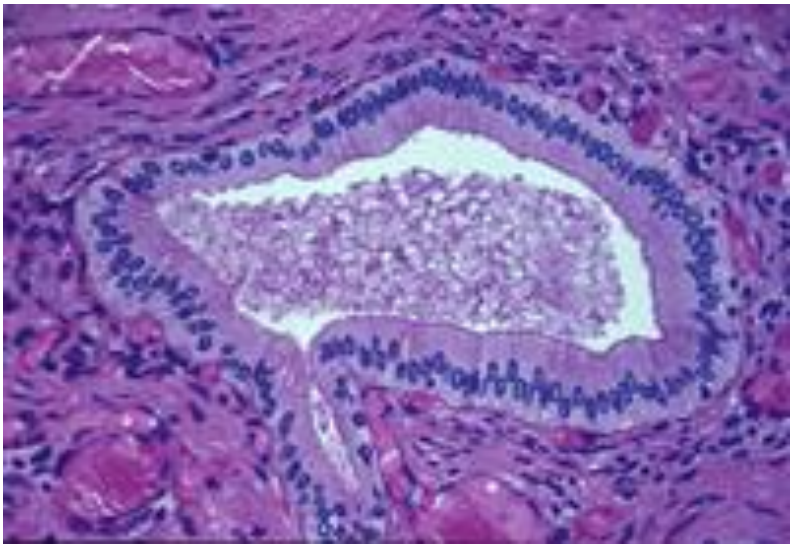
Western Health and Social Care Trust

Cellular Pathology User Manual



Cellular Pathology User Manual

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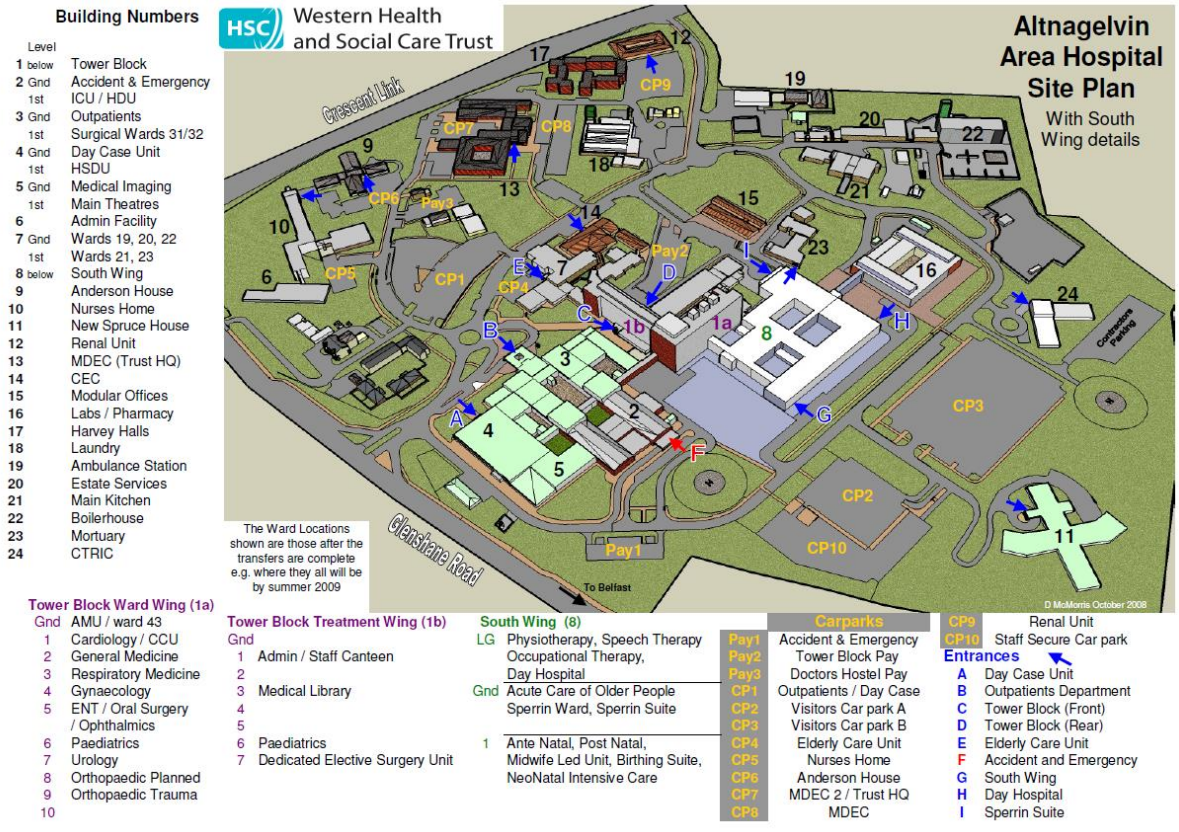
1.0 Laboratory Location

Altnagelvin Switchboard	028 713 45171 00 44 28 713 4171 (outside UK)

WHSCT Cellular Pathology	
Cellular Pathology Laboratory Altnagelvin Hospital Glenshane Road Londonderry Co. Londonderry N. Ireland BT47 6SB	Mortuary Department Altnagelvin Hospital Glenshane Road Londonderry Co. Londonderry N. Ireland BT47 6SB

The Western Health and Social Care Trust (WHSCT) Cellular Pathology Service is located on the first floor of the Laboratory/ Pharmacy Building in the South wing on the Altnagelvin Hospital site – see point 16 on the site map shown above.



Car parks are shown on the above map. There are also disabled car-parking spaces at the front of the Main Pharmacy/ Laboratory building. The main Altnagelvin Laboratory Reception Desk and Cellular Pathology laboratory are accessible by lift and therefore are accessible for disabled patients.

2.0 Key Contacts

Name	Position	Contact details
Dr Ciaran Flynn	Cellular Pathology Clinical Lead Secretary	Ext. 213967 ciaran.flynn@westerntrust.hscni.net Ext. 213436
Dr Kathleen Mulholland	Consultant Pathologist Secretary	Ext. 213968 kathleen.mulholland@westerntrust.hscni.net Ext. 213988
Dr Iain Cameron	Consultant Pathologist Secretary	Ext. 213969 iain.cameron@westerntrust.hscni.net Ext. 213989
Dr Niall Corry	Consultant Pathologist Secretary	Ext. 213966 Niall.Corry@westerntrust.hscni.net Ext. 213986
Dr Robert Harkness	Consultant Pathologist Secretary	Ext. 213981 Robert.Harkness@westerntrust.hscni.net Ext. 213436
Dr Ali Ben-Mussa	Consultant Pathologist Secretary	Ext. 213964 Ali.Benmussa@westerntrust.hscni.net Ext. 213986
Dr Ciaran O'Neill	Consultant Pathologist Secretary	Ext. 213976 Ciaran ONeill@westerntrust.hscni.net Ext. 213986
Nora McDonald	Cellular Pathology Lead	Ext. 213977 Nora.McDonald@westerntrust.hscni.net
Julie Wright-Dalton	Cytopathology Operational Manager & Cervical Cytology Section Lead	Ext. 213456 julie.wright@westerntrust.hscni.net
Jayne Donaghy	Histopathology Operational Manager & Histology Lab Section Lead	Ext. 213936 jayne.donaghy@westerntrust.hscni.net
Claire Kiepura	Quality & Andrology Section Lead	Ext. 213433 Claire.Kiepura@westerntrust.hscni.net
Dr Mary McMenamin	Molecular Testing & Research Section Lead	Ext. 213978 mary.mcmenamin2@westerntrust.hscni.net
Louise Matson	Immunohistochemistry Section Lead	Ext. 213404 louise.matson@westerntrust.hscni.net
Isobel O'Donnell	Diagnostic Cytology Section Lead	Ext. 213433 isobel.odonnell@westerntrust.hscni.net
Paul Magee	Dissection Section Lead & Mortuary Services	Ext. 213404 paul.magee@westerntrust.hscni.net
Mary McElroy	Advanced Dissector	Ext. 213975 mary.mcelroy@westerntrust.hscni.net

Sarah Ross-Lyttle	Failsafe and Audit Officer	Ext. 213410 sarah.ross-lyttle@westerntrust.hscni.net
Jean Ross	Administration Office Manager	Ext. 213972 jean.ross-lyttle@westerntrust.hscni.net

3.0 Service Operating Hours

Laboratory	Operational Hours	Further Information
Histopathology	08:00hrs to 20:00hrs Monday to Friday 08:00hrs to 12:00hrs Saturday only	Laboratory is closed on Sunday and all Bank Holidays. As no no-call service is available all samples taken outside operational hours **MUST** be stored appropriate – see relevant sample collection section for further information.
Cytopathology	08:00hrs to 19:00hrs Monday to Friday 08:00hrs to 12:00hrs Saturday only	Laboratory is closed on Sunday and all Bank Holidays. As no no-call service is available all samples taken outside operational hours **MUST** be stored appropriately – see relevant sample collection section for further information
Altnagelvin Body Store Facilities	08:00hrs to 16:00hrs Monday to Sunday	Between 08:00 to 16:00 hrs all hospital deaths must be reported to Body Staff on ext. 214559/ 214560 Bleep 8181
SWAH Body Store Facilities	08:00hrs to 16:00hrs Monday to Sunday	Between 08:00 to 16:00 hrs all hospital deaths must be reported to Body Staff on ext. 254458 Bleep 139. This facility is not UKAS accredited.
DIRECT ARRANGEMENTS MUST BE MADE WITH THE RELEVANT CONSULTANT PATHOLOGIST IF ANY SPECIAL ARRANGEMENTS ARE REQUIRED FOR ANY HISTOPATHOLOGY OR CYTOLOGY SAMPLES. PLEASE ALSO ENSURE THAT APPROPRIATE TRANSPORT/ PORTERING ARRANGEMENTS ARE ALSO IN PLACE.		

Please note that when any Cellular Pathology sample is not stored appropriately or is sent in an inappropriate sample container this will adversely impact the examination result/ diagnosis.

4.0 Comments or Complaints

We welcome comments about our service provision from any user. If you have any comments, please contact the Cellular Pathology Lead.

The WHSCT Complaints Policy is found on the Trust Document section of the WHSCT website.

Any complaint either verbal or written should also be directed to the Cellular Pathology Lead for further investigation.

Please use the information in Table 1 for contact details.

5.0 CLINICAL SERVICE INFORMATION

The following Clinical Services are provided:

- Breast Pathology
- Diagnostic Cytology
- Molecular Testing
- Cervical Cytology
- Andrology
- Bone/ soft tissue Pathology
- Cardiovascular Pathology
- Dermatopathology
- Body Store Services
- Endocrine Pathology
- ENT Pathology
- Gastrointestinal Pathology
- Lung Pathology
- Renal Pathology
- Urological Pathology
- Oral and dental Pathology
- Ultrasound Pathology

In certain instances specialist additional Clinical Diagnostic Cellular Pathology services are obtained by referral to other Laboratories, these are listed below:

SAMPLE/ TEST TYPE	PROVIDER	UKAS NUMBER
Haematopathology - Lymphoma	Institute of Pathology, Belfast HSCT Royal Victoria Hospital Grosvenor Road Belfast BT12 6BA	8638
Adult Consented Post-Mortem (non-coroners)	Institute of Pathology, Belfast HSCT Royal Victoria Hospital Grosvenor Road Belfast BT12 6BA	8638
Placenta Paediatric Post Mortems transported via BHSCT	Alder Hey Hospital, Children's NHS Foundation, Mortuary Dept. Eaton Rd, Liverpool, L12 2AP	9091
Molecular Diagnostic Testing	NI – Molecular Pathology Laboratory CCRCB 97 Lisburn Road Belfast BT9 7BL	8638
Ophthalmology	Scottish Ophthalmic Pathology Service Dr. Fiona Roberts Scottish Ophthalmic Pathology Service Department of Pathology South Glasgow University Hospital Glasgow G51 4TF For ocular melanoma: Dr Hardeep Singh Mudhar	9609

	Consultant Opthalmic Pathologist National Specialist Opthalmic Pathology Service. Histopathology, E-Floor, Royal Hallamshire hospital, Sheffield, S10 2JF.	
Hepatocellular	Royal Victoria Hospital Institute of Pathology, Belfast HSCT	8638
POC Medical Genetics	Northern Ireland Regional Genetics Laboratories Belfast Trust Laboratories A Floor Belfast City Hospital 51 Lisburn Road BELFAST BT9 7AB	8952
National: Charing Cross Hospital	Trophoblastic Tumour Screening and Treatment Centre Department of Medical Oncology Charing Cross Hospital Fulham Palace Road LONDON W6 8RF UK	9615
National: Amyloidosis Centre	National Amyloidosis Centre, UCL Division of Medicine Royal Free Hospital, Rowland Hill Street, London, NW3 2PF	
Source Bioscience	Source Bioscience, Medical Solutions Nottingham Business Park, Nottingham, NG8 6PX	9571

The Cellular Pathology Laboratory services are accredited by United Kingdom Accreditation Service (UKAS) to ISO 15189 Medical Laboratory requirements. Laboratory Management aim to maintain the highest standards in professional and service standards for all of our Service Users. Laboratory Management operates a comprehensive Quality Management System with integrated Audit, Internal Quality Assurance (IQC), Quality Assurance policies/ procedures and participates in accredited External Quality Control programmes (EQA).

Evidence of Cellular Pathology accreditation status and scopes of practice can be accessed on the UKAS web site by clicking the hyper link below.

http://www.ukas.com

Please use UKAS reference number 7912 to obtain the Cytopathology scope of practice and/ or reference number 7911 to obtain the Histopathology scope of practice in the "who's accredited" menu on the UKAS website.

6.0 Laboratory Reports and Accessing Clinical Advice

Relevant information is provided in the table below

PLEASE CHECK NIECR FOR RESULT AVAILABILITY BEFORE CONTACTING THE LABORATORY

SAMPLE TYPE	Operational Hours	Further Information
Histology	08:00hrs to 20:00hrs Monday to Friday 08:00hrs to 12:00hrs Saturday	Ext. 213986/ 213987/ 213988/ 213989/ 213432 and 213436. Please note no results are available on Saturday or Sunday or on any Bank Holiday.
Cytopathology	08:00hrs to 19:00hrs Monday to Friday 08:00hrs to 12:00hrs Saturday	Ext. 213409 and 213412. Please note no results are available on Saturday or Sunday or on any Bank Holiday.

