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
Website: www.nhslothian.scot.nhs.uk/edinburghivf

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1 Introduction

This manual describes the policies, procedures and range of services offered by the NHS Lothian Reproductive Medicine Laboratory (RML), which 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.

We provide a diagnostic and clinical service for Lothian and Borders patients who are referred from General Practitioners and clinicians in those areas.

Services provided include:

- Routine semen analysis:
  - as part of fertility investigation for couples wishing to conceive
  - following a vasectomy reversal
  - following treatments that can affect fertility (ie. chemotherapy, radiotherapy, surgery)
- Retrograde urine analysis
- Post-vasectomy semen analysis (confirmatory test following Pathology results)
- Semen cryopreservation
- Sperm donation

The professional and managerial links within Women's Health and in EFC are:

- Allister Short, Service Director of Women & Children's Service (HFEA licence holder)
- Dr K. Joo Thong, Clinical lead for EFC (HFEA Person Responsible)
- Dr Daniel Collins, Consultant Clinical Scientist in EFC and Head of Laboratory for RML.

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

This user guide, which replaces earlier editions, contains details of the tests and services available, including laboratory hours, how to refer patients, how results are reported, quality control parameters and additional information to assist in the proper interpretation of the results.

2 Contact Details

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).

Address: Reproductive Medicine Laboratory (RML)
Edinburgh Fertility Centre (EFC)
Royal Infirmary of Edinburgh
Little France Crescent
Edinburgh, EH16 4SA

Phone:	General Office (Enquiries / Request sample pots)	0131 242 2463
	Andrology Laboratory	0131 242 2456
	Edinburgh Sperm Bank (answer machine)	0131 242 2464
	Consultant Clinical Scientist	0131 242 2498
	RML Senior Biomedical Scientist (BMS) / Clinical Scientist	0131 242 2462

Email:	General Andrology	RML.Enquiries@nhslothian.scot.nhs.uk
	Edinburgh Sperm Bank	Edin.Donor@nhslothian.scot.nhs.uk

3 Opening Hours of the Laboratory

General Office: Monday to Friday, 08:00 – 16:00

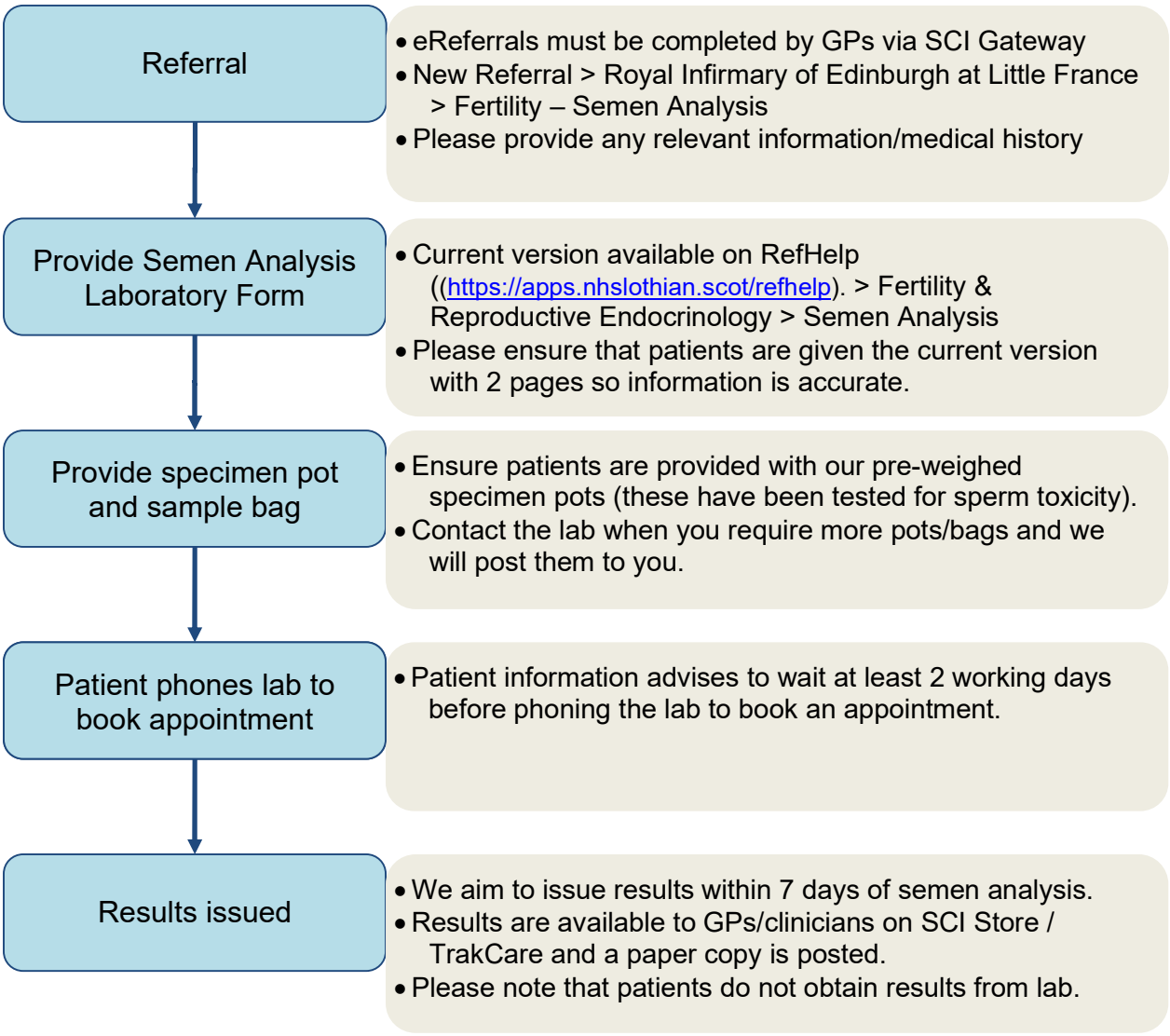
Semen Analysis: Monday to Friday, 09:00 – 15:00 (**by appointment only** following referral)

