



# Wythenshawe Histopathology and Cytopathology (Cellular Pathology) Service User Guide

# **Directorate of Cellular Pathology**

# Manchester University NHS Foundation Trust



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## **1** Introduction

**Note:** This user guide details information for the requesting of investigations, specimen requirements and communication of results for the department of **Histopathology and Cytopathology (Cellular Pathology) at Wythenshawe Hospital**; please see the separate user guide for Adult and Paediatric Histopathology services at Oxford Road site.

The Division of Laboratory Medicine (DLM) at Manchester University NHS Foundation Trust (MFT) Wythenshawe Hospital provides diagnostic services to Wythenshawe and Withington Hospitals as well as General Practitioner surgeries in the South Manchester area and beyond.

The Histology and Cytology laboratory (jointly referred to as Cellular Pathology) at the Wythenshawe Site offers a diagnostic service for tissue and body fluid samples. The department provides a service to the patients, clinicians and General Practitioners of the South Manchester and Tameside area including Tameside and Glossop Integrated Care Organisation. The department specialises in cardio-thoracic, breast, skin and gastrointestinal pathology.

We offer the following histopathology diagnostic services with consultant sub-specialist reporting:

- Gynaecological pathology
- Gastrointestinal, pancreaticobiliary and hepatic pathology
- Renal, urological and endocrine pathology
- Haematological and lymphoreticular pathology
- Osteoarticular and soft tissue pathology
- Head and neck pathology
- Dermatopathology
- Cardiothoracic and respiratory pathology
- Diagnostic Non-gynaecological Cytopathology

Specialties are supported by our on-site Immunohistochemistry service.

The histology department at Manchester Royal Infirmary also incorporates the Haematological Cancer Diagnostics (HCD) in partnership with the Christie, which is a Specialist Integrated Haematological Malignancy Diagnostic Service (SIHMDS) for the Greater Manchester area. This service is accredited by NHS England and its director is Dr John Burthem. Further information can also be found using the following link: <a href="http://haematologyetc.co.uk/Manchester\_Haematological\_Cancers\_Diagnostic\_Partnership">http://haematologyetc.co.uk/Manchester\_Haematological\_Cancers\_Diagnostic\_Partnership</a>

Autopsies are carried out by our Consultant Histopathologists, Specialist Doctors and Trainee Histopathologists within the adjacent Adult Mortuary. Further information can be found on the Adult Mortuary user guide or by contacting the relevant consultant pathologist.



Our department deals with approximately 40,000 surgical cases and around 200 autopsies on behalf of HM Coroner annually. Our department comprises over 60 medical, scientific and ancillary staff and has an excellent reputation for clinical and scientific training. We also have IBMS training status and support local universities in the training of Biomedical Science students.

## 2 Contact Us 2.1 Opening Hours (5.4.2 c)

The histology / cytology laboratory is open Monday – Friday from 8am until 5.30pm, excluding public holidays. Outside these hours relevant personnel are on call for dealing with urgent cardio-thoracic transplant biopsies. Notice needs to be given to the Consultant Histopathologist and the Biomedical Scientist of the intention to perform a biopsy and to the Biomedical Scientist when the specimen is dispatched for transport to pathology who is contactable through switch and ask for the cardio-thoracic Biomedical Scientist on call.

The Mortuary is open from 8.30am until 4pm and Anatomical Pathology Technicians operate a limited on-call service. They can be contacted via the duty manager in the first instance.

## 2.2 Location (5.4.2 a)

Our reception is located on the ground floor of the Clinical Sciences Building at Wythenshawe Hospital



Address: Histopathology and Cytopathology (Cellular Pathology) Clinical Sciences Building Wythenshawe Hospital Southmoor Road Wythenshawe Manchester M23 9LT



#### 2.3 Contact Information (5.4.2 I) Histology Reports

Generic contact details	Location Extension I		Information	
Report enquiries	Office	0161 291 4813	At times, this number may have an answering machine: please leave a clear request and a number for us to call you back	
Departmental nhs.net email address			Mft.wythenshawe.histosecs@nhs,net	

All enquiries for histology reports should be directed to our secretarial office.

All enquiries regarding frozen sections, specimen requesting, labelling, transport and requirements should be directed to our Specimen Reception (details below).

#### Key Contact Details

Laboratory	Tel No.	Email address
John Hayes Cellular Pathology Directorate Manager	0161 276 6138	John.hayes@mft.nhs.uk
Katherine Congdon Cellular Pathology Deputy Directorate Manager / Histopathology Laboratory Manager	0161 276 6138	katherine.congdon@mft.nhs.uk
Catherine McNulty Lead Biomedical Scientist	0161 291 4804	Catherine.mcnulty@mft.nhs.uk
Christopher Harreld Deputy Lead Biomedical Scientist	0161 291 4804	Christopher.harreld@mft.nhs.uk
Specimen reception	0161 291 4800	
Histology laboratory	0161 291 4800	
Cytology laboratory	0161 291 2156	

Consultant Name and Speciality	Office	Secretary	Email address
Dr Edmund Cheesman	0161 701 2375	0161 701 1272	edmund.cheesman@mft.nhs.uk
Clinical Director of Cellular Pathology			
Dr M Scott	0161 291	0161 291	
<b>Co-Clinical Lead Histopathology</b> Gynaecology, Gastrointestinal, Urology	2144	2123	michael.scott@mft.nhs.uk