Please note that all clinical advice must be made between 09:00hrs to 17:00hrs Monday to Friday by contacting the applicable Consultant Pathologist. In unforeseen circumstances there is a Consultant Pathologist on-call who can be reached by contacting the main Altnagelvin Hospital switchboard.

A hard copy report is generated and dispatched from the Cellular Pathology laboratory to all referring Clinicians after the report has been authorised in accordance with established laboratory reporting procedures.

When the sample examination report has been authorised the full report can be accessed electronically via the Northern Ireland Electronic Care Record (NIECR).

All Clinical requestors are required to access and check the NIECR system for their required examination report and/ or await receipt of the hard copy report before contacting the Cellular Pathology laboratory. Phoning our laboratory offices to ask for reports to be read out is an inefficient use of laboratory resource and ultimately causes delay to reports being generated on other cases. Requestors are required to await the hard copy report or access the electronic report through NIECR.

Only in exceptional cases only the reporting consultant can be contacted directly for a verbal report, for example sudden deterioration in patient condition.

Please provide the patient's full name; date of birth, sample type (s) and unique identification number e.g. H&C etc. when contacting the laboratory to discuss any patient. This information is required to comply with patient confidentiality requirements. Additionally all callers will be asked to provide their name and location. Failure to provide this information will result in Laboratory staff being unable to discuss any patient or sample.

7.0 Request Forms and Instructions for Completion

Information on the types of request forms used and additional guidance is provided in the table below. Each sample **MUST** be accompanied by a fully completed request form. Examples of all request forms are shown in Appendix 1.

All Cellular Pathology samples must be unequivocally traceable by request and labelling to an identified patient or site. This enables a Minimum Acceptance Criteria (MAC) to be evidenced.

Please note: Cellular Pathology samples are termed precious and non-repeatable. Examination of these sample types **will be delayed** where MAC requirements are not met.

THIS MAY ADVERSELY IMPACT PATIENT CARE.

Sample Type	Request Form	Additional Comments
Cervical Cytology	See appendix 10.1 Form reference CR 75.	Obtained from Campsie Stores via EProc
Diagnostic Cytology	See appendix 10.2	Provided by laboratory
Molecular Self HPV Test	See appendix 10.3	Provided by laboratory
Thyroid/ Ultrasound FNA	See appendix 10.4	Provided by laboratory
Histopathology	See appendix 10.5	Provided by laboratory
Breast Pathology	See appendix 10.6	Provided by laboratory
Consent for Histological and Disposal of Early Miscarriage	See appendix 10.7	Held at Ward/ Clinical/ Theatre sources.
Consent for burial of medical termination	See appendix ***** Need to obtain new regional form (which is not request form)	Held at Ward/ Clinical/ Theatre sources.
Placenta request form Aldherhey	See appendix ***** Need to obtain new regional form	Held at Ward/ Clinical/ Theatre sources.
Post Vasectomy Semen	See appendix 10.8	Provided by Laboratory

The following tables provide guidance on the completion of Laboratory request forms.

Essential Laboratory Request Form Criteria.

A: Patient Identification
ALL request forms MUST have the following Patient Identification: • Full given Patient name • Sex • Date of Birth • Location i.e. Ward, Clinic, Department, GP Practice etc. • Unique ID Number NHS Patients – H&C • Unique ID Number Non-NHS* – personal alpha or numerical number *This applies to Non-NHS patients such as Cross Border, Private users etc.
B: Referring Clinician/ Source Identification
All request forms MUST have the following Source Identification: • Name or other unique identifier for the requester legally authorised to request examination • Location/ destination source name for the report i.e. Ward, Clinic, Department, GP Practice etc. Please use a cypher code when possible.
C: Other Essential Criteria
All request forms MUST have the following information: • Type of primary sample submitted for examination • Anatomical site – where relevant • Examination requested • Clinically relevant information about the patient and examination request • Date that the sample was collected • Time that the sample was collected when this is critical to the examination requested

Essential Sample Container Labelling Criteria

A: Essential Sample Labelling Criteria
Any primary sample MUST be labelled appropriately to provide an unequivocal link with patient from whom it was collected. All sample containers MUST have the following minimum information: • Full given Patient name • Date of Birth • Unique ID Number NHS Patients – H&C • Unique ID Number Non-NHS* – personal alpha or numerical number *This applies to Non-NHS patients such as Cross Border, Private users etc.

Essential Slide Labelling Criteria (FNA)

A: Essential Slide Labelling Criteria
All slides MUST be labelled to provide an unequivocal link with patient from whom it was collected. All slides must have the following: • Full given Patient name • Unique ID Number NHS Patients – H&C • Unique ID Number Non-NHS* – personal alpha or numerical number *This applies to Non-NHS patients such as Cross Border, Private users etc.

Key additional points:

- All information provided on laboratory forms and sample containers **MUST** be legible;
- All information used to label the request form and sample container must match/ correspond exactly;
- Hospital or GP practice labels are preferred for both the request form and sample containers;
- Any handwritten requests **MUST** be legible and complete.

7.1 Criteria for Sample Acceptance/ Rejection

It is essential that the Cellular Pathology service provides information on established criteria used to accept or reject any sample sent to the laboratory for examination. Where any labelling does not comply with information in Section 7.0 of the manual laboratory, staff will, to the best of their ability, attempt to obtain this information but **ONLY** in the cases of samples that are unrepeatable. However where this is not possible the sample will be rejected for examination. Please note such instances have an adverse impact on Laboratory resources.

The Laboratory cannot accept responsibility for any loss of or delay to any sample examination where the incorrect laboratory request form was used by the requestor or when the sample container sent separate to the laboratory request form.

In the following instances the sample will be returned to the clinical team for resolution:

- Form received with no sample;

- Sample received with no form;
- Discrepancy between the patient details on the form and the sample container and vice versa;
- Unlabelled request form and/ or unlabelled sample container;
- Missing information from either the laboratory request form and/ or sample container labelling information;
- Samples which have leaked and are insufficient for examination;
- Samples deemed unsuitable for examination by Laboratory staff at the point of testing;
- Sample containers containing any foreign object;
- Sample containers with sample preservative which are out of date (e.g. LBC vials, formalin etc.);
- Broken FNA slides;
- Samples accompanied by a request form with no referring Clinician details which prevents laboratory report dispatch;
- Time dependent samples that are delivered to the laboratory in a manner which does not comply with specific pre-examination guidelines/ information provided in laboratory user manuals, patient information leaflets or other relevant materials;
- Samples such as body fluids that have been sent to the Laboratory in a drain bag (s).

When a sample is rejected, appropriate information will be included on the examination report issued by the Laboratory.

7.2 High Risk Samples

For suspected or known Category 3 pathogens it is essential that appropriate information is communicated to the Laboratory. It is the responsibility of the referring Clinician to ensure that the laboratory request form **AND** sample container are labelled with hazard warning Category 3 pathogen labels. Hazard labels must also be used to label any sample from patients with pyrexia of unknown origin following foreign travel.

A hazard Group 3 pathogen is defined as any biological agent that may cause severe human disease and presents a serious hazard to any person or persons who may be exposed to the pathogen. Such pathogens also present a risk of spreading in the community, but there is usually effective prophylaxis or treatment available.

Examples of Category 3 Pathogens are provided below:

Viruses	Bacteria	Fungi
• SARs • HIV • All viral Hepatitis • Prion Proteins • Kuru	• Bacillius anthracis • Brucella species • E. Coli	• Blastomyces dermatitids • Coccidioides immitis • Histoplasma species

• Fatal familial insomnia • Transmissible spongiform encephalopathies (TSE) e.g. the agents of CJD variant vCJD	• Mycobacterium tuberculosis and other strains there of • Salmonella typhi • Shigella dystenteriae (type1)	• Paracoccidioides brasiliensis • Penicillium marneffei

Please note that the Cellular Pathology Laboratory will not accept any sample that is vCJD positive or where there is a clinical suspicion of this condition. In this instance further guidance must be sought from the Microbiology Laboratory in Altnagelvin Hospital site.

The above lists are examples only and are not a comprehensive list – if there is and doubt whether a sample is high risk please, contact the Laboratory for further guidance.
Hazard Group 4 pathogens are defined as a biological agent that will cause severe human disease and is a serious hazard to any person or persons who may be exposed to the pathogen. It is likely to spread to the community, and there is usually no effective prophylaxis or treatment available. **Please contact the appropriate Medical Microbiology Laboratory immediately if a Hazard Group 4 pathogen is suspected. Under no circumstances should any samples be taken from such patients without prior consultation with the Cellular Pathology.**

7.3 Requirements for Informed Patient Consent
It is the responsibility of the Referring Clinician to ensure that informed consent is obtained and evidenced from the patient **BEFORE** their sample (s) are sent for examination and reporting. Where any patient withdraws their consent to any Cellular Pathology examination the Clinician MUST contact the BMS Cellular Pathology Service Manager and provide the necessary information.

Informed consent also extends to the provision of other information such as other patient information, family information, partner information, etc. Where any additional information is required by and provided to the Cellular Pathology service it is the responsibility of the referring Clinician to obtain consent from all relevant parties and to ensure that applicable GDPR requirements are adhered to at all times. Further information can be found at the Information Commissioners Office NI on the web site link below:

https://ico.org.uk/about-the-ico/who-we-are/northern-ireland-office/

In the case of early miscarriage it is essential that evidence of consent is provided to the Laboratory. In this instance the referring Clinician must ensure that a fully completed Consent of Histopathological Examination and Disposal of Early Miscarriage form which has also been signed by the patient is provided to the Laboratory in addition to Histopathology request form. Failure to provide this form will result in a delay to sample examination and could adversely the patient.

7.4 Protection of Personal Information

Protection of personal information pertaining to Cellular Pathology is an essential part of service provision. The Laboratory is required to comply with all applicable requirements within the WHSCT Data Protection and Confidentiality Policy to ensure protection of personal information; this can be accessed on WHSCT Web Site.

Any suspected breach of personal information protection must be reported to the BMS Cellular Pathology Service Manager.

8.0 Sample Transport

The Cellular Pathology Laboratory sample transport procedures are detailed in LAB/ADMIN/093 Specimen Transport and Referral to Reference Laboratories. This document can be requested from the laboratory.

The WHSCT operates a van transport system both for GP services and between the South West Acute Hospital, Enniskillen and the Tyrone County Hospital, Omagh sites and the Pathology Laboratory at Altnagelvin Hospital. A van transport system also operates between Altnagelvin Hospital and all Laboratory sites in the BHSCT. Samples transported in this way are housed in purpose made containers fitted and securely fastened. They are designed to contain spillage and are autoclavable. During transportation it is essential that these containers are securely fastened. A spill kit and disposable gloves are always carried on the Departmental van and held at both sample reception areas. Additional van transport also operates between the Pathology Laboratory and the NWIH site in Ballykelly.

The Trust operates a sample vacuum transport system delivery systems on the Altnagelvin site with a station in the Cellular Pathology Specimen Reception area Room 01.060 and the general reception area. The Trust is responsible for the operation and maintenance of these systems.

Referring Clinicians must ensure that they comply with all legal responsibilities when any sample is sent to the Cellular Laboratory for examination. They hold the legal responsibility to ensure that samples

are packaged and labelled in compliance with this manual and other relevant road, COSHH and postal regulations.

The duty of care to the patient is to ensure that the transport conditions do not damage the sample or in any way adversely impact the sample.

Sample containers must be securely closed to prevent leakage. Please also ensure that sample containers are placed inside a plastic transport bag. These are either attached to the corresponding Laboratory request form or are supplied with the Laboratory request form.

For larger samples such as theatre sample for Histopathology examination it is essential that these containers are securely closed and checked before dispatch as the contain 10% Buffered Formalin. Referring Clinicians must ensure that the Laboratory request form is suitable attached.

Under no circumstances should any sample where there is a known hazard group 3 pathogen MUST not be placed into the VTS system for transport to the Laboratory.

Where any patient is directed to deliver a sample to the laboratory in person (i.e. Andrology Patients), applicable guidance is provided in patient information leaflets. These leaflets are provided by the Laboratory to applicable Service Users and contain all information required.

Please refer to section 9.0 for additional information.

9.0 Sample Requirements and Turn Around Times

The Cellular Pathology laboratory operates a system of sample triage to prioritise samples using the information provided to the laboratory on the relevant sample request form.

Guidance on sample requirements, triage classifications and turn-around times are given below:

9.1 Cervical Cytology

Cervical Cytology Routine and Suspicious of Malignancy			
Laboratory Section	Sample and Container Type	Sample Requirements and other information	TAT
Cytopathology	Liquid Based Cytology (LBC) Thin Prep Vial containing PreservCyt solution.	Please ensure that the sample container and Laboratory request form are labelling as previously stated in Section 7.0. Please also include the smear taker code and GP cypher code on the request form. Samples for testing are collected in PreservCyt® Solution, and must be transported and stored at 2-30°C for a maximum of 6 months after date of collection. A LBC container is shown below:  • Always check the expiry date of the LBC vial prior to use.	100% within 28 days of date sample taken.

