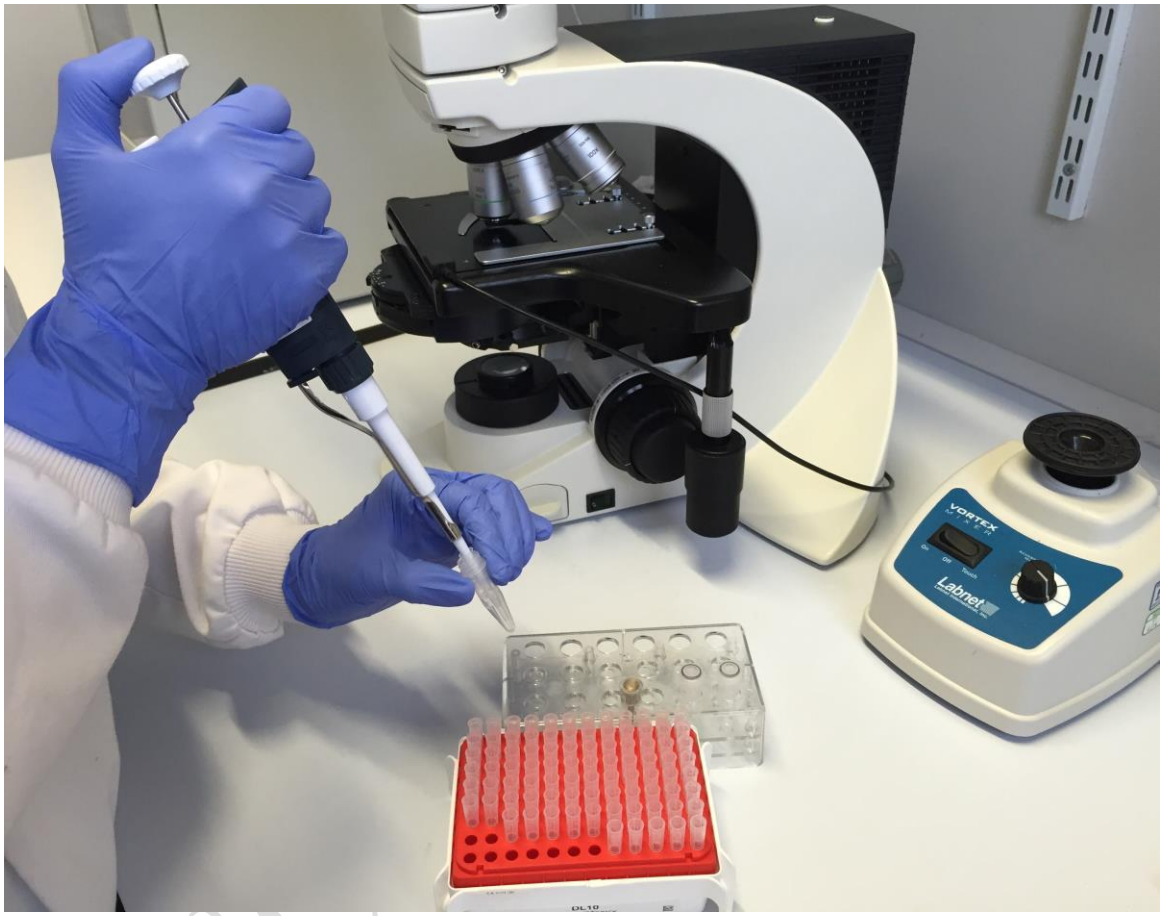
University Hospitals Birmingham
NHS Foundation Trust

Document code:	AY.P001
Version number:	7
Date of issue:	29/06/2020

USER HANDBOOK FOR ANDROLOGY SERVICES



Diagnostic Semen Analysis

Post Vasectomy Semen Analysis

Retrograde Ejaculation Analysis

Contents:

1. Introduction

The Andrology Laboratory at University Hospitals Birmingham (UHB) is currently operated from a single site located on the 1st Floor of the Sheldon Unit at Good Hope Hospital (GHH). The laboratory provides a comprehensive semen and urine analysis service for Consultants and GP's from the Birmingham and Solihull area.
Diagnostic semen analysis (DSA): some couples have difficulty conceiving and are referred for infertility investigations by their Doctor. 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. The Andrology Laboratory assesses semen and sperm quality to provide important diagnostic information.
Post vasectomy semen analysis (PVSA): vasectomies are considered a permanent form of contraception involving the separation/blocking of the vas from the testicle therefore preventing passage of sperm. Analysis of semen is performed to confirm the success (or failure) of a vasectomy operation and is part of the post-operative management of that patient. It is essential to know whether the operation has been successful which is where PVSA comes into play. There are strict pre-examination criteria that need to be adhered to in order for the clinician to manage their patient correctly.
Retrograde Ejaculation (RE): retrograde ejaculation is a disorder where the semen is expelled into the bladder instead of through the penis (antegrade). The laboratory will analyse the urine of patients following the sensation of ejaculation for the presence of sperm and motility (if alkalinisation of urine has been undertaken).

The laboratory operates a clinic-based service and has in excess of 2000 available appointments per annum to cover the workload for all examination procedures. 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 Andrology Laboratory has fully trained scientists who are highly proficient in performing quality diagnostic semen analysis in line with World Health Organisation (WHO) and allied professional body guidelines. The analysis of post-vasectomy samples is in-line with The Association of Biomedical Andrologists, British Andrology Society and British Society of Urological Surgeons 2016 Guidelines for Post Vasectomy Semen Analysis. The laboratory regularly performs internal quality control, participates in the UK National External Quality Assurance Services (UKNEQAS) for Reproductive Science for Andrology and has an interlaboratory comparison scheme for vitality and PVSA. The Laboratory has accreditation to ISO15189:2012.

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 1st Floor, Sheldon Unit 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
1st Floor, Sheldon Unit
Good Hope Hospital
Rectory Road
Sutton Coldfield, B75 7RR

3. Useful contacts

Contact	Details	Contact details
Appointment Centre	Appointment Centre 163 Yardley Green Road Birmingham B9 5XS	Tel: 0121 424 1234 e-mail:UHB-tr.appointments-centre@nhs.net
General Enquiries	Andrology Laboratory Pathology Website	Tel: 0121 424 9717 e-mail: uhb-tr.andrology@nhs.net www.heftpathology.com http://www.uhb.nhs.uk
Stuart Long	Clinical Scientist, Andrology Andrology Service Lead Deputy Quality Lead for Cellular Pathology	Tel: 0121 424 9717 e-mail: stuart.long1@nhs.net stuart.long@heartofengland.nhs.uk
Bryan Woodward	Clinical Advisor	Contact via Andrology
Bruce Tanchel	Consultant Lead for Cytology/Andrology	Tel: 0121 424 1191
Martin Collard	Head BMS Cellular Pathology	Tel: 0121 424 9717 Main lab for Andrology
PALS	Patient Advice and Liaison Service	Tel: 0121 424 0808

4. Services provided by the laboratory

1. Diagnostic semen analysis for fertility investigations.
2. Post vasectomy semen analysis for post-operative investigations.
3. Retrograde ejaculation analysis of urine for clinically relevant cases.

Services provided by a referral laboratory

There are no tests that are undertaken by a referral laboratory at present.

5. Requesting semen analysis

The preferred method of requesting semen analysis is by completing an Andrology Referral Form. These are available by contacting the laboratory or accessing it via GP services: http://www.heartofengland.nhs.uk/gps/ or on the pathology website; http://www.heftpathology.com/Departments/Andrology/. We also offer access to appointments via e-RS (electronic Referral Service) to enable the patient a degree of choice when booking his appointment.

Completion of referral form:

The referral form will appear as in the image below:

University Hospitals Birmingham NHS Foundation Trust

Andrology Referral Form

Document Code	AY.F005
Version	6
Date of Issue	05.02.19
Date of Review	05.02.21

Please complete all sections of this referral form, otherwise the referral may be rejected

There are three methods of referral:
Post to: Appointment Centre, 163 Yardley Green Road, Birmingham, B9 5XS
E-mail: UHB-tr.appointments-centre@nhs.net
eRS (Choose and Book – under Urology) routine diagnostic samples only: attach this form to the booking request (eRS can currently only be used for diagnostic semen analysis – any other referral will need to be posted or e-mailed).

