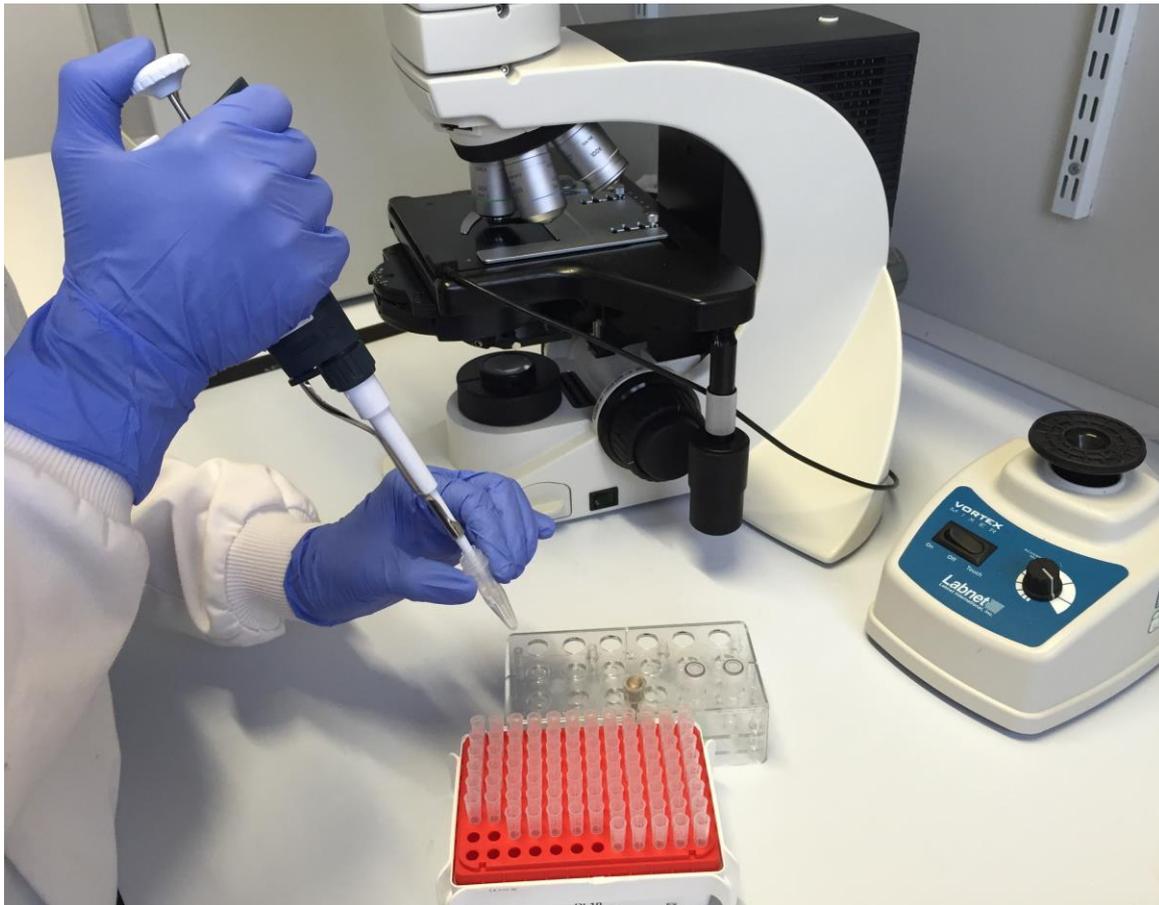


USER HANDBOOK FOR ANDROLOGY SERVICES



Diagnostic Semen Analysis

Post Vasectomy Semen Analysis

Retrograde Analysis

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1. Introduction

The Andrology Laboratory at the Heart of England Foundation Trust (HEFT) is currently operated from a single site located on the 2nd Floor of the Fothergill Block at Good Hope Hospital.