Dr N Ali Breast, Skin, Gynaecology, Gastrointestinal cytology	0161 291 5663	0161 291 4812	<u>nisha.ali@mft.nhs.uk</u>
Dr P Bishop Cardiothoracic, Skin, Head & Neck, Haematolymphoid Andrology	0161 291 2159	0161 291 2121	paul.bishop2@mft.nhs.uk
Dr A Davenport (part-time) <b>Co-Clinical Lead Histopathology</b> Gastrointestinal	0161 291 5311	0161 291 2143	anna.davenport@mft.nhs.uk
Dr Angeles Montero	0161 291 4786	0161 291 2123	Angeles.montero@mft.nhs.uk
Dr R. Hunt Breast, Gastrointestinal, Gynaecology, Urology, Gastrointestinal cytology	0161 291 4807	0161 291 4812	roger.hunt@mft.nhs.uk
Dr L Joseph Deputy Clinical Head of Division, Quality and Patient Safety Lead & Co- Clinical Lead Histopathology Skin, Breast, Cardiothoracic	0161 291 4808	0161 291 2123	leena.joseph@mft.nhs.uk
Dr S Pritchard <b>Co-Clinical Lead Histopathology</b> Breast, Gastrointestinal, Head & Neck, Gastrointestinal cytology	0161 291 4818	0161 291 2143	susan.pritchard@mft.nhs.uk
Dr A Paivi-Correia Cardiothoracic, max fax	0161 291 4805	0161 291 4810	Antonio.PaivaCorreia@mft.nhs.uk
Dr Kavita Singhal Breast, Skin	0161 291 4793	0161 291 2123	Kavita.singhal@mft.nhs.uk
Dr Nadine Elgeredly Breast,, Urology, Gastrointestinal	0161 291 2819	0161 291 2121	Nadine.elgeredly@mft.nhs.uk
Speciality trainees	0161 291 4814	0161 291 4815	
	0161 291 4816	0161 291 4817	

## **3 Quality**

Cellular Pathology (Histology and Cytology) is fully accredited by UKAS in conformance with ISO 15189:2012. Our UKAS Medical Laboratory Reference Number is 9083. The department participates in regular extensive assessments to maintain its accreditation status.

The department is licensed by the Human Tissue Authority (HTA) under licence number 12253.



The department is committed to delivering a quality service to our users and operates within a framework of continual improvement. A quality management system is utilised to ensure all documents, processes, quality records and clinical material are controlled to DLM (Division of Laboratory Medicine) policy. Processes and systems are regularly audited to identify non-conformities and quality improvements.

## 3.1 External Quality Assurance (EQA) (5.6.3.1)

The department participates in the following external quality assurance schemes:

UKNEQAS for Cellular Pathology Technique:

- General Cellular Pathology (Tissue Diagnostics Scheme and Specialist Techniques Scheme – from 2021)
- Frozen Sections/Mega Blocks

UKNEQAS for Immunocytochemistry and In Situ Hybridisation:

- Module 1 General Pathology 2 antibodies
- Module 2 Breast Pathology (Hormonal Receptors) 1 antibody
- Module 3 Breast Pathology (HER-2) 1 antibody
- Module 4 Lymphoid Pathology 2 antibodies
- Module 7a Alimentary Tract Pathology (GIST) 2 antibodies
- ISH Breast Pathology (DDISH only, scoring and technical).
- o ALK,
- o PD-L1
- o PD-L1 breast SP142
- o KI67

## 3.2 Data Protection (5.4.2 m)

The department complies with trust, DLM and departmental policies relating to the handling, use and protection of personal information (DLM-QUAL-PRO-022 Management of Data and Information).

- We only ask for information that we need to allow interpretation of results
- We protect the information and ensure only those staff who need to see the information can access it
- We share the information only when we need to for patient care, for example sending the information to another laboratory for testing
- We don't store information for any longer than is absolutely necessary

#### 3.3 Uncertainty of Measurement (5.5.1.4)

In clinical laboratory testing there are potential uncertainties that can affect test results, such as poor specimen collection or transport, patient related factors or other interfering factors. The laboratory examination process itself is subject to some degree of variability and our department regularly monitors this by the use of internal quality control and participation in external quality assurance schemes.



In accordance with the RCPath guidance, an assessment of the uncertainty of measurement will be carried out for any measurement that is included in the diagnostic report if it is deemed to have actual or potential "direct clinical impact."

Where weights and measurements are part of an overall description and do not impart prognostic or predictive value, an assessment will not be carried out.

## 3.4 Patient Consent (5.4.2 i)

It is the responsibility of the requesting clinician to ensure that any objections or restrictions expressed by a patient to the use of their tissue are clearly recorded on the request card.

It is vital to ensure that all early pregnancy tissue specimens for histological investigation have the appropriate **fully completed PS1consent form** enclosed with the histology request card.

#### **4 Requesting of Investigations**

The Division of Laboratory Medicine (DLM) guidelines for specimen acceptance must be followed to ensure that all samples are correctly and unambiguously identified. The policy provides an overarching process to specimen rejection to help balance the requirement to process against the risk to patient safety. Clinical governance issues may arise from errors in specimen identification and/or insufficient clinical information being given with a specimen. To ensure that specimens are linked to the correct patient, adequate identifiers are essential. Due to the difficulty in repeating a tissue specimen, different criteria are used in Adult Histopathology.

All <u>urgent</u> and specimens on a cancer tracking pathway (<u>HSC205</u>) should be clearly labelled as such. The date and time the specimen was taken is important information that should be included on all requests to determine the length of fixation of the tissue specimen.

4.1 Specimen Acceptance Policy (5.4.2 j)

All specimens need to be accompanied by a correctly completed histology / cytology request form.

For test requests ordered on the Hive Electronic Patient Record (EPR) system an order requisition printout must be submitted with the request.

For non-Hive requests or paper requests raised during Hive downtime see sample acceptance criteria below for more information.

The following mandatory information <u>must</u> be provided for us to accept the specimen:

#### **Essential Patient Identifiers:**

- Surname
- Forename
- Unique identification number Medical Record Number (MRN), NHS or external hospital number for external cases
- Date of birth



• Address – for GP or external locations

## **Essential Clinical Details:**

In producing a final diagnostic histopathology or cytopathology report the Pathologists are essentially looking to provide guidance and answers to clinical queries. Therefore it is essential that all relevant clinical information is provided on the request form (paper based or electronic) so that the histological and cytological features of the specimen can be interpreted within the clinical context. Rather than simply repeating oneself under each heading give relevant clinical details, procedure details, medical history and the clinically suspected (differential) diagnosis. This should include all previous malignancies, whether in the same or any other organ system. Under *Specimen Details*, give the precise anatomical site of the specimens sent. If there are multiple specimens, there should be a one-to-one correspondence between the specimens listed on the card and the labelling of the specimen pots. State any markers / sutures / clips, and their significance. Record any features of the specimen that are likely to be difficult to interpret after fixation, particularly for complex resections.

