



MFT Adult Histopathology Service User Guide Oxford Road and Wythenshawe

Department of Cellular Pathology

Division of Laboratory Medicine

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1 Introduction

This user guide details information for the requesting of investigations, specimen requirements and communication of results for the department of **Adult Histopathology at Oxford Road (ORC) and the department of Histopathology and at Wythenshawe Hospital**. Please see the separate user guide for Paediatric Histopathology and cytology including diagnostic cytology.

The Adult Histopathology department at ORC is situated in Clinical Sciences Building 1 at Manchester Royal Infirmary whilst our Cellular Pathology department at Wythenshawe is located on the ground floor of the Clinical Sciences Building at Wythenshawe Hospital. Both form part of the wider Department of Cellular Pathology.

Both sites provide comprehensive services to Manchester University NHS Foundation Trust including the Greater and Southern Manchester area, General Practitioners, Dental Practitioners and also provide specialist tertiary referral and opinion on a regional and national basis.

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 -Please note that with the exception of EBUS clinic samples all cardiothoracic and respiratory specimens should be sent to Wythenshawe Histopathology
- Ophthalmic pathology
- Breast pathology

Both sites are supported by our Immunohistochemistry, Electron Microscopy, Cellular Pathology Genomics Centre and Research services.

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:

http://haematologyetc.co.uk/Manchester_Haematological_Cancers_Diagnostic_Partnership

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 departments deal with approximately 75,000 surgical cases (35,000 at ORC and 40,000 at Wythenshawe) and around 1200 autopsies on behalf of HM Coroner annually. Our combined departments comprise of around 150 medical, scientific and ancillary staff and has an excellent reputation for clinical and scientific training. The ST1 Training School, which was opened in 2005, offers entry to run-through training for high quality entrants to the

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Histopathology specialist training scheme of the Northwest Deanery. 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 laboratory at ORC is open 07.00 – 17.00 Monday to Friday, excluding public holidays. We do not offer an out-of-hours or on-call service.

The laboratory at Wythenshawe is open 07.00 - 19.00 Monday to Friday 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.

2.2 Location (5.4.2 a)

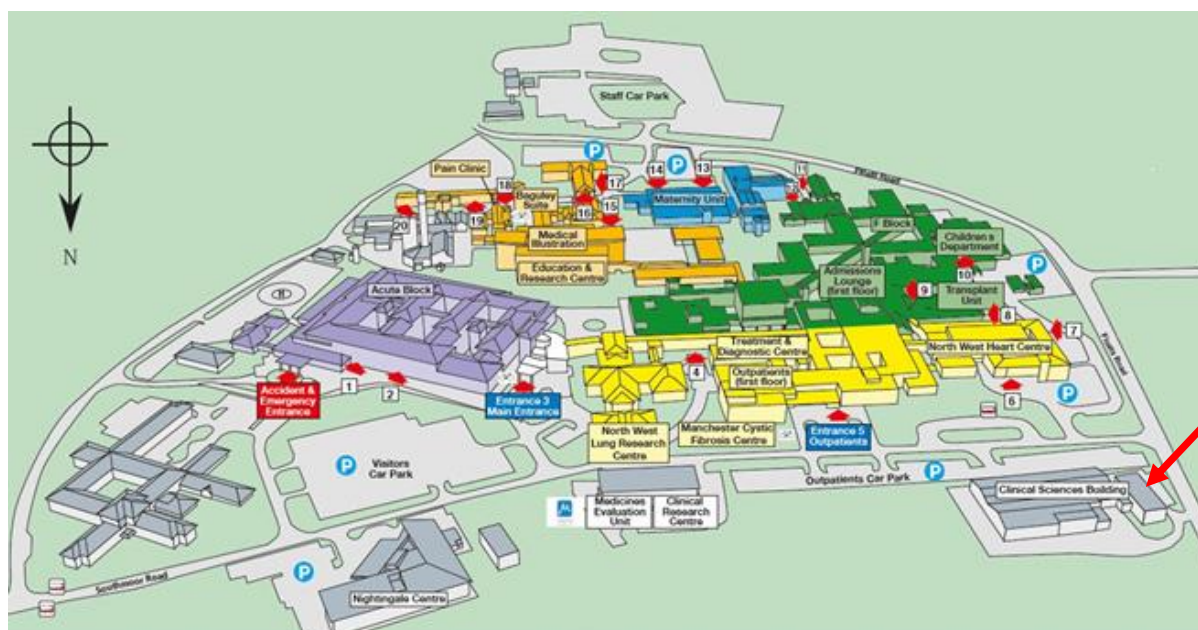
The reception at Oxford Road is located on the 1st floor of Clinical Sciences Building 1 (CSB1) at Manchester Royal Infirmary.



