**Andrology User Laboratory Handbook**

**Contact address:**

Newcastle Fertility Centre at Life
Biomedicine West Wing
International Centre For Life
Times Square
Newcastle upon Tyne
NE1 4EP

**Telephone:** 0191 213 8213

**Email:** nuth.nfcl.enquiries@nhs.net

**Website:** [Newcastle Fertility Centre - Newcastle Hospitals NHS Foundation Trust (newcastle-hospitals.nhs.uk)](https://www.newcastle-hospitals.nhs.uk/hospitals/fertility-centre/)

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**Meet the** **team**

**Head of Department**

* **Dr. Matthew Prior**

**Person Responsible to the HFEA**

**- Dr. Matthew Prior**

**License Holder (HFEA)**

* **Dr. Louise Hyslop**

**Consultant Andrologist**

* Mr. Kevin McEleny

**Laboratory Director/Operations Manager & Principal Embryologist**

* **Samantha Byerley**

**Consultant Embryologist**

* Dr. Louise Hyslop

**Andrology Lead & Advanced Embryologist**

* Lynne Botham

**Quality Development Manager**

* Andrea Sinclair

**Our Aim**

We aim to provide Safe, Effective, High Quality Patient Care to our patients.

**Statement of Purpose**

The Newcastle Fertility Centre Andrology Laboratory, forms part of the Newcastle Fertility Centre, Newcastle upon Tyne Hospital Trust. The laboratory performs diagnostic semen analysis to patients from the North East of England, UK and Overseas. The centre is currently licensed by the Human Fertility and Embryology Authority and accredited for the Diagnostic Andrology Laboratory by the United Kingdom Accreditation Service (UKAS) to ISO15189:2022 standards (Medical Laboratory). Accreditation number 20258, this service is accredited for Sperm motility, sperm concentration and semen volume. Our accreditation scope can be viewed here: <https://www.ukas.com/wp-content/uploads/schedule_uploads/977006/20258-Medical-Single.pdf>

**Welcome to the Andrology Unit**

## Quality Policy (Newcastle Fertility Centre)

The Newcastle Fertility Centre (NFC) at the International Centre for Life is dedicated to providing a clinical service to treating people with infertility associated problems. It is the intention of the management and staff of the centre to provide this service to the highest standards of ethical, professional and clinical practice to ensure that the service delivered is safe, effective and meets, or exceeds, the expectations of patients, the regulatory requirements placed on NFC and of other appropriate stakeholders.

To help manage these aspirations a Quality Management System (QMS) has been designed which covers all aspects of the service provided at NFC. Additionally, where appropriate, the quality of the service provided by NFC will be compared with other, similar, centres in the United Kingdom via processes such as benchmarking and participation in national equivalence programmes.

The QMS deployed at the NFC is based on the requirements of the Human Fertilisation and Embryology Authority and the United Kingdom Accreditation Service (for Diagnostic Andrology) and the various laws, regulations and guidance published and regulated through these bodies.

The QMS will include the following elements:

* Fully documented guidance on all procedures and processes carried out at NFC.
* Fully documented records of all patient consultations, treatments and laboratory processes.
* Defined processes for the control of writing, approval, issuing, amending and withdrawal of NFC documentation.
* Fully documented staff training process, to ensure that (where appropriate) a uniform approach is followed in performing the processes, procedures and practices used at the NFC.
* Fully documented audit (internal and external) process designed to assure patients, staff and regulators that appropriate procedures are followed at all times.
* Defined procedure for specifying and approving the use of appropriate suppliers for all materials used at NFC.
* Defined validation programmes for all equipment, processes and the operational environment at the NFC.
* Co-ordination of all third party service agreements with appropriate internal (Newcastle upon Tyne Hospitals NHS Foundation Trust) and external bodies.
* Co-ordination of centre participation in benchmarking and national equivalence programmes.
* Fully documented complaints procedure, including investigation and reporting processes.
* Fully documented process for management of procedural non-compliances; including investigation and reporting processes.

##

## Feedback and complaints

We constantly strive to develop our service and would welcome any feedback from users and patients. We value your opinion. If you have any suggestions, concerns or would like to make a complaint please contact our department. Alternatively, you can contact PALS (Patient Advice and Liaison Service) for help, advice and information about NHS services including how to pass on your compliments, suggestions and how you can make a complaint. PALS can be contacted on Freephone 0800 032 0202, e-mail northoftynepals@nhct.nhs.uk, text to 01670 511098 or in writing to FREEPOST PALS. For more information visit;

https://www.newcastle-hospitals.nhs.uk/information-for-all-patients-visitors/feedback/



**Complaints procedure;**

Concerns and complaints with regards to care, treatment or service provided by the Trust can be raised by a patient, those on behalf of a patient or other agencies such as GP services.

