Torbay and South Devon NHS
NHS Foundation Trust

Cellular Pathology Service
Users Guide

(Histopathology, Diagnostic Cytology and Mortuary Services)



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Aim of User Handbook

The Cellular Pathology (Histology and Diagnostic Cytology) Department is committed to providing a high quality, safe, efficient and cost-effective service. It is aware of and considers the needs and requirements of its service users. These include patients and staff of Torbay and South Devon NHS Foundation Trust, Primary Care Trusts, and other agencies within the district.

This guide is intended to enable all users to make best use of the various services provided, ensuring an accessible and efficient service.

If you have any comments on the content of this handbook, please contact a member of the management team. Details can be found in the key contact section.

This handbook is for professional service users. Information for patients who are in the care of Torbay and South Devon NHS Foundation Trust can be found on the Trusts public website www.torbayandsouthdevon.nhs.uk The Cellular Pathology department has no direct day-to-day contact with patients. All results from examinations are available to view in EPIC.

This is a controlled document. The most up to date version will only be available from the Department.

1. General Information

The Cellular Pathology Department is housed in a temporary building located within the grounds of Torbay Hospital.
The scope of the service offered by Cellular Pathology includes a full analytical and advisory service appropriate for a District General Hospital. More complex or rare investigations will be referred to other appropriate (UKAS Accredited) laboratories. A scope of the services offered is also available in the Laboratory Medicine's quality manual; a copy can be provided on request.

As of 6th July 2026, Diagnostic Cytology specimens will no longer be processed by the Cytology lab at Torbay hospital.
All Cytology specimens will be received into the Torbay Cytology lab and verified before being added to a packing list, packed in accordance with UN3373 and transported to the Cytology lab at RDUH via courier.
Specimens will be prepared, stained and pre-screened by the RDUH Cytology staff before being returned to the Cellular Pathology lab to be reviewed and authorised by TSDFT Pathologists.

The Cellular Pathology Department includes the following specialties:

- Histopathology
- Diagnostic Cytology – processed at RDUH Cytology laboratory
- Mortuary Services

The Cellular Pathology Department handles approximately 24,000 Histology requests and approximately 1000 Diagnostic Cytology requests per year.
Breast Pathology services are outsourced currently and are provided by Poundbury Cancer Institute. Other external outsourcing companies may be used to report cases.

We perform over 100 types of tests in-house and have a network of external laboratories to which more specialised tests can be sent, including Genetic Testing.

The Mortuary has capacity for 85 deceased patients, which includes 12 plus size, 8 Bariatric, 9 freezer space and Foetal. In addition to that, there are two temporary Nutwell units, each with space for 12 deceased patients. The mortuary handles approximately 2000 deceased a year and performs approximately 600 post-mortems per year, the majority of which, if not all, are done on behalf of His Majesty Coroners for Devon, Plymouth and Torbay area.

The Cellular Pathology Department is committed to providing comprehensive high quality, interpretive, advisory and consultancy service that is cost effective and responsive to the needs of our commissioners and patients.

All staff employed within the Department are trained and assessed for competency to comply with Trust and Departmental Policies and ISO 15189:2022 Accreditation.

1.1 Location



We are situated in Portacabin at Level 2, opposite the Acute Medical Unit (AMU) & Outpatients, and next to Outpatients Pharmacy

Access to the Department is controlled via a key to the external entrance door, and keycode for the inner door. All visitors must report to the Office and sign in upon entry and sign out when exiting the building.

1.2 Postal Address

Department of Cellular Pathology
Torbay and South Devon NHS Foundation Trust
Torbay Hospital
Lowes Bridge
Torquay
TQ2 7AA

Mortuary Services

Torbay and South devon NHS Foundation Trust
Torbay Hospital
Lowes Bridge
Torquay
TQ2 7AA

1.3 Normal Working Hours

Cellular Pathology - Opening Hours: Monday to Friday 08:30 to17:00hrs, excluding Bank Holidays

Mortuary Services – Opening Hours: Monday to Friday 08:00 to 16:00hrs.
A member of Mortuary staff is on-call outside of these times 24 hours a day, including weekends and Bank Holidays via Switchboard.

1.4 Contact Information

From outside the hospital call 01803 6 and then the extension number.

Results	GP Results: check ICE Hospital Results: check EPIC	
General Enquiries	Via Secretary Ext. 55259 tsdft.mdthistology@nhs.net	Mon-Fri 08:00 - 17:00
Consultant Histopathologist(s)	Via Secretary Ext. 55259	Mon-Fri 08:30 - 16:00
Mortuary Services	Ext: 55251	Mon-Fri 08:00 - 16:00

Clinical Advice can be obtained from a Consultant Histopathologist during normal working hours via ext. 55259. The laboratory is not open outside of normal hours but can provide an advisory service. Consultant Histopathologists are contactable via switchboard.

2.0 Tests Provided

2.1 Histopathology

If in doubt, please contact the laboratory

Test
Routine Processing – *including MEGA Blocks*
Rapid turnaround processing for urgent small biopsies – *Requested by Consultant Histopathologist ONLY*
Special staining – *For list of special stains please contact the laboratory*
Immunohistochemistry staining – *For list of antibodies / Probes for Immunohistochemistry*
Frozen Section service – ***must be booked in advance***
Skin Immunofluorescence Service
Provision of material for molecular testing
Research to Trust R&D and external establishments

2.2 Diagnostic Cytology

If in doubt, please contact the laboratory

Wet Fix preparations *(Papanicolaou - PAP)*
Air Dried Preparations *(May Grunwald Giemsa – MGG)*
Cell Blocks – from spontaneous and induced *(cytofoam discs)* clots
Immunohistochemistry staining – *For list of antibodies / Probes for Immunohistochemistry. Cell Blocks only*

2.3 Mortuary Services

If in doubt, please contact Mortuary.

HM Coroner's post-mortems
Hospital post-mortems
Viewing for families
Organ retrieval for donation

3.0 Quality Assurance

3.1 Accreditation

UKAS MEDICAL
8914
Accredited to ISO 15189:2022

Accreditation provides assurance that the laboratory is working to international standards and providing results that are of the highest possible quality.

The Cellular Pathology Department is a UKAS accredited medical laboratory No: 8914, which is accredited to standard ISO 15189:2022. The full scope of the tests that are accredited can be viewed on the UKAS website. The Department transitioned to 2022 standards in July 2025.

The Cellular Pathology Department and the Mortuary are licensed by the Human Tissue Authority (HTA) under license number 12181

3.2 External Quality Assurance (EQA)

The Department strives to continually update the repertoire it provides and for this reason some tests may not currently be included on the scope of accreditation. Tests are validated or verified before being brought into use and wherever possible a suitable Quality Assurance Scheme is in place. Current tests offered that are outside of scope are noted in **Appendix A** and will also be noted on the patient test report.