Please note that we do not offer an "out-of-hours" service.

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.

4 Diagnostic Semen Analysis

4.1 Overview of referring patients and obtaining results



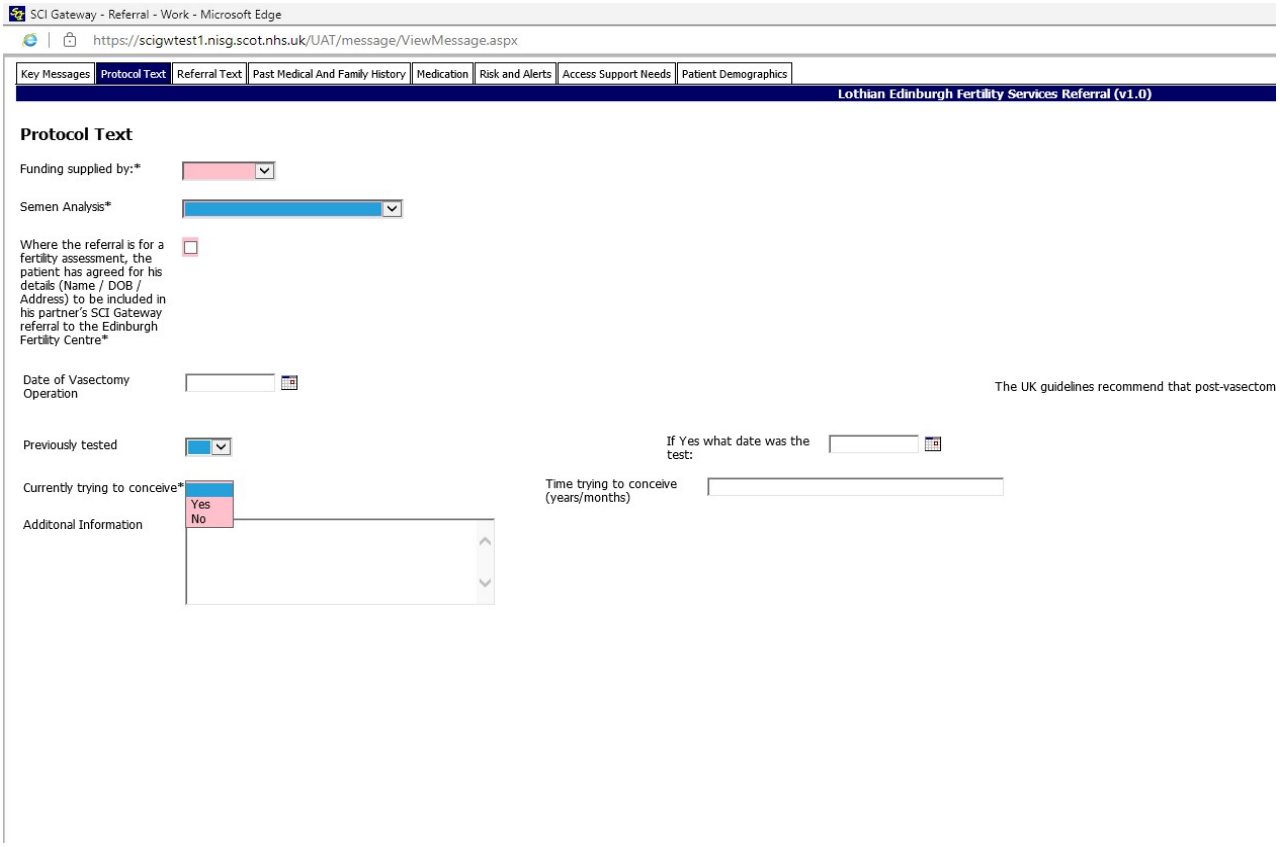
4.2 GPs referrals for patients

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.

A diagnostic semen analysis is the primary male fertility test required prior to referral to Infertility, as are the female fertility investigations. 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 investigation have been carried out, only then should they be referred to Infertility.

All referrals from GPs must be made via SCI Gateway:
New Referral ⇨ Royal Infirmary of Edinburgh at Little France ⇨ Fertility - Semen Analysis

1. Funding supplied by:
   - NHS funded:
     - For routine investigation if a patient and their partner are trying to conceive
     - Post-vasectomy semen analysis (see Section)
     - Post-chemotherapy/surgery follow-up
   - Self-funded
     - 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 (eg. if the next step is a referral to the fertility clinic).
2. Semen analysis:
   - Routine fertility investigation
   - Reversal of vasectomy
   - Post-vasectomy semen analysis
   - Post chemo/radiotherapy follow-up
   - Query retrograde ejaculation
3. 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.
4. Previously tested:
   - Yes or No
   - Date of previous test, if applicable
5. Currently trying to conceive:
   - Yes or No
   - Number of years/months



Provide the patient with the Semen Analysis Laboratory Form (only provide 2 pots if querying retrograde ejaculation):

- This is double-sided with patient information on page 2
- Attach a patient label to the "Patient information" section, including their name, address, date of birth and CHI to the appropriate box
- Attach your GP label (or handwrite details) to the "Referrer information" section
- As detailed in the Patient Information on page 2, patients should call the laboratory at least 2 days after the referral has been sent.