Patient Details (include NHS number):

Male	
Full Name:	
Date of Birth:	
Address	
NHS/Hospital PID	
Mobile Number	
Additional Contact Information	

Type of Analysis required (please indicate):

Diagnostic Semen Analysis	☐
Post Vasectomy Semen Analysis	☐
Retrograde Analysis	☐

Female (Only required if part of Hospital Fertility Pathway, do not include if from a GP).	
Full Name	
Date of Birth	
Hospital PID	

Referring Practitioner/GP Practice:

GP/Consultant Name:		*Practice/Clinic Stamp:*
Practice Address/Hospital Clinic: *This must be completed for all GP referrals*		
GP Practice Code:		

Other Information:

Is there a known infection risk? If yes, give details.	
Is there a known mental/physical impairment? If yes, please give details.	
Does the patient require any support e.g. an interpreter? Please give details.	
Please indicate any clinical details relevant for the request (this is useful for all test requests especially retrograde).	
Repeat Tests: state when the repeat is required clearly i.e. 3 months from date of referral/last test	
If this is a post-vasectomy request: 1. What date was the operation? (DD/MM/YYY)	
2. What sample number will this be? e.g. 1, 2, 3 etc.	

Signature		Date	

Page 1 of 1 Controlled document - do not photocopy, do not use after review date

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. If you require a retrograde analysis but also wish the laboratory to assess any semen that may be produced, please only select **'Retrograde Analysis'** as the diagnostic semen analysis will automatically be performed if antegrade ejaculation occurs.

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.

Fertility Consultants within the Trust who are requesting a repeat test must complete the 'female partner' details. 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 the GP practice 'M' (M*****) location code to enable us to return the report to the correct requestor.

Other information

Infection control risk – please indicate if there is a known infection risk. No further details are necessary.

Clinical details – this should be completed to give the laboratory an understanding of the issue and to ensure the correct referral has been undertaken. All retrograde requests must have this section completed so that we can book the appointment. You may also wish to include reasons for repeat tests in this section.

Repeat tests – this is important if you require the repeat in a set timeframe. This may be likely if the report is suggesting a 3-month repeat or you feel this may be best practice using clinical information.

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.

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

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

Appointment Centre
163 Yardley Green Road
Birmingham
B9 5XS

The request can be placed via e-RS for Diagnostic Semen Analysis and will require attachment of the referral form.

The pathway to access the andrology laboratory on e-RS for GPs is as follows:

The laboratory service for diagnostics comes under **'Urology'** and the subheading **'Andrology'** which has **'Male infertility, diagnostic semen analysis and investigations'**.

If you require a Urology referral for an andrology patient please follow the below:

Look under **'Urology'** and the Option is in the subheading of **'Not otherwise specified'** at the bottom.

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 7 week target (key performance indicator is monitored for this, contact the laboratory for details). Accompanying the appointment letter, the patient will also receive a Patient Information Leaflet giving instructions on how to prepare for the appropriate test. 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. Analysis test types

6.1 Diagnostic semen analysis (DSA) test for fertility

Some couples have difficulty conceiving and are referred for fertility 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 (x 10^6 per ml). This is performed using a phase contrast microscope and a specialized counting chamber.

Sperm Total Count - this is the total number of sperm contained within the ejaculate analysed by the laboratory, measured in millions per ejaculate it is calculated by multiplying the sperm concentration by the volume of semen produced.

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 motility
- Sluggish progressive motility
- Non-progressively motile
- Total progressive motility
- Total motility
- Non-Motile (This will not appear on the report)

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.

Suspected Azoospermia - semen is analysed using Large Volume Fixed Depth Chambers for the detection of sperm. If no sperm are seen, this will be reported as 'no sperm detected'. If sperm are present, motility and concentration will be reported.