Once a concern or complaint is raised, Newcastle Fertility Centre and/or the PALS team will aim to seek an informal resolution with the complainant within an agreed timescale. Formal complaints are referred to the Patient Experience Team of the Newcastle upon Tyne Hospitals Trust. These complaints will be acknowledged within 3 working days via letter or email and a copy will be sent, together with a request for an investigation, to the service or clinical board involved.

## Protection of personal information

We take the protection of personal information and data very seriously. All staff adhere to the Trust’s Information Governance and Information Security Policies and undertake annual training in Information Governance and Data Security. All hardware and software used within the department are protected and managed by the Trust’s IT department. All patient information and data is kept strictly confidential are therefore not shared or accessible to any unauthorised persons. When the laboratory is required by law or authorised by contractual arrangements to release confidential information, the patient concerned shall be notified of the information released, unless prohibited by law.

Our regulators UKAS and HFEA may access non-identifying information whilst on-site but this information is not retained for use. Any observations during their visits will be carried out with the appropriate consent.

**Information for General Practitioners**

## Diagnostic Semen Analysis

One of the services provided by the **Andrology Laboratory** at **Newcastle Fertility Centre** is the analysis of semen samples to determine male factor infertility. **Diagnostic Semen Analysis** is a routine part of an infertility investigation and is routinely requested by clinicians for couples who have concerns about their fertility.

## Referral

**Criteria -** If a patient has been having regular, unprotected sex for at least 12 months but not been able to conceive, it is recommended to arrange a referral for a diagnostic semen analysis.

The Andrology Laboratory operates by appointment only. Appointments can be booked via the NHS e-Referral Service and are available Monday to Friday. A referral form is also required – blank copies of this can be found on our website (Andrology – Semen Analysis- Referral Form).

On receipt of a referral, an appointment will be confirmed in writing. Patients may also be contacted by phone or text as part of the Newcastle upon Tyne Hospitals Trust reminder service.

Please inform the patient that prior to their appointment they need to **abstain** **from ejaculation** **for 48 hours-7 days**.

*We offer a patient information leaflet that should be given to the patient prior to attending their appointment. This leaflet is also available on the Newcastle Fertility Centre website.*

## Funding

Not all patients are eligible for treatment funded by the NHS. This is decided by the GP Commissioning Group, but we can advise whether a patient is eligible for NHS funding. We provide a fee-paying service for those who are not eligible. The current prices are available on our website under ‘Private fertility service’.

**Receipt of samples**

We do not provide a ‘drop-off’ service. This is to ensure that samples can be handled appropriately prior to processing. Also, this allows the time from ejaculation to analysis to be better controlled in accordance with WHO guidelines. Patients are required to produce their sample on site at the appropriate appointment time.

**Concerns over producing a semen sample**

If a patient is worried about being able to produce the sample, please encourage them to attend their appointment. If at the appointment the patient finds they are unable to produce a sample, the Andrology staff will arrange an appointment time for them to bring their sample from home. The sample needs to reach the department within **40 minutes** of production and be as close to their appointment time as possible. Samples delivered after 40 minutes may still be analysed but may require a repeat if parameters are outside the normal range.

##

## Tests performed

* Liquefaction/Viscosity assessment
* pH
	+ If low volume or low sperm count.
* Volume
* Sperm concentration (reported in millions/ml)
* Sperm motility
* Sperm morphology
* Round cells
	+ Presence of high numbers may require a repeat test for infection screening.
* Presence of aggregation or agglutination
	+ Please note – we **do not** perform anti-sperm antibody testing as this is no longer recommended by NICE guidelines due to insufficient evidence of their significance.
* Vitality testing
	+ Will be done only if deemed necessary on samples with no motile sperm.