- Forms can be found on:
  RefHelp:
  https://apps.nhslothian.scot/refhelp/guidelines/Pages/SemenAnalysis.aspx
  or
  The Edinburgh Fertility Centre website in the Document Library at the bottom of the page:
  Edinburgh Fertility Centre
  ⇨ *Fertility Investigations*
  ⇨ *Male Fertility Investigations*
  https://weare.nhslothian.scot/edinburghfertilitycentre/fertility-investigations/male-fertility-investigations/

Provide the patient with the andrology specimen pot and specimen bag:

- These pots are pre-weighed with handwritten numbers on the lid and side of the pot
- Andrology pots are toxicity tested to ensure the plastic is not harmful to sperm
- When medical practices require more pots, they should contact the RML to order more. We will send a large envelope with a stock of pots and specimen bags.

Samples from patients known to have a blood-borne virus (BBV) such as HIV, Hepatitis B or Hepatitis C are not processed differently to samples from BBV-negative patients. Universal precautions are used in the laboratory and appropriate personal protective equipment is utilised at all times.

4.3 Hospital and Chalmers referrals for diagnostic semen analysis

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

- Repeat testing for a patient attending Edinburgh Fertility Centre for patients going through fertility treatment or testing as part of fertility investigations after seeing a doctor within the 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)

The Edinburgh Fertility Centre website in the Document Library at the bottom of the page:
Edinburgh Fertility Centre
⇨ *Fertility Investigations*
⇨ *Male Fertility Investigations*
https://weare.nhslothian.scot/edinburghfertilitycentre/fertility-investigations/male-fertility-investigations/

We are unable to accept referrals from facilities where there is no Third Party or service level Agreement (TPA/SLA). Any request to set up a TPA/SLA is directed to the Senior BMS/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.