The laboratory participates in various External Quality Assessment schemes provided by **UK NEQAS** to ensure the quality of our results. These include:

- Tissue Diagnostics
- Specialist Techniques, Frozen Sections, MEGA Blocks
- Direct Immunofluorescence
- Bone Marrow Trephine

- Immunocytochemistry – General Pathology, Breast Pathology (ER/PR), Lymphoid Pathology, Alimentary Tract Pathology

The Department has extensive Quality Management System and Governance procedures in place to control all the processes within the laboratory. If you require any further information, please contact the Laboratory Manager / Deputy Manager.

3.3 Providing feedback

The Department is committed to continually improving the service it provides to patients and users. There is a quality policy which all members of staff are aware of and strive to follow. This combined with a detailed quality improvement policy and complaint management process ensures the Department is continually focused on the level of service it provides.

If you wish to provide feedback/compliments/complaints regarding the service provided by Cellular Pathology, please do not hesitate to contact a member of the relevant laboratory team.

3.4 Complaints and Compliments

The views of our users are very important to the service we provide. Information on how to raise complaints can be found by conducting a search on the Trust Intranet Site for the Trust Policy Page or by going via the Trust Policies & Procedures Icon on the main Trust Homepage. Any laboratory-based complaints should be directed to the Laboratory Manager.

3.5 Protection of Personal Information

We support the Torbay and South Devon NHS Foundation Trust in continuous compliance with legislation of data processing and handling of sensitive information.

Our vision is to create an environment of confidentiality, integrity and quality of information with the organisation; we achieve this by providing a high-quality service within a framework of tools that enables new ways of working and the provision of high-quality care.

We work to ensure the right information is available to the right people when and where it is required. Information is shared only when required for patient care, for example sending information to another laboratory when further specialised testing is required.

3.6 Measurement Uncertainty

In medical laboratory testing there are potential uncertainties that can affect the results, such as poor specimen collection or transport, patient related factors or other interfering factors. The laboratory process and examination of the sample is subjected to some degree of variability to which the Department regularly monitors using internal quality control and EQA schemes.

4. Sample Collection

4.1 Histology Consumables

For **internal** users, consumables are available upon request. Please contact Pathology stores via central reception, Level 3, or telephone ext. 55227 between 08:00 – 16:30 Monday to Friday

- Histology – Prefilled 60 ml Orange Top 10% Formalin (Neutral Buffered) Pots. These are routinely delivered three times per week to Main Theatres, Day Theatres, and once a week to Gynae.
- Larger 10% Formalin pre-filled specimen containers are supplied on request. Please contact ext. 55227
- Histology – Michel's Transport Medium for direct immunofluorescence is supplied via the Histology Lab please contact ext. 55214

For **external** users, i.e. GP Surgeries and external Departments i.e. Urology at Paignton Hospital - consumables are available upon request. Please contact Pathology stores via central reception, Level 3, or telephone ext. 55227. Stock is sent out via the Post Room and distributed by the courier service.

ALL Histology specimens, **excluding specimens for pre-booked frozen section service and Skin Immunofluorescence, MUST** be sent to the laboratory in a 10% Formalin filled specimen container suitable for the size of the specimen – ratio of 1:10 tissue to 10% Formalin for small specimens and ratio of 1:5 tissue to 10% Formalin for very large specimens.

The Department uses **10% Neutral Buffered Formalin** (contains 4% formaldehyde and methanol blend) Histological Fixative and this should **always be handled with care**.



DANGER

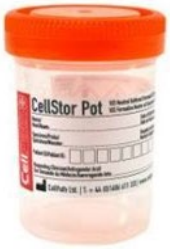
10% Formalin Exposure route: Oral; Dermal; inhalation

Acute Toxicity	Category 4 – Harmful if inhaled
Skin Sensitizer	Category 1 – May cause an allergic reaction
Carcinogen	Category 1B – May cause cancer
Mutagen	Category 2 – Suspected of causing genetic defects

Each sender who handles formalin should have their own policy or procedure and equipment for handling formalin. **See 4.3 Formalin Spillages**

Requirement	Container	Label Information

<table>
<tr><td rowspan="2">Routine:

Biopsy or small specimen</td><td>

Pre-filled Labelled 60 ml 10% Formalin Pot.</td><td>Essential information on sample pot:

• Patient's full name
• Date of Birth
• NHS Number / Hospital Number
• Date and Time sample collected
• Specimen type</td></tr>
<tr><td colspan="2">Transport to Histology or store at ROOM TEMPERATURE
(if unable to send to the laboratory straight away)</td></tr>
<tr><td rowspan="2">Routine:

Medium to large and Extra -large specimens</td><td>
Pre-filled (10% Formalin) Labelled Specimen tubs/ buckets. Sizes available: 250ml; 500ml; 1L; 2.5L; 5L; 10L; 20L; 25L; Rectangular Breast specimen container.</td><td>Essential information on sample pot:

• Patient's full name
• Date of Birth
• NHS Number / Hospital Number
• Date and Time sample collected
• Specimen type</td></tr>
<tr><td colspan="2">Transport to Histology or store at ROOM TEMPERATURE
(if unable to send to the laboratory straight away)</td></tr>
<tr><td rowspan="2">Skin Immuno-fluorescence service</td><td>
5 ml Vial
Contains Michel's Transport Medium</td><td>Essential information on sample pot:

• Patient's full name
• Date of Birth
• NHS Number / Hospital Number
• Date and Time sample collected
• Specimen type</td></tr>
<tr><td colspan="2">Transport to Histology as soon as possible or REFRIGERATE
if unable to send to the laboratory straight away for maximum of two days</td></tr>
<tr><td>Pre-Booked Frozen Section Service</td><td>Any appropriately sized clean container.

<u>MUST NOT</u> contain fixative</td><td>Essential information on sample pot:

• Patient's full name
• Date of Birth
• NHS Number / Hospital Number
• Date and Time sample collected
• Specimen type</td></tr>
<tr><td></td><td colspan="2">Transport to Histology IMMEDIATELY</td></tr>
</table>

4.2 Cytology Consumables

For **internal** users consumables are available upon request. Please contact Cellular Pathology on ext. 55214 between 08:30 – 17:00 Monday to Friday

<table>
<tr><th colspan="3">If in doubt, please contact the Cellular Pathology Laboratory on ext. 55214</th></tr>
<tr><th>Requirement</th><th>Container</th><th>Label Information</th></tr>
<tr><td rowspan="2">Routine
Non Gynae:
Small
Volume fluid
< 1 ml</td><td>
30 ml Sterile Universal Container formalin pot.</td><td>Essential information on sample pot:

• Patient’s full name
• Date of Birth
• NHS Number / Hospital Number
• Date and Time sample collected
• Specimen type</td></tr>
<tr><td colspan="2">Transport to Histology or REFRIGERATE (if unable to send to the laboratory straight away)</td></tr>
<tr><td rowspan="2">Routine
Non Gynae:
Moderate
Volume fluid
> 1 ml
To
50 ml – 70 ml
Maximum</td><td>
70 ml Sterile Yellow Top Pot</td><td>Essential information on sample pot:

• Patient’s full name
• Date of Birth
• NHS Number / Hospital Number
• Date and Time sample collected
• Specimen type</td></tr>
<tr><td colspan="2">Transport to Histology or REFRIGERATE (if unable to send to the laboratory straight away)</td></tr>
<tr><td>Bronchial and Biliary Brush tips ONLY</td><td>
PreservCyt Vial</td><td></td></tr>
<tr><td>Routine

Air-dried
Wet-fixed
FNA</td><td>
Positively Charged Slides

Slide Mailer

Cytospin Collection Fluid</td><td>Essential information on Slides:

• Patient’s Forename and Surname
• Date of Birth
• Hospital Number
• Wet-fixed or Air-dried</td></tr>
</table>

	Contact Cytology for supplies of slides, slide mailers and cytological fixatives	
	Transport to Histology or **REFRIGERATE** (if unable to send to the laboratory straight away)	

4.3 Formalin Spillages

Formalin should be handled with care in appropriately sized containers with secure lids to minimize the risk of spillage. Specimen pots should be secured in a sealable plastic specimen bag. For larger specimen pots, the lid must be secured and where appropriate for the size, carried using the handle provided.

Couriers and porters should not attempt to handle a Formalin spillage in transit without having received proper training. In the event of a spillage, ensure the safety of others in the vicinity and if assistance is required contact the laboratory immediately (working hours only. See 1.3) on 01803 655214 and state your location and fully trained laboratory staff will attend the spillage. Couriers must have a Formaldehyde spill kit onboard the vehicle.
If a spillage occurs enroute within the transport boxes (either small, medium size or transport box on wheels), **DO NOT** collect anymore samples and **DO NOT** open the lid again. Take the transport box directly to the Cellular Pathology Laboratory (Specimen reception), informing staff of the formalin leak within the box. Laboratory staff will put on the appropriate PPE, deal with the specimens, and clean out the transport box making it safe to use.
Guidance on the spillage procedure is dependent on the volume of 10% Formalin spillage. Our supplier Genta Medical has issued the following guidance on spillages.

Spillage Volumes:

- Minor Spillages (up to 200 ml) – usually dealt with by 1 or 2 members of staff using simple procedures
- Large Spillages (200 ml – 5 litres) – requires the use of a Formaldehyde spillage kit
- Major Spillages (over 5 litres) - should be dealt with by the fire service

The safety limit of harmful Formaldehyde vapours in the air is 2.00 ppm. This means workers should not be exposed to Formaldehyde vapour above this level for more than 15 minutes at a time. If exposed to vapour, the Formaldehyde content (4%) in the Formalin solution, at first, it will have a strong, unpleasant smell and will start to sting the nose and eyes - senses will quickly become acclimatized and less sensitive.

The sender must inform the laboratory of any spillage where the specimen may have been lost, partially lost or its integrity is compromised. This should be reported as an incident and the referring clinician should be informed as soon as possible.

4.3.1 Dealing with Minor Spillage

In most of the hospital clinical settings, formalin is handled in the pre-filled 10% formalin 60 ml pots. Clinics are advised to purchase and have on hand either Formalin Spill Wipes or Formalin Neutraliser Wipes or Spillage Granules which will absorb the fluid and neutralise Formaldehyde vapours. Staff must wear suitable impervious gloves such as nitrile gloves and eye protection when cleaning up following a spillage. The contaminated material must be sealed in a bag and removed from the room. If there is

access to a window which opens, ventilate the room if there is still a strong smell of Formaldehyde. If there is no ventilation in the room where the spillage occurred, it is advised to restrict access to the room until it is deemed safe to do so. If you are in doubt, or need advice, please contact the Laboratory on 01803 655214.

4.3.2 Dealing with Large Spillages

In most hospital theatres and Day surgery settings, formalin is handled in larger volumes (> 200 ml up to tens of litres) in specimen buckets. In the event of a spillage for these larger volumes of Formalin:

- Evacuate all staff from the immediate area and nearby spillage
- Wearing the appropriate Personal Protective Equipment, including respirator and gas-tight safety goggles, protective clothing and Nitrile gloves, trained staff must use Formaldehyde spillage kit to tackle
- Absorbent booms must be used to contain and prevent Formalin from entering drains
- Formalin contaminated materials used in the cleaning up must be sealed in an airtight container and removed from area for specialised disposal
- If no protective equipment, phone the laboratory or the emergency services (if over 5L)

Following the use of the Formaldehyde Spillage Kit stock must be replenished as soon as possible.

4.3.3 Dealing with Major Spillage

- Evacuate the area
- Break Nearest fire alarm point
- Phone emergency number and impart on the type of spillage.

5 Requests and Sample Identification

Where possible electronic ordering should be used to generate electronic requests for tests using EPIC or ICE. If possible, tests should not be requested in advance of taking the sample.

Request forms are only accepted from locations where there is no access to EPIC.
Consultant Histopathologists will not report samples without an EPIC generated order or fully annotated Cellular Pathology request form.

Histology samples where details of the date and time taken are missing from either the specimen pot label or Request Form will automatically incur a 24hr delay, minimum, to ensure adequate fixation of the samples prior to laboratory examination.

5.1 Consent

It is the responsibility of the requestor to firstly verify the identity of the patient, before obtaining the patient's consent to take a bodily sample.

It is the responsibility of the clinician to ensure the patient understands the reason for making the request for the examination and the range of tests that may be involved. The reason for investigation should be explained clearly to the patient.

It is vital to ensure all loss of early pregnancy tissue samples for histological investigation have the appropriate **fully completed** Consent Form for Sensitive Disposal of Early Pregnancy Tissue. Please make sure when tissue is sent to the Laboratory, the consent form has been electronically uploaded to EPIC. Consultant Histopathologists **will not** examine any Loss of Early Pregnancy Tissue without prior consent.

Mortuary cases - His Majesty's Coroners Service, by law, will provide the consent for a post-mortem to take place to investigate the cause of death, when required. For a Hospital Post-mortem investigation, consent is provided by relatives of the deceased patient. Independent of the type of Post-mortem undertaken, the laboratory will follow consent instructions from the relatives of the deceased patient as to what will happen to the tissue blocks and slides generated as part of the investigation. Once laboratory investigations are concluded, if instructed to repatriate tissue samples back to the body, this will be organised by Mortuary staff. If consent instructions allow the laboratory to retain tissue blocks and slides, they will be kept on secure premises and only accessible to relevant staff.

