH16 4SA
Tel: 0131 242 2463
Email: loth.rmlenquiries@nhs.scot
Website: https://services.nhslothian.scot/edinburghfertilitycentre

The RML is based at the Royal Infirmary of Edinburgh (Little France) and is situated on the ground floor of the Simpson Centre for Reproductive Health within the Edinburgh Fertility Centre (EFC).

For patients booking an appointment, they must phone 0131 242 2463.
Fertility preservation (sperm storage) referrals must be emailed to loth.rmlenquiries@nhs.scot

4 Opening Hours of the Laboratory

Monday to Thursday: 8:00am to 4:00pm
Friday: 8:00am to 3:30pm

Please note that we may not be open on public holidays. Any changes to service availability due to unforeseen circumstances will be communicated to all medical practices via email and staff within the RML will contact patients if appointments need to be rescheduled.

5 Diagnostic Semen Analysis

We are accredited to the standard, ISO 15189:2022 Medical laboratories – Requirements for quality and competence. This has been assessed by the United Kingdom Accreditation Service (UKAS). We perform accredited tests and additional tests for information as part of a semen analysis:

Accredited tests

- Volume
- Motility
- Concentration
- Morphology

Non-accredited tests (for information)

- Appearance
- Liquefaction
- Consistency
- pH

The process for semen analysis is shown below.

Referral

- eReferrals must be completed by GPs via SCI Gateway
- New Referral > Royal Infirmary of Edinburgh at Little France > Fertility – Semen Analysis
- Please provide any relevant information/medical history

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Provide Semen Analysis Laboratory Form

- Current version available on RefHelp (https://apps.nhslothian.scot/refhelp) > Fertility & Reproductive Endocrinology > Semen Analysis
- Please ensure that patients are given the current version with 2 pages so information is up-to-date.

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Provide Andrology Specimen Pot and Bag
(pre-weighed and toxicity tested)

- Ensure patients are provided with ONE pre-weighed specimen pot.
- Only provide two pots if the referral is querying retrograde ejaculation.

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Patient Phones Laboratory to Book Appointment

- Patient can phone the lab 2 working days after their referral. This is to allow referrals to be received and triaged.
- Patients must book their appointment within 12 weeks of referral. If they do not, they will be removed from the waiting list and re-referral will be required.

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Semen Analysis Carried Out

- Patient must arrive at their appointment time. If they are more than 10 minutes late, it is likely the appointment will need to be rescheduled.

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Results Issued

- We aim to issue results within 2 weeks of semen analysis.
- Results are available to GPs/clinicians on SCI Store/TrakCare. A paper copy is posted.
- Please note that patients cannot obtain results from the laboratory.

5.1 *Information for GPs and Referring Clinicians*

We accept referrals for patients living in Lothian and the Borders. Referrals must be made by a doctor in the medical practice in which the patient requiring a semen analysis is registered.

5.1.1 Referral criteria for infertility service

Before a couple can be referred to Infertility, there are a number of tests to be carried out beforehand. Information about primary investigation for a female partner can be found on RefHelp (https://apps.nhslothian.scot/refhelp/guidelines/fertilityreproductive-endocrinology). Please note that referring patients for a diagnostic semen analysis is separate to referring a couple to Infertility. Once the appropriate male and female fertility investigations have been carried out, only then should they be referred to Infertility.

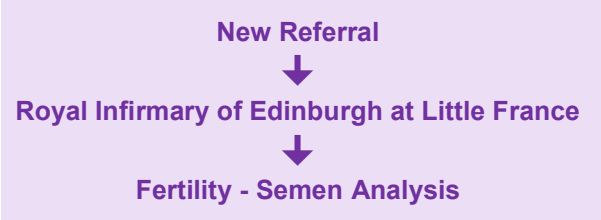
For couples trying to conceive, the semen analysis referral must include the time trying to conceive and any other relevant information. A semen analysis referral should only be submitted if the couple have been trying to conceive for at least 12 months. Exceptions to this criteria are if:

- The patient has any known issues that may affect their fertility
  OR
- If the female (or childbearing partner) is ≥36 years old, or they have reproductive issues of their own (e.g. PCOS, endometriosis, etc).

Please provide relevant information if the couple have been trying to conceive for less than 12 months.

5.1.2 Referring on SCI Gateway

All referrals from GPs must be made via SCI Gateway:



Please ensure the following information is included. If the referral does not contain this information, this may result in the referral being rejected and re-referral required.