Other parameters reported:

Volume - the amount of semen produced (measured in ml but ascertained from weighing the sample). The weight is used to ensure there is a standardised and accurate method of analysis, where semen density is assumed to be 1g/ml.

pH - measures the acidity or alkalinity of 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 reflex test to establish if sperm seen are dead or alive. This is then then reported as a percentage of live sperm. This test is only undertaken if the motility is severely reduced (<40% total motility). The laboratory uses a one-step method of staining sperm (Eosin G and Nigrosin) followed by bright field microscopic examination.

6.1a Instructions for collection of a semen sample for DSA (fertility)

The following are the instructions given on the Patient Information Leaflet:

1. Check that the label on the pot has your correct information written clearly and accurately. If there is anything incorrect please change accordingly.
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. Masturbate and collect any semen that is produced into the pot. It is important that you do not use any form of lubrication unless provided to you by the laboratory. Please only collect one ejaculate.
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) closing the door securely.
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 inside the room with your questionnaire. A member of the team will check your questionnaire and then staff will show you out of the department.

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 (adapted 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	Total number of spermatozoa, sperm concentration, percentages of progressively motile and morphologically normal spermatozoa are equal to or above the lower reference limit.
Asthenozoospermia	The progressive motility values are less than the lower reference limit
Oligozoospermia	The sperm total number and/or concentration is below the lower reference limit
Teratozoospermia	The percentage of morphologically normal sperm are below the lower reference limit
Oligoasthenoteratozoospermia	Sperm number and/or concentration, motility and morphology are all below the lower reference limit
Azoospermia	No spermatozoa found in the ejaculate
Mixture of the above prefixes i.e. Oligoteratozoospermia	Total sperm number and/or concentration 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 for example), health problems (such as diabetes) or surgery. The treatment modality will reflect the specific cause. Patients may 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 following:

- If sperm are present in the urine
- Where sperm is present, we assess if they are motile or immotile sperm.

Retrograde sample production must only take place on-site.

Prescribing sodium bicarbonate

The Andrology Laboratory request that patients are reviewed by their GP and prescribed Sodium Bicarbonate (4000mg in total) as this is required to reduce the acidity of the urine for sperm and enable us to assess motility if it is present. If the urine has not been neutralised we will not be able to assess motility. If you feel it is appropriate, ask the patient to take two Alka Seltzers instead of prescribing them sodium bicarbonate. You must ensure that you review medical history and advise the patient as appropriate.

If sodium bicarbonate is prescribed or advised, they need to take this dissolved in 1 pint of water 30 minutes before the appointment time. This will be the same for patients directed to use alka seltzers.

6.2a Instructions for collection of urine for retrograde ejaculation analysis

Once you have been left alone to produce your sample, please ensure that you follow these instructions carefully:

1. Check that the labels on the semen container and on the urine container have your details clearly written on them. If there is anything incorrect please change accordingly or highlight this to the staff member.

2. If you have 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. Masturbate and collect any semen that may be produced into the sample container with the word ‘semen’ written on the top. It is important that you do not use any form of lubrication or any other product whilst doing this unless provided to you by the laboratory. If no semen is produced then this pot will be discarded by the Andrology Team. Please do not worry if you do not produce semen as this rarely happens if you have retrograde ejaculation. Continue on to point 4.

   a. Replace the lid onto the container, ensuring that it is appropriately fitted to prevent leakage.

   b. Place the sample into the incubator (a small metal/glass unit located in the room) closing the door securely once your sample is inside.

4. Once you have ejaculated (or felt the sensation of orgasm), urinate into the larger container with the word ‘urine’ written on the top. More than one container will be provided if required. Collect all of the urine as this will help the laboratory give your doctor meaningful results. Place the lid on to the container(s) ensuring that it is fitted securely. Place the container(s) next to incubator.

5. Wash and dry your hands.

6. Take a few moments to answer section 2 of the questionnaire and sign/date the declaration.

7. Press the bell located in the room by the door and wait inside the room with your questionnaire. A member of the team will check your questionnaire and go through a second form required for retrograde samples. This will involve a few short questions and then staff will show you out of the department.

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

Once you have been left alone to produce your sample, please ensure that you follow these instructions carefully:

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. Please only collect one ejaculate.

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) closing the door securely 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 inside the room with your questionnaire. A member of the team will check your questionnaire before showing you out of the department.

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 'Measurement Uncertainty'.