5.2 High Risk Samples

If the patient sample is suspected or known for having Category 3 pathogens e.g. HIV/AIDS, TB, HbsAg, Hepatitis A, Hepatitis C, Necrotizing Fasciitis, CJD – a biological hazard warning label **MUST** be affixed to the specimen pot to ensure correct handling by staff. If there is any doubt as to whether a specimen is **HIGH RISK**, please contact the laboratory.

5.3 Fresh Tissue Samples

The Department accepts fresh tissue when the **pre-booked** Frozen Tissue Section service is requested and with at least **24 Hours' notice**. These types of specimens **MUST** be brought down directly to the laboratory and an order created in EPIC and **MUST** include a contact telephone number to telephone the results back to the requestor and fulfill all the specimen acceptance criteria. See. 5.4

At the time of booking a request for this service, the laboratory staff will ask the requestor if the patient is considered an 'infection risk, as part of a booking process. For Health and Safety reasons it is departmental policy not to perform frozen sections on known Category 3 pathogens e.g. HIV/AIDS, TB, HbsAg, Hepatitis A, Hepatitis C, Necrotizing Fasciitis, CJD infection risk specimens.

If the frozen section service is no longer required, please ring the Laboratory as soon as possible to notify us of the cancellation.

The Department also accepts fresh tissue on skin/oral specimens for direct immunofluorescence examination. Samples are delivered to the laboratory in vials containing Zeus Scientific tissue fixative (Similar properties to Michel's transport media). Specimens must be sent to the laboratory within five days of being taken. Any longer than five days, false negative results may occur. For Health and safety reasons it is departmental policy not to perform this examination on known Category 3 pathogens e.g. HIV/AIDS, TB, HbsAg, Hepatitis A, Hepatitis C, Necrotizing Fasciitis, CJD infection risk specimens.

Note to clinics: If vials containing tissue fixative forms insoluble crystals or salts, these vials must be discarded. Please contact the laboratory on 01803 655214 if replacements are required.

5.4 Specimen Acceptance Criteria

Due to the nature of specimens requiring Histopathological/Cytological examination, and how they are obtained, the Cellular Pathology Department will make every effort not to reject a sample. It is the responsibility of the requestor/clinical staff taking the sample to ensure all samples have sufficient and accurate information to be correctly and unambiguously identified.

The following **mandatory** information **MUST** be provided on the specimen pot*, request form^ or FNA Slide Preps° for us to accept the specimen:

- Surname*^°
- Forename*^°
- Unique identification number – Medical Record Number (MRN), NHS Number*^
- Date of Birth*^°
- Address for GP or external locations^ (Required on **ALL** specimens from Mount Stuart Hospital)
- Signature of requestor/clinician^
- Date and Time specimen taken*and/or^
- Clinical Information^
- FNA Slide Preps to be identified as either Wet-Fixed or Air-Dried, and placed in separate slide mailers, one for Wet-fixed and one for Air-dried slides°

With exception of GUM Clinic samples where identification is via initial and GUM number.

Clinicians should use the labels generated at ordering in EPIC for labelling the specimen pot(s).

Private patient samples are examined and reported in the laboratory on behalf of Mount Stuart Hospital. It is a requirement for all request forms to include the patients' GP and Surgery address for patients who are from outside the area.

Clinical Governance issues may arise from errors in specimen identification and/or insufficient clinical information given with the specimen. Errors arising in specimen identification are recorded and monitored by laboratory staff. Any specimens received containing errors **will not** be examined until the errors have been rectified. This may delay the report being available.

5.5 Factors Affecting Examination and Interpretation of Results

The following is a list of factors known to significantly adversely affect the performance of examination and interpretation of results:

- Failure to follow specimen acceptance criteria will result in a delay to specimen processing and reporting.
- Failure to supply adequate clinical information may result in a delay requesting specimen investigations and reporting.
- Failure to clearly label requests as 'URGENT' will result in a delay to specimen processing and reporting.
- Failure to fix specimens appropriately and in a timely manner will adversely affect specimen integrity and subsequent histological examination.
- Failure to follow instructions for the specific specimen requirements will prevent necessary examinations from being performed.

- Failure to disclose high risk status of the specimen will put staff at unnecessary risk of infection.
- Specimens for the Frozen Section Service placed in 10% Formalin will result in the frozen section not being performed and therefore a rapid report would not be possible.
- Failure to contact Consultant Histopathologist/laboratory in advance to book a request for the Frozen Section Service may result in a delay or even a scenario where it cannot be performed, due to lack of availability of technical staff and/or Consultant Histopathologist staff.
- Specimens for immunofluorescence placed in 10% Formalin cannot be used for this examination.
- Delay in sending specimens for immunofluorescence of more than 5 days may compromise tissue integrity for this examination.
- Specimens for Diagnostic Cytology being placed 10% Neutral Buffered Formalin as opposed to being sent fresh, in saline or cytological fixative as appropriate for the sample type and test required.
- Failure to send urine sample to the laboratory on the same day as collection may lead to deterioration of specimen and bacterial overgrowth which may obscure cellular content.
- Failure to provide Diagnostic Cytology with their own specimen and order at the time of collection for multi-discipline examination may cause a delay in examination, whilst the quality of this time sensitive specimen deteriorates.
- Diagnostic Cytology samples are time sensitive and delay in sending specimens to the laboratory may compromise the integrity of the examination and interpretation of results.
- Failure to identify each FNA slide prep as either Wet-fixed or Air-dried may cause the incorrect protocols to be used.

Should any of these factors affect the issuing of a final report, then an incident may be raised on the Laboratory's CA/PA system and where applicable also the Trust's DATIX reporting system.

5.6 Urgent Requests

Where possible, any request for urgent work must be arranged in advance and must be stated clearly in EPIC. Urgent samples will be done as soon as possible upon receipt in the laboratory within service hours.

Please be aware that the type and size of specimen will influence the processing and reporting of the case.

In some cases, a same day service can be offered (but ***NOT*** guaranteed) for very small urgent Histology Samples and is only available at the request of the reporting Consultant Histopathologist. Processing will be at the discretion of Senior BMS (technical) staff.

6 Histopathology Sample Requirements

ALL Histology specimens, **excluding** specimens for the pre-booked frozen section service and Skin Immunofluorescence service, **MUST** be sent to the laboratory in a 10% Formalin filled specimen container suitable for the size of the specimen – ratio of 1:10 tissue to 10% Formalin for small specimens and ratio of 1:5 tissue to 10% Formalin for very large specimens.

Secure attachment of the lids is essential to prevent leakage of the fixative, which may lead to suboptimal fixation of the sample.

6.1 Bone Marrow Trephines

Bone Marrow Trephine (BMT) specimens require 24Hrs fixation in 10% Formalin before decalcification in EDTA (Ethylenediaminetetraacetic acid). It takes a minimum of three days of fixation and decalcification before samples are processed.