If the relevant, appropriate clinical information is not provided this may lead to a delay in the final report being issued.

- High risk status to ensure health and safety of all staff
- Specimen site must match on specimen pot and request card
- Relevant clinical information see above
- Lung cancer For any sample where there is a clinical concern for lung cancer (primary or metastatic), please ensure details of smoking (never/light smoker or current/ex-smoker) and performance status (WHO 0 1 2 3) are recorded on the request form in the clinical details section.
- **Consent fully completed PS1 form and gestation date** or LMP for early pregnancy tissue specimens, with clear indication of cremation or burial wishes.
- Date/time taken essential to ensure proper fixation of high risk specimen

## **Essential Sender Details:**

- Ward/department required for return of reports
- **Consultant or GP** required for return of reports and contact in case of any errors/discrepancies
- Contact number/bleep for frozen sections

It is recognised that histology samples are often not repeatable therefore the department has protocols in place to deal with specimens and accompanied request forms that do not meet the specimen acceptance criteria. A final report will not be issued until such details have been corrected. The requesting clinician will be required to attend either the Laboratory at Wythenshawe or Tameside. Samples from General Practitioners will be returned for amendment. All specimen and/or request form amendments will need to have a specimen amendment form completed. If amendments are not addressed within seven calendar days then an incident will be raised in Ulysses.



For some external clinics we will accept corrections to patient detail discrepancies via email, e.g. Tameside.

Any high-risk specimens should be highlighted on the specimen request form and received in formalin. The specimen will be left to fix in formalin for 24 - 48 hours after receipt to ensure safe to handle and therefore there may be a delay in the report being issued.

#### 4.2 Request Cards (5.4.2 e)

All paper request cards should be completed in full (see above) and all information provided should be clearly legible. Any missing information or errors will result in a delay to specimen processing and reporting.

Correct patient and specimen information is vital for us to provide a quality service to our users. Any specimens deemed to be high risk or potentially high risk should be clearly labelled as such to protect the health and safety of all staff.

As we provide our service to a range of service users, please also state the type of unique patient identification number given, e.g. NHS, district, MRN. Please also indicate whether the patient is an NHS, private or waiting list initiative patient.

If a patient is part of a research project, this should be clearly labelled on the request card to ensure that the specimen undergoes the correct procedures. Similarly, patients that are part of a screening programme, e.g. BCSP BOSS, should be clearly labelled.

#### 4.3 HIVE Requests (5.4.2 e)

Unlike some of the other pathology disciplines, Cellular Pathology (Histology and cytology) still require a request card for all specimens requested on HIVE.

For test requests ordered on the Hive Electronic Patient Record (EPR) system an order requisition printout must be submitted with the request.

HIVE generates specimen labels for both the requisition printout and each sample pot created as part of the order entry. Please ensure the correct label is attached to the correct container. HIVE labels must be attached to the specimen container and not to the lid of the container.

4.4 Specimen Containers and storage of Specimens (5.4.2 h)

Sample containers



	Container type	Description	Use
Fixed or air- dried slides		Slide carrier If alcohol spray fixative is required (see <u>cytology</u> <u>sample table</u> ), this available from the <u>cytology</u> <u>laboratory</u> .	Cytology samples
Plain container	70ml Sterile container	Sterile container If cytology green collection fluid, or cytorich red preservative are required (see <u>cytology sample</u> <u>table</u> ), these are available from the <u>cytology</u> <u>laboratory</u> .	Cytology samples
Plain universal		Sterile container If cytology green collection fluid, or cytorich red preservative are required (see <u>cytology sample</u> <u>table</u> ), these are available from the <u>cytology</u> <u>laboratory</u> .	Cytology samples
CellPath CellStor	CellPartine CellStor CellBattante CellStor	Container prefilled with formalin Available from the <u>histology</u> laboratory	Small histopathology samples
Bucket		Bucket prefilled with formalin Available from the <u>histology</u> <u>laboratory</u> . Unfilled specimen containers for specific, lung specimens to be received fresh also available from histology.	Larger histopathology samples
One-Piece Microbiopsy Cassette		Tissue Cassette	For prostates core samples.



	Container type	Description	Use	
One-Piece Mini biopsy Cassette		Tisse Cassette	For small tissue samples.	

Most specimens for histology need to be placed in an appropriately sized container with adequate amount of formalin (ideally 10x the volume of the sample) as soon as removed from the patient. Specimen containers of all sizes, pre-filled with formalin, are available from histology, please contact the laboratory. For specimens to be sent to the department not in formalin, empty specimen containers of all sizes are also available.

Prior to transport to the laboratory, it may be necessary to temporarily store specimens. All specimens that are placed into Formalin should be kept at room temperature until transported to the laboratory. Specimens in Formalin <u>should not</u> be placed into the fridge as this will have a negative impact on fixation and therefore preservation of the tissue.

Specimen	Storage
Formalin	Room temperature
Dry unfixed	Fridge
Gel transport medium	Fridge

All dry specimens and specimens in gel transport medium ideally should be transported to the laboratory immediately. Where this is not possible, these specimens should be stored in the fridge.

## 4.5 Transport of Specimens (5.4.2 h)

Specimens for histology or cytology are not allowed to be transported via the pneumatic tube system.

The transport of the specimens to the department is undertaken by the respective hospital transport portering teams from both the Wythenshawe and the Tameside site. Dedicated barrels are provided, by the histology department, as the secondary packaging for use to transport the samples. The primary packaging being the container the specimen is in. Urgent samples, e.g. transplant biopsies, frozen sections, may be delivered to the department ad hoc; these should be transported in an appropriate container, with a tightly fitting lid. The transport containers should be labelled as Diagnostic Specimens – UN3373 and have the department name and telephone number to ensure the containers comply with transport regulations.

Specimens should not be transferred to the department without appropriate packaging. All specimens should be received with a documented tracking sheet detailing the patient



identifiers, specimen type and where the specimen has been taken. These tracking sheets are checked on arrival in the histology department and returned to the department or area the specimen was taken from for staff to record that the specimen has been received safely in Histology.