**We do not perform post vasectomy semen analysis – this can be carried out by Cytology at the RVI.**

**Viral positive samples (HIV, Hep B/C etc.) must be booked in directly with the Diagnostic laboratory at NFC as these require special processing appointments.**

## Results

To determine the quality of the semen sample, a number of factors are examined, as recommended by the 2021 WHO criteria. This criterion is based on data of semen quality of reference population of men, whose partners had a time to pregnancy of 12 months or less. Under these parameters, we consider the lower 5th percentile as a Biological reference limit for further investigation. See table below for details on each parameter:

## Report - Interpretative Comments

|  |  |  |
| --- | --- | --- |
| Parameter | Biological decision limitsWHO 2021 guidance – lower 5th centile | Comments and interpretation |
| Volume | ≥ 1.4 ml | Low volume could be due to partial sample loss (loss of a fraction of the ejaculate during sample collection), partial retrograde, obstruction or androgen deficiency. |
| Sperm Concentration | ≥ 16 x 106 M/ml | Sperm concentration is related to fertilisation and pregnancy rates. It can be affected by abstinence and sample loss (first part of the ejaculate is considered sperm rich). A very low sperm count may indicate a partial/full blockage or testicular failure. **Note that low counts <0.5M/ml will have an increased sampling error (>5%), associated with the result, due to insufficient numbers counted.**  |
| Progressive Motility  | ≥ 30% | The extent of progressive sperm is related to pregnancy rates. Sperm progression is temperature dependent and samples that take over 40 mins to reach the lab will be recommended to repeat if motility is low. |
| Morphology | ≥ 4% | This is related to how the sperm look and is a strict analysis. The low threshold and variability can make it difficult to interpret as a stand-alone parameter in a diagnostic analysis. Severe morphological defects may require referral as they may lower fertilising potential. |

*If any of these parameters are outside the lower 5th percentile, this may indicate male factor infertility and either a repeat sample or a referral to the fertility centre will be recommended. This lower 5th percentile represents the level under which less than 5% of the reference population were found. It’s important to note that semen analysis results should be used in conjunction with their medical history and partner’s fertility investigations.*

## Repeating a Semen Analysis

A number of factors can influence semen analysis results (i.e. length of abstinence; initial portion of the ejaculate not collected; illness; medication etc.) so a repeat analysis may be requested. This is a common occurrence and is often requested to confirm the results of the initial sample. It is recommended to wait **3 months** after the initial analysis before arranging a repeat test, this is due to the cycle of spermatogenesis (making sperm) which takes around 64 days.

##

## Rejection Criteria

* Samples that arrive without appointments. These samples will be rejected and the patient will be informed of the correct way to book an appointment and advised to go back to their GP.
* Patients arriving more than 10 minutes late for their apponitment will be required to book another appointment. This is due to the workload in the lab and ensuring samples are analysed in a timely manner.
* Post vasectomy samples – we cannot provide clearance for post vasectomy samples. Please refer patients to Clinical Cytology at the RVI.

## Turnaround time

Results are provided electronically, for GPs they can be accessed by ICE. If ICE cannot be accessed, then alternative arrangements can be made for results. The Newcastle Fertility Centre aims to turnaround samples within two weeks of semen analysis.

## Measurement of Uncertainty

Every measurement will have a level of uncertainty, for example if a patient was to return to provide a similar sample there would be variation in the results. As long as the two results fall within the “Measurement of Uncertainty” (depicted at U), the two results are not significantly different with a level of confidence of approximately 95%. This would mean a result of 14M/ml and 16M/ml for sperm concentration would fall within the 95% confidence interval and not be deemed significantly different. When considering the biological reference limits these uncertainities are taken into account during reporting (often referred to as borderline values).

|  |  |
| --- | --- |
| **Measurement** | **Measurement of Uncertainty (U)** |
| Volume | **± 0.013 ml** |
| Concentration | **± 12.6%**  |
| Morphology | **± 2.4 %** |
| Progressive Motility | **± 7.6 %** |

**Patient Information**

## Diagnostic Semen Analysis at Newcastle Fertility Centre

DiagnosticSemenAnalysis is a routine part of a fertility investigation. To determine the quality of the semen, a number of factors are examined, including the sperm concentration (the number of sperm), motility (how well the sperm are moving) and morphology (the shape of the sperm). A number of factors can influence sperm production so you may be asked to repeat the test. This is a common occurrence and is often requested to confirm the results of your initial sample.

**Common factors that can influence the semen analysis results are**:

* Being unwell (within last 3 months) with for example a respiratory or urinary tract infection, or with certain chronic health problems.
* Some medications, including both certain prescribed medicines and those that you might take yourself, including gym supplements and recreational drugs.
* Missing the pot with some of the sample (first part of sample is the most sperm rich)
* Incorrect abstinence (days since last ejaculation, this should be between 48 hours-7days).

## Where do I produce my sample?

Upon attendance at your appointment, you will be asked to produce your sample in one of the private production rooms at the Fertility Centre. This ensures there is minimum delay between production and analysis of your sample.

