East Lancashire Hospitals
NHS Trust
A University Teaching Trust

Andrology Service: Information for Users

1. Introduction

The Andrology Laboratory at East Lancashire NHS Trust (ELHT) operates from the Old Main Outpatients Department, Burnley General Teaching Hospital (BGTH).

The laboratory's priority is to provide a comprehensive semen analysis service for Consultants from within ELHT and for General Practitioners from across East Lancashire.

The laboratory operates on a clinic based service and will have approximately 2000 available appointments per annum to cover the annual workload of routine diagnostic semen analysis and post-vasectomy samples.

Routinely patients will be given an appointment to attend the Andrology Department to deliver their specimen (which is to be collected at home and not in a public area) to the department within the appropriate time interval of 1 hour. For patients who are unable to deliver their sample to the department there is a production facility they can use; this is booked by telephoning the department prior to their appointment. Details are found in the patient information leaflet and their appointment letter.

Social distancing measure will be followed as per Government and Trust advice.

The patient's details will be checked upon arrival to ensure they have followed the guidelines correctly and that the patient information data set is met.

The ELHT Andrology Laboratory has fully trained scientists who are highly proficient in performing quality diagnostic semen analysis in line with World Health Organisation (2010) and Association of Biomedical Andrologist (ABA) guidelines. The laboratory regularly performs quality control, participates in the UK National External Quality Assurance scheme for Andrology (UKNEQAS) and has UKAS accreditation to ISO15189:2012 standards.

This handbook has been produced to ensure that the service users are clear about all aspects of the services provided in regards to fertility and post vasectomy analysis.

2. Location and Opening Times

The BGTH clinic is located in Suite 3, Old Main Outpatients Department, Area 1, Level 2 and is open Monday, Tuesday, Thursday and Friday 8:00-14:00. Please note we are closed on Wednesdays at present.

The opening times are for patient appointments only. Do not send patient without an appointment.

We do not operate a service on Saturday or Sunday or bank holidays on either site.

The department's main address for any correspondence;

Andrology Department
Suite 3,
Out Patients
Area 1, Level 2,
Burnley General Teaching Hospital
Casterton Avenues,
Burnley
Lancashire
BB10 2PQ.

3. Useful contacts

Contact	Details	Contact Details
General Enquiries	Andrology Laboratory (ELHT)	01254 734380/ 01282 80 5409
Craig Rogers	Lead Biomedical Scientist (ELHT)	Tel: 01254 73 2438 Email: Craig.Rogers@elht.nhs.uk
Dayle Squires	Laboratory Manager (ELHT)	Tel: 01254 73 4162 Email:Dayle.Squires@elht.nhs.uk
Tina Berry	Senior Biomedical Scientist, Andrology Section Lead BMS (ELHT)	Tel: 01282 80 5409 Email: Tina.Berry@elht.nhs.uk
Cath Kinder	Biomedical Scientist, Andrology Deputy Section Lead BMS (ELHT)	Tel: 01254 73 5147/ 01282 80 5294 Email: Catherine.Kinder@elht.nhs.uk
Pending	Clinical Advisor, Consultant Histopathologist (ELHT)	Pending
Sushant Ghorpade	Pathology Quality Manager	Tel: 01254 73 3103 Email: Sushant.Ghorpade@elht.nhs.uk
Patient Affairs	Burnley General Hospital	01282 80 4486

4. Services provided by the laboratory

1. Diagnostic semen analysis for fertility investigations.
2. 1 hour post vasectomy semen analysis for post-operative investigation
3. Diagnostic semen analysis for Retrograde Ejaculation