		• Do not use the LBC vial if it has dried out, it is past the expiration date or the fluid does not appear clear. • Do not use the LBC vial if the fluid level is below the frosted level indicator. • Do not leave the cervi brush head in the vial. • Ensure the plastic seal is removed from the lid of the vial and discarded before taking the sample. • The cervix should be visualised and recorded on the visualisation of cervix section on the request form. • Immediately rinse the collected material into the vial. • Always securely close the vial. • Record the applicable smear taker and GP cypher codes in the relevant sections. • Complete all information on the request form to provide LMP details, and any other relevant information such as previous history, suspicious cervix, Post-Menopausal Bleeding (PMB), etc. Symptomatic patients should be referred for further gynaecological examination to the applicable clinic. • Please read further instructions found on the back of the form. • Where suspicion of malignancy is suspected, please ensure that this clearly highlighted on the request form. Patients should be referred to Colposcopy via the GP pathway if a suspicious cervix is visualised. • Place the labelled LBC vial into the plastic transport bag attached to the completed corresponding request form, remove the tape covering and seal the bag securely closed. • Follow established sample collection procedures for transport to laboratory for examination. Recommended procedures	

		• Insert a green cervix brush into the endo-cervical canal deep enough for the shorter bristles to fully contact the ecto-cervix. • Maintaining pressure against the ecto-cervix, rotate the brush in a **clockwise** direction **five** times. • Rinse the cervix brush immediately into the PreservCyt solution vial by pushing it into the bottom of the vial **ten** times, forcing the bristles apart. • Swirl the brush vigorously to further release material. Once completed, discard the collection device. Tighten cap onto the vial so that the black torque line on the cap just passes the black torque line on the vial. • If any of vial contents if spilled, please **DO NOT** top up; and indicate same on request form or contact the laboratory. • A training DVD is issued to all smear takers. Copies can be obtained from the Laboratory on request. As part of the NHSCSP quality control, the laboratory's sensitivity for all cervical abnormalities is monitored as an agreed regional approach. Please contact the Cytology Operational Manager for further details. LBC samples that have >2% blood contamination may lead to false-negative results; therefore these samples will be lysed with glacial acetic acid (GAA) before routine testing, including HR HPV testing. CINtec PLUS Cytology is an immunostain which is used by the laboratory as an adjunct to cervical cytology and is conducted on selected samples to aid diagnosis. In women aged <25 years, where HPV testing is not recommended, the test is used for colposcopy triage. Please contact the BMS Molecular Section Lead for further information if required. Consumables for this test are obtained from Screenlink.	

		Tel: 00 353 4605270 Email: order@screenlink.net Out of date vials or samples arriving in the laboratory more than 6 weeks from date taken CANNOT be processed. Out of date sample containers must be returned to the Cytology Laboratory for disposal. If the vial contents are spilled DO NOT top; instead please indicate on the request form that the sample was spilled. A training DVD has been issued to all smear takers, copies can be obtained from the Northern Ireland Public Health Agency on 02890311611. CINtec Plus Cytology is an immunostain which is used by the laboratory as an adjunct to cervical cytology and is conducted on selected samples to aid diagnosis. In women aged <25 years, where HPV testing is not recommended, this test can be used for colposcopy triage.	

9.2 Molecular Testing

Molecular Testing for HR HPV including Self Sampling			
Laboratory Section	Sample Type	Sample Requirements and other information	TAT
Molecular Testing	Liquid Based Cytology (LBC) Thin Prep Vial containing PreservCyt solution.	Please ensure that the sample container and Laboratory request form are labelling as previously stated in Section 7.0. Samples for HR HPV testing must contain a minimum of 4mls of sample for testing purposes. Always check the expiration date of any consumables/ kits used. Samples for HR HPV testing are collected and transported in the same manner as those used for Cervical Cytology. These samples may be	100% within 7 days of date test requested.

		tested for High Risk HPV genotypes to triage women with borderline or mild dyskaryosis cytology, and who test positive for HPV for immediate colposcopy. HPV testing is also used as a test of cure for women treated for CIN to verify treatment success. Please contact the Section Lead for Molecular Testing if you require further information is required on this test type. For further information on regional HPV testing procedures and recommendations please contact the Public Health Agency at 02890311611. LBC samples that have >2% blood contamination may lead to false-negative results; therefore these samples will be lysed with glacial acetic acid (GAA) before routine HR HPV testing. Within the Northern Ireland Cervical Screening Programme (NI CSP), women with a learning disability and women who are unable to tolerate smear collection are often under or never screened. Following requests from GPs and Colposcopists regarding options for cervical screening in these populations; the Cytopathology Laboratory at Altnagelvin Hospital now offers: **Vaginal self-sampling for HPV detection** Referring Clinicians **MUST** contact the BMS Molecular Section Lead to discuss this test and to organise all pre-examination requirements. To ensure that self-sampling is carried out correctly by patients with a learning disability, we recommend that the sample is collected under the	

		guidance or, if necessary, in the presence of a practice/colposcopy nurse or the patient's carer. The laboratory will supply a vaginal self-sampling device with instructions and request form to the relevant Clinician. It is the responsibility of the Clinician to: A self-sample device is shown below:  • Ensure receipt of the self-sampling kit' • Label the sample container and request form as per instructions in this manual, • Dispatch the kit to the patient, • Ensure that the completed test is returned to the Cellular Pathology Laboratory as per instructions in this manual. Self-collected vaginal samples can be tested for the presence of HPV. Women who test HPV positive have an increased risk of cervical lesions that if left untreated could lead to cervical pre-cancer and cervical cancer. If the patient tests HPV positive she should be advised to attend the GP practice to have a routine cervical screening test (cervical check). If the patient tests HPV negative she should be advised that she does not require further investigation at this time. Colposcopists should manage their patients according to their local protocols. Cervical screening at the next routine screening round will still need to be considered for these patients as per normal practice.	

HPV test requests from referring laboratories must be sent via the WHSCT HPV test email account using the Excel HPV request spreadsheet. Request spreadsheet templates are held by all referring Laboratories. Please only use HPV.tests@westerntrust.hscni.net for emailing this information to the Cellular Pathology Laboratory. Figure 1 shows how the referring Laboratory must complete the form and the information that the Cellular Pathology must be provided with (see information highlighted in red). A hard paper copy must accompanying sample vials being sent to the Laboratory for testing.

Figure 1: Format for HPV test requests from referring labs to the Cellular Pathology HPV testing laboratory.

Lab No sent by BCH	Date sent by BCH	Sent by (BCH)	Lab No. received by ALT	Date received by ALT	Received by (ALT)	Date HPV test by ALT	Tested by
312------	10/11/2012	JS					
312------	10/11/2012	JS					
312------	10/11/2012	JS					
312------	10/11/2012	JS					

Information highlighted in red MUST be provided to the laboratory or the sample may be rejected.

When HR HPV testing has been completed the Cellular Pathology will return a completed spreadsheet to referring laboratories. A completed spreadsheet is shown in Figure 2.

Figure 2: Format for completed HPV test requests from Cellular Pathology to referring labs.

Lab No sent by BCH	Date sent by BCH	Sent by (BCH)	Lab No. received by ALT	Date received by ALT	Received by (ALT)	Date HPV test by ALT	Tested by
312------	10/11/2012	JS	312------	11/11/2012	JW	11/11/2012	Mar
312------	10/11/2012	JS	312------	11/11/2012	JW	11/11/2012	Mar
312------	10/11/2012	JS	312------	11/11/2012	JW	11/11/2012	Mar
312------	10/11/2012	JS	312------	11/11/2012	JW	11/11/2012	Mar

All computers and email accounts within the WHSCT and other Trusts are password protected to protect patient confidentiality.

9.3 Diagnostic Cytology

Diagnostic Cytology Respiratory			
Laboratory Section	Sample Type	Sample Requirements and other information	TAT
Diagnostic Cytology	**Sputum**	Please ensure that the sample container and Laboratory request form are labelling as previously stated in Section 7.0. Please note the Cellular Pathology Laboratory does not supply sample containers for this sample type. Please refer to Ward/ Clinic/ Practice sample container guidelines. Early morning deep cough samples should be sent on 3 different days. These should be collected **before** the patient has eaten or brushed their teeth so as to prevent contamination of the sample. Samples must be sent in a **sterile** wide mouthed sputum pot immediately on collection each day and not accumulated over the 3 days. Any samples collected outside normal Laboratory hours must be refrigerated until they can be sent to the Cellular Pathology Laboratory. **Pneumocystis Analysis** – where samples are taken for suspected Pneumocystis infection, these MUST be collected in a sterile container e.g. sputum container. Sputum or bronchoalveolar lavage samples are the recommended sample type for this this investigation. These samples are sent to the Regional Virus Laboratory, Kelvin Building, Royal Victoria Hospital, Belfast, BT12 6BA for PCR testing. Please ensure that when this test is required that this is clearly stated on the laboratory request form.	7 days

Diagnostic Cytology Respiratory			
Laboratory Section	Sample Type	Sample Requirements and other information	TAT
Diagnostic Cytology	**Trap sputum** **Bronchial washings** **Broncho Alveolar lavage** **Trans Bronchial needle aspirate**	Please ensure that the container and Laboratory request form are labelled as stated in Section 7.0. The Laboratory supplies containers for all of these samples and these are obtained from the Cytopathology laboratory on extension 213403. An example is shown below.  These containers contain CytoLyt, please refer to label for further guidance on associated hazards and stored at room temperature. Please ensure that your staff are made aware of this information and that the expiration date is checked before use. Do not use any container that is out of date. Please note that these containers are pre labelled by the Laboratory using the label shown below:  **BRONCHIAL SAMPLES** **EXCEPT BRUSH SAMPLES** **CYTOLOGY ONLY** 70ml MAX PER SAMPLE STORE AT ROOM TEMPERATURE CONTAINS CYTOLYT	7 days

		BATCH: EXPIRES: It is **ESSENTIAL** that all sample containers are correctly labelled especially if multiple samples from different clinical sites are submitted. Please clearly indicate each separate clinical site on the sample containers **AND** on the request form especially if several containers are being placed into the same sample bag attached to one request form e.g. trans bronchial nodes FNA. A maximum of 70ml per sample pot can be sent for examination, more than one pot may be sent ensuring that they are correctly labelled. Return out of date or damaged containers to the Cytology laboratory for disposal.	

Diagnostic Cytology Respiratory			
Laboratory Section	Sample Type	Sample Requirements and other information	TAT
Diagnostic Cytology	Bronchial Brush	Please ensure that the container and Laboratory request form are labelled as stated in Section 7.0. The Laboratory supplies containers for all of these samples and these are obtained from the Cytopathology laboratory on extension 213403. An example is shown below.  These containers contain CytoLyt, please refer to label for further guidance on associated hazards and store at room temperature. Please ensure that your staff are made aware of this information and that the expiration date is checked before use. Do not use any container that is	7 days

		out of date. Please note that these containers are pre labelled by the Laboratory using the label shown below:  **BRUSH SAMPLES ONLY** **CYTOLOGY FIXATIVE** Contains CYTOLYT STORE AT ROOM TEMPERATURE BATCH: EXPIRES: If a disposable bronchoscopy brush has been used, the distal part of the brush's wire stem must be cut and the brush placed into this type of sample container. It is important to unsheathe the brush **prior** to immersion in CytoLyt to ensure optimal fixation. The sheath can be placed on the wire above the brush and placed in the CytoLyt. It is **ESSENTIAL** that all sample containers are correctly labelled especially if multiple samples from different clinical sites are submitted. Please clearly indicate each separate clinical site on the sample containers **AND** on the request form especially if several containers are being placed into the same sample bag attached to one request form. Return out of date or damaged containers to the Cytology laboratory for disposal.	

Diagnostic Cytology – Fluid Samples			
Laboratory Section	Sample Type	Sample Requirements and other information	TAT
Diagnostic Cytology	Serous Fluids Peritoneal, Pleural, Pericardial,	Please ensure that the container and Laboratory request form are labelled as stated in Section 7.0. The Laboratory supplies containers for all of these samples and these are obtained from the Cytopathology laboratory on extension 213403. An example is shown below.	7 days

	Cyst, and other fluids.	 These samples must be collected in body fluid containers containing sodium citrate with the following label: BIOHAZARD **FOR BODY FLUID** **CYTOLOGY & FNA WASHINGS** **DO NOT USE FOR CSF SAMPLES** Contains 3.8% Sodium Citrate Do not use if bottle is dry or if fluid is no longer clear. Store in the fridge. BATCH: EXPIRES: These containers MUST be refrigerated when stored before use. Any sample (s) collected outside normal laboratory hours MUST be refrigerated until dispatch to the laboratory for processing. A minimum of 50ml and up to 75ml is recommended (approximately 4 containers) can be sent to the laboratory for analysis; however a maximum of 100ml will be accepted for processing. To ensure a minimum of 20ml of sample for evaluation please fill the containers to the rim below the lid. **Do not send drain bags to the laboratory for processing as these cannot be accepted as they pose a risk of infection to staff working with them. In the event of a drain bag being sent to the**	

		laboratory, these will be return to the sender for transfer to the corrected containers which may result in a delay to the test result.	

Diagnostic Cytology – Fluid Samples			
Laboratory Section	Sample Type	Sample Requirements and other information	TAT
Diagnostic Cytology	CSF	Please ensure that the container and Laboratory request form are labelled as stated in Section 7.0. The laboratory does not supply containers for the test. Only those fluids requiring investigation for malignant cells should be sent to the Cytopathology Laboratory for analysis. Aspirated fluid should be placed into a sterile universal container (see below) and dispatched immediately to the laboratory. Samples should be kept refrigerated for up to 24 hours if there is a delay in transport to the laboratory or if the sample is collected at the weekend.  A 2ml sample is usually sufficient for cytological examination.	7 days
Diagnostic Cytology – Fluid Samples			
Laboratory Section	Sample Type	Sample Requirements and other information	TAT
Diagnostic Cytology	Synovial (joint) Fluid	Please ensure that the container and Laboratory request form are labelled as stated in Section 7.0. The laboratory does not supply containers for the test.	7 days

		Only those fluids requiring investigation for malignant cells should be sent to the Cytopathology Laboratory for analysis. Aspirated fluid should be placed into a sterile universal container (see below) and dispatch immediately to the laboratory. Samples should be kept refrigerated for up to 24 hours if there is a delay in transport to the laboratory or if the sample is collected at the weekend.  When examination for crystals is required then the sample should be collected as stated and sent to the Bacteriological Laboratory in the Royal Victoria Hospital, Belfast for examination and reporting. For a differential WBC count and/ or O+S investigation, then a separate sample should be sent as stated to the Microbiology Laboratory, Altnagelvin Hospital. Please consult the WHSCT Microbiology Laboratory User Manual for further information. Please ensure that a Microbiology Laboratory request form is used. For investigation of Rheumatoid Arthritis a clotted blood sample should be collected as sent to the Microbiology Laboratory, Altnagelvin Hospital as stated above. The Microbiology Laboratory can be contacted on ext. 214017.	