The laboratory's priority is to provide a comprehensive semen analysis service for Consultants from within HEFT and for General Practitioners from the Birmingham and Solihull area. Retrograde analysis will not be undertaken in Andrology at HEFT, but referrals for this investigation will be actioned by the laboratory staff who will forward the details to Midland Fertility where these tests will be undertaken.

The laboratory operates on a clinic based service and will have 2400 available appointments per annum to cover the annual workload of routine diagnostic semen analysis and post-vasectomy samples. At present, the ratio of diagnostic semen analysis to post vasectomy patients is undetermined but this will be monitored and feedback given in future versions of this handbook. Routinely patients will be given an appointment to attend the Andrology Department for on-site sample production in a designated private clinic room, however in exceptional circumstances samples may be produced off site if then able to be delivered to the laboratory within an appropriate time interval.

The HEFT 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 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, retrograde and post-vasectomy analysis.

2. Location and Opening Times

The Andrology Laboratory is on the 2nd Floor of the Fothergill Block at Good Hope Hospital and is open Monday to Friday from 08:00 to 16:00 except for Bank Holidays. The address is;

**Andrology Department
2nd Floor, Fothergill Block
Good Hope Hospital
Rectory Road
Sutton Coldfield, B75 7RR**

3. Useful contacts

Contact	Details	Contact details
Semen Analysis Appointment Centre	Appointment Centre, Lyndon Place, 4 TH Floor, 2096 Coventry Road, Sheldon, Birmingham, B26 3YU	Tel: 0121 424 1234 e-mail: bhs-tr.appointments-centre@nhs.net
General Enquiries	Andrology Laboratory HEFT Pathology Website	Tel: 0121 424 9717 e-mail: bhs-tr.andrology@nhs.net www.heftpathology.com
Stuart Long	Senior Biomedical Scientist Andrology Service Lead BMS/Cellular Pathology Quality Deputy	Tel: 0121 424 9717 or 0121 424 1191 e-mail: stuart.long1@nhs.net
Mrs Su Barlow	Clinical Advisor: (Midland Fertility)	Tel: 01827 311170 e-mail: su.barlow@midlandfertility.com
Gina Aldis	Laboratory Manager (Midland Fertility)	Tel: 01827 311170 e-mail: gina.aldis@midlandfertility.com
Jane Adams	Andrology Operational Manager	Tel: 0121 424 0541 e-mail: jadams5@nhs.net
Martin Collard	Head BMS Cellular Pathology	Tel: 0121 424 0189 e-mail: martin.collard@heartofengland.nhs.uk
Karen McLeod	Deputy Head BMS Cellular Pathology	Tel: 0121 424 0189 e-mail: karen.mcleod@heartofengland.nhs.uk karen.mcleod2@nhs.net
PALS	Patient Advice and Liaison Service	Tel: 0121 424 0495

4. Services provided by the laboratory

1. Diagnostic semen analysis for fertility investigations.
2. Post vasectomy semen analysis for post-operative investigation.

Services provided by a referral laboratory (Midland Fertility)

These will be organised by the laboratory:

1. Suspected retrograde ejaculation analysis (upon referral for retrograde investigation)

There are differences between each type of analysis, not only with laboratory procedures but also for the expectations of how the patient prepares for the test. Please ensure the following sections are read and understood so that we can process samples appropriately.

5. Requesting semen analysis

The preferred method of requesting semen analysis is by completion of the Andrology Referral Form. These are available by contacting the laboratory or accessing it via GP services: <http://www.heartofengland.nhs.uk/gps/>. We also offer access to appointments via ERS (Electronic Requesting Service) to enable the patient a degree of choice when booking his appointment.

Completion of referral form:

Analysis type required

This is the type of test you wish to request and must be chosen from the following set categories (test types discussed later):

- Diagnostic semen analysis
- Post Vasectomy analysis
- Retrograde Analysis

Please clearly indicate which test type is required for the patient.

Patient Details

Male partner - Name, date of birth, address, contact number and NHS/Hospital number should be included for all referrals.