Transport of samples on the Wythenshawe site occurs twice daily with specimens delivered at 9am and 3.30pm, Monday – Friday.

Transport of the Tameside samples occurs twice daily. The transport collects specimens from theatres, endoscopy and then pathology before leaving pathology at 9.30 am and 3.30 pm. This transport also delivers samples from GP surgeries within the Tameside borough. This transport also delivers supplies from Wythenshawe Site back to Tameside for the relevant theatres and clinics.

For specimens received from hospitals where there is not a routine transport service arranged, a courier service is used. This includes specimens transported from Stepping Hill Hospital and independent providers. Transport between Wythenshawe Histopathology, Withington Community Hospital, and Oxford Road Campus is in place at regular intervals throughout the day to ensure timely transport of specimens to be processed at each site.

Samples from all sites should be delivered to Histopathology specimen reception in the clinical sciences building so Histopathology staff can accept these and ensure all specimens are accounted for. Delivery of specimens should be Monday – Friday between 8.00am and 5.30 pm unless by prior arrangement as there are no staff on site over the weekend to accept specimens into the department.

Any fresh specimens (not delivered in formalin or preservative for non-gynae cytology specimens) should be delivered directly to a member of histopathology staff to ensure processing is undertaken quickly with no degradation to specimen.

If you have any queries or should extra transport be required for any reason please contact the Trust transport department via switchboard.

Samples received from both Trusts are recorded using a paper-based system and in some cases electronically. Please ensure such records are completed before dispatch of samples.

For paper-based requesting, only specimen request forms provided by histopathology should be used to request specimen testing. These forms should not be photocopied, for a supply of forms, please contact the laboratory.

Samples from the GP surgeries within the South Manchester District are delivered to the main pathology reception area and then collected by histology staff on an ad hoc basis. Some of these samples are requested electronically others are accompanied by handwritten request forms. For paper-based requesting, only specimen request forms provided by histopathology should be used to request specimen testing. These forms should not be photocopied, for a supply of forms, please contact the laboratory.

If samples from Wythenshawe Site cannot be accepted due to failing the specimen acceptance criteria, the requesting Clinician will be contacted via the messaging facility in HIVE and asked to attend the laboratory as soon as possible to make the necessary amendments and complete a Specimen Labelling Amendment form. This will form part of the record of this sample.



If samples are from GP's within the Wythenshawe borough, these are returned to the GP practice for amendments and completion of a Specimen Labelling Amendment Form. The specimen can then be returned to the Wythenshawe Histology department for processing. Records are maintained at Wythenshawe hospital of all specimens returned to GP surgeries.

If samples from Tameside Hospital cannot be accepted due to failing the specimen acceptance criteria, the requesting Clinician will be contacted and informed the sample will be returned to Tameside Pathology Specimen Reception. The Clinician should then attend the department to make any necessary amendments and complete a Specimen Labelling Amendment form. This will form part of the record of this sample. The sample is then returned to Histology at Wythenshawe Site for processing. Records are maintained at Wythenshawe hospital of all specimens returned to Tameside.

If samples are from GP's within the Tameside borough, these are returned to Tameside Specimen Reception to then be sent to the GP practice for necessary amendments to be made and Specimen Amendment Form. This is then returned to Wythenshawe Histology via Specimen Reception at Tameside. Records are maintained at Wythenshawe hospital of all specimens returned to Tameside.

Please be aware that a final report will not be made available until the necessary amendments have been made (although specimens may be processed should there be a clinical urgency or risk in specimen degradation should processing be delayed). Failure to amend the specimen request form of specimen pot in a timely fashion will lead to a delay in the final report and if the specimen is not amended in 7 days, a Ulysses record will be raised.

All specimens should be transported in the relevant fixative or transport medium as indicated below in section 5. All specimen pots should be tightly sealed and transported using specimen bags, where appropriate. The request card should be placed in the pocket of the specimen bag, and the pot inside the sealed bag to ensure the safety of all staff.

All specimens sent via Royal Mail should adhere to the packaging guidance available on the Royal Mail website. It is the responsibility of the sender to ensure that specimens are appropriately labelled and packaged.

#### 4.6 Specimen Tracking (5.4.2 h)

Many of our service users have systems in place to track specimens. If specimen acceptance criteria are applied at the time of tracked receipt, the specimen can be returned to the sender quickly should any discrepancy be identified.

Appropriate action in the event of a specimen acceptance failure involving fresh tissue (e.g. frozen section, gel sample) or an Urgent / HSC 205 sample is decided at the discretion of the reporting pathologist. The decision to accept and process pending confirmation may be taken.

If a specimen has been requested using HIVE, the sender can use HIVE to check whether the specimen has been received.

#### 4.7 Requesting Formalin Pots (5.4.2 h)



We supply prefilled containers of all sizes to departments at Wythenshawe Hospital and empty buckets and prefilled biopsy pots to Tameside Hospital. We also supply specimen pots and buckets to external hospitals on a like for like basis following receipt of specimens for processing e.g. to the Spire hospital.

The exceptions to this rule are specimens requiring an urgent frozen section report, lung wedges and resection specimens and specimens being transferred to the department by the Biobank team for which they will have explicit patient consent for sampling. These specimens should not be sent in formalin.

Prefilled specimen pots are only to be transported by the Trust transport department using the dedicated barrels.

Any formalin that is identified as out of date and therefore shouldn't be used should be returned to the Histology department at Wythenshawe site so that the fluid can be safely disposed of.

Most specimens for histology need to be placed in an appropriately sized container with adequate amount of formalin (ideally 10x the volume of the sample) as soon as removed from the patient. Specimen containers of all sizes, pre-filled with formalin, are available from histology, to request, please contact the laboratory on 0161 291 4800. For specimens to be sent to the department not in formalin, empty specimen containers of all sizes are also available.

Please be aware that porters and transport have limited capacity to deliver formalin pots. Frequent smaller orders are advised rather than occasional large orders.