6.2 Bone Specimens

Bone, such as mandible and head/neck femur specimens require adequate fixation in 10% Formalin before decalcification in 10% Formic Acid. Samples must pass Decalcification Endpoint Testing (Calcium Oxalate Test) before they can begin processing, this can take many weeks.

6.3 Prostate Needle Cores (PRNs)

Prostate Needle Cores (PRN) specimens must be sent to the laboratory 'sandwiched' between two biopsy pads. The biopsy pads are placed into an unlabelled cassette, which is then placed into a 60 ml 10% Formalin specimen pot and labelled with the patients' details etc. Where only one biopsy pad has been used, this will be recorded by the laboratory on their QMS as a CA/PA, and the sender of the sample will be informed and will be asked to fill out a DATIX, due to the potential loss of diagnostic material. It is imperative that two biopsy pads are always used when obtaining this type of sample.

6.4 Alopecia Specimens

Alopecia specimens as stated in RCPath guidelines, standard practice for histological assessment of alopecia is for two 4 mm punch biopsy samples to be sent – one will be dissected vertically (visualisation of dermo-epithelial junction), and the other will be dissected transversely (Visualisation focal follicular pathology).

6.5 Breast Pathology

Breast Unit specimens are examined and reported off site at Poundbury Cancer Institute, Dorchester. Please make sure specimens are sent to Cellular Pathology in a timely manner, so they can be booked in on the laboratory's LIMS, prior to packaging up and collecting by the Poundbury courier. Any errors in labelling must be rectified before the specimens are allowed to be sent for examination and reporting. This may delay the report being available. Turnaround times are monitored for these specimens.

6.6 Conjunctival/Pterygium/Eye Pathology

All conjunctival/Pterygium and eye evisceration specimens are examined and reported off site by Dr Mudhar, Royal Hallamshire Hospital, Sheffield. Turnaround times are monitored for these specimens.

6.7 Tests Requested by Clinician

Please make sure any additional tests to the routine Haematoxylin and Eosin stain i.e. Amyloid, Cytomegalovirus (CMV), Fungus etc. are **clearly** indicated at the time of electronic ordering on EPIC. Usually, additional tests required to facilitate diagnostic reporting are requested by the reporting Consultant Histopathologist.

7 Cytology Sample Requirements

7.1 Fine Needle Aspirates (FNA)

Slides must be labelled in **PENCIL** only and have 3 patient identifiers as the minimum data set. Fully labelled air-dried slides for May Grunwald Giemsa staining protocol, fully labelled wet-fixed slides for Papanicolaou staining protocol.

Spreading technique for slide preparation is determined by the amount of aspirated material. Please be careful when using any type of spreading technique, not to crush the cellular content, as this will impede diagnosis.

Any FNA slides and fluid samples collected for Diagnostic Cytology investigation **MUST** be accompanied by a **FULLY ANNOTATED** TSDFT Diagnostic Cytology order in EPIC.

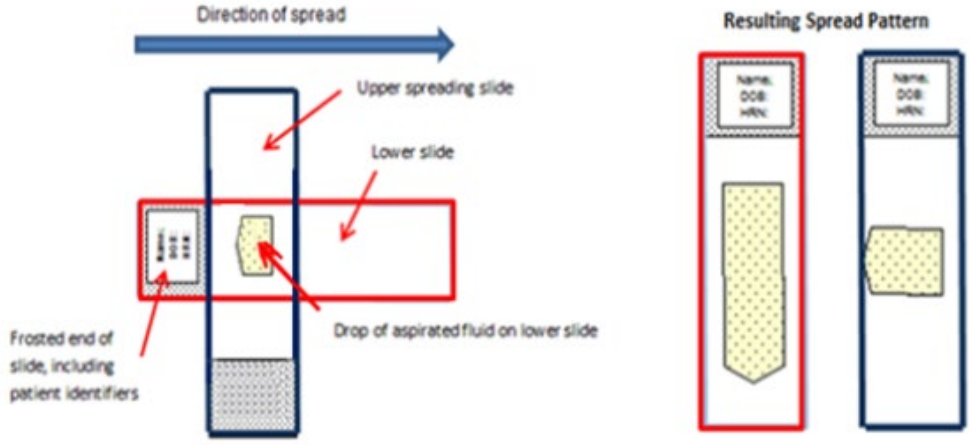


Fig. 1. Spreading techniques are useful for medium size drop of fluid. For smaller amounts of fluid, use Blood-Film spreading technique. (Fig.2.)

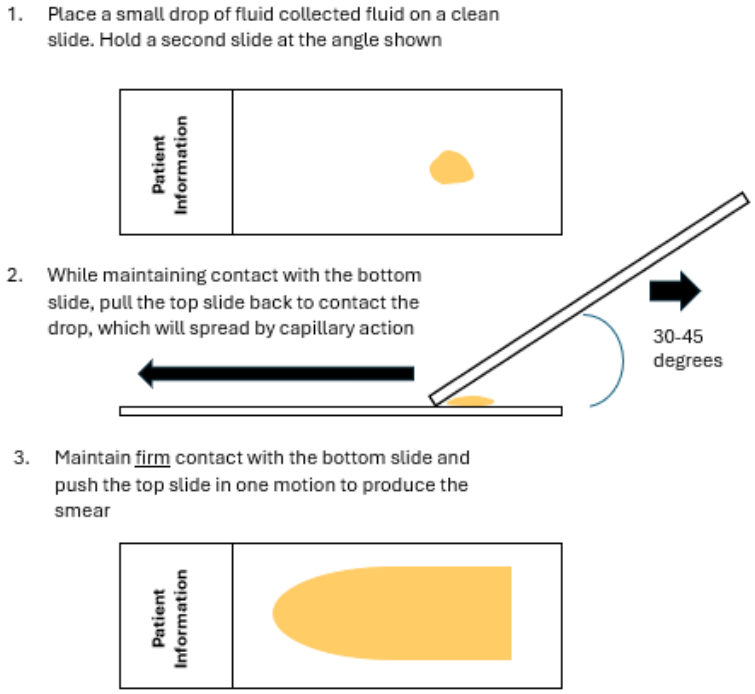


Fig.2. Blood Film (Smear) Spreading technique. Spread from the bottom of the slide upwards so majority of the cellular content is underneath the area of the coverslip which is attached post-staining to protect the smear from damage and contaminants.