Funding supplied by:

- NHS funded:
  - For routine investigation if a patient and their partner have been trying to conceive for at least 12 months (unless there is a reason for early referral as mentioned above).
  - Post-vasectomy semen analysis
  - Post-chemotherapy/surgery follow-up
  - Single semen analysis for medical information as part of monitoring or treatment planning (e.g. referred from Urology).

- Self-funded
  - If a patient and their partner have been trying to conceive for less than 12 months and they do not meet the criteria for early referral
  - If a patient is interested in finding out their sperm quality rather than trying to conceive
  - If a patient wishes to have additional analyses when not required according to previous laboratory recommendation (e.g. if the next step indicated in guidance is a referral to the fertility clinic).
  - Please note that for a self-funded semen analysis, the medical practice will need to be able to invoice the patient. The medical practice is charged the self-funded fee centrally by Laboratory Medicine.

Semen analysis:

- Routine fertility investigation
- Reversal of vasectomy
- Post-vasectomy semen analysis
- Post chemo/radiotherapy follow-up
- Query retrograde ejaculation

Previously tested:

- Yes or No
- Date of previous test, if applicable

Currently trying to conceive:

- Yes or No
- Number of years/months

Date of vasectomy (if applicable):
The UK guidelines for post-vasectomy semen analysis state that testing should take place a minimum of 12 weeks after surgery and after a minimum of 20 ejaculations.

5.1.3 Manual referrals for hospital and Chalmers clinicians

Semen analyses may be requested by a clinician in an NHS Lothian Hospital, Chalmers Centre or Spire Murrayfield. Reasons for semen analyses referrals may include:

- Repeat testing for a patient attending Edinburgh Fertility Centre or Department of Reproductive Endocrinology
- Assessing the impact or monitoring a medical condition or certain drug treatments that can affect fertility
- Assess effectiveness of a vasectomy reversal
- Follow-up semen analysis following chemo/radiotherapy or surgery
- Post-vasectomy semen analysis (Chalmers Centre)

We are unable to accept referrals from facilities where there is no Third Party Agreement (TPA). Any request to set up a TPA is directed to the Senior Biomedical Scientist/Consultant Embryologist and EFC Quality Manager in the first instance. If feasible, the request is to be discussed between operational/service management for both parties.

5.1.4 What to give to the patient

Semen Analysis Laboratory Form

- Please ensure this is the current version – available on RefHelp.
- Please print both pages as the second page has important information for the patient
- Please attach a patient label and GP label to the corresponding sections of the form

It is important that patients are given the current version that is available on RefHelp to ensure they have correct and up-to-date information. Additionally, there are occasions when the laboratory is required to update the lab entry information.

Andrology Specimen Pot (pre-weighed and toxicity tested) and Specimen Bag

- ONE specimen pot only (unless querying retrograde ejaculation for which two are provided)
- Our pots are pre-weighed with handwritten numbers on the lid and side of the pot
- We toxicity test andrology pots to ensure the plastic is not harmful to sperm.

If the incorrect specimen pot is given, this can negatively impact semen analysis results. Even if results show normal parameters, it may not be entirely accurate or representative for the patient.

The andrology pots incur a higher cost than normal sputum pots because they are pre-weighed and toxicity tested, so we kindly request that our pots are stored separately to other similar looking pots so that they are not given out for other laboratory tests.

5.1.5 Turnaround time for results

Results are entered onto our laboratory system (Apex) and all reports are checked, authorised and signed off by the HCPC Registered Clinical Scientist in Andrology (Senior BMS) or Consultant Clinical Scientist. We aim to authorise and issue results within 2 weeks of analysis. Once they are clinically authorised, the results transfer to SCI store so that they are available electronically to the referring GP/clinician. A paper copy of results is also posted to the referring medical practice.

Please provide the patient their results – there may be additional information in the comments section of the results report.

Please note that the laboratory does not give results directly to patients.

5.1.6 Repeat semen analysis

If results in the patient's first sample are considered normal (i.e. equal to or better than the reference values), a repeat sample is not required. The only exception to this is if there are factors that may cause results to appear "normal" but results may not be representative. However, it is important to note that even when results may not be entirely representative/accurate for a patient, a repeat may not be necessary – full guidance will be provided in the comments section of the report containing results. If the comment is "essentially a normal sample", a further test is not required.

If the comment on the report suggests a repeat to confirm/exclude results, you do not need to complete another referral on SCI Gateway. From your original referral, we are able to transfer it onto our system for the repeat semen analysis.