4.4 Post-vasectomy semen analysis (PVSA)

Most referrals for PVSAs are received from the Chalmers Centre in Edinburgh although a small number may be received from GPs.

In any case, the first sample is analysed by the Pathology Department, which is part of the Directorate of Laboratory Medicine at the Royal Infirmary of Edinburgh. This is a separate service to that offered within the Edinburgh Fertility Centre and such samples are delivered directly to pathology. If sperm has been identified, RML carries out confirmatory testing. If no sperm are seen by Pathology, the confirmatory test by RML is not required.

4.5 Appointments for semen analysis

Patients must have an appointment for a semen analysis. As detailed in the information section of the Semen Analysis Laboratory Form, patients should wait at least 2 days before phoning the laboratory office to make an appointment. The referral will be kept on the system for up to 1 year before being removed, if no appointment has been scheduled by the patient.

If the patient lives less than 50 minutes away from the hospital, they are asked to produce their sample at home and deliver it to the laboratory within 50 minutes of production, at their booked appointment time. If the patient is unable to deliver the sample to the laboratory within 50 minutes of production, we request that they use one of our dedicated private rooms in which to collect their semen sample. The requirement to use one of these rooms should be confirmed at the time of appointment with the patient.

When booking their appointment, we will ask patients to confirm their name, date of birth and CHI from the Semen Analysis Laboratory Form. We will also check that they have been given the correct specimen pot which has been pre-weighted, batch tested and issued by RML. If the patient does not have the correct pot, we will ask that they collect the correct one from their medical practice.

If a patient phones to book an appointment and we have not received the referral from their medical practice, we advise the patient to contact their GP to a referral via SCI Gateway.

4.6 Instructions for production of semen samples

Patients should be advised to read the information on page 2 of the Semen Analysis Laboratory Form and follow the instructions in order to optimise the semen sample that they produce. The patient should:

- Abstain from ejaculation for a minimum of 48 hours and no more than 7 days before producing the semen sample for analysis.
- 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 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).

If the patient is unable to produce a semen sample by masturbation (eg. for religious reasons), they should contact the laboratory. The patient still requires to be given a sample pot and request form.

4.7 Transportation of samples to the Reproductive Medicine Laboratory

All fresh semen samples should be delivered by hand as soon as possible to the RML sample reception and **within one hour** of production during the allocated appointment time (Section 3). The sample should be kept upright to avoid leakage, and kept as close to body temperature as possible (eg. if producing the sample at home, the container should be kept in an inside pocket when transporting it).
Alternatively, the sample may be produced in EFC in a private room allocated for this purpose, providing they have informed us that they require the use of a room when they arranged their appointment. On arrival a member of the team will show the patient into the private room, ask that they read the laminated “instruction for semen collection” information sheet before producing their sample and then they are left to produce their sample.

4.8 Appointments

It is important for patients to arrive at our laboratory reception at their allocated appointment time. This is not only to manage the number of patients in the centre at any one time, but also because testing is time-sensitive and there are several appointments throughout the day. Arriving at the appointment time allows the scientists to effectively manage workload without compromising any patient samples.

The maximum flexibility we are able to offer without impacting other patient appointments is 10 minutes; if a patient arrives more than 10 minutes late for their appointment we are unlikely to be able to process their sample. Likewise, if a patient is more than 10 minutes early, it is unlikely that a scientist will be available to accept the sample and start analysis.

If a patient thinks they might be late for their appointment, they should phone the laboratory and we will be able to provide advice and further guidance.

When the patient arrives at laboratory reception with their sample, a member of the laboratory team will check that all the required information is on the sample pot and the Semen Analysis Laboratory Form.

	Semen Analysis Laboratory Form	Specimen Pot
Mandatory Data Set (MDS)	• 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

Specimens produced more than two hours before delivery will not be processed as the accuracy of the tests cannot be ensured.

4.9 Sample rejection

Samples received without the MDS will be rejected; however, this is normally avoided as this information is checked by a member of laboratory staff when the sample is delivered to the RML by the patient (or their partner, etc). Other reasons for not analysing samples are:

- If the sample has leaked
- If the sample is more than 2 hours old
- Patient arrives too late for their appointment (eg. >10 minutes late)
- Patient has no appointment

Patients will be required to produce another sample if the sample is rejected.