5. Requesting semen analysis

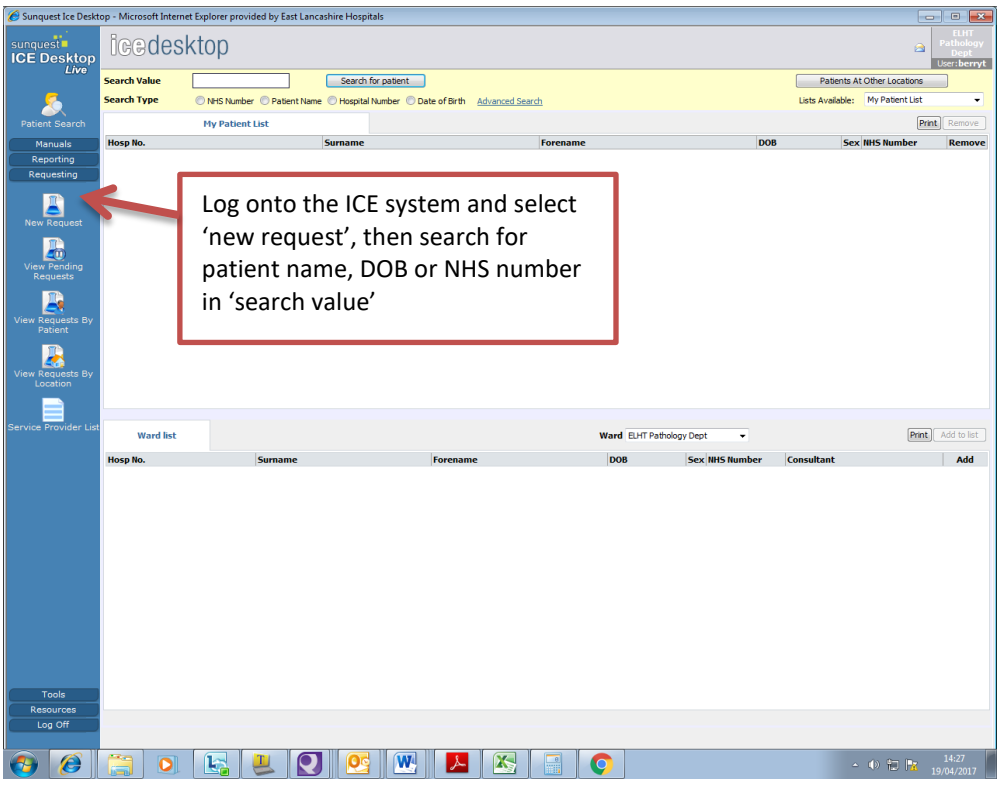
Please do not ask the patient to contact the department for an appointment. We will only allocate an appointment to the patient upon receipt of an electronic request from the referring clinician.

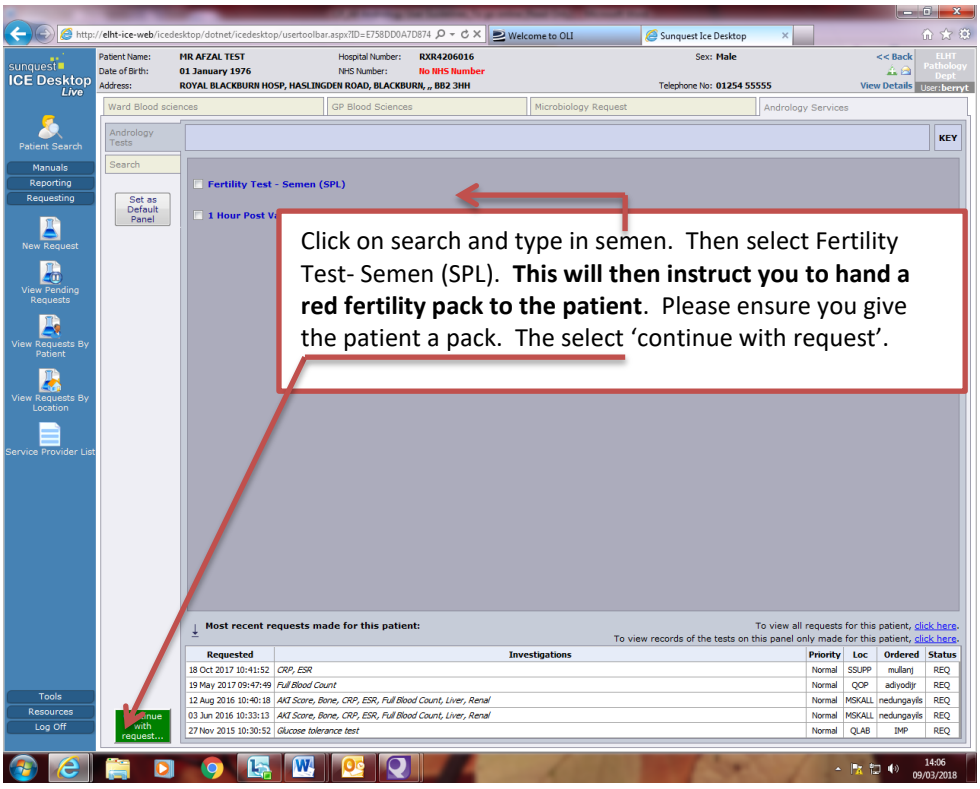
At consultation, please hand the patient a red fertility pack or blue post vasectomy pack, both will contain a leaflet and a container that has been batch tested and accepted for use. Please do not give patients a container that does not have batch number on or has reached its expiry date.