## 4.8 Handling Formalin (5.4.2 h)

The department uses 10% neutral buffered Formalin (4% formaldehyde) and this should be handled with care at all times. Genta is our supplier of Formalin and has issued the following safety information:

#### 10% Formalin

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

All solutions containing formalin are suspected carcinogens, mutagens and sensitisers. The solutions should be handled with care, minimising skin contact. Safety equipment including gloves should be worn and any spill on the skin should be washed as soon as possible. Contaminated clothing should be removed immediately and washed before re-use as the chemical can soak through clothing to stay in contact with the skin for a long period of time. In general, formalin solution, like any other chemical should be treated with respect. Handle with care and avoid any situations which could potentially result in formalin spillage.

Formaldehyde vapours in the air are also harmful. The safety limit for formaldehyde in air is two part per million (2ppm). This means workers should not be exposed to formaldehyde



vapour above this level (averaged over the period) for more than 15 minutes at a time. Testing machines are available to monitor the level of formaldehyde vapour in air but as a rough guide, 2ppm of formaldehyde will have a strong, unpleasant smell and will start to sting the nose and eyes on first entering the room. This check is only valid on first entering the room as the senses quickly acclimatise and will be less sensitive. In most hospitals with proper bench extraction it is unlikely that the limit will be reached in normal use but may be in the event of a spill.

#### Information from: Formalin Usage Guide for Hospitals – Genta, Version 2.1 (Jan 2016)

Formalin can be disposed of down a sink suitable for clinical waste with copious amounts of running water in a well-ventilated room.

## 4.9 Formalin Spillages (5.4.2 h)

Formalin should be handled with care and sent in appropriately sized containers with secure lids to minimise the risk of a spillage. Specimen pots should be secured in a sealable plastic specimen bag.

Each sender who handles Formalin should have their own policy or procedure and equipment for handling Formalin and dealing with a spill. Spillages should be dealt with as soon as it safe to do so. Salvage of any specimen should be of the highest importance as it is likely to not be repeatable. Specimens must not be discarded.

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

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 contact the laboratory immediately on **0161 291 4800**. Please give full details of your location and a fully trained member of staff will attend the spillage.

Our Formalin supplier, Genta, has issued the following guidance on spillages. Spillage volumes:

- Minor spillages (up to 200ml) usually can be dealt with by 1 or 2 staff using simple procedures
- Large spillages (200ml 5 litres) require the use of a Formaldehyde spillage kit
- Major Spillages (over 5 litres) should be dealt with by Fire Service

## 4.9.1 Dealing with minor spills

In a hospital environment formalin is mostly handled in very small containers with less than 100ml of 10% formalin solution. A spill of this size is unlikely to contaminate the air to dangerous levels if dealt with promptly. The spill can be wiped up with absorbent material by staff members wearing suitable impervious gloves such as nitrile gloves. The contaminated material should be sealed in plastic bags for disposal and removed from the room as soon as possible. It is important not to simply dispose of the contaminated material in an open bin as the formaldehyde will continue to contaminate the air.



## 4.9.2 Dealing with large spills

Some hospitals use formalin solutions in larger quantities, for example large specimen containers/buckets for whole organ fixing. A spill in this case can be up to ten litres and can cause more serious air contamination. Such a spill should only be tackled by trained personnel with appropriate personal protective equipment. This should include protective gloves, over-suit, boots and respiratory protective equipment (R.P.E.) with forced air feed or formaldehyde selective filters. The spill should be contained by absorbent booms and prevented from entering drains. The spill should then be absorbed into an appropriate absorbent medium, sealed in an airtight container and kept as special waste for professional disposal.

- Evacuate all staff from immediate area and nearby areas of spillage
- Wearing the appropriate personal protective equipment and full face mask, use a Formaldehyde spill kit to contain the spillage
- Ensure all materials used to tackle the spillage are appropriately contained and disposed of
- If no protective equipment phone emergency number for your department (e.g. 2222)
- Inform of nature and site of spillage

#### 4.9.3 Dealing with major spills

- Evacuate the area
- Break nearest fire alarm point
- Phone emergency number for your department (e.g. 2222)
- Inform of nature and site of spillage

## **5 Specimen Requirements**

All specimens should be sent to the laboratory in an appropriately labelled specimen pot that is large enough to easily accommodate the specimen. It is unsafe practice to label specimen pots in advance of a procedure.

## 5.1 Factors Affecting Performance (5.4.2 k)

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

- Failure to follow the specimen acceptance policy will result in a delay to specimen processing and reporting.
- Failure to supply adequate clinical information may result in a delay to requesting of specimen investigations and reporting.
- Failure to label requests as urgent or HSC205 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 frozen section placed in 10% neutral buffered Formalin will result in a frozen section not being performed and therefore a rapid report would not be possible.
- Specimens for cytology being placed into 10% neutral buffered Formalin as opposed to being sent fresh, in saline or cytological fixative as appropriate for the sampel type and test required
- Failure to contact consultant/laboratory in advance for a frozen section may result in a delay or even a scenario where it cannot be performed, due to a lack of availability of technical staff and/or Consultant staff.
- Specimens for immunofluorescence placed in 10% neutral buffered Formalin will prevent necessary immunofluorescence examinations.

Should any of these factors affect the issuing of a final report, then an incident may be raised in Ulysses. If a final report is able to be issued, factors that may have affected this result will be included in this report.

## 5.2 Specimen Fixation (5.4.2 k)

Specimens for routine histology are required to be placed into 10% neutral buffered Formalin, which is available on request from the laboratory. Formalin is used to fix the specimen and preserve the tissue in as life-like state as possible. If there is a delay between the removal of the tissue and fixation in Formalin, this can adversely impact the specimen integrity and therefore report.

To ensure proper specimen fixation, the following guidelines should be adhered to:

- Specimen container should be appropriately sized and large enough to easily accommodate the specimen
- Formalin ensure adequate volumes of Formalin are used
  - o 1:5 tissue to Formalin ratio for very large specimens
  - o 1:10 tissue to Formalin ratio for small specimens where possible
- Ensure the details on the specimen pot and request card match and are legible
- Ensure the lid of the specimen container is securely fastened
- Use a plastic biohazard sealable specimen bag (where possible) for the specimen pot and place the request card in the pocket

All specimens in Formalin should be stored at room temperature and <u>not</u> in the fridge prior to transport to the laboratory.