We ask that when providing your patient with their results, if a repeat is required, please provide them with a new specimen pot and semen analysis laboratory form. They will need to follow the instructions to book another appointment.

If a patient has submitted two samples within a year and both show abnormal parameters, a referral to the fertility clinic will be suggested. Most referrals are for couples trying to conceive so referrals are submitted as described on RefHelp: (https://apps.nhslothian.scot/refhelp/guidelines/fertilityreproductive-endocrinology/).

Referral to other another department (e.g. urology) may be appropriate based on the patient's medical records held by the medical practice and this will be determined by the GP.

A repeat semen analysis may be requested because one or more of the semen parameters are below the clinical decision limit. The repeat should ideally be 3 months later (NICE guidelines) providing all sample requirements were met to obtain the optimum sample (e.g. abstinence period, analysis within 1 hour of production). The exception to the 3 months would be if the sperm count is very low or no sperm have been seen; referring GPs/clinicians do not need to do anything except provide the results to the patient along with a new specimen pot and form. The laboratory will have the information about the appropriate timescale for a patient's repeat appointment and book this accordingly.

These types of repeat analyses will not affect timescales to refer a couple to the fertility clinic (Infertility) – because you have at least one result that is representative for that patient, they may be referred providing all other criteria and partner tests have been carried out. The patient must still book their repeat analysis and these results should be available for the fertility doctor when the patient is seen at the Edinburgh Fertility Centre.

5.1.7 Interpretation of results and clinical advice

Semen assessments are carried out in accordance with the 2021 World Health Organisation (WHO) laboratory manual for the examination and processing of human semen (6th Edition). See Section 5.5 for reference values (clinical decision limits).

Numeric values on the report are highlighted in bold if they are outside the normal parameters; normal parameters are also shown on the report. The comments section will support interpretation of results and any recommendation to repeat or refer, if appropriate.
If further advice is needed, the referring GP/clinician can contact the Senior Biomedical Scientist/Clinical Scientist or Consultant Embryologist.

Senior BMS/Clinical Scientist	0131 242 2462	Laura.Wales@nhs.scot
Consultant Embryologist	0131 242 2498	Daniel.Collins@nhs.scot

Alternatively, please phone 0131 242 2463 or send an email to loth.rmlenquiries@nhs.scot with "Clinical Advice Required" in the subject heading and this will ensure it is forwarded to the appropriate scientist available.

5.2 *Information for Patients*

5.2.1 Booking your appointment

After being referred by your GP or hospital/Chalmers clinician for a semen analysis, please allow 2 working days for the referral to be received and reviewed before phoning to book your appointment.

When you contact us, a member of the laboratory team will ask for the following information:

- Your name and date of birth
- If you have a form and specimen pot
- The numbers on the lid of your pot – this is to check that you have been given the correct type of pot. We pre-weigh our pots to ensure accuracy of certain semen analysis parameters and we toxicity test the pots to ensure the plastic is not harmful to sperm. If you have been given the incorrect pot, you will need to collect the correct one before providing your sample; otherwise your results may be affected and you may have to provide a further sample for analysis.
- If you have not been given a laboratory form, you will need to obtain one as there is important information on page 2 to ensure you are aware of factors that are needed to optimise the quality of your sample.
- We will ask if you are able to deliver your sample to the laboratory within 50 minutes of production (45 minutes for post-vasectomy semen analysis). This is to determine if you are able to produce your sample at home or if you will need to use one of our private rooms within the centre. Please note that the use of other areas (i.e. a public toilet) to produce a sample is unlawful under the Sexual Offences Act (2003).

If we have not received a referral from your GP or clinician, we will not be able to book an appointment.

You must contact the laboratory within 12 weeks of being referred to book your appointment. If you do not contact us within this time, you will be removed from our waiting list and you will need to be re-referred.

If you are more than 10 minutes late for your appointment, it is unlikely that we will be able to analyse your sample. This is because tests are time-sensitive and we have other patient samples to analyse throughout the day. If you think you are going to be late for your appointment, contact the laboratory as soon as possible and they will advise you on whether or not it may be possible to accept your sample.

5.2.2 Producing your sample

- Abstain from ejaculation (through masturbation or sexual intercourse) for at least 48 hours before your appointment and no more than 7 days should have passed since your last ejaculation.
- Immediately before producing the sample, pass urine and wash hands and genital area with soap and warm water.