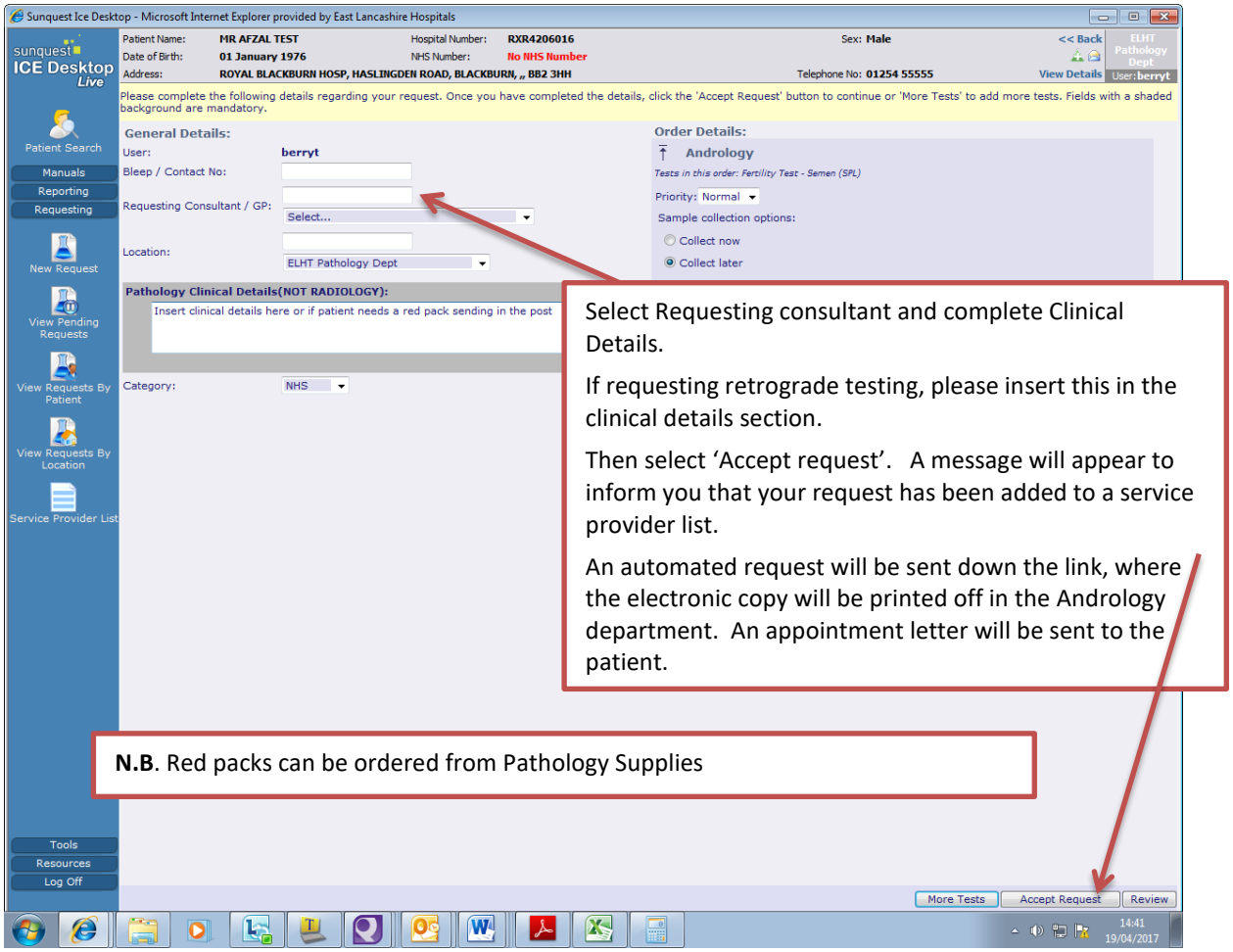
Further supplies of packs can be ordered using an External Consumables order form available from the Pathology Supplies office at RBTH.
https://www.elht.nhs.uk/application/files/8615/2587/9605/External_Consumables_Order_Form.pdf