Diagnostic Cytology – Fine Needle Aspirate (FNA) Samples			
Laboratory Section	Sample Type	Sample Requirements and other information	TAT

Diagnostic Cytology	Breast FNA Samples	Please ensure that all slides and the Laboratory request form are labelled as stated in Section 7.0. Laboratory request form CELLPATH/FORM/060 must be used for these samples. If a cyst fluid sample is sent as part of this sample type for processing please refer to the Serous Fluid Section of this manual for further information – these must be sent separately from the FNA sample. If aspirating from more than one site please use different sodium citrate containers ensure that they are labelled accordingly. Ensure that these containers are stored as previously stated. All FNA slides must be labelled with the patients full given first and surname **AND** their health and care number / unique identification number. **These must be written in pencil.** The sample must be aspirated onto a pre-labelled slide and spread evenly along the slide, allow the slide to air dry. Please do not aspirate too much material onto the slide as this may adversely affect staining and hence final diagnosis. If these slides are not stained as part of the BSU clinics by Laboratory staff they must sent to the Cytology laboratory. These slides must be placed into a plastic slide holder before dispatch to the laboratory with a request form.	7 days
	Other FNA Samples including Thyroid	Please ensure that all slides and the Laboratory request form are labelled as stated in Section 7.0. Please note that CELLPATH/FORM/298 must be used for Thyroid FNA samples, please use form CR76 for all other FNA samples. Primarily LBC (Liquid Based Cytology) is the optimum diagnostic methodology used. These FNA samples should be gently aspirated into universal containers containing Sodium Citrate preservative as per Serous	7 days

		Fluids stated above. Ensure that any material in the hub of the needle is aspirated into the collection fluid. **DO NOT SEND NEEDLES.** If aspirating from more than one site please use different sodium citrate containers ensure that they are labelled accordingly. Please ensure that these sample containers are stored as previously stated. Any samples collected outside normal laboratory hours must be refrigerated until they are sent to the laboratory for processing. If a sample is taken later in the day (after 19:00hrs) it can be kept in the fridge at source and sent to the laboratory the following morning. Whilst slides can be made at the time of procedure these cannot be checked for adequacy which can prohibit ancillary testing often vital in diagnosis particularly of malignancy. Any remaining sample should be aspirated into a container with sodium citrate as previously stated. This container should always accompany the FNA slides as this allows for ancillary testing. To ensure adequacy another pass may be required which can be aspirated into the same sodium citrate container. Please note syringe holders can be ordered from Morton Medical U.K. email sales@mortonmedical.co.uk product code 391-946-E, Cameco universal (10ml and 20ml) syringe pistol/ gun. To obtain further information, obtain sample containers etc. please contact the Cytology laboratory on extension 213403. Please note a supply of Sodium Citrate containers is held at Laboratory Reception in the South Western Acute Hospital, Enniskillen. Please ensure that stock levels are checked before commencing any FNA procedures. Please contact the laboratory as stated at least 30 minutes	

		prior to any FNA procedure to ensure that any materials needed can be dispatched in time.	

Diagnostic Cytology – Fluid Samples			
Laboratory Section	Sample Type	Sample Requirements and other information	TAT
Diagnostic Cytology	Urology Samples Urine Renal Washings Bladder Washings Ureteric Washings	Please ensure that the container and Laboratory request form are labelled as stated in Section 7.0. The Laboratory supplies containers for all of these samples and these are obtained from the Cytopathology laboratory on extension 213403. An example is shown below.  A sample of voided urine collected mid-morning is required for cytological examination. Early morning samples are of little value as these show marked cellular degeneration. Samples should be sent to the laboratory in urine containers containing PreservCyt with the following label with a red/ orange dot on the container lid:  **URINE CYTOLOGY ONLY** **50ml MAX PER SAMPLE**	7 days

		Contains PreservCyt STORE AT ROOM TEMPERATURE BATCH: EXPIRES: If a PreservCyt container is not available please use a sterile universal container (s). **Containers with Boric Acid MUST NOT be used for these sample types.** A maximum of 50ml (2 containers) per sample can be sent for analysis. Please state on the request form if the patient was catheterised, had had any form of instrumentation, has stones in the urinary tract or is on any form of chemotherapy or relevant treatment. All washings should be submitted as in containers containing PreservCyt as per urine sample. All of the sample should be submitted for analysis. It is extremely important that these samples are correctly labelled especially if multiple samples from different sites are submitted. Please indicate the different sites on the sample containers AND on the corresponding laboratory request form especially if included in the same sample bag attached to one request form.	

Diagnostic Cytology Other Brush/ Stent Types			
Laboratory Section	Sample Type	Sample Requirements and other information	TAT
Diagnostic Cytology	Bile Duct and Stent samples	Please ensure that the container and Laboratory request form are labelled as stated in Section 7.0. The Laboratory supplies containers for all of these samples and these are obtained from the Cytopathology laboratory on extension 213403. An example is shown below.	7 days

		 These containers contain CytoLyt, please refer to label for further guidance on associated hazards and store at room temperature. Please ensure that your staff are made aware of this information and that the expiration date is checked before use. Do not use any container that is out of date. Please note that these containers are pre labelled by the Laboratory using the label shown below:  **BRUSH SAMPLES ONLY** **CYTOLOGY FIXATIVE** Contains CYTOLYT STORE AT ROOM TEMPERATURE BATCH: EXPIRES: If a disposable brush has been used, the distal part of the brush's wire stem must be cut and the brush placed into the labelled universal container as stated. It is important to unsheathe the brush prior to immersion in CytoLyt to ensure optimal fixation. The sheath can be placed on the wire above the brush and placed in the CytoLyt, alternatively place the sheath into the fluid along with the brush.	

Diagnostic Cytology – Flow Cytometry			
Laboratory Section	Sample Type	Sample Requirements and other information	TAT

Diagnostic Cytology	FNA Node and Washing Samples	These samples should be aspirated into a flow cytometry container (pink solution for haemato-oncology).  These samples must be sent to the Haemato-oncology Laboratory, Floor C, Belfast City Hospital, for processing and reporting. They must be accompanied with a fully completed Haematology or Non-gynaecology Request Form that is clearly labelled for Flow Cytometry. Containers are obtained from the Haematology Laboratory on extension 213489. Aspirates should not be undertaken on a Friday afternoon or prior to any Bank Holiday as the samples need to be received by 15:00hrs to permit processing/ completion of testing. Samples are viable for 24hrs provided they are collected as stated and stored at room temperature. Please liaise with Haemato-oncology Laboratory on 02895040913.	
	Serous Fluid Samples – Pleural, Peritoneal and Pericardial	These samples should be placed in a purple topped EDTA container and labelled as previously stated.	

		 These are processed and reported as stated above.	

Diagnostic Cytology: Covid Positive Samples			
Laboratory Section	Sample Type	Sample Requirements and other information	TAT
Diagnostic Cytology	Any Diagnostic Cytology Sample Type EXCEPT CSF	Please ensure that the following procedures are carried out when any patient is Covid positive **only**. Users must ensure that these sample types are labelled correctly. This will ensure that Laboratory staff can safely and correctly examine and report applicable samples. Below is shown an example of how bronchial wash and brush samples are labelled by the Cellular Pathology Laboratory. 	7 days

		Please ensure Clinical/ Ward staff use the appropriate sample containers and that these are solely used for Covid positive patients only as the sample preservative medium is different from routine Diagnostic Cytology sample containers. To obtain these sample containers please contact the Cellular Pathology using the contact information previously provided. Please ensure that the laboratory request form clearly indicates that the patient is Covid positive and labelled with a category 3 sticker.	

9.4 Histology

All samples for routine histological examination MUST be placed into suitable containers with 10% neutral-buffered formalin. There MUST be sufficient formalin in the container to completely cover the sample. (Ideally there should be at least 3 times the volume of fixative in ratio to the size of the sample to ensure adequate fixation).

An appropriately sized container must be used and samples that have been forced into containers may be returned unprocessed. It is important to ensure that samples are properly sealed before transportation. Containers should not be overfilled as they tend to leak and obviously leaking containers should not be sent to the laboratory under any circumstances.

Sample containers for large specimens used in theatre/DESU in both acute hospitals are supplied by the histopathology department. Pre-filled 60ml formalin sample containers can be obtained through the e-procurement system through EMM stores, please requisition 10% Neutral Buffered Formalin 60ml (pk/25) Code: HBB001156 Supplier: Roche Diagnostics. Note: the histopathology laboratory provides these sample containers to low turnover users; e.g. health centres.

10% Neutral Buffered Formalin is a hazardous substance and due care must be taken when working with it. Beware of spillages or inhalation of the vapour as it is a toxic agent that may cause mild to severe irritation to skin and mucous membranes. Appropriate Personal Protective Equipment must be worn when dealing with histopathology

samples. If any advice is needed in relation to leaking formalin containers or 10% neutral buffered formalin please contact the Histopathology Department directly.

Samples MUST NOT be placed into any other solution or into a dry container (exceptions to this applies to Product of Conception (POC) samples, refer to the relevant section below for further information), as irreversible deterioration of the sample will take place, making accurate microscopic interpretation impossible. Large surgical resection samples SHOULD NOT be sliced or opened by the surgeon, but sent directly to the laboratory without delay. Samples in 10% neutral buffered formalin MUST NOT be placed in the fridge as this may affect the fixation of the specimen.

All samples from known or potential carriers of Hazard Category 3 pathogen (TB, Hepatitis B, Hepatitis C or HIV) MUST be clearly labelled with Category 3 stickers on both the request form and the sample container and sealed in a separate specimen bag.

All samples must be transported to the laboratory in a safe and timely manner. In accordance with Trust policy they MUST NOT be sent via VTS within the hospital and must be delivered by hand to the main laboratory reception. Samples can be sent to the laboratory via porter staff or Trust transport as per the clinic/wards current protocol. Samples from GP practices, Tyrone County Hospital, North West Independent Hospital and the South West Acute Hospital should be transported to the main laboratory reception on the ground floor by van. Samples being sent to the laboratory from within Altnagelvin Hospital should be brought to the main laboratory sample reception by relevant staff. Samples which are not fixed in 10% buffered formalin i.e. dry or in saline should be sent to the laboratory or body store in a timely manner to avoid deterioration of the sample. It is imperative that there is good communication between source and laboratory when transporting frozen section samples.

Histopathology Turn Around Time Guidance

Referral status	Consultant or other diagnostic modality finding	Information that should be provided on histopathology request form	Pathology standard
Routine - This includes benign biopsy and resection samples	Not obviously malignant/suspicious of malignancy box on the request form not ticked	Salient clinical history	90% reported in 60 calendar days
Urgent - Malignant/Suspicious of malignancy (box on request form ticked), biopsies and resections which are suspicious of malignancy	Suspicious of malignancy	Salient clinical history + Suspicious of malignancy **AND** reason for suspicion	90% reported within 10 calendar days*
Accelerated resections with a previous malignant diagnostic biopsy	Any	Salient clinical history which does not indicate malignancy but requires the sample to be processed expeditiously	90% reported within 28 calendar days

* Procedures for resection samples, post dissection, are triaged to ensure the earliest possible inclusion in the relevant MDT. For any further information please contact the clinical lead for Histopathology

Histology – Routine Sample		
Laboratory Section	Sample Type	Sample Requirements and other information
Histology	Routine and Surgical Biopsies	Please ensure that the sample container and Laboratory request form are labelling as previously stated in Section 7.0.  It is **ESSENTIAL** that all sample containers are correctly labelled especially if multiple samples from different clinical sites are submitted. Please clearly indicate each separate clinical site on the sample containers **AND** on the request form especially if several containers are being placed into the same sample bag attached to one request form. Return out of date or damaged containers to the Histology laboratory for disposal.
	Muscle Biopsies Medical Renal Biopsies Skin Immuno-	Please contact the : Institute of Pathology Royal Victoria Hospital Grosvenor Road Belfast

	fluorescence	Contact Telephone: 02890240503 These samples must be treated as Red Flag and require immediate transportation under specialized circumstances. It is the responsibility of the requestor to directly arrange with the provider in Belfast. All suspected lymphoma cases are sent to the Belfast Trust for expert opinion.
Histology	Eye Biopsies	Please send these biopsies to the Histology Laboratory as per routine surgical biopsies ensuring that the sample is labelled as directed and in an appropriately sized container. Please note that the sample MUST be fixed in 10% formalin. These biopsies will then be referred on to Dr. Fiona Roberts, Scottish Ophthalmic Service, Department of Pathology, South Glasgow University Hospital, Govan Road, Glasgow, G51 4TF. Returned reports are received by the referring Cellular Pathology Pathologist, these will then be transferred to NIECR by Laboratory Administration staff.

Histology		
Laboratory Section	Sample Type	Sample Requirements and other information
Histology	Early Miscarriage: Products of Conception	**These procedures are to be followed when NO medical genetic testing is required. Please refer to the next section for procedures to be undertaken when medical genetic testing is required.** Please ensure that the sample container and Laboratory request form are labelling as previously stated in Section 7.0. The Histopathology laboratory provides an efficient and dignified service for all early miscarriage cases (POC) throughout the WHSCT.

		In addition to the sample labelling requirements outlined above, these samples require patient consent for post mortem form. It is the responsibility of ward based medical professional staff to ensure that the correct consent form is correctly completed and sent to the Laboratory. Failure to provide this form will delay the process. Staff must complete this form in accordance with WHSCT Consent For Hospital Post- Mortem Examination. This ensures: • Confirmation that the patient has read and understood the contents of the form • Completion of the relevant consent section on the form(See Appendix 5) • Confirmation or Refusal of the consent • Patients Signature & Date • Doctors/Healthcare Professional Taking the Consent Print & Signature & Date If there is any discrepancy with the consent forms the POC and relevant forms are BOTH returned to the ward for correction. The sample cannot be examined until the fully completed consent form and sample have been returned. If Products of Conception are NOT to be examined then this must be clearly stated on the consent form. These cases MUST be sent directly to the Body Store with **NO** histopathology request form. It is the responsibility of ward based staff to organise transport to the Body Store for these samples.
	Early Miscarriage: Products of Conception and Placental Sample **THAT REQUIRE**	**These procedures are to be followed when medical genetic testing IS required.** The Histopathology Laboratory will process cases for medical genetics (up to 12 weeks gestation) between the hours of 8 -4 Monday – Friday. Samples for medical genetics will be sent to the regional medical genetics laboratory in Belfast City hospital at the first available opportunity via hospital transport.