4.10 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” (5th Edition, 2010). A routine semen analysis will assess the following parameters:

Semen Parameter	Explanation
Ejaculate volume	The volume of the ejaculate measured in millilitres (ml).
Semen pH	The pH of the ejaculate.
Sperm motility	Whenever possible, the motility of at least 200 sperm is assessed and expressed as a percentage showing progressive, non-progressive and immotile (%).
Sperm concentration	Millions of sperm per millilitre (million/ml).
Sperm morphology	Percentage of sperm with normal morphology / normal forms (%).
Appearance	A qualitative assessment of the visual appearance of the ejaculate (Normal / Abnormal).
Liquefaction	A qualitative assessment of sample liquefaction – measured at least 30 minute (Normal / Abnormal).
Consistency	A qualitative assessment of viscosity (Normal / Abnormal).

We carry out other macroscopic and microscopic assessments and any 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 and red blood cells.

If no sperm are observed in a semen sample for a routine semen analysis, the sample will be concentrated by subjecting it to centrifugation. The pellet will then be examined. However, this may not be possible if the sample volume is too low.

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.

4.11 Reference ranges

The lower reference values as published in the WHO manual (5th Edition, 2010) are shown below. These represent quality of semen where a couple may expect to achieve a pregnancy within 12 months of regular unprotected intercourse. Semen is a non-homogenous fluid and measurements cannot be completely accurate, as demonstrated in the confidence limits provided.

Parameter	Lower Reference Limit	WHO 95% confidence interval
Semen volume	1.5 ml	1.4 - 1.7
Progressive motility (progressive)	32%	31 - 34
Total motility (progressive and non-progressive)	40%	38 - 42
Sperm concentration	15 million/ml	12 - 16
Total number of sperm	39 million	33 - 46
Sperm morphology (normal forms)	4%	3 - 4
pH	≥ 7.2	N/A

The RML works to ISO15189 standards and is accredited for the following tests:

- Volume
- Motility
- Concentration
- Morphology

Non-accredited tests are for information and include:

- Appearance
- Liquefaction
- Consistency
- pH

4.12 Additional tests

Add-on tests are not possible with semen analyses as samples are discarded once the patient's analysis is been completed. A list of tests included as part of the semen analysis is detailed in Section 4.10.

Mixed Antiglobulin Reaction (MAR) tests are not carried out by the RML

4.13 Microbiology tests

If a semen sample has been produced for routine semen analysis or post-vasectomy analysis, an aliquot **cannot** be taken for laboratory tests to be carried out by the Microbiology Department due to the risk of contamination, which could lead to inaccurate results.

4.14 Reporting of results

All reports are checked, authorised and signed off by the HCPC State Registered Clinical Scientist in Andrology (Senior BMS) or Consultant Clinical Scientist.

Printed cumulative reports for semen analysis and tests of sperm function will normally be issued to the requesting clinician within one week of sample receipt. The reports are delivered to wards and

departments in the Royal Infirmary of Edinburgh by porters and the van service delivers the reports to other hospitals and to most medical practices. Reports to medical practices not served by the van service are sent out by mail.

The comments section will provide information on whether or not a repeat sample may be appropriate (Section 4.10).

Results are not given out over the telephone or faxed/emailed. Routine semen analysis results are available electronically on SCI Store on the day they have been authorised. Diagnostic results will not be communicated directly to patients by RML staff; they are advised when submitting their sample that results will be given by the clinician who referred them.

4.15 Repeat testing

If results in the patient's first sample are considered normal (ie. 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 in the comments section of the report containing results. If the comment is "essentially a normal sample", a further test is not required. If a repeat is recommended, the report will indicate "suggest repeat to confirm/exclude" and request that the patient is provided with a new pot and form and asked to contact the laboratory for an appointment.

If an additional sample is required, this should be about 4 weeks after the last sample and the number of days abstinence should be as constant as possible at each visit. However, if the sperm count is very low or the sample is azoospermic, a further sample should be produced for analysis as soon as possible (with an abstinence of at least 48 hours and no more than 7 days).

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

More than 2 samples are not required to be analysed unless otherwise indicated in the comments section of the result.

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

Following referral to EFC, if necessary, a further sample may be requested by the clinician, to be provided after 3 months (as per NICE guidelines).