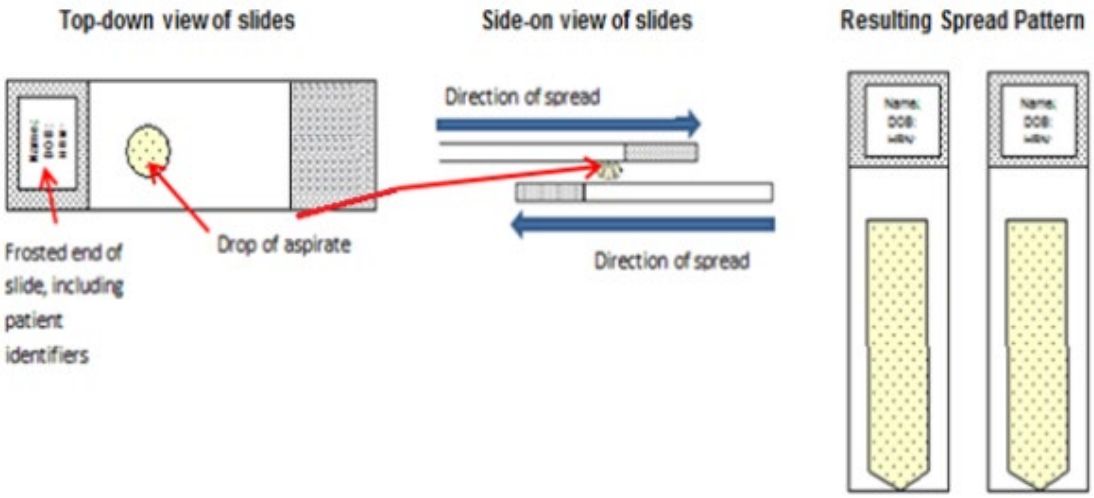


Fig. 3. Spreading technique is useful for larger size drop of fluid.

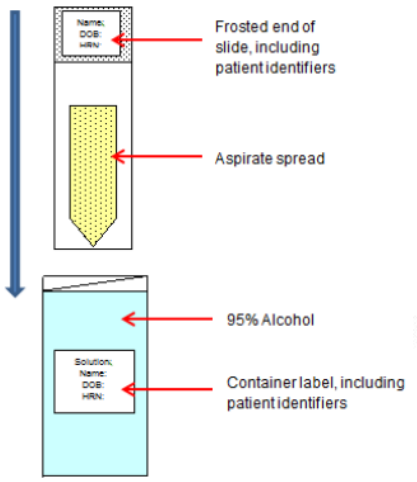


Fig.4. As soon as spread, **immediately immerse in fixative**. **Write on slide Wet-Fixed**

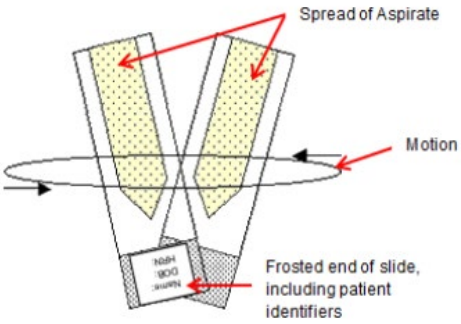


Fig.5. Air-dried Slides. **Write on slide Air-dried**.

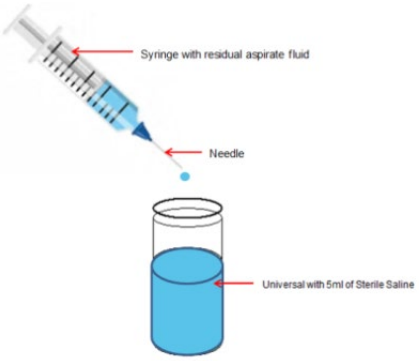


Fig.6. Drawer up Cytospin Collection Fluid in FNA needle, **rinse out into labelled sterile container** i.e. 30 ml Universal

7.2 Urine Cytology

In order for urine samples to be suitable for Diagnostic Cytology, the appropriate criteria must be met. The patient should be adequately hydrated and the whole output 2nd or subsequent urine sample of the day collected. The urine sample must be collected into a 60 ml sterile container that **DOES NOT** contain any preservative.

An early morning urine sample is **NOT** suitable for Diagnostic Cytology as exfoliated cells degenerate in the bladder overnight.

A mid-stream urine sample is **NOT** suitable for Diagnostic Cytology as cellular material is more commonly found at the beginning or end of voiding.

Clear and legible indication if the sample is considered **HIGH RISK** must be included in the clinical details. Please also include if the patient has a urinary catheter in situ, history of deep X-ray therapy (DXT) or chemotherapy.

Cells rapidly degenerate in urine samples, so to minimise deterioration of the sample, please deliver directly to Cellular Pathology.

Any urine samples collected for Diagnostic Cytology investigation **MUST** be accompanied by a **FULLY ANNOTATED** TSDFT Diagnostic Cytology order in EPIC.

7.3 Washing Cytology

Cytology washing is a type of exfoliative cytology that includes bronchial washings, ureteric washings, peritoneal washings and oesophageal washings. This procedure is useful for the diagnosis, classification and/or staging of benign and malignant tumours or to identify infections.

The cellular content of a washing specimen may be sparse as this procedure does not sample a site directly but acts by exfoliating loose cells from the target site and recollecting any cells shed into the sterile fluid. Lack of diagnostic cellular material within a sample can result in an inadequate specimen.

The aspirated washing sample should be collected into a 60ml sterile container that **DOES NOT** contain any preservative (ideally a yellow top universal container). **DO NOT send the drainage apparatus.**

As washing specimens are unfixed there is a risk of cellular degeneration and bacterial overgrowth which may lead to an inadequate result. To minimise the risk the sample should be delivered directly to the Cytology lab **WITHOUT DELAY.**

Clear indication if the sample is considered **HIGH RISK** must be included in the clinical details.

Any washings samples collected for Diagnostic Cytology investigation **MUST** be accompanied by a **FULLY ANNOTATED** TSDFT Diagnostic Cytology order in EPIC.

7.4 Serous Fluid Cytology

When collecting a serous fluid (including peritoneal, ascites, pleural and pericardial samples) RCPath recommends an optimal fluid volume of between 50 – 75ml is sent for Cytology investigation.

Serous fluid specimens should be collected into a 60ml sterile container that **DOES NOT** contain any preservative (ideally a yellow top universal container). If more than one specimen container of fluid is collected this should be indicated on each container e.g. 1 of 2, 2 of 2 etc.

Clear indication if the sample is considered **HIGH RISK** must be included in the clinical details.

Send a **separate sample** and order in EPIC to Microbiology if a microbiological investigation is required.

Any Serous Fluid samples collected for Diagnostic Cytology investigation **MUST** be accompanied by a **FULLY ANNOTATED** TSDFT Diagnostic Cytology order in EPIC. The specific location the sample was collected from **MUST** be included i.e. Pleural fluid, right side

7.5 Sputum Cytology

Sputum cytology is recognised to be a specimen of limited or no clinical value and hence should be rarely received. However, sputum samples are sometimes submitted to the laboratory if the patient is unfit for a more invasive investigation.

If cytological diagnosis is required, then it is recommended that three separate consecutive deep cough specimens are sent to the laboratory.