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.

Queen Elizabeth referrals:

Consultants who have referred their patients from the Queen Elizabeth site can access the PVSA reports on the Prescribing Information and Communications System (PICS) 7 days from appointment.

Where applicable some patients may be requested to return for a second appointment. These patients will have had sperm identified on their first sample. Consultants and Secretaries at the QE can access the PORTAL system to identify which patients have been allocated a second appointment.

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

The current method used within UHB 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.

URL: https://www.ncbi.nlm.nih.gov/pubmed/27083211

There are two methods that can be used for the estimation of sperm concentration within this guideline. The method employed by UHB is the large volume fixed depth (LVFD) 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 provide 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 summarised 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

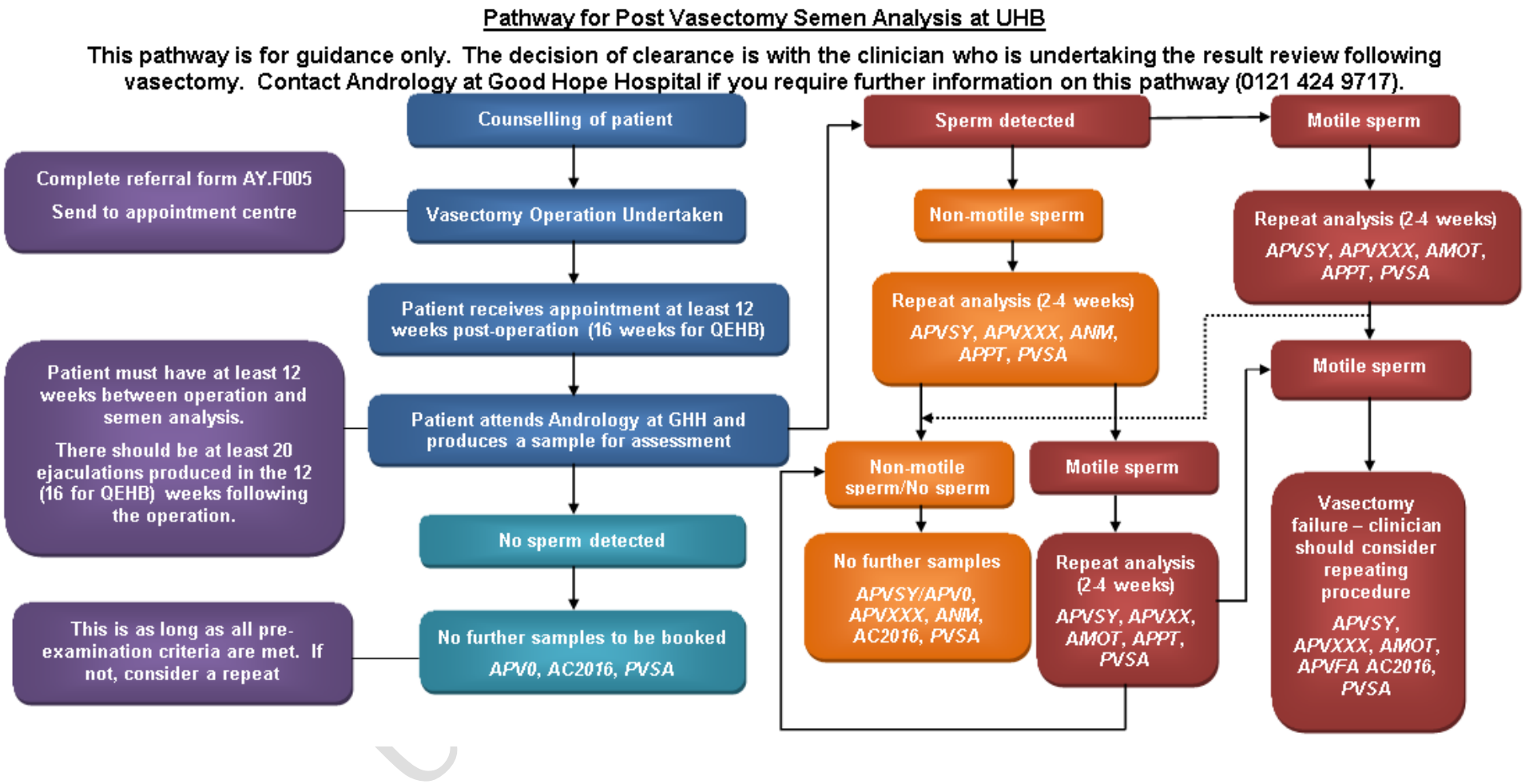
Special Clearance:

- 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 guideline link can be found on the UHB Andrology page (https://heftpathology.com/Andrology/andrology-service-home.html).