4.16 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 (eg. patient compliance or use of the correct specimen container) are outside the control of the RML. 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 of production - If the sample is delivered to the laboratory more than 50 minutes 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.

4.17 Turnaround times

We aim to authorise and issue results within 7 days of analysis. A paper copy of results is posted to the referring clinician but is available electronically on SCI store after they are authorised.

4.18 Interpretation of results

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 include interpretation of results and any recommendation to repeat or refer, if appropriate.

4.19 Provision of clinical advice

Guidance regarding interpretation of results can be obtained from:

Senior BMS / Team Leader	0131 242 2462	Laura.Wales@nhslothian.scot.nhs.uk
Consultant Embryologist	0131 242 2498	Daniel.Collins@nhslothian.scot.nhs.uk

5 Clinical Applications

5.1 Investigations of infertility

Semen analysis is the basic initial test applied to male partners in couples undergoing fertility investigations. Semen quality is measured according to criteria published by the World Health Organisation (2). These criteria include semen volume, sperm motility, concentration, morphology, liquefaction, appearance and consistency. The test is sensitive (it will detect approx. 90% of men with a "true" semen abnormality) but is relatively non-specific, classifying approx. 10% of normal men as abnormal. Repeat testing of men with abnormal semen parameters can reduce this to 2%.

NICE guidelines for semen analysis recommend testing a single sample in the first instance. If the semen analysis is normal there is no need for a repeat analysis. If the result of the first semen analysis is abnormal, a repeat confirmatory test should be offered. Repeat tests should ideally be undertaken 3 months after the initial analysis to allow time for the cycle of spermatozoa formation to be completed but repeat samples produced after a shorter time will be accepted (usually after 4 weeks). If a gross spermatozoa deficiency (azoospermia or severe oligozoospermia) has been detected, the repeat test should be undertaken as soon as possible following the appropriate number of days abstinence. If the repeat test is reported as normal the semen can be regarded as normal and no further test is needed.

It should be borne in mind that many men with "normal" criteria have dysfunctional sperm resulting in infertility; equally, a proportion of men with sub-optimal criteria has functional sperm, and is therefore fertile.

5.2 Efficacy of vasectomy

The 2016 laboratory guidelines for post-vasectomy semen analysis: Association of Biomedical Andrologists, British Andrology Society and British Association of Urological Surgeons (5). recommends that PVSAs should take place a minimum of 12 weeks after surgery and after a minimum of 20 ejaculations.

As per the 2016 laboratory guidelines for post-vasectomy semen analysis:
"Assessment of a single sample is considered to be acceptable to confirm vasectomy success if all recommendations and laboratory methodology are met and no sperm are observed. Clearance can then be given. The level for special clearance should be <100 000/ml non-motile sperm. Special clearance cannot be provided if any motile sperm are observed and should only be given after assessment of two samples in full accordance with the methods contained within these guidelines. Surgeons are responsible both pre-operatively and postoperatively for the counselling of patients and their partners regarding complications and the possibility of late recanalisation after clearance. These 2016 guidelines replace the 2002 British Andrology Society (BAS) laboratory guidelines and should be regarded as definitive for the UK in the provision of a quality PVSA service, accredited to ISO15189:2012, as overseen by the United Kingdom Accreditation Service (UKAS)."

6 Cryopreservation and Storage of Semen

The Human Fertilisation and Embryology Authority (HFEA), established under the Human Fertilisation and Embryology Act (1990), regulates the storage and use of human sperm. The RML is licensed by the HFEA to store sperm and the premises housing EFC are licensed for the processing and storage of gametes and embryos.

Sperm may be stored for purposes of fertility preservation and back-up storage for patients scheduled for fertility treatment.

All documents required can be found on the following website/webpage in the Document Library located at the bottom of the webpage.

Edinburgh Fertility Centre
⇨ Treatments and Services
⇨ Fertility Preservation: Sperm Freezing
https://services.nhslothian.scot/edinburghassistedconceptionprogramme/Treatments-and-Services/Pages/Sperm-Freezing.aspx

6.1 Fertility preservation

This service is available to patients wishing to store sperm prior to treatment that may impair their fertility (eg. chemotherapy, radiotherapy specific cytotoxic drug or hormone treatment).

6.1.1 Referral Form

The referring member of clinical staff must complete the Fertility Preservation Referral Form and send it to the RML team (RML.enquiries@nhslothian.scot.nhs.uk). 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 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.