Address: Adult Histopathology
1st Floor, Clinical Sciences Building 1
Manchester University NHS Foundation Trust
Oxford Road
Manchester
M13 9WL

The reception at Wythenshawe hospital is located on the ground floor of the Clinical Sciences Building

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

2.3 Contact Information (5.4.2 I)

Histology Reports

Generic contact details	Location	Extension	Information
Report enquiries – ORC	Office	0161 701 1615	At times, this number may have an answering machine: please leave a clear request and a number for us to call you back
Report enquiries - Wythenshawe	Office	0161 291 4813	
Departmental nhs.net email address	ORC		mft.adult.histosecs@nhs.net
	Wythenshawe		mft.wythenshawe.histosecs@nhs.net

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

All enquiries regarding frozen sections, specimen requesting, labelling, transport and requirements should be directed to our Specimen Reception. Details for this as well as our sub-departments, please see below.

Specimen Reception	ORC	0161 276 8808
	Wythenshawe	0161 291 4800
Main Laboratory - Histology	ORC	0161 276 6449
	Wythenshawe	0161 291 4800
Immunohistochemistry	ORC	0161 276 8786
	Wythenshawe	0161 291 3315
Electron Microscopy	ORC	0161 701 0795

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Research	ORC	0161 276 8814
Ophthalmic	ORC	0161 276 5806

Key Contact Details

Senior Leadership Team	Site	Tel No.	Email address
John Hayes Cellular Pathology Directorate Manager	Both	0161 276 6138	John.hayes@mft.nhs.uk
Dr Chitra Sethuraman Cellular Pathology Clinical Director	Both	0161 701 2375	Chitra.sethuraman@mft.nhs.uk
Peter Helliwell Deputy Directorate Manager Cellular Pathology	Both	0161 701 7783	Peter.helliwell@mft.nhs.uk
Gajan Sivarajah Lead BMS – ORC	ORC	0161 276 5806	Gajan.sivarajah@mft.nhs.uk
Catherine McNulty Lead BMS - Wythenshawe	Wythenshawe	0161 291 4804	Catherine.mcnulty@mft.nhs.uk
Anna McEwen Lead BMS – Ophthalmic	ORC	0161 276 5806	Anna.McEwen@mft.nhs.uk
Lee Crompton Lead BMS – Electron Microscopy	ORC	0161 701 0795	Lee.Crompton@mft.nhs.uk
Alma Askew Deputy Lead BMS – ORC	ORC	0161 276 6449	Alma.askew@mft.nhs.uk
Christopher Harreld Deputy Lead BMS – Wythenshawe	Wythenshawe	0161 291 4804	Christopher.harreld@mft.nhs.uk

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MFT Consultant Name, Contact Details and Speciality

Consultant Name ORC Based Wythenshawe Based	Telephone	Email	Breast	Cardio-thoracic	Dermatology	Endocrine	Gastro- intestinal	Gynaecology	Head and Neck	Lympho- reticular	Ophthalmic	Osteoarticular	Renal	Urology
Dr Guy Conlon	0161 276 8811	Guy.conlon@mft.nhs.uk					✓						✓	
Dr Dane Pointing	0161 276 8811	Dane.pointing@mft.nhs.uk					✓							
Dr Charlotte Wilson	0161 701 6248	Charlotte.Wilson@mft.nhs.uk							✓					
Dr Diana Oelofse	0161 701 1614	Diana.oelofse@mft.nhs.uk								✓				
Dr Amani Brown	0161 701 3559	Amani.brown@mft.nhs.uk												
Dr Sidra Jahangir	0161 701 6248	Sidra.Jahangir@mft.nhs.uk					✓	✓						
Dr Praveen Shankar Balasubramanian		P.Balasubramanian@mft.nhs.uk											✓	
Dr Rachna Khera		Rachna.Khera@mft.nhs.uk					✓	✓						
Dr Tegan Esme Alexandra Miller	0161 276 6348	TeganEsmeAlexandra.Miller@mft.nhs.uk						✓						✓
Dr Richard Chasty	0161 701 1614	Richard.Chasty@mft.nhs.uk								✓				
Dr Luciane Irion	0161 701 1614	Luciane.Irion@mft.nhs.uk									✓			
Dr Debbie Baishnab	0161 276 8812	Debbie.Baishnab@mft.nhs.uk						✓						
Dr Richard Byers	0161 701 1614	richard.byers@mft.nhs.uk								✓				
Dr Asma Haider	0161 701 6248	Asma.Haider@mft.nhs.uk						✓				✓		
Dr Lucy Foster	0161 276 8812	Lucy.Foster2@mft.nhs.uk					✓							
Dr Guy Betts	0161 701 6248	Guy.Betts@mft.nhs.uk							✓					