- Avoid touching the inside of the pot as this area is sterile.
- Produce the sample by masturbating directly into the sample pot. Do not collect the sample by intercourse or use a condom to collect the sample (ordinary condoms contain spermicide which kill sperm).
- Collect the entire ejaculate into the sample pot.
- Replace the lid on the sample pot, ensuring a good seal to avoid spillage.
- Ensure your name and date of birth is on the pot.
- Place the pot in an upright position into the sealable part of the sample bag.
- Complete the required information on the Andrology Request Form (refer to Section 4.3).
- **Post vasectomy samples:** Analysis is to be after a minimum of 12 weeks after surgery and after a minimum of 20 ejaculations.

If you are unable to produce a sample by masturbation, please contact the laboratory.

5.2.3 Transporting your sample to the laboratory

All samples are to be delivered directly to our laboratory reception at your appointment time.

- If producing at home, we need to receive your sample within 50 minutes of production (45 minutes for post-vasectomy)
- Complete the top half of the Semen Analysis Laboratory Form
- Keep the sample upright to avoid leakage
- Keep the specimen pot containing your sample as close to body temperature as possible (i.e. in an inside jacket pocket)

If you have booked an appointment to produce your sample in one of the private rooms, a member of our team will show you into the room and provide instructions for semen collection. After you have produced your sample, complete the relevant sections of the Semen Analysis Laboratory Form and hand your sample and form to the member of staff at the laboratory reception.

5.2.4 Information on the specimen pot and laboratory form

	Semen Analysis Laboratory Form	Specimen Pot
Mandatory Information	• Surname • Forename • Date of birth • CHI (Community Health Index)* • Requestor location (Ward / Clinic / GP and medical practice) • Date sample produced • Time sample produced	• Surname • Forename • Date of birth
Other information required:	• If complete ejaculate was collected • Number of days since last ejaculation • (PVSA) Date of vasectomy • (PVSA) Confirmation that it has been a minimum or 12 weeks since surgery and sample produced after a minimum of 20 ejaculations	N/A

5.2.5 Sample rejection

There are some circumstances where we will not be able to analyse your sample:

- If you do not have an appointment
- If you have not produced your sample but a home production appointment has been booked
- If you are late for your appointment (more than 10 minutes after your appointment time)
- If the sample has leaked
- Samples more than more than 2 hours old

5.2.6 Getting your results

We aim to authorise and issue results within 2 weeks of analysis. Results are sent directly to your referring GP/clinician and via the NHS Lothian electronic system and a paper copy is also posted. Please note that results must be provided by your referring GP/clinician and they are not given out by the laboratory team.

5.3 Semen Analysis Tests

The RML provides a range of diagnostic andrology tests and follows guidelines from the World Health Organisation (WHO) "Laboratory manual for the examination and processing of human semen" (6th Edition, 2021). A routine semen analysis will assess the following parameters:

Parameter	Explanation
Semen volume	The volume of the ejaculate measured in millilitres (ml).
Motility	Whenever possible, the motility of at least 200 sperm is assessed and expressed as a percentage showing fast progressive, slow progressive, non-progressive and immotile (%).
Concentration	Millions of sperm per millilitre (million/ml).
Normal forms	Percentage of sperm with normal morphology / normal forms (%). Teratozoospermia index (TZI) scoring method is not currently used by the laboratory.
pH	The pH of the ejaculate.
Appearance	A qualitative assessment of the visual appearance of the ejaculate (Normal / Abnormal).
Liquefaction	A qualitative assessment of sample liquefaction – measured at least 30 minutes (Normal / Abnormal).
Consistency	A qualitative assessment of viscosity (Normal / Abnormal).

We carry out other macroscopic and microscopic assessments and these observations will be included in the comments of the report containing results. This may include the presence of round cells, debris, mucus threads/strands/clumps, aggregation, agglutination, epithelial cells, gelatinous bodies, non-specific aggregation and red blood cells. The number of non-sperm cells in the ejaculate is not included on the report unless there are >5 million/ml, in which case it will be added to the comments section. It should be noted that no differentiation is made between immature germ cells and leukocytes.

Tests accredited to ISO15189:2022:

- Volume
- Motility
- Concentration
- Morphology

Non-accredited tests (for information):

- pH
- Appearance
- Liquefaction
- Consistency

5.4 Post-Vasectomy Semen Analysis

We perform confirmatory analysis on samples that have initially been assessed by the Pathology Laboratory at the Royal Infirmary of Edinburgh. Only if sperm has been sperm, would the Reproductive Medicine Laboratory carry out the confirmatory test to assess if sperm are motile. We use the 2016 laboratory guidelines for post-vasectomy semen analysis.