6.1.3 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.

There are a number of specialist nurses/clinicians across NHS Lothian in oncology (uro-oncology, haematology, neuro-oncology, colorectal and Teenagers & Young Adult) and the Chalmers Centre who are trained in obtaining consent relating to HFEA-licensed sperm storage.

When referring a patient, they should be provided with the following:

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

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).

Those who are trained and competent to obtain storage consent will go through each consent form and provide relevant information to the patient, as appropriate (Section 6.5). It is also 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”. This is for ease but we are happy to receive the information contained within it by email (the version of the information sheet will need to be referenced).

If possible, scan completed consent forms to the RML and give the originals to the patient to bring to their appointment. The RML need to retain the originals so we can exchange these with the copies so the patient still has their own copy to review if required. If for any reason, the patient does not bring the originals to the appointment, new consents can be completed easily with the scanned copies as a reference.

6.2 Back-up sperm storage for scheduled fertility treatment

Clinicians with the EFC 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 or if the sperm provider is not going to be present on the day of egg collection (eg. if they work off-shore or in the forces).

Referrals may be received from the infertility clinic or Reproductive Endocrinology. These cases should 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 cryopreserve sperm, particularly if there is no significant decline in parameters.

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

6.2.1 Referral Form

The Semen Cryopreservation for Back-up Referral Form (EFR-F-392) is located within the EFC document control system, 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.

6.2.2 Eligibility for NHS funded sperm storage

The referral form includes information about eligibility for NHS funded sperm storage. If the patient is not listed for fertility treatment at the EFC (eg. if the couple do not meet the criteria for NHS funded fertility treatment), we are able to offer self-funded sperm storage. The cost of this is provided on the EFC webpage, “Self-Funded Treatment”.

6.2.3 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.

When referring a patient, they should be provided with the following:

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

Clinical staff trained and competent in obtaining HFEA consent for gamete/embryo storage will provide written and verbal information during the patient's clinic appointment (Section 6.5). Copies of relevant consent must be given to the RML along with the referral. A member of the RML team will contact the patient once blood (and urine if required) screening results are available and they are acceptable for sperm to be stored at the EFC.

6.3 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*

It is recommended that ward staff who refer immunocompromised patients for semen cryostorage on a regular basis request a test order set via the TRAK Team.

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 the HCV PCR can take up to 7 days therefore. If the cryostorage appointment is before this, the screening should 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 (VirologyAdvice@nhslothian.scot.nhs.uk).

6.4 Counselling

All patients must be offered the opportunity to speak with one of the EFC fertility counsellors prior to sperm storage and signing consent. 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.

More information on our counselling service can be found on the EFC website:
Edinburgh Fertility Centre
⇨ *Treatments and Services*
⇨ *Counselling*
https://services.nhslothian.scot/edinburghassistedconceptionprogramme/Treatments-and-Services/Pages/Counselling.aspx

6.5 Consent prior to sperm storage

Current versions of the HFEA consent forms can be found on

Edinburgh Fertility Centre
⇨ Treatments and Services
⇨ Fertility Preservation: Sperm Storage (go to the Document Library at the bottom of the page)
https://services.nhslothian.scot/edinburghassistedconceptionprogramme/Treatments-and-Services/Pages/Sperm-Freezing.aspx

The consent forms are also available on Q-Pulse and the HFEA website:
https://portal.hfea.gov.uk/knowledge-base/consent-forms/

Consent must be obtained by a staff member who has received appropriate training, specifically for gamete/embryo storage. A summary of each consent form is provided below.

6.5.1 HFEA GS form: Your consent to the storage of your eggs or sperm

This consent form covers the general consent to storing sperm and the storage period. If a patient is storing sperm because they are likely to become prematurely infertile (eg. chemotherapy, radiotherapy, specific drug treatment), they may store their sperm for up to 55 years. It should be noted that even though consent can be given for 55 years, storage is subject to review every 10 years. Every 10 years, the patient will need to renew their consent to continue to store. Storage is only funded by the NHS where the patient is premature infertility. Where the patient is not prematurely infertility, they may continue storage but will be required to self-fund.

If the patient does not have a partner they wish to name to use their stored sperm in future fertility treatment, the GS form also includes their consent on using their sperm in the event of their death or mental incapacity.