Patient contact telephone number – this is important for communication between the appointment centre and the patient in an emergency. Please include this on all referrals.

Female partner – this is only required if the couple are being referred from within the Hospital (Fertility). If it has been completed we will omit inclusion on any GP referred reports.

Consultants within the Trust who are requesting a repeat test must complete this. If information is considered to be unnecessary, it can be put in as N/A.

Referring Health Practitioner and GP Practice

This **MUST** be completed to enable results to be issued to the correct healthcare provider. Please provide practice 'M' (M*****) location code to enable us to return the report to the correct requestor.

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.

Add the date of the vasectomy if applicable. This is important for two reasons:

- So that the appointment can be booked after an appropriate time interval to allow clearance
- So that the laboratory can ascertain if the sample is within the appropriate time frame according to current guidelines.

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.

All retrograde referrals must have the 'additional clinical information' field completed. We will not refer without necessary details that imply a retrograde assessment is warranted.

Once complete, the referral form should then be emailed to the HEFT Appointment Centre: bhs-tr.appointments-centre@nhs.net.

Alternatively the form may be posted to the Appointment Centre, address as follows:

**Appointment Centre,
Lyndon Place, 4TH Floor, 2096 Coventry Road,
Sheldon,
Birmingham,
B26 3YU**

The request can be placed via ERS.

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

Once the referral is received, the patient will be issued with an appointment to attend the Andrology Department at Good Hope Hospital within the 6 week target (key

performance indicator set at $\geq 95\%$ within 6 weeks). Accompanying the appointment letter the patient will also receive a Patient Information Leaflet giving instructions on how to prepare for the appropriate test (diagnostic semen analysis or post vasectomy semen analysis). He will also receive a Patient Request Form/Questionnaire which he will be asked to complete (section 1) to confirm his details and to bring this with him to his appointment.

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 ($\times 10^6$ per ml). 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:

- Rapid progressive motile
- Sluggish progressive motile
- Non-progressively motile
- Total progressive motility
- Total motility

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 (Rapid Romanowsky) 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 the semen using pH paper strips

Viscosity – this refers to how ‘thick or thin’ the sample is. This is measured using a 1ml pipette and estimating the bead length as the semen falls from the aperture. Increased viscosity over time may indicate imbalances/infections within the secretory glands and potentially impact on sperm motility. This is reported as ‘normal’ or ‘high’.

Round Cells – this is the presence of cells that may be either germ cells and/or leukocytes and is reported within the comment section as being greater than 1 million per ml if detected as such. Erythrocytes are not classed as round cells but we may comment on their presence if observed.

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 this is only a visual assessment and not a diagnostic test.

Vitality – 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 (<40% total motility). We use a one-step method of staining sperm (Eosin G and Nigrosin) followed by bright field microscopy.

6.1a) Instructions for collection of a semen specimen for diagnostic semen analysis (fertility)

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

1. Check that the label on the pot contains your correct information. If there is anything incorrect please change appropriately.
2. If not already done so, please wash your hands and penis with soap and water and rinse thoroughly to remove all traces of soap. Finally, please ensure that your hands and penis are dried thoroughly.
3. Collect your semen sample by masturbation directly into the sample container given to you. It is important that you do not use any form of lubrication* or any other product whilst doing this.
4. Replace the lid onto the container, ensuring that it is appropriately fitted to prevent leakage.
5. Place the sample into the incubator (a small metal/glass unit located in the room) ensuring that the door is closed once your sample is inside.
6. Wash and dry your hands.
7. Take a few moments to answer section 2 of the questionnaire and sign/date the declaration.
8. Press the bell located in the room by the door and wait outside the room with your questionnaire. A member of the team will check your questionnaire before showing you out of the department.

*Lubrication oil can only be used if provided by the laboratory and the patient produces his sample on site. No other circumstances will be acceptable as we

cannot verify the nature of the reagent used and what impact this may have on the sperm.