5.1 Fertility Investigation

To request a semen analysis for fertility or Retrograde investigations complete an electronic ICE request. **All patients require an electronic ICE request- any patient bringing their sample to the department on an ad hoc basis will result in specimen rejection.** **See section 6.5 for more details**







5.2 Post Vasectomy Investigation

Request post vasectomy specimen test on ICE as above when the patient has their vasectomy procedure; this ensures they are in the system and the Andrology department can issue an appointment to the patient upon receipt of the request.
Instead of selecting Fertility sample; select 1 Hour Post Vasectomy (SPL). Then continue as per fertility request, but with the addition of the date of the vasectomy if applicable.
This is important for two reasons:

a) So that the appointment can be booked after an appropriate time interval to allow clearance (approximately 12 weeks after procedure)
b) So that the laboratory can ascertain if the sample is within the appropriate time frame according to current guidelines.

You will need to hand the patient **a blue post vasectomy pack** (available from Pathology Supplies).

5.3 Other information

Please complete details to identify whether this is the first or subsequent semen sample. Further details can be given if relevant i.e. previous abnormal results. Infection control risk – please indicate if there is a known infection risk. No further details are necessary.
Additional clinical information - this can be useful i.e. if a repeat fertility or second vasectomy test, but if no further information is applicable, please put N/A.
Please indicate if the test required is for retrograde ejaculation as this will require a separate leaflet and further containers to be given to the patient for urine collection.

Please note there is **NO** facility to receive referrals by fax or by post.

Once the referral is received electronically, the patient will be issued with an appointment to attend the Andrology Department at BGTH within a 6 week target (key performance indicator set at ≥95% within 6 weeks). The accompanying letter will detail their appointment date and time and where they are to attend. There are four clinic days at BGTH.

On the back of the Andrology leaflet is a generic form for the patient to complete whether their test if for fertility or pat vasectomy. This tear off portion details their partner's name (if for fertility) and D.O.B. (used as a reference for current or future referrals); number of days since last ejaculation; time the specimen was produced; whether the collected sample was complete and any details of any recent illnesses or medication.

For patients who are unable to deliver their sample to the department there is a production facility they can use; this is booked by telephoning the department prior to their appointment. Details are found in the patient information leaflet and their appointment letter.

Translations of the patient guidelines are available in several languages and can be requested by either Clinician or patient.

Inside the red or blue pack is a pre-weighed specimen container (to help ascertain volume results) that has been batch tested and accepted for use by the laboratory. Please only use these containers as any other container given to the patient or used by the patient will be rejected at their appointment. The container should be stored in a dry place away from direct sunlight and will be labelled with the batch number and expiry date.

6. Semen analysis test types

6.1 Diagnostic semen analysis test for fertility

Some couples have difficulty conceiving and are referred for infertility investigations by their General Practitioner. One common cause of infertility is sperm dysfunction. A high quality Andrology service is therefore essential for correct management of the male patient and thus the couple. Here at the Andrology Laboratory, we assess the 'main' factors (sperm concentration and total count, motility and morphological appearance) as well as other parameters that are helpful in providing important diagnostic information.

Here is a brief description for each parameter:

Sperm concentration - this is measured in millions of sperm per millilitre of semen. This is done using a phase contrast microscope and a specialized counting chamber.

Sperm Total Count - this is the total sperm contained within the ejaculate analysed by the laboratory, measured in millions per ejaculate. This will be the defining factor of whether there is a 'normal' count or not.