	MEDICAL GENETICS	Should a sample be retrieved outside normal working hours it MUST be placed in a saline filled container and sent to the laboratory where it will be kept in a fridge until processed. **DO NOT PLACE THE POC INTO FORMALIN.** For Intrauterine death, stillbirth and neonatal death after 12 weeks it may be important to undertake genetic analysis. If the baby is for post mortem examination in Belfast the paediatric pathologist will submit a sample of skin for genetic testing if required. If there is to be no post-mortem then the clinicians may request genetic analysis. The clinician MUST contact the regional medical genetics laboratory directly for advice. For any placenta samples that require medical genetic examination the ward staff must ensure that the sample is placed into an appropriately sized dry container that does not contain any formalin or other fluid type. The lid and side of the container must be labelled as per Section 7 and must be accompanied with the corresponding laboratory AND consent forms.

Histology		
Laboratory Section	Sample Type	Sample Requirements and other information
Histology	Frozen Section Samples	Frozen sections should only be requested if the immediate management of the patient is likely to be altered as a result. This service is only available between the hours of 09:00hrs and 16:00hrs Monday to Friday. In cases where an unplanned frozen section is required, as much notice as possible must be given to the laboratory as the equipment used requires appropriate preparation. If the procedure is delayed, or if it is subsequently found that the frozen section is not required, please notify the Histopathology Department without delay.

		Urgent requests for frozen section MUST always be discussed with a Consultant Pathologist, these should be directed to the appropriate Cellular Pathology Consultant Pathologist. Otherwise a letter requesting a frozen section will be accepted provided the letter states; • Date of Biopsy and time • Sample type • Clinical suspicion • Consultant in charge • Ward/Area frozen section will take place and EXTENSION NUMBER. ALL correspondence should be sent to Dr Ciaran Flynn. Please note that Hazard Category 3 cases e.g. High TB risk, known HIV, Hepatitis B or C are contraindications to frozen section. If such a sample is inadvertently processed, full decontamination of the equipment used will be required, and during this time no further frozen sections can be performed for at least 24hrs. Such instances will be recorded as clinical incidents.

9.5 Andrology

Andrology			
Laboratory Section	Sample Type	Sample Requirements and other information	TAT

Andrology	Semen Diagnostic Fertility Analysis (DFA).	Please note all patients requiring this test **MUST** have an appointment before submitting a sample. Samples sent to the laboratory without an appointment will not be examined. Clinicians must ensure that where they are providing additional information to our laboratory, such as partner's names/ details, that they have obtained appropriate consent for this information to be used/ shared. Failure to do so may risk non-compliance with data control procedures e.g. GDPR. Please **DO NOT** email any test requests to the laboratory. **DFA Referrals Using the CCG Referral System.** Clinicians with access to the CCG **MUST** use the secondary care e-referral template to refer patients for DFA analysis. Please access and follow the referral pathway as outlined in the HSCI issued and controlled CCG User Manual. Please ensure that all relevant sections of the e-referral template are completed and ensure that the patient's full name, DOB, address, contact number and unique identification number (e.g. Health and Care number) are provided along with any high risk factors, special needs or the need for an interpreter. Clinicians must also ensure they include their full name and location details in the relevant section. Failure to provide ALL information will result in the request being rejected. **DFA Referrals - Standard Referral Letter** Clinicians who cannot access the CCG system may organise a this test by sending a written standard referral letter to the Cellular	95% within 1 calendar day. 100% within 3 calendar days

		Pathology Laboratory. Referral letters must be address to Mr Stephen McLaughlin (see Section 2 for further information). Referral letters MUST provide the following information: • MALE patient's full name, address, DOB, and unique identification number (health and care number – H&C). Non NHS/ private patients also require a unique identification number e.g. H&C or NWI or other hospital number; • Name, address and Consultant/ GP/ Practice code of the referring clinician; • Full details of any Clinician who requires a copy of the DFA report; • Please also provide other relevant information such as high risk factors, the need for an interpreter or other any special needs the patient may require. Incomplete or illegible referrals will be returned to the referring clinician. Please do not use any other referral form as the patient may be referred to the wrong laboratory. The laboratory cannot accept any responsibility for lost requests made on any other type of request form. Provided all referral requirements are accepted by the Laboratory, the Laboratory Admin team are responsible for organising an appointment and sample pack for the patient. Please ensure that all patient special requirements (e.g. need for interpreter, etc.) are communicated to the Laboratory on the written letter of referral or CCG comment section.	
Andrology	Semen	Please note all patients requiring this test **MUST** have an appointment before submitting a sample. Samples sent to the laboratory without an appointment will not examined.	

	Post Vasectomy Viability Testing Sample	A patient will require viability testing when two Post Vasectomy Semen Sample examinations show the presence of non-motile sperm. Clinicians who require a viability test for their patients must refer the patient to the Cellular Pathology laboratory using a referral letter as outlined in the section above and must clearly state that a Post Vasectomy viability test is required. When we have received the viability test request and provided all relevant information is provided we will provide the patient with an appointment and sample pack and organise their appointment.	
	Semen Post Vasectomy Testing Sample	Please note all patients requiring this test **MUST** have an appointment before submitting a sample. Samples sent to the laboratory without an appointment will not be examined. Information on how to organise an appointed is contained in the patient instruction leaflet provided by this laboratory and it is the responsibility of the patient to organise their appointment directly with the laboratory. These patients must be issued with a sample pack **BEFORE** submitting their sample for examination. It is the responsibility of all Referring Clinicians (i.e. Primary and/ or Secondary Care) to provide their patients with a sample pack. Only packs provided by the Cellular Pathology Laboratory can be used. Please DO NOT provide any patient with any other type of sample pack. To obtain a pack please email the BMS Andrology Section Lead. The pack consists of a WHSCT – Post Vasectomy Semen Analysis	

		Request Form (see appendix 10.8), an instruction leaflet and 1 sample container. It is essential that SECTIONS A and C of the PVSA semen analysis request form and the sample container are FULLY labelled by healthcare staff, using block capital or pre-printed labels that provide: • Patient's full given names; • Patient's date of birth; • Patient's unique identification number e.g. H&C or Private Hospital Number. • All referring Clinician details including any Consultant/ GP cypher code; • Full address of the referring Clinician e.g. Ward, GP cypher code etc; • Relevant clinical details e.g. date of procedure; The sample container MUST be fully labelled with the following information: • Patient's full given names; • Patient's date of birth; • Patient's unique identification number as previously stated. This information is essential to ensure a quality service and to meet our laboratory sample acceptance policy. Please ensure that these procedures are completed BEFORE issuing a sample pack to your patient. Failure to provide this information may result in the sample NOT being processed. Please do not use any other referral form as this may result in the sample being taken to the wrong Laboratory.	

ORGANISING A REPEAT ANDROLOGY TEST

In the event that a repeat test is required please follow the procedures outlined in the relevant section above. Repeat tests are at the discretion of the referring Clinician and it is their responsibility to organise a repeat test.

REFERRAL FOR ASSISTED CONCEPTION

If you wish to send a patient for further investigation and treatment, the Regional Fertility Centre (RFC) can provide this service for NHS patients and can be contacted on 028 90635888.

PLEASE DO NOT INSTRUCT ANY PATIENT TO CONTACT THE LABORATORY TO OBTAIN OR DISCUSS THEIR RESULTS AS WE ARE UNABLE TO DISCUSS ANY TEST RESULTS WITH ANY PATIENT.

AVAILABILITY OF ANDROLOGY RESULTS AND INTERPRETATION OF RESULTS

All Andrology results are available via the Electronic Care Record system (ECR). A paper copy of the result will be posted to referring Clinicians who do not have access to this system. Under certain circumstances verbal Andrology examination results may be given however, verbal reports will only be issued to referring Clinicians by BMS staff trained in DFA. No result can be emailed or faxed due to patient confidentiality. Please provide the patient's full name, date of birth, and, unique identification number (e.g. H&C) when requesting a verbal result. No results will be given to the patient under any circumstances. Please contact the Laboratory on 02871345171 ext. 213403 and ask for the BMS Andrology Section Lead if you require general assistance, all clinical interpretation queries must be directed to the relevant Clinician Dr. Michael McKenna. Please provide the list of patient details listed above as failure to provide this information will prevent laboratory staff from discussing any individual patient or their examination results. Additional information is provided below.

INTERPRETATION OF ANDROLOGY EXAMINATION RESULTS

THE DIAGNOSTIC FERTILY ANALYSIS TEST

We provide a comprehensive diagnostic DFA examination service and report the following parameters.

SAMPLE APPEARANCE: A normal liquefied semen sample has a homogenous appearance. It may appear less opaque if the sperm concentration is very low; the colour may also different when e.g. red blood cells are present, or yellow if the patient is jaundiced or taking certain vitamins.

SAMPLE VOLUME: The volume of the semen sample is recorded and allows the total number of spermatozoa ejaculated to be calculated. The volume of the ejaculate is contributed mainly by the seminal vesicles and prostate gland.

Sample volumes of less 1.5ml may suggest an incomplete sample, short abstinence period, retrograde ejaculation, obstruction, abnormal accessory gland function or recent illness. Volumes of more than 5mls may indicate infection, abnormal accessory gland function, long abstinence period or contamination with urine.

SAMPLE pH: The pH of the sample is recorded and reflects the balance between the pH values of the different accessory gland secretions.

SPERM CONCENTRATION: This is measured in millions of sperm per millilitre (10^6 x ml or M/ ml) of semen. This is either done using a phase contrast microscope and a Neubauer counting chamber or by means of the CASA semi-automated system depending on the actual concentration found.

SPERM MOTILITY: Sperm are graded on their ability to swim into four classifications – rapid, sluggish, non-progressive and immotile. The fast forward motile spermatozoa (i.e. rapid and sluggish) are generally the most fertile and show progressive motility. Non-progressive and immotile spermatozoa show an absence of progression. Motility is assessed using phase contrast microscopy or the CASA semi-automated system depending on the concentration data obtained.

LIQUEFACTION: This is determined by a macroscopic examination of the sample. Incomplete liquefaction can affect sperm motility and concentration.

SAMPLE VISCOSITY: A normal semen sample will not be viscous.

AGGREGATION: Phase contrast microscopy of a sample aliquot is used. The adherence of either immotile spermatozoa to each other or of motile spermatozoa to e.g. mucus strands, non-sperm cells etc. is classified as aggregation. If observed this will be reported.

AGGLUTINATION: Phase contrast microscopy of a sample aliquot is used to examine whether or not motile spermatozoa adhere to each other. This is classed into four grades where Grade 1 is isolated agglutination and Grade 4 is gross agglutination of all spermatozoa observed. If agglutination is observed the parts of the spermatozoa involved will be reported.

SPERM MORPHOLOGY: The percentage of sperm in the sample that have normal appearance is assessed. This is done by using a stained aliquot of sample examined by light microscopy.

ANTISPERM IgG and IgA ANTIBODIES: These are found in some patients and can reduce sperm motility and cause sperm to stick together. They are common in men who have had vasectomy reversal operations. This is assessed by means of the MAR antibody test.

PRESENCE OF NON-SPERM CELLS: When large numbers of non-sperm cells are observed they are reported. In this instance a Combur7 Test may be used to calculate the numbers of leucocytes seen, this result will be expressed as the number of leucocytes present per micro litre of sample. It is recommended that the cause/ source of high numbers of leucocytes is investigated before repeating any Andrology test.

Our testing methodologies are based on the World Health Organisation (WHO) Laboratory Manual for the Examination and Processing of Human Semen 5th Edition standards and Association of Biomedical Andrologists Guidelines for Good Practice.

Results have a standard format providing all available examination results. When applicable, additional comments/ observations are provided when any factor (s) which may adversely affect examination results are noted (e.g. incomplete sample etc.). The lower reference limits for DFA semen analysis are given below along 5th centiles and their 95% confidence interval data, shown in brackets. These have been adapted from W.H.O. Laboratory Manual for the Examination and Processing of Human Semen 5th Edition. These will aid in the interpretation of DFA results.

PARAMETER	W.H.O LOWER REFERENCE LIMIT
Semen Volume (ml)	1.5ml (1.4 – 1.7)

Total sperm number ($x10^6$)	39 $x10^6$ (33 – 46)
Sperm Concentration ($x10^6$/ml)	15 $x10^6$/ml (12 – 16)
Total Motility % (rapid progression+ sluggish progression + non-progressive)	40% (38 – 42)
Progressive Motility % (rapid progression + sluggish progression)	32% (31 – 34)
Sperm morphology (normal forms %)	4% (3.0 – 4.0)
pH	≥ 7.2
MAR IgA and IgG test (motile spermatozoa with bound beads %)	<40% = negative ≥40% = positive

Please note the laboratory does not conduct any additional testing on DFA samples (e.g. microbiological analysis). The result will also include interpretative comments outlining factor (s) which may adversely affect the examination result e.g., viscous sample, incomplete sample provided etc. Clinicians must carefully consider all examination results as well as all interpretative comments to determine if a repeat sample is needed or other clinical care pathway.

Where a patient has provided TWO samples both showing parameters outside WHO recommended reporting parameters e.g. low concentration, motility and/ or morphology referral for another semen analysis examination is not recommended. Instead consideration for further treatment should be discussed and agreed with the patient.

THE POST VASECTOMY SEMEN ANALYSIS (PVSA) TEST

It is recommended that Clinicians and other applicable staff, in addition to this user manual, refer to the 2016 Laboratory guidelines for post vasectomy semen analysis: Association of Biomedical Andrologists, the British Andrology Society and the British Association of Urological Surgeons Hancock, P; et al J Clin Pathol. 2016: 69 (7) 655 – 660 for further additional guidance. It is recommended that all PVSA results are interpreted in conjunction with these recommendations. In order to evidence and comply with ISO 15189 standards the laboratory is guided by the recommendations from Hancock et al in this manual and laboratory procedures.