Use a 60ml sterile container that **DOES NOT** contain any preservative (ideally a yellow top universal container). There should be adequate clinical information provided on the order in EPIC, which should clearly indicate a cytological examination.

Collect three specimens on consecutive days and complete three Torbay orders in EPIC. Dispatch each specimen to the lab as soon as it has been collected. Indicate the date and time of the specimen collection on each order and specimen container.

A good deep cough specimen is required. Do not use toothpaste and no food or drink should be taken prior to sputum collection.

Indicate on the order if there is a history of relevant clinical data including foreign travel. Clear indication if the sample is considered **HIGH RISK** must be included in the clinical details.

Any sputum samples collected for Diagnostic Cytology investigation **MUST** be accompanied by a **FULLY ANNOTATED** TSDFT Diagnostic Cytology order in EPIC.

Send a separate sample and EPIC order to Microbiology if a microbiological investigation is required.

7.6 Cerebrospinal Fluid (CSF) Cytology

CSF may reflect pathology within the brain, spinal cord or membranes. CSF cytology is indicated as part of an investigation of known or suspected CNS malignancy (primary or secondary) or in cases of aseptic meningitis

CSF cytology is usually performed in conjunction with CSF microbiology and biochemistry tests. Ideally, send as much fresh specimen to the laboratory as possible - for an optimal sample, 10ml plus, with 2-3mls as a minimum requirement. CSF specimen should be collected into a sterile container that **DOES NOT** contain any preservative.

Send separate samples and EPIC orders for microbiological investigation (if an infection is suspected) and Biochemistry.

CSF must not be submitted for cytological examination where the clinical diagnosis is of known or suspected CJD. In such cases, there should be prior discussion with a consultant Pathologist.

Any CSF specimen collected for Cytology investigation **MUST** be accompanied by a **FULLY ANNOTATED** TSDFT Diagnostic Cytology order in EPIC.

7.7 Synovial Fluid

Synovial fluids should be assessed for crystals and a cell count performed. This procedure is performed in the **Microbiology lab** for information regarding these investigations please contact the Microbiology lab on 01803 614567 ext. 55234 or 01803 655234

Synovial fluid samples requiring Diagnostic Cytology investigation should be collected into a 60ml sterile container that **DOES NOT** contain any preservative (ideally a yellow top universal container). If more than one specimen container of fluid is collected this should be indicated on each container e.g. 1 of 2, 2 of 2 etc.

Any Synovial sample collected for Cytology investigation **MUST** be accompanied by a **FULLY ANNOTATED** TSDFT Diagnostic Cytology order in EPIC.

7.8 Miscellaneous Cyst Fluid and Aspirates

Any miscellaneous cyst fluid samples or aspirates requiring Diagnostic Cytology investigation should be collected into a 60ml sterile container that **DOES NOT** contain any preservative (ideally a yellow top universal container).

Send separate samples and EPIC orders for microbiological investigation (if an infection is suspected) and Biochemistry.

Any miscellaneous cyst fluid and/or aspirate collected for Cytology investigation **MUST** be accompanied by a **FULLY ANNOTATED** TSDFT Diagnostic Cytology order in EPIC.

7.9 Brushing Cytology

Cytology brushings are performed primarily for the diagnosis and classification of benign and malignant tumours but can also be used to identify infection. The main brushing types received are taken from the bronchus, biliary duct and oesophagus. Brush sampling allows clinicians to sample areas that are prone to bleeding if biopsied. Brushings can be taken from the surface of a tumour visualised with a bronchoscope or endoscope.

Any brushing Cytology investigation must have the brush tip placed into the PreservCyt vial and **MUST** be accompanied by a **FULLY ANNOTATED** TSDFT Diagnostic Cytology order in EPIC.

7.10 Cervical Cytology

These samples are collected by the City Sprint courier service at approximately 9.15 Monday to Friday and dispatched to the Cytology lab at **Southmead hospital, Bristol** for testing.

Cervical samples also known as LBC samples or ThinPrep samples will still be sent directly to Torbay hospital's main Pathology reception at level 3 from the clinics and GP surgeries.

Enquiries Should be directed to the Cytology lab at Southmead hospital. By phone on 0117 4149889. Monday to Friday, 9.00am to 5.00pm. By email at cellularpathologycytologyadmin@nbt.nhs.uk

8 Sample Transportation

All samples being transported across the Trusts site to the Cellular Pathology Laboratory must follow Trust Information Governance policies and have patient identifiers hidden from view to protect patient confidentiality. The use of opaque, rigid and leak-proof transport boxes and the transport box on wheels for larger samples from Theatres and/or Day Surgery is strongly recommended. Any type of transport box used must have **UN 3373** label displayed on the outside – packaging and transport regulation of patient samples for diagnostic purposes. The large transport box on wheels must contain spillage containment equipment such as nitrile gloves, absorbent materials and spillage granules.

8.1 Histology

8.1.1 Small Specimen Pots

Small specimens for Histology must be placed in a sealable bag. Please ensure each screw top lid for each of the specimen pots is correctly tightened to avoid spillage of the specimen pot contents into the

sealable bag. If there are multiple specimen pots for the same patient on one EPIC order and not all pots can fit in the same sealable bag, place the rest of the pots in a second sealable bag, and if possible, staple or tape the two bags together.

8.1.2 Medium Specimens Pots

Medium sized specimen pots, for Histology must be placed in a sealable bag where possible. Specimen pots of this size must be kept upright at all times, to avoid spillage if the lid is not firmly sealed.

8.1.3 Large Specimen Pots and Buckets

If the container is too large to fit in a sealable specimen bag, please make sure the lid is securely fastened. Specimen pots of this size must always be kept upright, to avoid spillage if the lid is not firmly sealed. If there is a handle on the specimen pot/bucket, please use it when carrying it.

8.2 Diagnostic Cytology

Diagnostic Cytology specimens should, wherever possible, be sent to the laboratory on the same day as obtained. Any specimens taken at weekends should be kept in a refrigerator and promptly sent to the laboratory on the first day of the working week.

9 Health and Safety

Health and Safety at Work Act (1974) – it is the duty of every employee to take reasonable care for the health and safety of themselves and other persons who may be affected by their acts or omissions at work.

It is the responsibility of the requesting clinician to ensure the specimen is transported safely and arrives in the laboratory in a timely manner. Laboratory responsibility for the specimen starts when it arrives at the Cellular Pathology Department.
Samples that are considered **HIGH RISK** must be clearly labelled. Biohazard specimen bags and stickers are available and can be bought commercially.

Formaldehyde vapour levels are monitored within the laboratory setting every working day. During examination downflow benches are used alongside PPE. Post examination, Formalin Storage cabinets are used for the storage of specimens to reduce staff exposure to Formaldehyde vapours.