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Consultant Name ORC Based Wythenshawe Based	Telephone	Email	Breast	Cardio-thoracic	Dermatology	Endocrine	Gastro- intestinal	Gynaecology	Head and Neck	Lympho- reticular	Ophthalmic	Osteoarticular	Renal	Urology
Dr James Bolton	0161 276 8811	James.Bolton@mft.nhs.uk						✓						✓
Dr Katalin Boros	0161 701 6248	Katalin.Boros@mft.nhs.uk			✓							✓		
Dr David Osborne	0161 701 1614	David.Osborne@mft.nhs.uk								✓				
Dr Thomas Pilkington	0161 276 8811	Thomas.Pilkington@mft.nhs.uk						✓						
Dr Sarah Morcos	0161 701 1614	Sarah.Morcos@mft.nhs.uk			✓					✓				
Dr Gabrielle Slavin	0161 701 1614	Gabrielle.Slavin@mft.nhs.uk								✓				
Dr Stephanie Edwards	0161 701 6248	Stephanie.edwards4@mft.nhs.uk							✓					
Dr Mohsin Mazhari	0161 701 1614	Mohsin.Mazhari@mft.nhs.uk			✓									
Dr Noreen Akhtar	0161 701 6248	Noreen.akhtar@mft.nhs.uk							✓					
Dr Umar Hussain (Due to CCT in February 2025)	-	umar.hussain2@mft.nhs.uk			✓				✓ (H&N skins)					
Dr Irem Buldum (Speciality Dr)	-	irem.buldum@mft.nhs.uk						✓						
Dr Weihong Ma	-	weihong.ma@mft.nhs.uk						✓						
Dr Mickhael Barrow (Bank Consultant)	-	mickhael.barrow@mft.nhs.uk			✓	✓	✓	✓	✓	✓				✓
Dr Leena Joseph	0161 291 4808	leena.joseph@mft.nhs.uk	✓	✓	✓									
Dr Nadine Elgeredly	0161 291 2819	Nadine.elgeredly@mft.nhs.uk	✓											✓
Dr Nisha Ali	0161 291 5663	nisha.ali@mft.nhs.uk	✓		✓			✓						

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Consultant Name ORC Based Wythenshawe Based	Telephone	Email	Breast	Cardio-thoracic	Dermatology	Endocrine	Gastro- intestinal	Gynaecology	Head and Neck	Lympho- reticular	Ophthalmic	Osteoarticular	Renal	Urology
Dr Sarah King	0161 291 4818	Sarah.king@mft.nhs.uk	✓				✓							
Dr Susan Pritchard	0161 291 2143	susan.pritchard@mft.nhs.uk	✓				✓							
Dr Antonio Paiva Correia	0161 291 4805	Antonio.PaivaCorreia@mft.nhs.uk		✓	✓									
Dr Claire Ruddiforth	0161 291 2598	Claire.ruddiforth@mft.nhs.uk	✓		✓									
Dr Kavita Singhal	0161 291 4793	Kavita.singhal@mft.nhs.uk	✓		✓									
Dr Laura Ann Shepherd	0161 291 4??	lauraann.shepherd@mft.nhs.uk	✓		✓									✓
Dr Paul Bishop	0161 291 2159	paul.bishop2@mft.nhs.uk		✓						✓				
Dr Krishnendu Halder	0161 291 4930	Krishnendu.halder@mft.nhs.uk		✓			✓	✓						
Dr Jonathan Shanks	0161 291 4796	Jonathan.shanks@mft.nhs.uk			✓									✓
Dr Preethi Joseph	0161 291 4756	preethi.joseph@mft.nhs.uk			✓		✓							✓
Dr Iman Borghol	-	Iman.borghol2@mft.nhs.uk						✓						✓
Dr Anna Davenport	0161 291 5311	anna.davenport@mft.nhs.uk					✓							
Dr Nichola Gaunt	0161 291 4812	Nichola.gaunt2@mft.nhs.uk			✓									
Dr Ishitha Gunadala	0161 291 2138	Ishitha.gunadala@mft.nhs.uk		✓	✓									
Dr Rebecca Mckerrell	0161 291 4786	Rebecca.mckerrell@mft.nhs.uk	✓	✓	✓									
Dr Michael Scott	0161 291 2144	Michael.scott@mft.nhs.uk					✓	✓						✓
Dr Emily Tyler		Emily.Tyler2@mft.nhs.uk	✓				✓							

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3 Quality

Our Cellular Pathology Service across all sites is fully accredited by UKAS in conformance with ISO 15189:2022. Our UKAS Medical Laboratory Reference Number is 8648. The department participates in regular exhaustive assessments to maintain its accreditation status. The department is licensed by the Human Tissue Authority (HTA). The department is committed to deliver a quality service to our users and 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

- Tissue Diagnostics – submission of H&E and corresponding block from each processor that is registered as an asset.
- Specialist Techniques – submission of stained slides which includes
 - Special Stains on sections provided by UKNEQAS,
 - Renal Biopsy Pathology,
 - Bone Marrow Pathology,
 - Mega slides
 - and Frozen Sections.