5.5 Reference Values / Clinical Decision Limits

Measurements made on semen samples need to be compared with reference values to allow decisions to be made about further investigations or treatment pathway. The WHO (6th Edition) provides these decision limits and are based on results from men in couples starting a pregnancy within one year of unprotected sexual intercourse leading to natural conception. The table below shows the lower reference limits (5th centiles and their 95% confidence intervals) for semen characteristics.

Parameter	Lower reference/ decision limit
Semen volume (ml)	1.4 (1.3 - 1.5)
Progressive motility (%)	30 (29 - 31)
Total motility (%)	42 (40 - 43)
Concentration (million/ml)	16 (15 - 18)
Total sperm number (million/ejaculate)	39 (35 - 40)
Normal forms (%)	4 (3.9 - 4.0)
pH	≥7.2

A semen analysis can support healthcare practitioners understand how the reproductive system is working in terms of sperm production. It is not considered an indicator of fertility/infertility but can provide important information that supports pathways for further investigation or fertility management or treatment.

Routine semen analysis:

- Where there are very low numbers of sperm seen during the initial examination of the semen sample, if there are fewer than 25 sperm seen per counting chamber, this means that there are too few sperm counted for an accurate determination of concentration and we will report it as <56,000/ml.
- If there are no sperm seen during the initial examination, a different counting chamber is used – this is called a large volume fixed depth (LVFD) slide. If there are fewer than 25 sperm counted in both chambers of the slide, there will be too few sperm counted for an accurate determination of concentration and we will report this as <2,000/ml.

5.6 Measurement Uncertainty

Every measurement is subject to a degree of uncertainty. There are a number of factors in the processing of semen during analysis that can contribute to measurement uncertainty such as sample collection and transport, the measuring equipment, the environment, the operator or from other sources. Through good laboratory practice such as equipment calibration, careful calculation, accurate record keeping and audits, measurement uncertainty can be minimised. Our laboratory has identified potential factors that may contribute to variation of measurement for each parameter and have quality control processes in place to ensure such variation or uncertainty is maintained at an acceptable level to minimise the clinical impact and risk to patients. The measurement uncertainty for our laboratory is regularly reviewed and reassessed whenever there is a significant change (e.g. test method, equipment or operators).

When reviewing a patient's results against the reference values/decision limits, the uncertainty is to be taken into account, especially if there are factors that may have impacted results or where parameters are borderline. For example, a patient may submit a sample for semen analysis and have a sperm concentration of 16 million/ml and then provide a repeat sample which has a sperm concentration of 18 million/ml. These two results are not significantly different as they fall within the measurement uncertainty range within the confidence interval of 95%.

5.7 Additional Tests

Add-on tests are not possible with semen analyses as samples are discarded once the patient's analysis is been completed.

5.8 Factors that can affect results

Sample analysis is standardised to minimise procedural variation but this cannot be excluded entirely as certain aspects of the process (e.g. patient compliance or use of the correct specimen container) are outside the control of the laboratory. Factors that could affect the performance of the examination and results are shown below.

Factor	Example
Patient preparation	Is the patient on medication that might interfere with results? Optimal abstinence for semen analysis samples is 2 to 7 days. - Less than 2 days could result in lower volume and concentration, and therefore lower total sperm count. - More than 7 days could result in lower progressive motility, total motility and total motile sperm, and higher concentration, volume and total sperm count. Whole sample must be collected for accurate results - If the entire ejaculate is not collected, this could result in a lower volume, concentration and total sperm count. If the first part of the ejaculate (most sperm-rich fraction) is not collected, this is likely to have more of an effect on results. For patients with potential retrograde ejaculation, a post ejaculate urine sample should also be collected and handed in along with the ejaculate.
Time of specimen collection	Was the sample analysed within 50 minutes (45 minutes for post vasectomy) of production? - If the sample is delivered to the laboratory more than 50 minutes (45 minutes for post-vasectomy) since production, motility can be decreased. - If the sample is more than 2 hours old, the sample will not be analysed. Time since last specimen - It is recommended that the number of days abstinence for a repeat sample should be around the same number of days.
Collection container	An appropriate sterile container must be used for sample collection. - The container must be supplied by the RML as they are weighed and toxicity tested. - If the pot is not pre-weighed, this can result in a lower volume, total sperm count and total motility. - If the pot has not been toxicity tested, the plastic could potentially damage the sperm and result in a decrease in motility and total motile sperm count.
Transport to the laboratory	Accurate semen analysis is dependent on timely delivery of the sample to the laboratory, whilst maintaining body temperature. - If the sample has not been kept near to body temperature and the specimen pot is cold upon arrival at the laboratory, this can result in decreased motility. - If the sample pot has been kept above body temperature, this can kill all sperm and result in no motile sperm.