## 5.3 High Risk Specimens (5.4.2 k)

All specimens from patients who are identified as (or are likely to be) in the high-risk category must be clearly labelled to ensure the health and safety of all staff. The following are common hazard group 3 pathogens considered high risk (this list is not exhaustive): HIV, AIDS, TB, Hepatitis B and Hepatitis C. Specimens from patients with **Covid-19**, who are immunosuppressed, drug abusers and other high risk groups are also considered high risk.

Any samples taken where the patient is suspected of having <u>TB MUST</u> be divided within theatre so as to provide sufficient samples for Histology (sent in formalin) and Microbiology (sent in an empty sterile container).



To ensure health and safety of staff, high risk specimens are to be fully fixed before being processed by the laboratory. The date and time that the specimen is taken should be recorded on the request card for all high-risk specimens to enable the laboratory to calculate the fixation time on receipt. This information will minimise the infection risk to staff and prevent undue delay to processing.

Frozen sections and immunofluorescence investigations will <u>not</u> be performed on any high risk or potentially high-risk specimen.

## 5.4 Frozen Sections (5.4.2 d) 5.4.1 Booking cardiothoracic frozen section requests

To book a cardiothoracic frozen please liaise with the cardiothoracic booking clerks who can access the shared electronic diary for booking such requests. The laboratory access the electronic diary regularly to see what frozen sections are booked. Any changes to these booking should be communicated to the Histopathology department as soon as these changes are known.

## 5.4.2 Booking other frozen section requests

Frozen section requests, from either Wythenshawe or Tameside, need to be booked 24 hours in advance by calling the secretarial service on 0161 291 4813 to ensure the availability of the appropriate scientific and consultant staff.

Should the notice for a frozen section be less than 24 hours, the service may be unavailable.

# Frozen sections will <u>not</u> be performed on any high-risk or potentially high-risk specimen.

When booking a frozen section, please provide the following information;

- Patient information
- High risk status
- Clinical information
- Clinician name
- Theatre number
- Contact number

The specimen for frozen section should be transported to the laboratory in an appropriately labelled **dry** specimen container and must arrive by 4.30pm. Formalin <u>must not</u> be added. Specimens should be handed directly to the technical staff at histopathology specimen reception as a matter of urgency to ensure a timely report is issued.

When the specimen is ready to be sent to the laboratory, or if there is a delay in theatre, please contact specimen reception 0161 291 4800. If a frozen section is no longer required, please contact the laboratory immediately to cancel.

## 5.4.2 Once the frozen section has been taken

Once taken, the specimens should be delivered to the department fresh (not in formalin) as soon as practically possible, together with a tracking form / book to audit the delivery of the specimen to the department. Wythenshawe frozen sections requests are delivered directly



to the Histopathology department at Wythenshawe: specimens taken at Tameside are taken directly to the Tameside Pathology laboratory. Delay in delivery of the specimen will delay the issuing of the frozen section report.

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

A preliminary report will be issued stating the diagnosis obtained from the frozen section. To ensure a timely report is available, please provide contact details of where this report should be issued. A full report will follow once the tissue has been formalin fixed and paraffin sections examined by a Pathologist.

#### 5.5 Skin Immunofluorescence (5.4.2 d)

Skin biopsies requiring immunofluorescence need two samples to be taken from the same area. One is to be placed in formalin; the other for immunofluorescence should be placed in Mikel's medium which is obtainable from the Histopathology Department at Salford Royal Hospital. Specimens should be sent to Wythenshawe hospital histopathology; to be tracked then booked onto the laboratory information management system and then packaged by laboratory staff for hospital transport to Salford Royal hospital. Reports are returned to Wythenshawe histopathology, where they are then uploaded onto the laboratory information system.

#### 5.6 Oral Immunofluorescence samples (5.4.2 d)

The Oral Pathology Department at Oxford Road Campus has special gel tubes to preserve the specimens. Please contact them for advice on how to source the relevant specimen containers and any instructions that need to be adhered to for taking the specimen.

Specimens should be sent to **Wythenshawe hospital histopathology in the gel tubes**; these will be tracked then booked onto the laboratory information management system and then packaged by laboratory staff for hospital transport to Oxford Road Campus. Reports will be entered and released by Oxford Road and will either be available via the patient chart on HIVE or printed and issued to the appropriate location.

If the specimen taken is larger than the containers in use then please contact the histopathology department at Oxford Road Campus for further advice.

All renal biopsies should be transported to the laboratory immediately to enable urgent processing of the specimen. All specimens placed into gel transport medium for immunofluorescence should be stored in the fridge if immediate transport to the laboratory in unavailable.

#### 5.7 Pregnancy Remains (5.4.2 d)

The emergency gynaecology unit is based at Wythenshawe. It is important to ensure that the request form and PS1 form is completed fully to prevent undue delay and distress to the patient following the loss of a pregnancy. If documentation is incomplete, it may be necessary for the sender to contact the patient to confirm details.

Requests for Post Mortems (PM) on pregnancy remains that are over 12 weeks gestation should be sent to Paediatric Mortuary at Oxford Road Campus with consent and clinical



history. All pregnancy remains sent to Wythenshawe Histopathology <u>must</u> have an accompanying **fully completed PS1 form**.

#### 5.8 Limbs (5.4.2 d)

Amputated limbs for disposal should not be sent to either the Mortuary or Histopathology for disposal. Should any limbs be received for disposal, the requesting theatre will be contacted and arrangements made for the limb to be returned immediately

## 5.9 Haematological Cancer Diagnostics (HCD) (5.4.2 d)

All Histology HCD samples should be fixed in 10% buffered formalin and labelled clearly with the correct patient identifiers in accordance with the departments acceptance policy. The request should be entered onto the HOD system and allocated a unique HODS number at the clinic where the specimen has been taken.