6.1b) How Diagnostic Semen Analysis assessments are reported

The results will be given in a typed report using a combination of obtained values and general comments (if necessary). A descriptive term relating to the main characteristics will also be provided to help summarise the outcome. **Table 1.** gives the parameters measured together with the lower reference limits. **Table 2.** shows commonly used nomenclature with a descriptive summary (from WHO 2010 guidelines).

Table 1. Lower reference limits for semen characteristics (5th centiles and 95% confidence limits)

Parameter	Lower Reference Limit
Semen volume (ml)	1.5 (1.4-1.7)
Total sperm number (10 ⁶ per ejaculate)	39 (33-46)
Sperm concentration (10 ⁶ per ml)	15 (12-16)
Total motility (progressive motility and non-progressive motility) (%)	40 (38-42)
Progressive motility (%)	32 (31-34)
Sperm morphology (%)	4 (3.0-4.0)
pH	Greater than or equal to 7.2
Vitality (live spermatozoa) (%)	58 (55-63)

Table 2. Nomenclature relating to semen quality (not fully comprehensive)

Nomenclature Term	What this means
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
Cryptozoospermia	Sperm present in the pellet of a centrifuged sample but not in the initial wet preparation
Mixture of the above prefixes i.e. Oligoteratozoospermia	Total sperm number and the percentage of morphologically normal sperm are below lower reference limit

6.2 Retrograde Analysis

Retrograde ejaculation is the process where semen passes into the bladder instead of through the urethra, resulting in 'aspermia' or no apparent ejaculate. This can be caused by medication (treatments for hypertension and depression), health problems (diabetes) or surgery. The treatment modality will reflect the specific cause. Patients will often have cloudy urine after ejaculation or, as mentioned, little or no semen.

Retrograde ejaculation can be confirmed through examination of post-ejaculatory urine for the presence of spermatozoa. It is usually conducted as a confirmatory test after initial investigations.

Post-ejaculatory urine is analysed to establish the presence of motile or immotile sperm. To prepare patients for retrograde analysis requires sodium bicarbonate to be prescribed by a doctor.

For more information please contact the Andrology Laboratory.

No instructions will be given in this handbook for sample collection for retrograde referrals as these will be forwarded to Midland Fertility in Tamworth for them to arrange the test.

6.3 Post vasectomy semen analysis

Sperm tests to confirm the success (or failure) of a vasectomy operation are part of the post-operative management of that patient. It is essential to know whether the operation has been successful.

General Advice - individual preference of doctor

Patients are advised to produce a sample of seminal fluid **no earlier than 12 weeks** after the operation and with a minimum of **20 ejaculations**.

The date of the vasectomy will be asked for on the referral form and must be completed.

We recommend the above guidelines are adhered to, but the patient is ultimately **YOUR** responsibility as the referring clinician. It is your decision how to best manage the patient and to advise him on sample numbers and time intervals. We cannot be held accountable for decisions made against our guidelines. Advice can be sought from our clinical lead but this will require notice.

The assessment of a single sample is sufficient to give clearance/special clearance (under stated conditions-see 6.3c) but we will accept further requests if required/preferred.

6.3a Instructions for collection of semen for post vasectomy samples - what the patient must do

1. Check that the label on the pot contains your correct information. If there is anything incorrect please change appropriately.
2. If not already done so, please ensure that you wash your hands and penis with soap and water and rinse very well (please remove all traces of soap). Dry thoroughly.
3. Collect your semen sample by masturbation directly into the sample container given to you. It is important that you do not use any form of lubrication* or any other product whilst doing this.
4. Replace the lid onto the container, ensuring that it is securely fitted to prevent leakage.
5. Place the sample into the incubator (a small metal/glass unit located in the room) ensuring that the door is closed once your sample is inside.
6. Wash and dry your hands.
7. Take a few moments to answer ALL of the remaining questions on your request/questionnaire form and sign the declaration.

8. Press the bell located in the room by the door and a member of staff will come and check your request form before showing you out of the department.