UHB Post vasectomy pathway:



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

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.

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 rejected 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 4 hours following production. Patients are advised to bring samples to the laboratory within 45 minutes to avoid any risk of rejection.

- 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.

- Not taking sodium bicarbonate for retrograde analysis – this will impact the laboratories ability to detect motility.

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, including a Clinical Scientist (Andrology).

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 regardless of 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 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 a non-spermicidal condom 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. Non-spermicidal condoms cannot be used for collecting samples for post vasectomy analysis.

Retrograde patients will not be offered off-site production due to the timing and complexity of the test.

10. Patients who do not attend (DNA) and who cancel their appointments

Patients who DNA their appointment will not routinely be offered a second one. The referral information will be checked to ensure that the request is acceptable, that the appointment letter went to the correct address and that adequate notice was provided to attend. If these are all in-line with our procedures, then we will require a new referral in order to book a second appointment.

Patients who wish to cancel their appointment must contact the appointment centre. This can be no later than 2 pm on the date of their appointment. Where possible, more notice would be appreciated in order to fill cancelled appointment slots. Trust policies do not allow more than two attempts to move an appointment unless there are extenuating circumstances, otherwise a new referral may be required. See the Trust Policy for further details.

11. 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 any type of condom or if incomplete.
- Diagnostic semen analysis samples produced in any other condom than a laboratory provided condom (Pasante®)
- The sample is collected in a non-laboratory container for DSA and PVSA with motility analysis

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

12. 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 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.

13. Reports

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

- Electronically if a link is established (including ICE) or via PICS/Concerto internally
- Paper copy

Patients should be made aware that they cannot receive the result directly from the laboratory unless exceptional circumstances and in conjunction with the clinical scientist.

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. If patients do require results, approval of transmission will be sought by the clinical scientist before discussing with the patient.

14. Interpretation and Clinical Advice

Interpretative comments are added to reports. The Andrology laboratory has Biomedical Scientists that 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 either the Clinical Scientist or 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.

If the report to be transmitted is of a sensitive nature, the laboratory advises that the patient books to see a GP or time with the clinical scientist at Good Hope Hospital.

15. 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.
- The patient has sperm detected in an initial post vasectomy semen analysis.

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 a diagnostic semen analysis 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.

All post vasectomy samples are to be reviewed by the clinician responsible for the patient. The laboratory will routinely repeat any initial samples where sperm are detected. Any incomplete samples will be rejected and a repeat organised with the patient.

16. Measurement Uncertainty

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.

In Andrology at UHB, sample uncertainty can be given based on the coefficient of variation (CV). This is also known as 'relative standard deviation' can be used to derive a range that results may fall within for a given value.

If you require the uncertainty, please contact the laboratory. This will need to be in advance of when you require the information but staff will be able to provide you with this within 7 days of receipt.

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 102 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.

PVSA Limit of Detection: 102 sperm/ml (ascertained on 04.12.19)

Retrograde Analysis

Retrograde samples have multiple factors that can influence the uncertainty of the results. The laboratory has established a limit of detection for sperm of 45 sperm/ml. The motility will be assessed if the patient has neutralized their urine. This will fall into the DSA uncertainty, but the environment will have an unknown impact that we cannot quantify. Motility may be present in non-alkalinised samples, although this is very unlikely.

17. 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.

18. Comments/Complaints

Comments and complaints should be directed to the Laboratory Lead in the first instance. This can be in written form through e-mail, post 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 lead is not the appropriate person to contact, the PALS service can provide support on 0121 424 0808.

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.

19. 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 or via e-mail. We are more than happy to help you.