These guidelines recommend that:

- PVSA should take place a **minimum** of 12 weeks after surgery and after a minimum of 20 ejaculations;
- Laboratories should routinely examine PVSA samples within 4 hours of production if assessing for presence of sperm.
- If non-motile sperm are observed, further PVSA samples must be examined within 50 minutes of production;
- Assessment of a single PVSA sample is acceptable to confirm vasectomy success if all recommendations and laboratory methodology are met and no sperm are observed. Clearance can be given.
- The level for special clearance should be <100,000 sperm/ml non motile sperm. Special clearance cannot be provided if any motile sperm are observed and should only be given after assessment of two PVSA samples in full accordance with the ABA recommendations.

When sample transport temperature cannot or is not controlled (i.e. is outside the control of the laboratory and the PVSA sample is not kept as close to body temperature by the patient) such factors may adversely affect sperm motility and therefore viability to the extent where these may be lost.

It is the considered opinion of the laboratory that when PVSA examination occurs outside recommended parameters that the sample can only be examined for the presence or absence of sperm.

When non-motile sperm are reported in two PVSA sample examinations the laboratory recommends that the patient is referred for viability testing and that clearance cannot be given.
When the presence of motile sperm are reported in the patients first PVSA sample the laboratory recommends a referral for viability testing, as this may be due to several procedural failures, this should be carried out after the recommended additional ejaculations. Clearance cannot be given.

Further motile sperm present in the repeat PVSA sample the referring clinician can then determine if the patient is assessed for failure of procedure and/ or re-canulisation of the vas deference; clearance cannot be given in this

instance. In this instance a repeat vasectomy procedure may be required. Results issued from the laboratory should be interpreted accordingly by the referring Clinician.

A PVSA examination reports the following parameters:

SAMPLE VOLUME: The volume of the semen sample is recorded.

PRESCENCE OF SPERM: Phase contrast microscopic examination of a sample aliquot in a large fixed depth chamber slide is used to determine the presence or absence of sperm. Sperm numbers (if observed) are expressed as numbers observed per ml of sample.

SPERM MOTILITY: If spermatozoa are observed, their ability to swim is classified into motile (i.e. shows movement including flagellar/ tail movement) and/ or non-motile (i.e. no movement observed). The presence of motile sperm suggests that viable sperm are present.

PRESENCE OF NON-SPERM CELLS: When large numbers of non-sperm cells are observed they are reported. In this instance a Combur7 Test may be used to calculate the numbers of leucocytes seen, this result will be expressed as the number of leucocytes present per micro litre of sample. It is recommended that the cause/ source of high numbers of leucocytes is investigated before repeating any Andrology test.

Other interpretative comments are provided to the Clinician to assist with interpretation of results provided e.g. period of abstinence, interval from production to examination etc. Comments will also mention any factor (s) which may adversely affect the examination result e.g. no time or date of production given, viscous sample incomplete sample etc. Clinicians should considered these carefully and determine if a repeat sample is required or other suitable clinical follow up.

THE VIABILITY TEST

The result issued for this examination will follow the format used for DFA examination; however the MAR test, or morphological examination, is not undertaken.

When non-motile and/ or motile sperm are observed in a viability test sample, clearance cannot be given, a repeat test is not recommended, and the possibility of vasectomy failure/ recanulisation should be investigated.

FACTORS WHICH CAN AFFECT ANDROLOGY EXAMINATION RESULTS

The following factors can adversely affect Andrology examination results:

- Non-compliance with any pre-examination instruction/ procedure;
- Patient is not provided with an instruction leaflet or other information provided in this manual;
- Samples are not transported at the correct temperature outside the control of this Laboratory;
- Patient uses or is provided with a sample container not provided by the Cellular Pathology;
- Sample does not undergo complete liquefaction or is viscous;

ANDROLOGY PATIENT PREPARATION

DFA and PVSA VIABILITY TEST PATIENTS

These patients should be advised that following receipt of their referral by the laboratory they should:

- Receive an appointment letter and sample pack in the post addressed to the male patient delivered to the address provided on the request form or referral letter;

Other essential preparation information will be provided to the patient by laboratory staff prior to their appointment, it is outlined below and it is good practice to discuss with the patient. The patient is expected to:

- Abstain from any form of sexual activity for a minimum of 48 hours BEFORE their appointment but NOT more than 7 days;
- Empty their bladder before producing your semen sample;
- Produce their sample by masturbation and not to use a condom or lubricant when producing their sample;

- Collect ALL of their sample into the container provided and advise a member of the laboratory staff if any of the sample is not collected;
- Only use the container provided to collect their sample;
- Provide relevant medical history information to laboratory staff e.g. had a viral infection in the last three months and/or current medication;
- Transport their sample keep at body temperature by carrying it in an inside jacket or trouser pocket;
- Transport their sample to the laboratory within **50 minutes** of production – suitable arrangements are in place if any patient cannot produce their sample at home and transport it to the laboratory within this time frame;
- NOT to spill any of their sample;
- Please discuss with the patient any special needs they may have (e.g. cultural, need for an interpreter, physiological etc.) – ensure these are communicated to and discussed with the laboratory **BEFORE** submitting your referral by contacting the laboratory using the information given and speaking to the Andrology Section Lead BMS or other laboratory staff trained in DFA.

These patients are required to sign the consent section of their request form on the date of sample submission, please ensure that this is discussed with the patient before submitting a referral. By signing the consent section, the patient also consents to the laboratory using their sample for internal quality assurance and/ or training purposes procedures. Please note that no part or parts of any semen sample is retained by the laboratory.

PVSA PATIENTS

It is the responsibility of all referring Clinician and other key staff (i.e. day surgical staff, out-patients staff, General Practitioners) to prepare PVSA patients for this test. It is essential that these patients are provided with their sample pack and the following information BEFORE they submit their sample for examination:

- That they must make an appointment for this test, submit their sample after a minimum of 20 ejaculations **AND** after a minimum of 12 weeks **AFTER** their procedure date;
- Must not ejaculate/ refrain from any form of sexual activity for a minimum of 48 hours but not more than 7 days BEFORE the date of their appointment;
- Empty their bladder before producing their sample;

- Instructed to produce their sample by masturbation into the container provided and not to use a condom or lubricant when doing so;
- Instructed to securely close the sample container, place it into the transport bag attached to their request form and then close the bag by removal of the backing tape;
- Complete ALL of the information in Section B of the request form on the day of their appointment – failure to provide all of this information may require a repeat test;
- Instructed to produce their sample and transport it to any of the collection points indicated on their instruction leaflet **WITHIN 50 MINUTES** of production;
- Instructed to keep their sample as close to body temperature as possible during transportation by keeping the sample in an inside pocket;
- Write relevant medical history information in the other relevant information section e.g. viral infection in the last three months or current medication;
- NOT to spill any of their sample;

Failure to comply with these requirements may adversely affect the PVSA sample and diagnostic accuracy of the laboratory examination.

Only sample containers provided by the Cellular Pathology laboratory can be used as these have been examined to ensure they are non-toxic to sperm. Samples received in any other type of container will not be examined by the laboratory and a repeat sample will be required.

All PVSA patients are required to sign the consent section of their request form, please ensure that this is discussed with the patient. By signing the consent section, the patient also consents to the laboratory using their sample for internal quality assurance procedures and/ or training purposes. Please note that no part or parts of any semen sample is retained by the laboratory.

ADDITIONAL CONSIDERATIONS IN PATIENT PREPARATION

Should any patient require additional considerations relating to their cultural, ethnic, physiological etc. needs please ensure that these are clearly communicated to and discussed with the laboratory at time of referral. Referring Clinicians must contact the laboratory using the details previously provided to discuss with relevant Laboratory staff

any queries or needs that any patient may have. Queries should be directed to the Andrology Section Lead in the first instance.
Patients, who have undergone a reversal of vasectomy and require semen analysis, should be referred as per DFA patient referral by their Clinician. Please ensure that the referral clearly states that the sample is a reversal of vasectomy.

PLEASE NOTE: WE DO NOT OFFER A SAMPLE "DROP IN" SERVICE FOR DIAGNOSTIC FERTILTY ANALYSIS

9.6 Mortuary and Body Store Facilities

On notification of a death the body of the deceased is transported to the body store. The deceased must have an identification armband/addressograph label on the right wrist with corresponding band on left leg. These must be placed on the deceased by ward staff before the deceased can leave the ward and must include the following information:

- Surname
- Forename
- Health and Care number
- Date Of Birth
- Ward
- Address
- Hospital Number/ Unique Identification Number (Non NHS only)
- Consultant
- Date of Death

Body Store/ portering staff must complete all registration procedures in the Body Store. Appropriate sections of the transfer form and identification can only be completed by Body Store staff, Portering staff cannot undertake these duties.

In exceptional circumstances a member of laboratory staff is on-call for the body stores and can be contacted through switchboard.

All Hazard Group 3 Cases must be clearly identified to either the Body Store staff. It is responsibility of Ward staff to undertake this.

A body will not be released until the staff member in the body store receives the Death Certificate.

9.4.1 Autopsies

Where there is cause to inform the Coroner this should be done at the earliest opportunity and the staff member covering the body store should be made aware. These cases can be transported to the body store as per section 4 above as the procedure for transport of a body to the body store is the same.

Ward staff must inform Body Store immediately if immediate transport is required.

If a Coronial Autopsy is required the PSNI will, on behalf of the coroner, arrange for the deceased to be transported to Belfast.

When the death of an adult occurs in the hospital and no coronial autopsy has been ordered the death certificate should be completed without delay. Failure to do so will mean a delay in the release of a body to family.

There is no adult consented autopsy service available in the WHSCT.

9.4.2 Paediatric Autopsies
Coronial Paediatric autopsies should be dealt with in the same manner as that for any other reportable death.

Consented Paediatric autopsies are undertaken by Alder Hey Children's NHS Foundation Trust, Eaton Road, Liverpool, L12 2AP by means of a Service Level Agreement with the BHSCT. Reports are uploaded to NIECR by the BHSCT.

All requests for this service must be pre-booked. Body Store staff must be informed as soon as possible so they can arrange transport of baby to Belfast. The baby and placenta must be sent to the mortuary Altnagelvin at least 2 hours before the appointed time of autopsy to allow for travelling to Belfast.

The following documents must also accompany the baby to the body store,
- a signed and witnessed consent form,
- a concise and complete clinical summary in association with a completed perinatal autopsy proforma.

In cases of a foetus that is less than 24 weeks gestation the Regional consent form regarding burial intentions must be completed and signed. Where family burial has been indicated the body store staff will liaise with either the undertaker or appointed nurse.

It is important that ward staff do not make arrangements for the eventual release of a body without first contacting the body store staff to ensure that families are not given unnecessary expectations of return of a body.

9.4.3 Early Pregnancy Loss
In most cases the miscarriage consists of placenta, blood clots and lining cells from the uterus. The placental tissue is microscopically examined to see if there is a reason for the miscarriage. If only a small amount of tissue is miscarried it may be necessary to process all of the tissue for examination under the microscope and so there will be no tissue remaining for burial.

Following examination and if there is foetal tissue/placental tissue remaining the tissue will be sensitively dealt with in accordance with the mother's wishes as indicated on the Consent for Histopathological Examination and Disposal of Early Miscarriages form (see appendix 10.7).
In the Western Health & Social Care Trust, this method is burial. This is scheduled on the first working Monday of each month at Ballyoan Cemetery. If the first Monday of the month is a bank holiday, then burials are scheduled

for the second Monday of that given month. There is a service followed by the burial. Any parent can attend this service.

If the mother decides to bury her early pregnancy loss, she has to contact the body store directly and arrange a date and time for collection. If contact is not made within 3 months then the hospital will bury the early pregnancy loss at the next scheduled hospital burial.

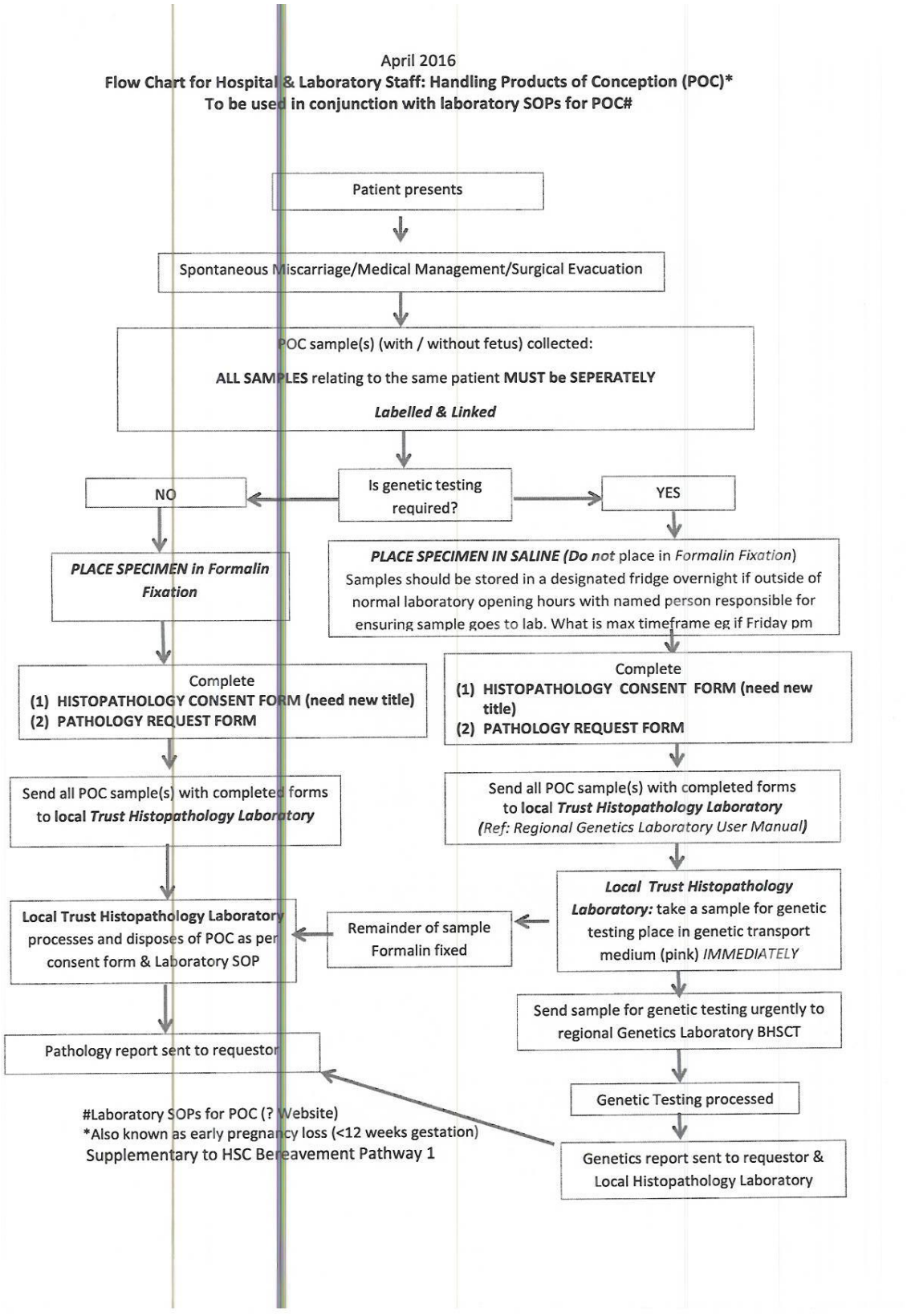
In the case of planned medical termination these samples are received to the histopathology laboratory with the abortion – consent to bury form. Note no histology request form is required to accompany these specimens and no record of patient information is recorded as these patients are allocated a unique number at clinical source.