Sperm motility - sperm are graded on their ability to move and the speed at which they do this. The fast forward swimming sperm are generally the most fertile. This is given as a percentage of sperm counted and divided into the following categories:

a) Progressive motile
b) Non-progressively motile
c) Immotile

Sperm morphology - the proportion of sperm in the sample that have a normal or more typical appearance (to strict criteria) is assessed from a stained (Papanicolaou) preparation. This is given as a percentage of normal forms detected.

Other factors reported:

Volume - the amount of semen produced (measured in ml but ascertained from weighing the sample).

pH - measures the acidity or alkalinity of the semen using pH paper strips.

Agglutination – this is the visual assessment of the proportion of motile sperm cells that are 'sticking' to each other and preventing progressive motility. Agglutination can be indicative of anti-sperm antibodies which may impair male fertility potential, however the visual assessment we do is not a diagnosis of this. Agglutination will be indicated within the report and described as either isolated (< 10 sperm/agglutinated with many free swimming sperm), moderate (10-50 agglutinated with some free swimming sperm), large (>50 agglutinated some sperm still free) or gross (all sperm agglutinated).

Agglutination cont

1. Isolated (< 10 sperm/ agglutinate, many free sperm	2. Moderate (10–50 sperm/ agglutinate, free sperm)	3. Large (agglutinates > 50 sperm, some sperm still free)	4. Gross (all sperm agglutinated, and agglutinates interconnected)

Parts Involved

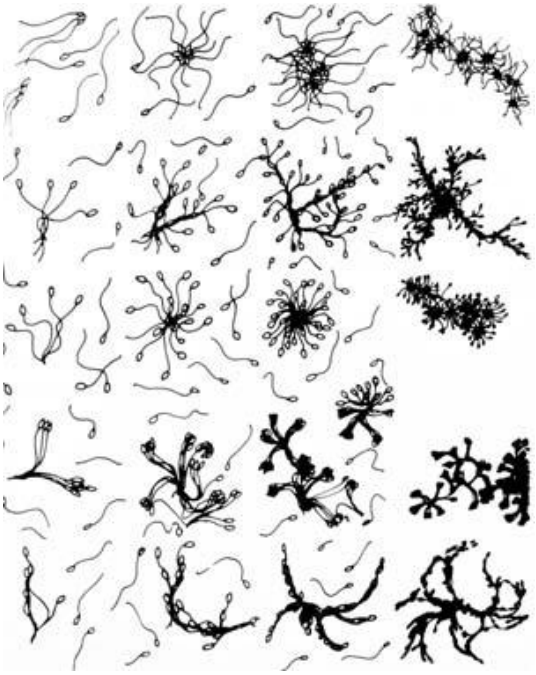
A. Head to Head

B. Tail-to tail (heads are seen to be free and move clear of agglutinates)

C. Tail-tip-to tail-tip

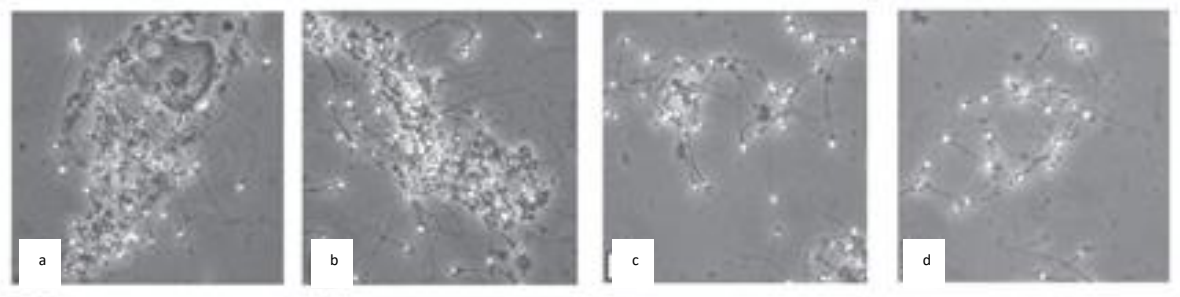
D. Mixed (clear head-to-head and tail-to tail agglutinations)

e. Tangled (heads and tails enmeshed. Heads are not clear of agglutinates as they are not clear of tail-to-tail agglutination



Aggregation - This is the adherence either of immotile spermatozoa to each other or of motile spermatozoa to mucous strands, non –sperm cells or debris is considered to be non-specific aggregation and should be recorded (figure 2). Report as Isolated (<10 sperm/aggregate), Moderate (10-15 sperm/aggregate, free sperm), large aggregates (>50 sperm, some still free) or gross aggregates (all sperm and agglutinates interconnected).