These <u>must</u> be sent directly to Central Specimen Reception (CSR) on the ground floor of the Clinical Sciences Building, ORC.

## 5.11 Non-gynae Cytology Samples (5.4.2 d)

Non-gynae cytology specimens are either fluid based or received as smears of fine needle aspirations (FNA) or imprints of tissue biopsies on glass slides.

Specimens should be sent in sample containers of an appropriate size to adequately hold the specimen. Some specimens are received fresh, with no additives and therefore should be delivered to the department as soon as collected to prevent deterioration of the sample (see table below). Other specimens are received in cell collection fluid or a preservative such as cytorich red. These preservatives assist with preservation of the cells within the sample. In the case of <u>thyroid aspirates</u> some slides should be fixed using the alcohol based fixative spray and some air dried. The air dried slides are for Giemsa staining.

Cytorich red and alcohol spray fixative are both available from cytology by contacting the cytology laboratory.



Cytology samples						
Test	ТАТ	Sample type	Biological Interval / Clinical Decision Values	Special precautions/ Information		
Serous fluid	7 days					
Urine	7 days					
Bronchial washings	7 days					
Bronchial-alveolar lavage	7 days					
Sputum	7 days					
Bladder washings	7 days					
Urethral washings	7 days	and the second s	Ν/Δ	N/A		
Ureteric washings	7 days		N/A			
Cyst fluid	7 days	70ml Starile container				
Serous fluid	7 days	70mi Sterlie container				
Urine	7 days					
Bronchial washings	7 days					
Bronchial-alveolar lavage	7 days					
FNA	7 days					
EUS	7 days					
Bronchial brushings	7 days			Cytorich red available from the cytology		
Bile brushings	7 days	OR	N/A	laboratory		
FNA lymph node	7 days	Plain container 70ml Sterile container				

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Cytology samples						
Test	ТАТ	Sample type	Biological Interval / Clinical Decision Values	Special precautions/ Information		
FNA thyroid	7 days					
FNA parotid	7 days					
FNA breast	7 days	Plain container OR   70ml Sterile container   AND 2 air-dried slides	N/A	Cytorich red available from the <u>cytology</u> <u>laboratory</u> .		
Buccal smears	7 days		N/A	4 fixed smear slides Alcohol spray fixative is available from the <u>cytology laboratory</u>		
Tongue smears	7 days					
	7 days			1 fixed smear slide		
EBUS	7 days	CellStor Pot Minute Address of Ad		Ensure 10% Neutral Buffered Formalin Histology Pot is labelled with the patient's details before the procedure (you can use HIVE generated labels but ensure sample is only transferred when pot is correctly labelled). <u>cytology laboratory</u>		



Cytology samples								
Test	ТАТ	Sample type	Biological Interval / Clinical Decision Values	Special precautions/ Information				
				Please change the 10% Neutral Buffered Formalin Histology Pot every time a new station is being sampled				



## 5.11.1 Broncho-alveolar lavages (BAL)

These specimens requiring a differential cell count should be received on ice and by 5pm on working days only. This is to ensure the appropriate slide preparations can be made. The non-gynae cytology department can examine for Pneumocystis carinii on Broncho-alveolar lavage specimens if required however, the preferred method is for the sample to be sent to microbiology.

#### 5.11.2 Endobronchial ultrasound guided aspirate specimens (EBUS)

These should be delivered to the department as soon as possible so that preparation of the samples can be undertaken. It is appreciated that reports are wanted on these specimens in a timely fashion for MDT discussion.

#### 5.11.3 Joint Fluids

Joint fluids should be sent to Cytology. For any cases where microbiology testing is also required, two separate samples should be collected and two requests made; one for cytology testing and the other for microbiology testing. Failure to request separate testing will result in a delay in cytology testing as the sample will first be sent to microbiology based at Oxford Road Campus, before being returned to the Cytology department at Wythenshawe Hospital for testing. This may lead to an erroneous result due to the delay in testing and potential degradation of the specimen.

## 5.12 Cervical Cytology (5.4.2 d)

Cervical cytology is sent to Oxford Road Campus for reporting. The contact details are:

Jacquelyn Medlock <u>Jacquelyn.Medlock@mft.nhs.uk</u> Cytology Manager	Manchester Cytology Centre Clinical Science Building 2	Tel: 0161 276 5119 Fax: 0161 276 5113
Adanna Ehirim <u>Adanna.Ehirim@mft.nhs.uk</u> Lead BMS Cytopathology	Manchester Royal Infirmary Oxford Road Manchester M13 9WL	

## 5.13 Immunohistochemistry (5.4.2 d)

The Immunohistochemistry Laboratory is situated on the ground floor of the Clinical Sciences Building and provides IHC testing for both our ISO accredited histology and cytopathology services.

We currently house two automated Ventana BenchMark Ultra staining machines which we use to carry out our routine clinical work. We currently hold a repertoire of over 90 antibodies, listed on our Antibody Repertoire List and are enrolled in the UKNEQAS ICC quality assurance scheme.



Any clinician wishing to request specific immunohistochemistry antibody markers should discuss this with the reporting pathologist. It is not appropriate to contact the laboratory directly to request IHC.

## 5.14 Specialised testing (5.4.2 d)

The laboratory performs the following specialised tests for patients accessing Wythenshawe hospital Histopathology services as well as referral tests for hospitals within Greater Manchester and wider regions;

- Breast HER-2 confirmatory testing (DDISH).
- PD-L1 (triple negative breast cancer)
- PD-L1 (lung cancer)
- ALK (lung cancer)

Full scope of practice can be found on the UKAS website.

## 5.15 Referrals (4.5)

The laboratory on occasion refers material (paraffin embedded blocks or stained slides) to the Manchester Haematological Cancers Diagnostic Partnership. This is a joint partnership between Manchester Foundation Trust and the Christie Hospital for confirmation and classification of lymphomas and to the Christie Hospital for opinion and / or confirmation of pathology in a small number of cases.

Material may also be referred to St. Marys Genetics department for Genetic / molecular testing which quotes a 10-day turnaround time for results. This includes EGFR, BRAF and KRAS.