Additional Information for Users on Monthly POC Burials in the WHSCT

- The WHSCT offers the option of family burial or hospital burial as consented by the mother at the time of pregnancy loss.
- Consent is taken by medically trained personnel whom offer support to the mother throughout the process.
- The mother is given contact details for the mortuary staff should she have any queries re. the burial etc.
- The pregnancy loss (POC) is transported to the laboratory for analysis or directly to the mortuary if consent for analysis if not provided.
- On completion of the pathology report the mortuary staff will prepare each pregnancy for the monthly hospital burial (Please note those for family burial are collected directly from the Mortuary).
- Monthly burials occur on the 1st Monday of every month.
- Monthly burials are **NOT** held on Bank Holidays. Burial date defaults to the 2nd Monday of the month on these occasions.
- There is a two week cut off point prior to each hospital burial, this allows time for reflection for the mother involved. A change of mind re. burial can be facilitated if requested.
- All pregnancy losses received after this cut off point will be included in the next burial, **UNLESS** specifically requested by the mother to be included in the upcoming burial.
- The Hospital appointed undertaker is contacted on the Friday prior to the monthly burial and informed how many coffins there are to be interred so they can make arrangements for the graves.

April 2016

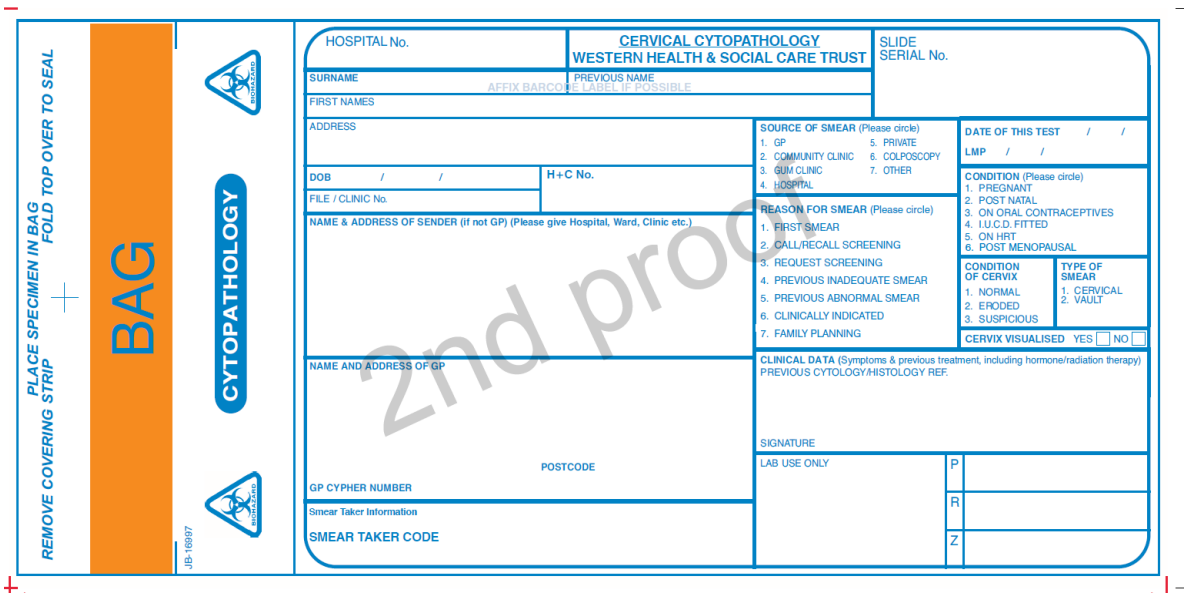
Flow Chart for Hospital & Laboratory Staff: Handling Products of Conception (POC)*
To be used in conjunction with laboratory SOPs for POC#



#Laboratory SOPs for POC (? Website)
*Also known as early pregnancy loss (<12 weeks gestation)
Supplementary to HSC Bereavement Pathway 1

10.0 APPENDIX

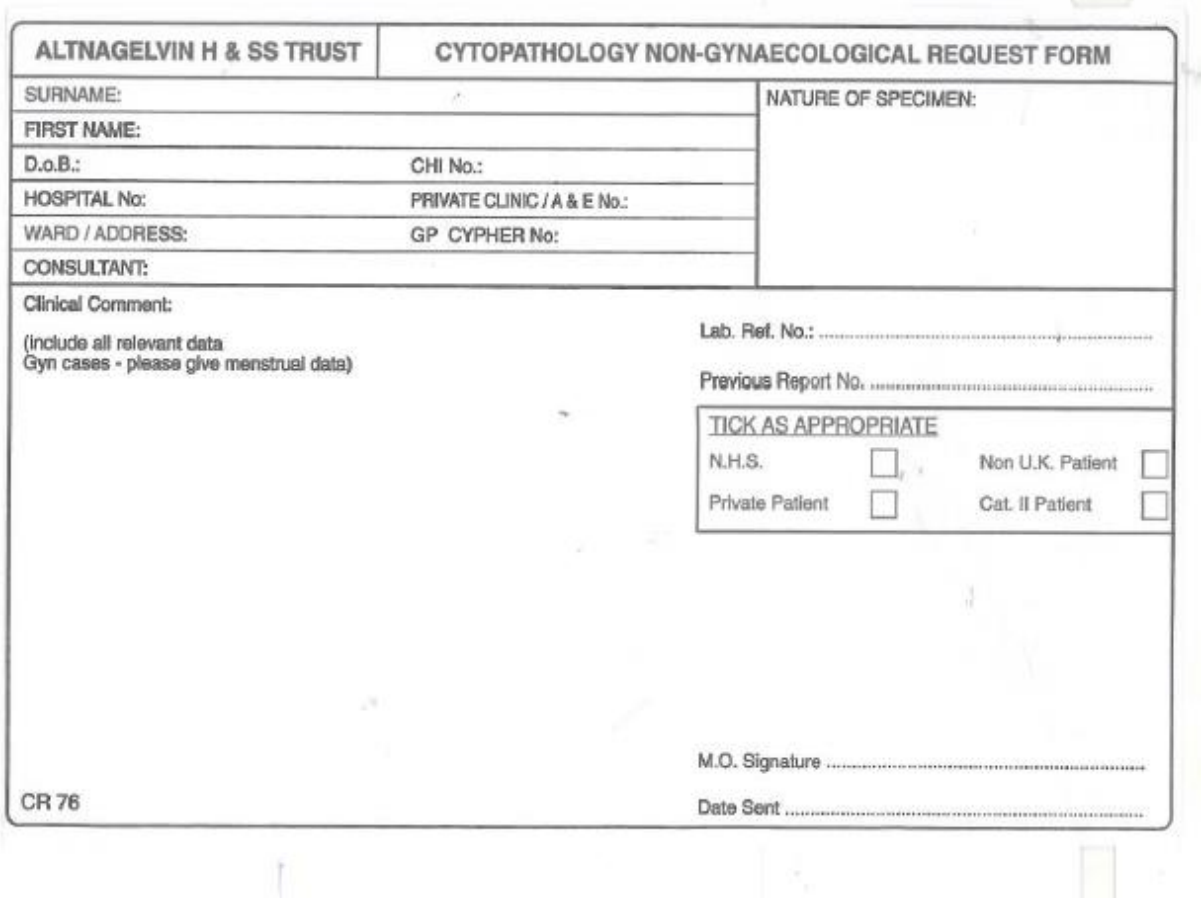
Appendix 10.1 WHSCT Cervical Cytology Referral form CR75



Please ensure to indicate in the appropriate section of the form if the cervix was visualised or not.

Please insert smear taker code.

Appendix 10.2: WHSCT CR76 Diagnostic Cytology Referral Form.



ALTNAGELVIN H & SS TRUST	CYTOPATHOLOGY NON-GYNAECOLOGICAL REQUEST FORM
SURNAME:	NATURE OF SPECIMEN:
FIRST NAME:	
D.o.B.: CHI No.:	
HOSPITAL No: PRIVATE CLINIC / A & E No.:	
WARD / ADDRESS: GP CYPHER No:	
CONSULTANT:	

Clinical Comment:

(include all relevant data
Gyn cases - please give menstrual data)

Lab. Ref. No.: .....

Previous Report No. .....

TICK AS APPROPRIATE

N.H.S. ☐ Non U.K. Patient ☐

Private Patient ☐ Cat. II Patient ☐

M.O. Signature .....

CR 76

Date Sent .....

Appendix 10.3: WHSCT Self-sample for HPV Test Request Form

Western Health and Social Care Trust

Lab. Ref. No:_____

Dept. of Cellular Pathology, Altnagelvin Hospital

SELF-SAMPLE FOR HPV TEST REQUEST

Affix addressograph or complete

Patient Name: _____

Address: *(inc postcode)* _____

DOB: _____ **H&C No:** _____

GP Name and Address: _____

Date of Test: _____ **LMP:** _____

LAB. USE ONLY

HPV Result: _____ **Tested By:** _____ **Authorised By:** _____
Date *Date*

CELLPATH/FORM/290 1.0 10/04/2018

Blank copies held in main Cytology Lab 01.046, completed copies held by Molecular Section Lead.

Important Information for the GP Practice

The sample should be collected under the guidance or, if necessary, in the presence of a practice nurse or the patient's carer.

Please return the labelled sample and request form to: Department of Cellular Pathology, Altnagelvin Hospital, Glenshane Road, Londonderry BT476SB.

Patient HPV result will be issued to the GP as per normal practice.

If the patient tests HPV negative she can be advised that she does not require further investigation at this time. However, cervical screening at the next routine screening round will still need to be considered as per normal practice.

If the patient tests HPV positive she should be advised to attend her GP practice to have a routine cervical screening test (smear test).

For further information please contact: Mary McMenamin at the address above or email mary.mcmenamin2@westhealth.n-i.nhs.uk.

Appendix 10.4: WHSCT Thyroid FNA ultrasound and cytopathology assessment request form

Western Health and Social Care Trust
Dept. of Cytopathology, Altnagelvin Hospital, Glenshane Road, Londonderry, BT47 6SB
Telephone: 028 71345171 ext 213403

Lab. Ref. no.

THYROID FNA ULTRASOUND AND CYTOPATHOLOGY ASSESSMENT FORM

Patient name……..…… H&C no……....
Hospital no……..…… Consultant/ward……..……....
Date of Birth……..….. Aspirator……..……....
Address……..…. Signature……..……....
……..….. Date……..……....

General clinical impressions
Clinically suspicious Yes ☐ No ☐ If Yes give details……

Previous thyroid FNA Yes ☐ No ☐ Not known ☐

If yes give reference number and diagnosis……..……

Type of nodule		**Site**		**Nature**	
Solitary	☐	Right lobe	☐	Solid	☐
Dominant nodule in MNG	☐	Left lobe	☐	Cystic	☐
Other nodule in MNG	☐	Isthmus	☐	Mixed solid and cystic	☐

Maximum diameter (mm)……

US features

Microcalcification Yes ☐ No ☐ Not sure ☐

Level of ultrasound suspicion Low ☐ High ☐ Not sure ☐

U1 ☐ U2 ☐ U3 ☐ U4 ☐ U5 ☐

Comments……..

……...

Enlarged cervical nodes Yes ☐ No ☐

FNA technique 23G ☐ 25G ☐

Number of passes……

Dept. of Cytopathology, Altnagelvin Hospital, Glenshane Road, Londonderry, BT47 6SB
Telephone: 028 71345171 ext 213403

Lab use only

Cytopathology Report Classification

THY1	☐
THY1c	☐
THY2	☐
THY2c	☐
THY3a	☐
THY3f	☐
THY4	☐
THY5	☐

Comments…….....

……..

……..

Appendix 10.5: Histopathology Examination Request Form

HISTOPATHOLOGY REQUEST FORM

Western Health and Social Care Trust

Lab. Ref. No:

Dept. of Cellular Pathology, Altnagelvin Hospital, Glenshane Road, Londonderry, BT47 6SB
Telephone: 028 71345171 ext 213400

PATIENT DETAILS

Affix addressograph or complete by hand

Surname: First name:
H&C No: Male: ☐ Female ☐
DOB:
Address:
Consultant: Ward/Clinic:
Private Patient: Yes ☐ No ☐

CLINICAL DETAILS

Nature of Specimen: CAT 3 Patient: Yes ☐ No ☐

Suspicious of malignancy ☐

Signed: ..... Date: ..... Time: .....