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6 Clinical Andrology: Sperm Storage

The Human Fertilisation and Embryology Authority (HFEA) regulate the storage and use of human sperm. The Edinburgh Fertility Centre is licensed by the HFEA for the processing and storage of gametes and embryos. Sperm may be stored for the purpose of fertility preservation, back-up storage for patients scheduled for fertility treatment or for donation. All documents required can be found on the Edinburgh Fertility Centre website (Edinburgh Fertility Centre – NHS Lothian | Our Services).

Edinburgh Fertility Centre

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Treatments and Services

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Fertility Preservation: Sperm Freezing

https://services.nhslothian.scot/edinburghfertilitycentre/treatments-and-services/fertility-preservation-sperm-freezing/

6.1 Information for Referring Clinicians

This service is available to patients wishing to store sperm prior to treatment that may impair their fertility (e.g. chemotherapy, radiotherapy, specific cytotoxic drug or hormone treatment). Referrals may be accepted from NHS Lothian hospital departments or from the Gender Identity Clinic at Chalmers Centre. We do not accept patient self-referrals or referrals where there is no medical reason for fertility preservation.

6.1.1 Referral for fertility preservation

The referring member of clinical staff must complete the Fertility Preservation Referral Form and send it to the RML team (loth.rmlenquiries@nhs.scot). If the referral has not been fully completed, it will be returned to the referrer for further information.

The last section of the form is the medical practitioner's statement which must be completed by a GMC-registered medical professional.

- If the referral is emailed by a specialist nurse, the form will need to be signed and dated by a GMC registered clinician then scanned to the RML enquiries mailbox.
- If the GMC registered clinician emails the RML directly, a signature is not necessarily required and confirmation in writing within the email is acceptable.

6.1.2 Referral for IVF back-up/SSR (from within EFC)

Clinicians with the centre may request sperm storage for patients who are due to undergo fertility treatment with our centre. Reasons for sperm storage may include:

- Poor sample quality (in case a fresh ejaculate on the day of treatment is not suitable)
- If there is significant production anxiety
- If the sperm provider is not going to be present on the day of egg collection (e.g. if they work off-shore or in the armed forces).

Referrals may be received from the infertility clinic or Reproductive Endocrinology and these cases are to be discussed with an appropriate clinical scientist (Consultant Embryologist, Lead Embryologist or Senior BMS/Clinical Scientist in Andrology). Poor sperm quality on its own does not present the requirement to store sperm, particularly if there is no significant decline in parameters.

The Semen Cryopreservation for Back-up Referral Form [EFR-F-392] is located on Q-Pulse. The referral form also functions as a checklist. Each section must be completed, including the funding stream. The referral should be given to the RML team along with copies of relevant consent forms as detailed.

Back-up storage is intended for patients who are to undergo fertility treatment at the Edinburgh Fertility Centre, so if they do not meet the eligibility criteria for NHS funded fertility treatment, they would be required to self-fund sperm storage for their intended treatment. This helps to manage storage tank capacity by avoiding the storage of sperm which is may not be used in treatment in the centre.

6.1.3 Eligibility for NHS funded sperm storage

The referral form includes information about eligibility for NHS funded sperm storage. If the patient does not meet the criteria, we are able to offer self-funded sperm storage. The cost of this is provided on our website on the "Self-Funded Treatment" webpage.

6.1.4 Provision of information and consent forms

To enable patients to provide informed consent, they need to have sufficient time to read relevant information and consent forms although we understand that for urgent oncology referrals, this may not always be possible. When referring a patient, they should be provided with the following:

- Patients Information: Sperm Freezing
- HFEA CD form (Your consent to disclosing identifying information)
- HFEA GS form (Your consent to the storage of your eggs or sperm)

  ***OR**, if the patient has a partner they wish to name:*
- HFEA MT form (Your consent to your sperm and embryos being used in treatment and/or stored (IVF/ICSI)
- Patient Consent and Contract - Sperm Freezing and Storage

6.1.5 Screening for transmissible infections

Prior to storage, the HFEA requires that specific screening tests are carried out.