## What should I do to prepare for my appointment?

You should abstain from sexual intercourse or masturbation for at least **48 hours, but no longer than 7 days**. Having an abstinence period of longer than 7 days can have a detrimental effect on your sperm.

## What should I expect when I attend my appointment?

Please report to Reception upon your arrival. PLEASE COME AT YOUR SPECIFIED TIME TO ALLOW SOCIAL DISTANCING, IF YOU ATTEND MORE THAN **10 MINUTES** LATE YOUR APPOINMENT WILL BE CANCELLED because there will be insufficient time for the laboratory to process your sample. A member of the Andrology team will call your name and take you to the production room. They will explain the process to you and give you the opportunity to ask any questions.

**When producing your sample:**

* Wash your hands and penis thoroughly with antibacterial soap and wipe dry before you produce the sample. Contamination of the semen during production must be avoided.
* The container must be labelled with your **full name** and **date of birth**.
* Collect your sample directly into the container via masturbation. It is important that you collect the entire ejaculate as the initial part is the most sperm rich and if some of the sample misses the container, it may make your sperm count appear lower than it actually is.
* The use of lubricants or condoms is not permitted as these contain substances that are detrimental to sperm quality.

## Can I bring my sample from home?

Semen analysis is more accurate when performed under controlled laboratory conditions from a freshly produced sample which is the routine protocol at the Centre. Should you be unable to produce a sample on-site, we can arrange an appointment time for you to produce a sample at home and bring it to the Centre. The sample would need to reach us within **40 minutes** of production and be as close to your appointment time as possible. This can be requested from the Andrology team if necessary.

## Additional factors

**When I have sex/orgasm no semen is produced.**

Some men find it difficult to reach orgasm or if they do, find that little or no fluid is produced. This can be due to certain medicines, to nerve problems or sometimes to psychological issues. If you are unable to produce semen then please discuss this with your GP as you may require more specialised tests.

**I am finding the situation difficult.**

Fertility concerns and tests can be very stressful and if you are finding the situation difficult, please discuss this with your GP.

**I have a disability.**

Before your appointment, please let us know if you have a disability and we will endeavour to provide the best care possible and accommodate your needs.

**How to contact us**

## Opening Hours

The Fertility Centre’s core working hours are:

**Monday - Friday 08:00 – 16:00** (excluding Bank Holidays)

The Andrology Laboratory has predetermined appointment times for diagnostic semen analysis – first appointment of the day is 08:20 and the last appointment is 14:40 (14:00 on Fridays).

**Please note: if you have been referred by your GP for a semen analysis, we will be unable to provide you with results; these will be issued by your referring GP. Clinical advice can be given to GPs between 8.30am and 4.00pm by contacting the unit.**

## Contact Information

**Telephone:** 0191 213 8213

**Website:** [Newcastle Fertility Centre - Newcastle Hospitals NHS Foundation Trust (newcastle-hospitals.nhs.uk)](https://www.newcastle-hospitals.nhs.uk/hospitals/fertility-centre/)

**Non-urgent enquiries can be emailed to**: nuth.nfcl.enquiries@nhs.net

Newcastle Fertility Centre at Life
Biomedicine West Wing
International Centre For Life
Times Square
Newcastle upon Tyne
NE1 4EP

## How to find us

The Newcastle Fertility Centre is situated on the third floor of the Biomedicine West Wing at the International Centre for Life, Time Square in Newcastle. The Centre is located next to Newcastle Central Railway Station and Metro Station (about a two-minute walk). Alternatively, if you drive, parking spaces are available in the Times Square multi-storey car park - a two-minute walk from the Centre.



**Useful links and more information**

## Patient Support

* [Fertility Network UK (INUK)](http://www.infertilitynetworkuk.com/)

<https://fertilitynetworkuk.org/>

* [Donor Conception Network](http://www.dcnetwork.org/)

<https://www.dcnetwork.org/>

* [British Infertility Counselling Association](http://www.bica.net/)

<https://www.bica.net/>

## Professional bodies

* [British Fertility Society](http://www.britishfertilitysociety.org.uk/)
* [Royal College of Obstetricians and Gynaecologists](http://www.rcog.org.uk/)
* [British Infertility Counselling Association](http://www.bica.net/)
* [Association of Reproductive and Clinical Scientist](http://www.ivf.net/ace/)s
* [European Society of Human Reproduction and Embryology](http://www.eshre.eu/)

## Government bodies

* [Human Fertilisation and Embryology Authority](http://www.hfea.gov.uk/)
* [Department of Health](http://www.doh.gov.uk/)

**Others**

* [The International Centre for Life](http://www.centreforlife.co.uk/)