10 Storage and Disposal of Specimens

10.1 Patient Samples

The laboratory will store and dispose of all patient samples sent for Histology/Diagnostic Cytology/Post-mortem/loss of Early Pregnancy tissue – examination, Departmental policies are based on current guidelines from RCPath (Royal College of Pathologists) and HTA (Human Tissue Act).

The specimens are stored at the correct temperature according to specimen type. Temperatures are monitored 24Hrs per day, every day throughout the year.

Specimens, until they are disposed of, are in a secure laboratory, accessible only to staff required to handle the specimens. Histology Specimens are disposed of following 28 days post authorization and

Loss of Early Pregnancy tissue is held for 42 days post authorisation before sensitive disposal if authorised on the consent form. If the parents wish to make their own funeral arrangements, tissue blocks will be melted down and slides scraped of the mounted tissue, sensitively packaged up and given back to the parents.

10.2 Paraffin Wax Blocks and Microscope Slides

The laboratory stores approximately 2 years' worth of microscope slides and wax blocks on site. Each year there is an uplift (to make room for the coming years blocks and slides) – excluding Post-mortem blocks and slides (on site storage 5 years +), and any other blocks and slides to be returned to the laboratory's' main archive holding site (Wales) run by CellNass delivered by CellPath Ltd, in accordance with RCPath guidelines.

11 Turnaround Times (TATs)

To keep TATs to a minimum, send all specimens to the laboratory as quickly as possible by using either porters and/or transport, as appropriate.

TATs, Key Performance Indicator (KPI), are based on RCPath Guidelines and start on receipt of specimen into the Cellular Pathology Laboratory and the report going out. TATs do not include postal/courier delivery times to and from the laboratory.

11.1 Histology

Reported within 7 days of sample, RCPath Guidelines (Target >80%):
Reported with 10 calendar days of Sample RCPath Guidelines (Target > 90%):

Exceptions can arise causing a delay in the report being issued. Where possible an interim report can be issued to the clinician by authority of the reporting Consultant Histopathologist

- Complexity of the specimen
- Ancillary testing required such as Immunohistochemistry
- Genetic testing required (See 12 Genetic Testing)
- Second Opinion
- Direct referral (NHS England directive) to Reference Laboratory
- Outsourced specimens

11.2 Diagnostic Cytology

Reported within 7 days of sample, RCPath Guidelines (Target >80%):
Reported with 10 calendar days of Sample RCPath Guidelines (Target > 90%):

Exceptions can arise causing a delay in the report being issued.

- Complexity of the specimen
- Immunohistochemistry (IHC) Ancillary testing required - An induce clot is made using Cytopath® Disc from sample of fluid received which requires minimum 12 hrs. Formalin fixation and overnight tissue processing. IHC may take another 24 hrs. to complete.

12 Reports

All reports issued by the Department are available on the relevant Trusts' electronic systems. Paper copies are also printed and sent to relevant Departments/GP surgeries, via Pathology Reception. Reports for the private Mount Stuart Hospital are sent out as paper copies.

Histology Reports

Generic contact details	Location	Telephone Number	Information
Report Enquires	Cellular Pathology Office	01803 655214	Out of hours there is an answer phone. Office is manned during working hours
Departmental Email address	Cellular Pathology		tsdft.mdthistology@nhs.net

Please note – Clerical staff **WILL NOT** give report details over the telephone.

13 Genetic Testing

Genomic tests are sent to **South West Genomic Laboratory Hub** in Bristol. Samples are sent in the form of 5 µm slide mounted sections or 10 µm curls/scroll dependent on tumour DNA and/or RNA extraction and sample requirement for the genomic test requested.

A few examples are:
Colorectal/Pancreatic/Oesophageal/Gastric cancers: MSI testing – Laboratory sends one Eppendorf or universal of 5 x 10 µm curls/scrolls

Melanoma – Adult: Small variants (*BRAF,KIT,NRAS*) – Laboratory sends one Eppendorf or universal of 5 x 10 µm curls/scrolls
Ovarian Carcinoma: HRD (Homologous recombination deficiency) analysis and *BRAC1/2* (1st line) – Laboratory sends 10 x 5 µm slide mounted sections.

Any sample requiring PD-L1 testing (Lung cancer) the tissue block is sent to Royal Devon University Hospital, Exeter, then returned following completion of tests.

14 Referral Laboratories

Referral laboratories used by the laboratory are selected on several criteria, including:

- Known laboratory expertise and availability of interpretative advice
- Recognised Regional Hub
- Turnaround time
- Accreditation Status

In general, NHS accredited laboratories or recognised laboratories with conditional status are used. This provides an indication of a particular quality of service.

The UKAS accreditation status of each laboratory used is checked on the UKAS website to ensure that the laboratory has maintained its accreditation status. The scope of each provider or potential provider can also be viewed to ensure the tests required are included in the referral laboratory's scope of practice.

Individual Consultant Histopathologist reserves the right to refer to other Histopathologists if deemed to be more appropriate. Pathologists are identified and selected based on clinical relevance and professional standing.

Electronic records of patients block/slides are annotated when and where the referral was sent, and why. Records are also kept when they are returned to the laboratory. Reports are sent electronically and are uploaded to patients LIMS records as supplementary reports.

15 Risk Management

The Department manages risks associated with laboratory examinations (pre-examination, examination and post-examination) primarily to the patient but also our staff, equipment and environment by:

- Reviewing our work processes
- Evaluating the impact of potential failures on examination results
- Modifying the process to reduce or eliminate the identified risks
- Documenting the decisions and actions taken

The Department has an agreed Risk Management Procedure and will identify, eliminate, control and monitor the risks through:

- Risk assessment
- Complaints
- Internal Audit
- Corrective and Preventative Action (Recorded and Monitored on QMS)
- Minor Errors Record
- Trend Analysis
- Safety Checklists
- Quality Control
- Management Review – performed yearly
- External Assessment – Accreditation and EQA (See 3.1 and 3.2)

This is implemented both through regular audit and by filling out of the incident-reporting system – DATIX, available to staff on Hospital intranet.

APPENDIX A

The following are a list of tests which are currently outside of our scope of UKAS Accreditation:

Test	Type	Action
CD31	Immunocytochemistry	Currently awaiting outcome from UKAS Extension to Scope application

PAX-8	Immunocytochemistry	Currently awaiting outcome from UKAS Extension to Scope application
GATA3	Immunocytochemistry	Currently awaiting outcome from UKAS Extension to Scope application
PHH	Immunocytochemistry	Currently awaiting outcome from UKAS Extension to Scope application
PRAME	Immunocytochemistry	Currently awaiting outcome from UKAS Extension to Scope application
Manual H&E staining for frozen sections.	Staining Techniques	
Modified Giemsa for Mast cells	Staining Technique	

All reports clearly identify which tests are unaccredited.