Patient Screening (minimum testing requirements)	Trak Order (as they appear)
HIV-1 and -2	*HIV Ag/Ab Antibody screen*
Hepatitis B surface Ag	*Hepatitis B Surface Antigen Qualitative (ACTIVE INFECTION)*
Hepatitis B core Ab	*Hepatitis B Core IgG Ab*
Hepatitis C core Ab	*Hepatitis C Antibody (HCV) IgG Screen*

Additional tests are required if sperm samples are likely to be used in surrogacy treatment and patients undergo the same initial screening as a gamete donor. In addition to the minimum testing requirements, the following tests are also required.

Additional tests (donors and patients likely to require surrogacy treatment)	Trak Order (as they appear)
Hepatitis C Ag **or** HCV PCR if Ag unavailable	*Hepatitis C Antigen (Initial screen and Annually)* *Hepatitis C Virus (HCV) RNA PCR (Viraemia)*
HTLV-1/-2	*Architect HTLV I/II Ab Assay*
CMV IgG	*(CMV) IgG – (immune status)*
CMV IgM	*CMV IgM (VIDAS) Profile*
Syphilis	*Anti-Treponema IgG antibody*
Chlamydia	*Chlamydia Gonorhoea dual*
Gonorrhoea	*As above*

Please note that screening must be carried out **before** the cryostorage appointment. The turnaround time for routine virology screening is usually around 3 - 4 days but screening can be processed as "urgent" – the Virology Laboratory must be notified in advance by telephone (0131 242 6086). If screening has been carried out and a test has been missed from the order/test request, Virology should be emailed as soon as possible with the add-on test request (loth.virologyadvice@nhs.scot). We are unable to store sperm if any of the tests, except for CMV IgG are positive.

6.1.6 Counselling

All patients must be offered the opportunity to speak with one of our fertility counsellors prior to signing consent forms. This may not be feasible or practical for oncology patients but in any case, counselling can also be arranged after sperm storage if the patient wishes.

6.1.7 Obtaining consent for sperm storage

Those who are trained and competent to obtain storage consent will go through each consent form and provide relevant information to the patient. It is important to record information provided before obtaining consent. There is a document available in the Document Library, “Information Provided before Obtaining Consent - Sperm Freezing Record”.

In some circumstances, the online consent platform may be used.

6.1.8 Patient contract and financial declaration

Each patient storing sperm must have complete a Sperm Cryopreservation Patient Contract and Financial Declaration (NSD) [EFR-F-486]. The front page is completed by clinic staff (this includes RML scientific staff) to indicate if the patient is currently required to pay for storage.

This form is usually completed in the centre but for patients referred from Chalmers, this can be included in the information and consent pack posted before their clinic appointment.

When ready to book an appointment, we are happy to arrange this via phone call or by email. Most oncology appointments are booked by phone when the patient is at their appointment with the specialist nurse – at this point, the referral and consents will be completed and blood screening carried out (Section 6.3).

6.2 Information for Patients

Following your referral, you will need to carefully read information about sperm storage and complete consent forms and a financial declaration. You will also need to undergo screening tests (see Section 6.1.5).

6.2.1 Consent for sperm storage and use in future treatment/training

The consent form you complete for sperm storage will depend on whether or not you have a partner you wish to name to use your sperm for future fertility treatment.

HFEA GS form: Your consent to the storage of your eggs or sperm
If you do not have a partner you wish to name at the time you are referred for sperm storage, you will need to complete the HFEA GS form. This allows you to decide on the following:

- How long you wish for your sperm to be stored
- If you consent to your sperm being used for training purposes
- If your sperm can be used for training purposes in the event of your death or being unable to make decisions (mental incapacity)

HFEA MT form: Your consent to your sperm and embryos created outside the body using your sperm being used in treatment (IVF and ICSI) or stored
If you have a partner you wish to name at the time of sperm storage, you will need to complete the HFEA MT form. This allows you to decide on the following:

- If you consent to embryos being created for your named partner’s treatment
- How long you wish for your sperm (and embryos, if applicable) to be stored
- If you consent to your sperm/embryos being used for training purposes
- What you wish to happen to your sperm/embryos in the event of your death or mental incapacity
- If you consent to being registered as the legal parent of a child born using your sperm in the event of your death.

6.2.2 HFEA CD form: Your consent to disclosing identifying information

This consent form covers consent relating to your personal and identifying information. You will need to state if you give consent for their information being disclosed to appropriate people outside the Edinburgh Fertility Centre, such as your GP, other healthcare professionals, auditors or administrative staff. The consent also covers the type of research you may or may not consent to be included in (i.e. non-contact and contact).