The department regularly receives requests for expert/second opinion from other hospitals. A very small number of cases are referred to other Specialist Histopathologists for expert second opinion or review and in response to service pressures. The following are the most used:

Туре	Address		
Lymphomas	Via the HCD partnership with The Christie.		
Reporting/Vacancy cover	Source Bioscience, 1 Orchard Place, Business Park, Nottingham, NG8 6PX		
Reporting/Vacancy cover	Diagnexia, Science Park Centre, 6 Babbage Way, Exeter Science Park, Clyst Honiton, Exeter, EX5 2FN		
Preparation of samples	Cellular Pathology Services, Unit 12, Orbital 25 Business Park, Dwight Road, Watford, WD18 9DA		
Genetics	Manchester Centre for Genetic Medicine 6th Floor, St Mary's Hospital, Oxford Road, Manchester M13 9WL		

## 5.16 Return of tissues (5.7.2)

On occasion, patients request the return of tissues following a surgical procedure. This may be for various cultural or religious reasons. Patients have a right to have their tissues



returned to them. Any request for the retention of specimens should be referred to a Histopathologist and Deputy Laboratory Manager within Histopathology at Wythenshawe hospital.

- 1. If there is no need for the tissue to be examined histologically and the patient wishes to take it away immediately, then it does not need to be sent to the Histopathology department.
- 2. In some cases, the tissue needs to be examined histologically. The remaining tissue will then be returned to the patient by the Histopathology department. Sometimes the patient is hospitalised or is uncertain as to what he wants done with the tissue, in which case it will be stored by the Histopathology department. In such cases, please speak to the Deputy Laboratory Manager or Lead Biomedical Scientist to ensure that the patient's wishes are met with regard retention and return of their tissue sample. Please be aware that failure to inform the department that the patient wishes to have their tissue sample retained and returned to them may result in the specimen being disposed of as tissue samples are only kept in the department for 4 weeks following the issue of a histology report. If the specimen is able to be returned to the patient, written advice as to the hazards of the formalin fixative used will be provided.

## 5.17 Disposal of tissues (5.7.2)

Specimens are not permitted to be sent to histology for disposal purpose. We provide a diagnostic service, not a disposal service. Any specimens received where disposal is indicated will be processed and a report issued. Pregnancy remain (POC) specimens may be disposed of without histological examination if indicated by the patient on the PS1 form. If so, the specimen should be sent directly to the Mortuary for disposal to be arranged as per the patient's wishes.

## 5.18 Manchester Cancer Research Centre Tissue Bank (5.7.2)

The <u>Homepage - Manchester Cancer Research Centre</u> is an initiative to collect and bank tissue samples from cancers to facilitate research. The project started collecting in April 2008. To contact the team please ring 0161 446 3659 or click on the hyperlink above.

## **6 Communication of Results**

## 6.1 Reports (5.4.2 I)

All reports issued by the department are available on the relevant Trusts' electronic systems. This will be EPR at Wythenshawe site and Lorenzo within Tameside. For primary care, paper reports are distributed to the GP practice systems.

Paper reports are still sent to the users at Tameside and some GP practices. Tameside reports, including those for the Tameside GP practices, are transported back to the Pathology Department at Tameside site using the twice daily transport. They are then



distributed as required from Tameside Pathology. Paper reports for GP practices within the Wythenshawe Site catchment area are sent via second class post.

#### **Histology Reports**

Generic contact details	Location	Extension	Information
Report enquiries	Office	0161 291 4813	At times, this number may have an answering machine: please leave a clear request and a number for us to call you back
Departmental nhs.net email address			Mft.wythenshawe.histosecs@nhs,net

Users are requested to check if final reports are available on the patient chart in HIVE before making enquiries. Please note that clerical staff <u>will not</u> give report details over the telephone.

#### 6.2 Turnaround Times (5.4.2 d)

The Histopathology department monitors turnaround times in line with the RCPath key performance indicators – proposals for implementation July 2013. This document states that 80% of diagnostic cases should be reported within 7 calendar days and 90% within 10 calendar days.

For up-to-date information on the department's current turnaround figures, please contact the Laboratory Manager.

The department works to RCPath Key Performance Indicators (KPI). The target is to report 80% of diagnostic biopsy cases within 7 days, and 80% of all specimens within 10 days (except those requiring decalcification).

Reporting times for all specimens, including urgent and HSC205, may be extended if they are high risk specimens, large resection specimens or calcified or bony samples. Any case requiring specialist techniques such as immunohistochemistry or electron microscopy will also likely have extended reporting times. Some cases may require referral to a specialist referral centre, which can prolong reporting times. This would include samples such as lymphomas, which are routinely referred to the Christie via the Haematological Cancer Diagnostics Service. However, a preliminary report would be issued beforehand. An appropriate frozen section request will aim to be reported by telephone within 60 minutes. Frozen sections should normally be booked with the laboratory beforehand.

To ensure we meet our turnaround time targets, all urgent and HSC205 specimens <u>must</u> be clearly labelled as such. There are several factors that may affect the turnaround time of a specimen, such as those mentioned in 5.1 Factors Affecting Performance.

#### 7 Enquiries and Complaints (5.4.2 n)

To enable us to deal with enquiries efficiently, please ensure you use the correct contact information, as detailed in section 2 (Contact us).



## 7.1 Errors and complaints (5.4.2 n)

There is evidence that the rate of clinically significant reporting errors for Histopathologists is 1 to 2%. Since histology often provides the definitive diagnosis, error in histology may have a profound impact on patient management. There are things that you can do to reduce the occurrence and impact of errors:

- Make sure that request cards and specimen pots meet the requirements of the sample acceptance criteria with unambiguous and correct patient demographics.
- Provide clinical information on the request card, including details of previous specimens, whether here or in another hospital.
- Question cases where there is an apparent discrepancy between the clinical, radiological and pathological diagnosis.
- Review cancers at an MDT

The department is committed to fully investigating all complaints regarding the standard and quality of services that we offer. Please contact our laboratory manager according to information below.

Laboratory Manager							
Katherine Congdon	0161 276 6138	katherine.congdon@mft.nhs.uk					