Laboratory Use Only

Specimen Code: ☐

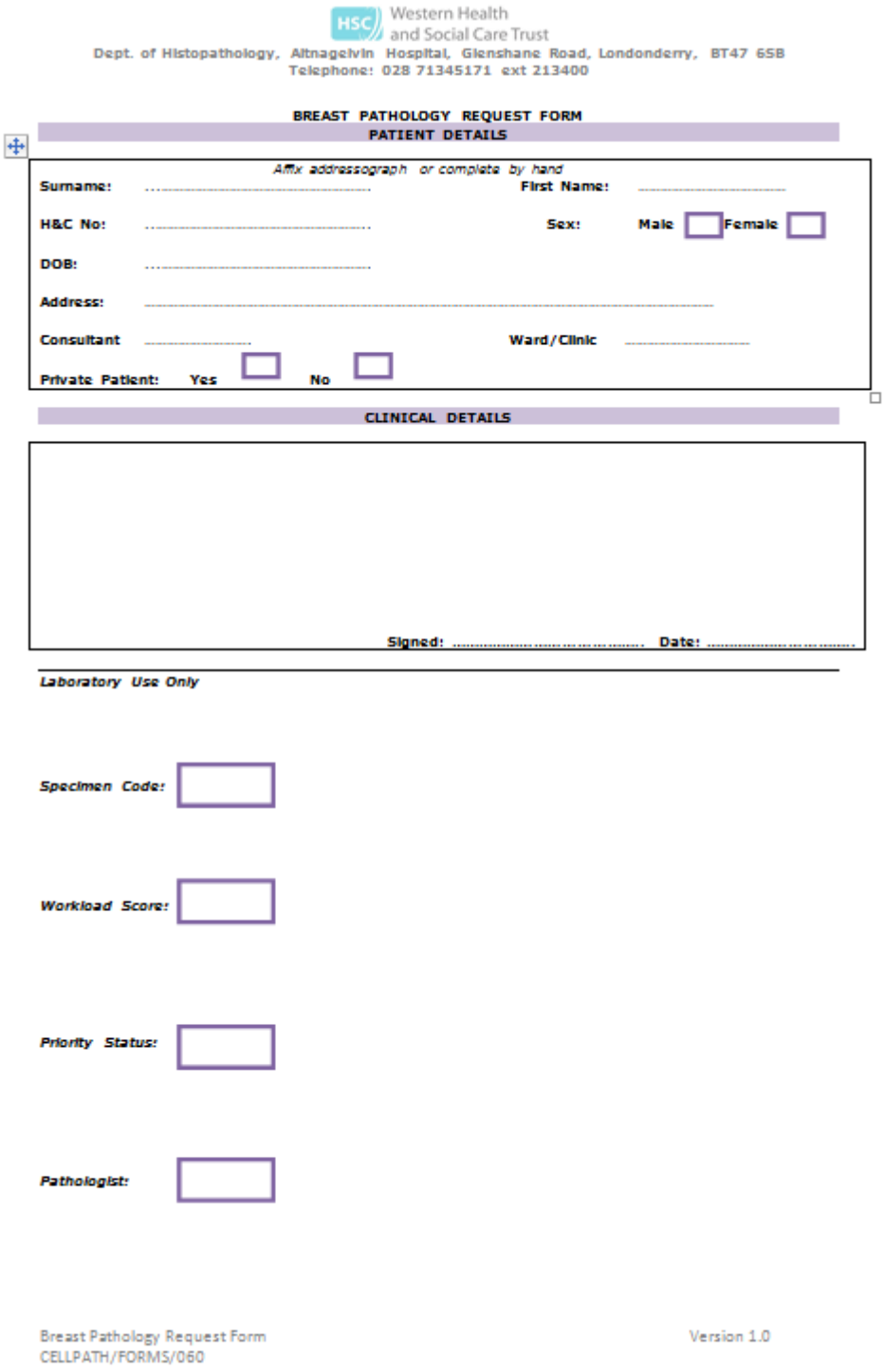
Workload Score: ☐

Priority Status: ☐

Pathologist: ☐

Histopathology Request Form Version 1.0 CELLPATH/HIST/FORMS/044
WPH000354 Revised 9/14 OS17800

Appendix 10.6: WHSCT Breast Pathology Request Form



Western Health and Social Care Trust

Dept. of Histopathology, Altnagelvin Hospital, Glenshane Road, Londonderry, BT47 6SB
Telephone: 028 71345171 ext 213400

BREAST PATHOLOGY REQUEST FORM

PATIENT DETAILS

Affix addressograph or complete by hand

Surname: ..... **First Name:** .....

H&C No: ..... **Sex:** **Male** ☐ **Female** ☐

DOB: .....

Address: .....

Consultant ..... **Ward/Clinic** .....

Private Patient: **Yes** ☐ **No** ☐

CLINICAL DETAILS

Signed: ..... **Date:** .....

Laboratory Use Only

Specimen Code: ☐

Workload Score: ☐

Priority Status: ☐

Pathologist: ☐

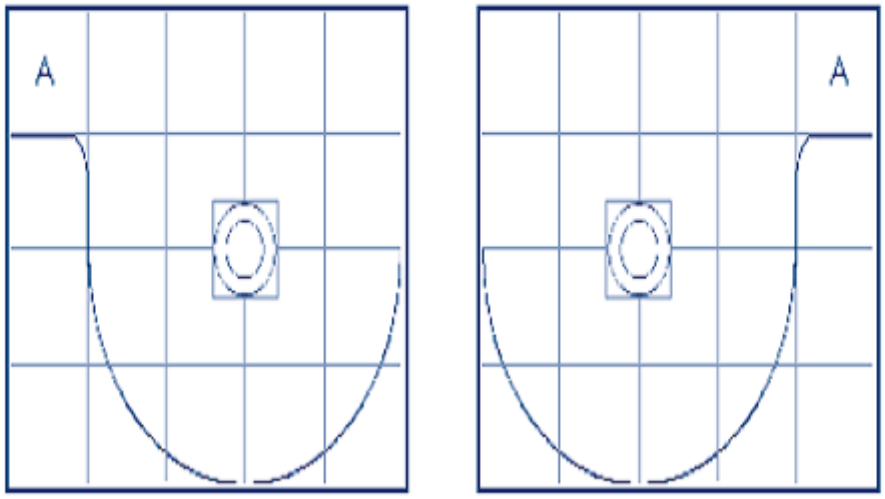
Breast Pathology Request Form
CELLPATH/FORMS/060

Version 1.0

Western Health and Social Care Trust
Dept. of Histopathology, Altnagelvin Hospital, Glenshane Road, Londonderry, BT47 6SB
Telephone: 028 71345171 ext 213400

Please Tick

Intra-operative Examination ☐ **Theatre Ext No:** _____



If Mastectomy, Why: _____

Multifocal ☐ Yes ☐ No, if yes Number and Site: _____

Micro-calc ☐ Yes ☐ No, if yes Size and Distribution: _____

Specimen(s)	
1	
2	
3	
4	

Specimen Orientation: (please tick)

- ☐ Mastectomy - long lateral suture
- ☐ WLE - long lateral, short anterior, double superior
- ☐ Cavity shave - stitch on old cavity
- ☐ Other:_____

Appendix 10.7: Consent for Histological Examination and Disposal of Early Miscarriages Form

Consent for Histopathological Examination and Disposal of Early Miscarriages

Department of Health, Social Services and Public Safety

Use for early pregnancy losses without fetal remains or with a fetus less than 6cms crown rump size, usually first trimester

Part 1: Patient's Details *DO NOT USE ADDRESSOGRAPH LABELS*

Full name: ..... Date of birth: .....

Address: ..... GP's name & address: .....

.....

H&C no: ..... Date of Miscarriage: .....

Hospital: ..... Ward: ..... Consultant: .....

Part 2: Information

A miscarriage is when a pregnancy ends in the early months. In most cases the miscarriage consists of the placenta, blood clots and decidua (lining of womb). Although a tiny baby may be seen on ultrasound scan in early pregnancy, fetal remains can only be identified in around 1 out of 100 early miscarriages. There are several reasons for this: no embryo may have developed or the baby may have died quite some time ago and the remains have been reabsorbed. Also at this very early stage of pregnancy, the tissues of a tiny baby are very delicate and fragment easily, becoming mixed in with the placental tissues, and are not easily seen.

The placental tissues are routinely examined to see if a reason can be found for the miscarriage.
If only a small amount of tissue is miscarried it may be necessary to process all of it for examination under the microscope and so there may be no tissue remaining for burial or cremation.

If an embryo, fetus or fetal parts are seen your wishes concerning their examination and disposal will be followed.

Part 3: Examination of fetal remains

If you give consent the fetus or fetal parts will be carefully examined by the naked-eye. Then the tissues will be processed by making wax blocks and glass slides for examination under a microscope.

☐ I consent to the examination of the fetal remains

☐ I do not consent to the examination of the fetal remains

Part 4: Disposal of tissues from miscarriage

The hospital will bury or cremate any unprocessed tissue and fetal remains unless you indicate below that you will collect them for family burial or cremation. Staff will explain whether **burial or cremation** is the practice in your hospital. **Ashes cannot be returned to you following hospital cremation.** If you indicate that you want the tissues returned you will be contacted when they are ready for collection. If you do not arrange this within 3 months of contact the hospital will bury or cremate them.

☐ If fetal remains are identified I will collect these and any unprocessed tissues within 3 months

☐ If fetal remains are **not** identified I will collect any unprocessed tissues within 3 months

Part 5: Confirmation of consent decisions

Patient's signature ..... Date .....

Healthcare professional's signature ..... Designation .....

PRINT NAME..... GMC/NMC no .....

FORMS: TOP copy to pathology, MIDDLE copy to patient, BOTTOM copy to health records

Appendix 10.8: Post Vasectomy Analysis Request Form

JB: 117611 BLACK

CELLULAR PATHOLOGY - POST VASECTOMY REQUEST FORM

WHSCT - POST VASECTOMY SEMEN ANALYSIS REQUEST FORM

CELLPATH/FORM/289 Version 1.0 Issued: 15/05/2018

CELLULAR PATHOLOGY LABORATORY - ALTNAGELVIN HOSPITAL

SECTION A
PATIENT IDENTIFICATION – Please complete ALL sections

Surname:

Forename:

Date of Birth:

H&C Number:

Hospital Number:

Address – please include full post-code

Gender:

SECTION B
PATIENT MUST COMPLETE ALL SECTIONS

Date of Vasectomy:

Date sample collected:

Time sample collected: :

Complete sample: YES/ NO

Date of last ejaculation:

PLEASE SIGN BELOW TO INDICATE THAT THIS IS YOUR OWN SAMPLE WHICH YOU CONSENT TO SUBMIT FOR EXAMINATION.

SECTION C
REFERRING CLINICIAN IDENTIFICATION: Please complete ALL sections

Full name and address:

Private Patient: YES/ NO

Copy of examination result to (if required):

OTHER RELEVANT INFORMATION: e.g. clinical details, etc.

SECTION D – LAB USE ONLY
UNIQUE SAMPLE NUMBER

Attach label here

SAMPLE LABORATORY CODE

DATE AND TIME SAMPLE RECEIVED

EXAMINATION RESULT

SAMPLE EXAMINED BY

SAMPLE APPEARANCE and VOLUME (ml)

10.9 Clinical User Information

IMPORTANT

CLINICAL USER INFORMATION

MEASUREMENT UNCERTAINTY IN CELLULAR PATHOLOGY

All types of measurement have some inaccuracy due to bias, imprecision and operator
variation, and therefore measurement results can be only estimates of the values of the
quantities being measured.

Measurements can be made with either:-

- A ruler – e.g. macroscopic measurements of tissues, tumours and excision margins.
- Eyepiece graticule in a microscope – e.g. measuring microscopic distances in tissue
- Measurement tool in NIPACS

There will be a degree of variation in all such measurements and it is this uncertainty that
should be considered when interpreting the final histology report.

Where tumour sizes and excision margins have been measured by the department there is a level of uncertainty in the measurement step. In macroscopic tumour measurements we have calculated this to be up to +/- 2.0mm.

In order to minimize such uncertainty we have a number of steps and assurances in places.

- Measuring tumours in the largest dimension.
- For tumours of a size close to the limits of different tumour staging we are aware that
  inaccuracies could upstage tumour.
- Understanding that it is not possible to measure more accurately than to nearest
  millimetre.
- Measuring to nearest millimetre with a UKAS calibrated ruler.
- Discussion at MDT is actively encouraged regarding measurements close to staging
  limits.

- Final assessment of staging is a clinical decision based on multiple information sources.

Every measurement will have a level of uncertainty if a repeat sample is requested a level of variation is expected. The department has calculated uncertainty for named parameters has using 95% confidence intervals for higher and lower parameters recorded. The wider confidence interval means greater uncertainty level and narrower one indicate greater certainty level.

Parameter	Reference intervals	Degree of Uncertainty
Concentration of spermatozoa in Diagnostic Fertility Analysis samples fixed depth chamber (automated)	≤ 10 x 10^6/ ml	0.106%
Concentration of spermatozoa in Diagnostic Fertility Analysis samples fixed depth chamber (automated)	≥ 10 x 10^6/ ml	0.133%
Concentration of spermatozoa in Diagnostic Fertility Analysis samples fixed depth chamber (manual)	≤ 10 x 10^6/ ml	0.076
Concentration of spermatozoa in Diagnostic Fertility Analysis samples fixed depth chamber (manual)	≥ 10 x 10^6/ ml	0.592%
Morphology of spermatozoa in Diagnostic Fertility Analysis samples	≤ 4%	0.048%
Morphology of spermatozoa in Diagnostic Fertility Analysis samples	≥ 4%	0.057%
Progressive motility of spermatozoa in	≤ 30%	0.244%

Diagnostic Fertility Analysis samples automated using fixed depth chamber (CASA)		
Progressive motility of spermatozoa in Diagnostic Fertility Analysis samples automated using fixed depth chamber (CASA)	≥ 30%	0.731%
Progressive motility of spermatozoa in Diagnostic Fertility Analysis samples automated using fixed depth chamber (manual)	≤ 30%	0.146%
Progressive motility of spermatozoa in Diagnostic Fertility Analysis samples automated using fixed depth chamber (manual)	≥ 30%	1.050%
Post Vasectomy Semen analysis	Spermatozoa observed vs not observed, motile spermatozoa vs not motile spermatozoa	0%
Post Vasectomy Semen analysis	Spermatozoa observed vs not observed, motile spermatozoa vs not	0.521%

In order to minimize such uncertainty we have a number of steps and assurances in place. All patients should receive the patient information pack which gives all necessary parameters in place for the sample to be accepted and processed, including days of abstinence and production to processing time. Any clinical interpretation should go through the relevant named clinician.