*Lubrication oil can only be used if provided by the laboratory and the patient produces his sample on site. No other circumstances will be acceptable as we cannot verify the nature of the reagent used and what impact this may have on the sperm.

6.3b) How post vasectomy samples are reported

This will depend on what is found upon investigation.

All samples will have a description of macroscopic characteristics.

All samples will be reported based on assessment of the 'wet preparation' unless centrifugation has been undertaken.

The laboratory currently report:

- If sperm are detected or not
- If motility is detected when sperm are observed
- The concentration of the sperm in numbers per ml
- Any other relevant information (including if another appointment is booked)
- Generic comment for all tests

It is important to understand that the estimation of numbers has an associated error. These are explained further in the handbook under 'Uncertainty of Measurement'.

The Andrology Department has produced a pathway for advice on vasectomy management but it is the clinician who must decide on what the appropriate management shall be and when a patient can be cleared following a vasectomy.

6.3c) Methods used in Post Vasectomy Semen Analysis and Clearance/Special Clearance

The current method used within HEFT for the examination of post vasectomy semen samples follows:

2016 Laboratory guidelines for post-vasectomy semen analysis: Association of Biomedical Andrologists, the British Andrology Society and the British Association of Urological Surgeons.

There are two methods that can be used for the estimation of sperm concentration within this guideline. The method employed by HEFT is using large volume fixed depth disposable chambers which uses an aliquot of semen to estimate the total concentration within that sample.

The laboratory cannot give clearance or special clearance on any samples. This is primarily the responsibility of the surgeon or the referring clinician and therefore no advice can be given. The guidelines stated do give information on what is deemed acceptable in terms of giving a patient clearance or special clearance. In order to help you with this we have summarized the content below, although it is ultimately your decision whether the patient requires more assessments.

In each case below, **ALL** the criteria must be met.

Clearance:

- Abstain from ejaculating prior to sample production (2-7 days).
- Ejaculated a minimum of 20 times since their operation.
- Had a minimum of 12 weeks post operation for first sample.
- Sample must have been delivered/produced no more than 4 hours prior to examination within the laboratory.
- The complete sample is collected (the laboratory would reject incomplete samples).
- One sample can be examined where:
 - No sperm are detected