6.2.3 Local consent and financial contract

You will need to complete a local consent and financial contract. These forms confirm that you have read and understood the information in the information sheet and the HFEA consent forms. It also includes a section relating to the funding for your sperm storage. This may be NHS funded or self-funded at the time of storage but it is important to understand that even if it is NHS funded at the time of storage, this may change if circumstances change and you no longer meet the criteria for NHS funded sperm storage. The laboratory will contact you as part of a regular review and our team will be able to guide you and provide you with the relevant information.

6.2.4 Review of stored sperm

The laboratory will contact you every few years to check that your information/circumstances have not changed and to establish if you wish to change your consent. You will also be contacted when it is nearing the end of the consented storage period. It is therefore important that you notify the laboratory of any change in address or contact details.

Since the changes in the law with regards to gamete and embryo storage on the 1st July 2022, patients can now store their gametes and embryos up to 55 years in total from the day of cryopreservation. However, we are still required to carry out a storage review every 10 years where you will need to renew the relevant HFEA consent forms to continue storage.

For many oncology patients, chemotherapy agents are not as toxic as older treatments and fertility can be restored. A diagnostic semen analysis is not required to continue storage but is required to determine if storage can be funded by the NHS or if you must self-fund. In some circumstances, a semen analysis is not appropriate (e.g. bilateral orchidectomy or a genetic basis for premature infertility, such as Klinefelter's).

6.3 Post-chemotherapy semen analysis

As part of the follow-up for patients who have stored sperm before treatment (e.g. chemotherapy), it is recommended to provide a semen sample for analysis at least 12 months after treatment has stopped, to assess their fertility.

The analysis should be treated as a routine semen analysis (refer to previous sections in this User Guide) and this can support a decision to dispose of samples stored or to continue storing sperm depending on the results.

6.4 Transporting sperm between licensed fertility centres

If you are due to have fertility treatment at another centre, your stored sperm may be transported to the other centre. Contact the laboratory for more information.

7 Patient Confidentiality

The laboratory operates under NHS Lothian's strict patient confidentiality policy and is also required to comply with the HFEA guidelines, regulations and standards. The laboratory is also required to comply with patient confidentiality under the Data Protection Act 2018, the General Data Protection Regulation (GDPR) 2018, the Human Rights Act 1998 and the Public Health (Scotland) Act 2008 as well as the common law in Scotland on privacy and confidentiality.

GDPR introduced the concept of "special category data" which includes, but not limited to, a person's health, sex life, sexual orientation, race, ethnic origin and gender history. 'Special category data' requires a greater degree of protection because it is more sensitive than any other personal data.

The Special category data processed by the laboratory is done so lawfully as it is pertinent to patient care and treatment.

All personal health information is held under strict legal and ethical obligations of confidentiality. Information given in confidence will not be used or disclosed in a form that might identify a patient without their consent.

8 Complaints and Feedback

The laboratory is committed to continually improve services offered and welcomes all forms of feedback. As detailed in the NHS complaints procedures, a person may complain in person, by phone, by email or in writing to the department involved or by using the Patient Experience Team's (PET) online complaints form. Information can be found on:
https://www.nhslothian.scot/yourrights/patient-experience-team-tell-us-about-your-experience/

If a patient submits a complaint in writing, or they want the information in another language or format, they may contact the PET.

Patient Experience Team (PET)
Freepost RSTR-RLJH-YLTR
Waverley Gate
2 - 4 Waterloo Place
Edinburgh, EH1 3EG

Tel: 0131 536 3370
Email: loth.feedback@nhs.scot
Website: https://www.nhslothian.scot/yourrights/

9 References

(1) ISO 15189. Medical laboratories - Requirements for quality and competence. Geneva, Switzerland: International Organization for Standardization; 2022

(2) World Health Organization: WHO laboratory manual for the examination and processing of human semen. 6th ed. Geneva: World Health Organisation; 2021. Licence: CC BY-NC-SA 3.0 IGO.

(3) The 2016 laboratory guidelines for post-vasectomy semen analysis: Association of Biomedical Andrologists, British Andrology Society and British Association of Urological Surgeons (2016). J Clin Pathol. Jul;69(7):655-60. doi: 10.1136/jclinpath-2016-203731. Epub 2016 Apr 15.

(4) Fertility, pregnancy and childbirth (Commissioned by NICE) (2013). Fertility problems: assessment and treatment (Clinical guideline [CG156]).

(5) Human Fertilisation & Embryology Authority Code of Practice (9th Edition)