Examples of spermatozoa aggregated with epithelial cells (a), debris (b) or spermatozoa (c,d)



Viability – if appropriate we will perform a test to establish if sperm are dead or alive which is then reported as a percentage (live sperm). This is only carried out if the motility is severely reduced (<32%

total motility). We use a one-step method of staining sperm (Eosin and Nigrosin) followed by bright field microscopy.

6.2 Diagnostic semen analysis test for Retrograde Ejaculation

Typically during ejaculation, the ejaculate is propelled forward in the urethra and out of the body through the head of the penis. This is because the sphincter muscle located at the entrance of the bladder closes the opening to the bladder and prevents semen from entering. During retrograde ejaculation, the sphincter does not function properly and allows all or some of the ejaculate to travel into the bladder at the time of the retrograde ejaculation. In some men, semen passes into the bladder at ejaculation, resulting in aspermia (lack of semen), or no apparent ejaculate.

Confirmation of this situation is obtained by examining a sample of post-ejaculatory urine for the presence of spermatozoa.

The patient will be sent an appointment letter and asked to collect a container for his urine sample and a specimen container for semen analysis from the department before his appointment. He will be asked to collect a semen sample via masturbation, he will then be asked to empty his bladder immediately after ejaculation.

The patient will be asked to bring both specimens into the laboratory within 1 hour of production. The service will then test and report his semen sample as per Fertility methods and will report if any sperm are seen in his sampled and centrifuged urine sample.

6.3 How the fertility assessments are reported

The results will be given in a typed report using a combination of obtained values and general comments (if necessary). Terms relating to the main characteristics and expected parameters are as follows (World Health Organisation (WHO) 5th edition, 2010).

Macropathology

Test	Reference Range	Comment
Appearance:	Grey/opalescent	
Age of specimen:	Max 60 minutes	
Ejaculate Volume:	>1.5ml	(5th centile, 95% confidence interval (CI), 1.4–1.7)
Ejaculate pH:	>7.2pH	
Viscosity:	Normal	Viscous specimens will be initially assessed for motility; then α-chymotrypsin (liquefaction agent) will be added to reduce viscosity so other tests can be performed. The motility results reported state motility before the addition of α-chymotrypsin; the laboratory will look again at motility after liquefaction has occurred and report in the comments at the bottom of the report if motility improved. This information will give an indication if the viscosity if the cause for infertility.
Liquefaction:	Complete	

Micropathology

Test	Reference Range	Comment
Progressive Motility:	32%	The lower reference limit for total motility (Progressive + Non-progressive) is 40% (5th centile, 95% CI 38–42). The lower reference limit for PR is 32% (5th centile, 95% CI 31–34).
Non-progressive Motility	8%	
Immotile:	<60%	
Agglutination:	Absent	
Aggregation	Absent	
Viability	>75%	Only be tested on patients with <32% PR and NP motility
Cell Debris and non-sperm cells:	Absent	

Count

Test	Reference Range	Comment
Million/ml:	15 million/ml or more	The lower reference limit for sperm concentration is 15 × 106 spermatozoa per ml (5th centile, 95% CI 12–16 × 106). If there is evidence of severe oligozoospermia (less than 2million sperm/ml), the result will be reported alongside a sampling error expressed as a percentage. The sampling error will be greater the fewer sperm are examined (e.g. 5 sperm seen in a preparation has a 44.7%sampling error)
Million/ejaculate	39 million/ejaculate or more	The lower reference limit for total sperm number is 39 × 106 spermatozoa per ejaculate (5th centile, 95% CI 33–46 × 106).

Morphology

Test	Reference Range	Comment
Normal forms (%)	4% or more	The lower reference limit for normal forms is 4% (5th centile, 95% CI 3.0–4.0).