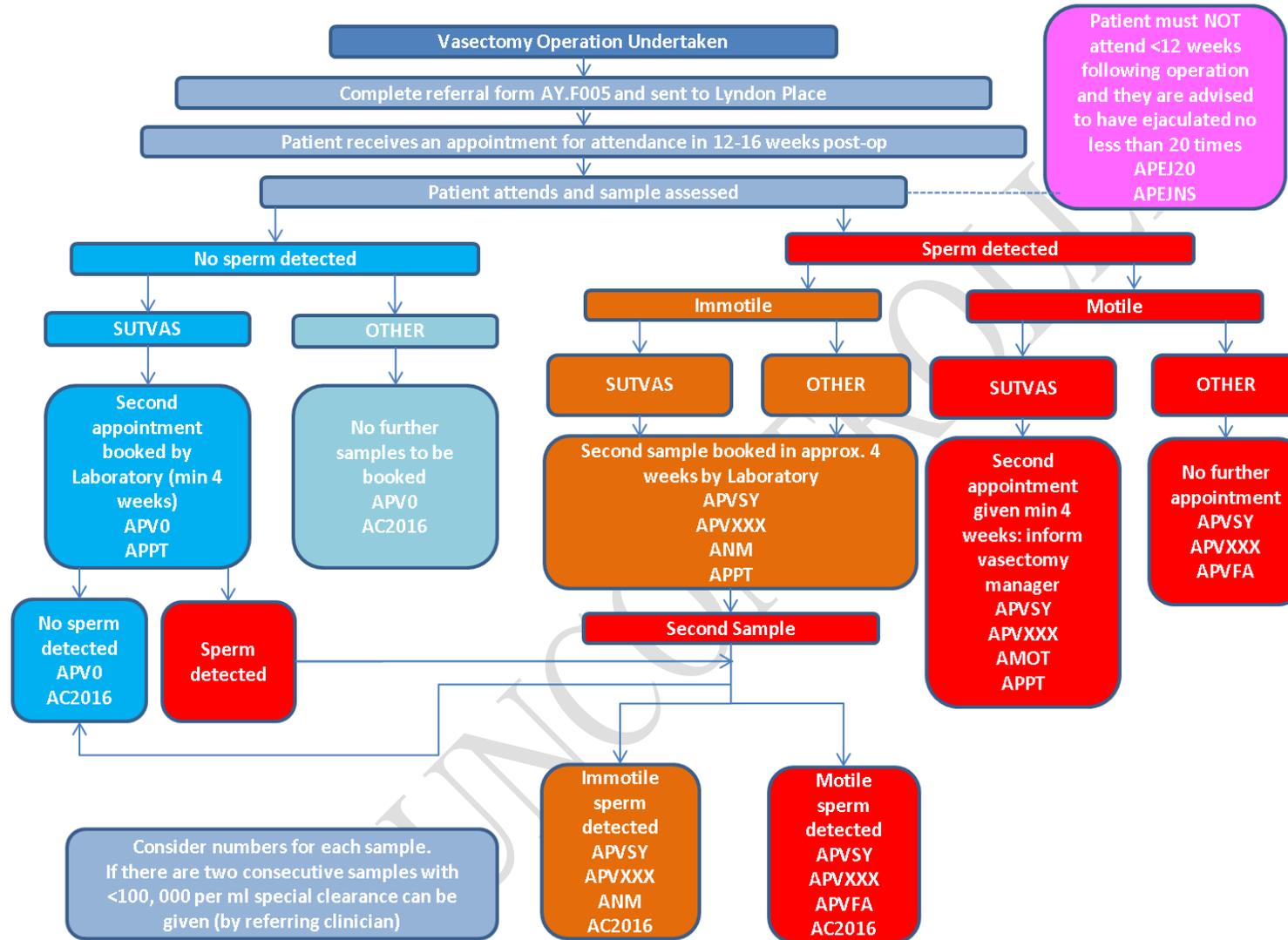
Special Clearance:

- Abstain from ejaculating prior to sample production (2-7 days).
- Ejaculated a minimum of 20 times since their operation on first sample.
- Had a minimum of 12 weeks post operation for first sample.
- Sample must have been produced within an hour of examination.
- The complete sample is collected (the laboratory would reject incomplete samples).
- Minimum of two analysis to have been undertaken, each showing:
 - <100, 000 sperm per ml
 - No motility detected
 - All criteria above met for EACH sample (although if there are zero sperm detected this can be examined within a 4 hour period).

The laboratory team can help you through the criteria above but cannot advise what you should do.

The guidelines can be found on the HEFT Andrology page (www.heftpathology.com).

Post vasectomy pathways:



7. Factors that can affect the test results of semen samples (diagnostic and post vasectomy)

There are many and often multiple factors that can have an effect on the results that can be minimised by following the guidance on the instructions for collection.

There are numerous factors that may contribute to the outcome of the test. The list below describes why some of these are important:

- Abstinence period – if the patient has not abstained for the requested time (2-7 days) then this may affect the numbers of sperm detected.
- Completeness of sample – we must know whether the entire sample has been collected. Incomplete post vasectomy samples will be discarded as sperm that may be present could be lost in the missing part.
- Use of products to produce sample – any chemical whether soap, lubrication or other, may be toxic to sperm causing a decrease in motility and vitality (whether sperm are alive or dead).
- Incorrect container – containers that have not been tested by the laboratory may leak or cause harm to the sperm (toxic). The estimation of volume will also be less accurate and thus cause the total number of sperm to be reported with a higher uncertainty that cannot be quantified. The laboratory will reject samples that are received in a non-laboratory container.
- Delayed delivery of a sample produced off-site – if the patient has taken the option of producing off site then failure to bring this to the laboratory within the requested time period will cause uncertainty with motility assessments. It will also mean that reflex tests may not be undertaken i.e. vitality, as the laboratory cannot be sure that this will not affect the results. We will reject specimens that arrive ≥ 60 minutes from production for all diagnostic specimens. Post vasectomy samples may be accepted up to four hours following production.
- Temperature – this will not be an issue if producing on-site but should the patient bring his sample to the laboratory, we do ask that he keeps the sample warm (keep sample close to the body).
- Recent illness and medication – some illnesses and medications may cause harm to the body's process of producing sperm.