6.5.2 HFEA CD form: Your consent to disclosing identifying information

This consent form covers consent relating to the patient's personal and identifying information. They will need to state if they give consent for their information being disclosed to appropriate people outside the EFC, such as their GP, other healthcare professionals, auditors or administrative staff. The consent also covers the type of research they may or may not consent to be included in (ie. non-contact and contact).

6.5.3 HFEA MT form: Your consent to your sperm and embryos being used in treatment and/or stored (IVF/ICSI)

This consent only needs to be completed if the patient has a partner they wish to name to use their stored sperm in future fertility treatment. They will need to provide their partner's name and date of birth and consent to creating embryos through IVF treatment. They will provide consent on embryos being stored, along with the storage period. The same criteria apply as with the GS form in terms of the storage period of up to 55 years. The patient will indicate if they consent to sperm and/or embryos being used for training and what they wish to happen to their stored sperm and embryos in the event of their death or mental incapacity, including posthumous birth registration.

6.5.4 Patient consent and contract – Sperm freezing and storage

This is a local consent which confirms that the patient has read and understood the information in the information sheet and the HFEA consent forms. It also includes a section relating to the funding stream.

6.5.5 Training in referrals and obtaining consent for HFEA-licensed sperm storage

It may be appropriate for staff in some wards to receive this training if they refer patients on a relatively regular basis. If you would like to discuss for consideration, phone 0131 242 2462 or email RML.Enquiries@nhslothian.scot.nhs.uk.

6.6 Post-chemotherapy semen analysis

As part of the follow-up for patients who have stored sperm before treatment (eg. chemotherapy), it is recommended that they provide a semen sample for analysis at least 6 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). If fertility has been restored and is of equivalent or better quality than the stored sample, the patient may wish to discard the samples stored. The patient can contact the RML to arrange this.

6.7 Review of stored sperm

The RML will contact patients with sperm in storage at the EFC every few years to check that their information/circumstances have not changed and to establish if they wish to change consent. Patients will also be contacted when it is nearing the end of the consented storage period or when the samples have been in storage for 10 years since storage or the last review. Although several checks are made to ensure we have the patient's current address, there may be occasions where the patient has moved address and not informed the Laboratory.

Since the changes in the law with regards to gamete and embryo storage on the 1st of 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 the patient will need to update the relevant HFEA consent forms to continue storage.

As a GP or medical consultant, your patient will need you to complete a referral for a follow-up semen analysis at least 6 months after their treatment has concluded. Many chemotherapy agents are not as toxic as older treatments and fertility can be restored. This semen analysis is not required to continue storage but is required to determine if storage can be funded by the NHS or if they must self-fund. In some circumstances, a semen analysis is not appropriate (eg. bilateral orchidectomy or a genetic basis for premature infertility, such as Klinefelter's).

6.8 Transporting sperm between licensed fertility centres

If a patient has sperm stored in a fertility centre and is going to be undergoing fertility treatment in another centre, cryopreserved sperm samples may be transported between centres by prior arrangement via a licensed courier. Consent is required for the transport and associated communication between all relevant parties. Enquiries relating to the transport of sperm should be directed to RML.enquiries@nhslothian.scot.nhs.uk or 0131 242 2463.

7 Referral Laboratory

Samples are not referred to another laboratory from RML, therefore there are no referral laboratories.

8 Patient Confidentiality

The RML operates under NHS Lothian's strict patient confidentiality policy and is also required to comply with the HFEA guidelines, regulations and standards. The RML 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 RML 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.

9 Complaints and Feedback

The RML is committed to continually improve services offered and welcomes all forms of feedback including complaints. 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:
http://www.nhslothian.scot.nhs.uk/YourRights/PatientExperienceAndFeedback/Pages/default.aspx

The following public document can be shared with patients, carers or anyone wishing to make a complaint or raise concerns:

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: feedback@nhslothian.scot.nhs.uk
Website: www.nhslothian.scot.nhs.uk/YourRights

10 References

(1) Advisory Committee on Dangerous Pathogens (2021). The Approved List of biological agents, 4th Edition

(2) World Health Organization: WHO laboratory manual for the Examination and processing of human semen. 5th ed. Cambridge: Cambridge University Press 2010.

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

(4) Human Fertilisation & Embryology Authority (2019). Code of Practice. 9th Edition

(5) 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.