Nomenclature relating to semen quality (not fully comprehensive)

Normozoospermia- Sperm numbers, motility and morphology are equal to or above lower reference limit

Asthenozoospermia- The progressive motility values are less than the lower reference limit

Oligozoospermia- The sperm total number is below the lower reference limit

Teratozoospermia- The percentage of morphologically normal sperm are below the lower reference limit

Oligoasthenoteratozoospermia- Sperm number, motility and morphology are all below the lower reference limit

Azoospermia- No spermatozoa found in the ejaculate

6.4 How post vasectomy assessments are screened reported

The post vasectomy specimen will be weighed to ascertain the volume produced and will then be screened using 2 x 25µl aliquots of sperm in a fixed depth chamber, recommended by the ABA, BAS and Society for Urological surgeons (proof of validation is available on request).

The sample is screened at x40 magnification and the number of sperm and the motility is recorded. Numbers of motile or immotile sperm are reported as sperm per ml and sperm per ejaculate.

Limits of detection for CellVision fixed depth chamber

The CellVision CV 1100-2ch type is specially designed for PV-testing. The limit of detection for the laboratory is **2000 sperm per ejaculate** and based on previous measurement of uncertainty having a CV of 7.04 with a 95%CI.

The report will state whether there are motile sperm seen, which will help determine if special clearance can be given to the patient. Guidelines produced by the ABA, BAS and Society for Urological Surgeons state that special clearance can be given if patients have followed all guidelines (i.e. produced and tested

within 1 hour of production; 2-7 days abstinence; using a pre-weighted cytotoxic container). **The level for special clearance is <100,000/ml non motile sperm (according to BAS/ABA guidelines) and is at the discretion of the requesting clinician. The department recommend <50,000 per ml non motile sperm as special clearance after consultation with the author of the ABA guidelines.**

Reports are available on ICE or a paper copy is available on request. Patients will not receive results directly from the laboratory.

The Andrology service can offer technical advice in helping understand the report, but if clinical advice is needed we can assure that we will be able to answer your query within 7 days.

Turnaround times of the results should be within 7 days.

6.5 Instructions for collection of a semen specimen for diagnostic (fertility) and post vasectomy semen analysis

The following are the instructions given on the patient information leaflet:

1. In order that an optimum specimen is obtained there should be a period **without sexual activity** no less than **2 and no more than 7 days** before the specimen is produced. This allows sperm to reach full maturity before degeneration occurs after 7 days.

2. Enclosed is a specimen pot for the specimen. **The specimen should be collected at home and not in a public place as it is illegal. A production room is available on request and may be used for a 20 minute period. This must be pre-booked in advance by telephoning the department.**

3. The specimen must be collected by masturbation only (lubricants must not be used) and passed **directly** (without loss) into the sterile container provided (**condoms or other containers must not be used**). Ensure that the container is properly sealed. The specimen should be collected **no more than 1 hour** before delivery to the laboratory.

4. The specimen pot must be clearly labelled with the patient's full name and DOB. The information on the back of the appointment letter must be completed stating the time of collection; number of days since last sexual activity; partner's details; any illnesses or medication and if all the sample was collected into the container. If any of this information is missing the report may be delayed.

5. After the sample is collected it must be transported to the laboratory within 1 hour. Any delay could affect the nature of the specimen.

6. **When transporting the specimen- the container must be placed close to the body to keep warm and taken directly to the Andrology Department at BGTH**

Instructions for retrograde samples differ only in that after n°.4 the patient must urinate into a container provided by the department and label it with their name and DOB.

6.6 Consent for use of residual sample and confidentiality of data

The patient is able to opt out of the department using their sample for quality control and training by ticking the QC box on either the post vasectomy leaflet or on their appointment letter when they bring their specimen in to the department. Any quality control results obtained from the samples will not affect patient results. Further advice can be sought if required.