Please remember that we need to know of anything mentioned above so that we can provide the most accurate report possible. Staff are available if patients wish to discuss these issues with them in private.

8. Consent for use of residual sample and confidentiality of data

On the patient questionnaire there is a section asking whether the laboratory may use any residual sample left over after reporting for quality control and training. We have to maintain levels of quality by regularly assuring procedures are followed and to ensure that no-matter what scientist carries out the test, you can be confident of the results. Training is an important part of this procedure, and for new scientists working within the laboratory.

All samples used for quality or training are anonymised and will not affect the patient's results in any way. We will not use the sample for anything else other than quality and training.

The patient must answer 'NO' on the request form to 'opt out' of this and they must sign and date the bottom of the form. Staff can advise if there are difficulties in understanding what we may use the sample for.

All patient data is protected by Trust confidentiality regulations which encompass the Data Protection Act. The laboratory acts in the best interest of the patient and will not tolerate deviation from these procedures. Further advice can be sought if required.

9. What if the patient has problems collecting or delivering the sample?

For those patients who cannot produce a sample on site, or have some religious or cultural objection, we can provide a non-spermicidal condom (Male Factor Pak™) for specimen collection. If the patient needs to request one of these condoms please ask them to ring 0121 424 9717 and speak to a member of the Andrology Department. The use of the Male Factor Pak™ is not regularly advised as there are implications to their use (i.e. volume can be lost) so please discuss this with us prior to offering this option to patients. Male Factor Pak™ cannot be used for collecting samples for Post vasectomy analysis.

10. Rejection of Specimens

The sample will be rejected if:

- There is a long delay between production and delivery/analysis:
 - > 4 hours for post vasectomy samples following vasectomy
 - > 1 hour for any diagnostic semen analysis samples or a repeat post vasectomy sample should sperm have been detected in the initial sample

- We cannot match the sample pot and the request form
- Post vasectomy samples produced in a Male Factor Pak™ or any type of condom.
- Diagnostic semen analysis samples produced in any other condom than a Male Factor Pak™.
- The sample is collected in a non-laboratory container.

There may other reasons for a rejected sample, but the details of this will be given on the report.

11. Cancelled Clinics

Clinics operate Monday to Friday, with the exception of bank holidays. The Cellular Pathology department ensures staffing is adequate to cover clinics, although this may not always be possible in extenuating circumstances. In these rare instances, the department works closely with Lyndon Place Appointments Centre to ensure that patients are contacted in advance so that new arrangements can be made. Should the clinic be cancelled on the day of the appointment, patients will be contacted prior to attendance where possible. If this fails and the patient attends the clinic, hospital staff will be on-site to direct patients to a contact for further discussion.

There are Trust policies and procedures in place that are followed by the department in order to manage long- and short-term clinic cancellations.

12. Reports

All reports will be sent to the referrer in two ways:

- Electronically if a link is established (including ICE)
- Paper copy

Patients should be made aware that they cannot receive the result directly from the laboratory.

If a report is required for a specific appointment date, this should be stated on the request form to allow the report to be authorized prior to this date. This may not always be possible so we therefore ask clinicians to ensure that a timely referral to Appointment Centre for the patient to be booked in as soon as possible.

Unfortunately, the Andrology laboratory staff are unable to provide results over the phone or through the facsimile method. We can offer another copy of the report to be issued by post or can e-mail a copy report via nhs.net ALTHOUGH there will be a

one day turnaround for these. Most will be available electronically and therefore there is no requirement to have further copies.

Interpretative comments are added to reports. The Andrology laboratory can offer **technical interpretation** and help in understanding the report. If you require **clinical interpretation or advice** contact the laboratory and they will ensure that the information is transferred to the Clinical Adviser. Please be aware that clinical advice may take 7 days or longer dependent on the nature and complexity of the request.

Care must be taken to ensure the report is read correctly as some electronic systems may not transfer the information as set-up on the Pathology Laboratory Information System. The comments will reflect the results obtained.

The turnaround time of the laboratory for all results is within 7 - 10 days including weekends and bank holidays.

13. Repeat tests

Sometimes it is necessary to repeat a test. This may include one or more of the following reasons, but the list below is not intended to be fully comprehensive:

- Part of the sample was lost by the patient at the time of production.
- The patient did not abstain from sexual activity before the test.
- The patient had abstained for too long in advance of the test.
- The patient had been ill in advance of the test.

A repeat test is then necessary to help clinical staff to make an accurate decision on the most suitable type of fertility treatment should this prove necessary. If any of the factors tested are below the normal range it is advisable to repeat the semen analysis test.

Abnormalities in the sample can occur for a number of reasons e.g. patient did not collect the whole sample. In addition illness, stress or medication can also affect sperm quality. Confirmation of a true sperm problem may require a second test. A note on the report form will state if a repeat is required.

14. Uncertainty (Diagnostic and Post Vasectomy Semen Analysis)

Diagnostic Semen Analysis

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 but if this cannot be achieved, we will report the approximate sampling error

percentage which will be written into the authorized report for the parameter that has been affected.

Post Vasectomy Semen Analysis

Post vasectomy semen analysis is an area where very low numbers of sperm may be detected. Lower numbers of sperm being counted increase the sampling error. The method used in the laboratory will enable extrapolation of the numbers of sperm into estimated concentration values based on duplicate counts. These results are then compared to acceptable limits (the 95% confidence intervals). These reporting acceptance confidence intervals are based on theoretical lower limit of detection, lower limit of quantification and counting errors. We will not report the confidence intervals with the result but it is important that you are aware of the implications of this. An example here is when we report 'No sperm detected'. This can actually mean that there are between 0 and 120 sperm per ml present in the semen, theoretically. In order to ensure compliance with the clearance levels of the 2016 post vasectomy guidelines (<100, 000 sperm/ml) the laboratory have ensured that sperm can be detected in samples that contain 1000 sperm/ml (as ascertained through multiple dilutions). This is subject to minimal but existing errors from:

- Counting errors
- Sampling errors
- Equipment uncertainties
- Human error

The equipment is calibrated, staff are trained and an extensive IQC programme is in place so that there is minimal impact on the results.

The laboratory undertakes extensive consideration of uncertainty and more information is available if required by contacting the Scientists and senior team of Andrology and Cytology.

15. Notification on quality and changes to the service

In the event that there are any quality issues or changes to the service that need to be disseminated to user's, the laboratory will do this through the e-mail system or in writing direct to each surgery.

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

The laboratory participates in an external quality assessment scheme and will address any poor performance issues if they arise through the channels provided by the scheme and through clinical support.

In the event of a failure of the service that leads to an inability to ensure the accuracy of the result, the laboratory will notify the user's involved directly in writing or by direct telephone conversations.

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

16. Comments/Complaints

Comments and complaints should be directed to the Operations Manager in the first instance. This can be in written form through e-mail, postal or verbally via telephone. We are here to provide you with a service and welcome any feedback whether good or bad.

If any problems occur where you feel the laboratory manager is not the appropriate person to contact, contact PALS on 0121 424 0945.

We will send out 'User Satisfaction Surveys' and would like to ask for you to complete these in order for us to improve our service to you.

17. 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 0121 424 9717- we are more than happy to help you. The senior team of Cellular Pathology can be contacted on 0121 424 1191.