7. Specimen rejection

The sample will be rejected if:

- The patient has delivered the sample to the department without an appointment
- There is a long delay between production and delivery/analysis
- Abstinence guidelines have not been adhered to
- We cannot match the sample pot and the request form
- The sample is collected in a non-laboratory container that is unsuitable.
- The sample is leaking extensively
- Contamination with an unknown substance that has affected the sperm
- There may other reasons for a rejected sample, but the details of this will be given on the report

7.1 Repeat tests

If the specimen is rejected either due to the above rejection reasons or that the patient has been ill or stressed in advance of the test or the entire sample has not been collected. A note on the report will indicate if a repeat is recommended/required. The patient will be automatically sent another appointment; the patient will also need to be given a relevant pack from the requesting clinician.

Please ask the patient to abstain from sexual activity for the same number of days as their previous test if possible; this will ensure consistency between samples.

8. Quality assurance

The andrology department at ELHT participate in external quality assurance scheme (UKNEQAS) and in-house IQA on a regular basis.

8.1 Measurement of Uncertainty

Confirmation of a true sperm problem may require a second test. A note on the report form will state if a repeat is required.

8.1.1 Uncertainty

There is a level of uncertainty with semen analysis that needs to be recognised. We attempt to achieve 5% sampling error with our analysis for diagnostic semen analysis with a confidence interval of 95%. Measurement of uncertainties for each test have been evaluated by the department and are available upon request.

8.1.2 Reducing error

Due to the nature of the specimens there will always be a degree of uncertainty associated with any laboratory measurement of biological processes, actions are in place to eliminate, reduce or take into account uncertainty when interpreting results.

The following are the factors contributing to uncertainty in the Andrology service and procedures in place to reduce it.

Factor contributing to uncertainty	**Procedures in place**
Pre analysis:	
Delay in sample transport	Clear instructions to the patient Appointment system Reporting comment if > 1 hour Allocation of a production room
Motility reduction during transport and pre-testing	As above Pot batch toxicity testing Lab protocol for specimen receipt 37^{o}C storage on arrival
Incorrect or unsuitable sample	As above Abstinence instructions and reporting comment Patient question sheet Specimen acceptance/rejection policy
Factor contributing to uncertainty	**Procedures in place**
Examination phase:	
Inadequate staff training	Training program IQC program Competence scheme Ensuring adequate rotation Audit program EQA participation and Bias measurement Inter-laboratory comparison for post vasectomy and viability

Technical errors	As above Validated SOP's in place Heated stage Calibrated counting chambers Increased numbers of sperm counted and duplicate counts counting 200 sperm will give error of 7.1% (WHO) Label on forms to reduce calculation errors Temperature monitoring Equipment maintenance program and validation Positive displacement pipette and calibration Narrow range pH paper Audit trail sheets attached to report Results checked and authorised by second BMS
Sample gelatinous and inhomogeneous	Sample mixing Vortex of tubes
Post examination	
Interpretation	Normal ranges printed on all reports All requests checked before report issued

8.1.3 Notifications of quality

Users of the service will be contacted by the Senior Biomedical Scientist if any quality issues become evident that will lead to an inability to guarantee accuracy of results. Users will be contacted by letter, email or telephone depending on the nature of the issue.

The department participates in an External Quality Assurance scheme and will address any poor performance with the assistance from scheme organisers and managerial support.

We will attempt to give you at least 1 months' notice of changes dependent on the circumstances and the particular change/issue involved.

Rejected samples due to a failure to comply with procedures will always be explained within the report.

9. Notifications of changes to the service

The Andrology service will communicate to users any developments or changes via email, letter or telephone and aims to give at least 1 month notice dependent on the nature of the issue involved.

10. Comments/Complaints

Comments and complaints should be directed to the Senior Biomedical Scientist, in the first instance. This can be in written form through e-mail, postal or verbally via telephone.

The department takes pride in the service they provide to users and appreciate constructive feedback.

If any problems occur where you feel the Senior Biomedical Scientist is not appropriate person, please contact the Lead Biomedical Scientist, Laboratory Manager or Patient Affairs as appropriate.

11. Data Protection:

All data and patient information will be handled in line with Trust Policies 'Guide to Data Protection' and C077 'Confidentiality of Personal Information'.

12. Further assistance

If this handbook has not answered all of your questions or you would like further clarification, please do not hesitate to contact a member of the Andrology Team on 01282 805409- we are more than happy to help you.

Human Fertilisation and Embryology Authority (HFEA) http://www.hfea.gov.uk/