UKNEQAS for Immunocytochemistry and In Situ Hybridisation

- General Pathology – Both Sites
- Breast Pathology (Hormonal Receptors) – Wythenshawe Only
- Breast Pathology (HER-2) – Wythenshawe Only
- Breast Pathology Low Her-2- Wythenshawe Only
- Lymphoid Pathology – Both Sites
- Alimentary Tract Pathology – Both Sites
- ISH – Breast Pathology (DDISH only). – Wythenshawe Only
- MMR – ORC Only
- ALK NSCLC – Both Sites
- PD-L1 – Both Sites
- PDL1 clone 22C3 (pilot) ORC only
- PD-L1 breast SP142– Wythenshawe Only
- ROS-1 – ORC Only
- KI67– Wythenshawe Only
- Head and Neck Advance Staining for P16 (Pilot) – ORC Only
- Electron Microscopy- ORC only

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

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- 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 PS1 consent 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 urgent and specimens on a cancer tracking pathway (HSC205) 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 samples sent to the laboratory must comply with our specimen acceptance requirements and be accompanied by a correctly completed histology request form. For test requests ordered on the Hive Electronic Patient Record (EPR) system. For non-Hive requests, samples sent from an External source or paper requests raised during Hive downtime, the following mandatory information must be provided for us to accept the specimen:

Essential Patient Identifiers:

- Surname
- Forename

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- **Unique identification number** – Medical Record Number (MRN), NHS or external hospital number for external cases
- **Date of birth**
- **Address** – for 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 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 of infection status** – to ensure health and safety of all staff
- **Specimen site** – must match on specimen pot and request card
- **Relevant clinical information** – to ensure all necessary investigations are performed, gestation date and LMP for gynaecological specimens
- **For Lung cancer** - 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 specimens

Essential Sender Details:

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

Specimens that do not contain the required information or have discrepancies between the request card and specimen pot will not be processed in the laboratory until the necessary information has been obtained. The sender will be contacted via email or instant messaging on Hive (internal MFT only) to rectify any problems. In the event the sample is unrepeatable, the department has protocols in place to deal with specimens/request forms that do not meet the specimen acceptance criteria however, a final report will not be issued until such details have been corrected.

If the discrepancy cannot be rectified by email or instant messaging or the changes are too substantial the sender will be asked to attend the laboratory to rectify the issue.

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The person correcting the patient or specimen details should be of appropriate seniority and able to take responsibility for the labelling of the specimen. This will result in a delay to specimen processing and reporting.

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, Medical Record Number (within MFT). 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) still require a request card for 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)

Labelling multiple samples from the same patient



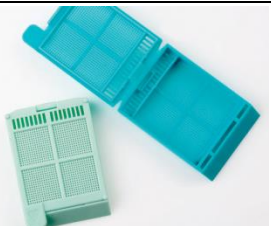

If there are multiple samples from the same patient from different sample sites or multiple samples from the same site:

1. Ensure each sample is collected in the appropriate sample collection pot (see section 4.4)
2. Ensure each pot is fully labelled with all the appropriate patient demographic information (see section 4.1)– for HIVE orders each pot should have a unique sample label generated
3. Ensure each pot is labelled with the specific sample source location i.e. skin lesion left arm

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4. If there is more than 1 sample / pot for a specific sample source location label each pot numerically, in the order they were taken.

Sample containers

Container type	Description	Use
CellPath CellStor	 Container prefilled with formalin Available from the histology laboratory	Small histopathology samples
Bucket	 Bucket prefilled with formalin Available from the histology laboratory . 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.
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 should not be placed into the fridge as this will have a negative impact on fixation and therefore preservation of the tissue.

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Specimen	Storage
Formalin	Room temperature
Dry unfixed	Fridge
Zeus medium	Room temperature
Gel transport medium	Fridge
Michel's transport medium	Fridge
Gluteraldehyde	Room Temperature

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. Specimens in Zeus medium should be stored at room temperature. Zeus medium should ideally be stored in the fridge prior to use.

4.5 Transport of Specimens (5.4.2 h)

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

The transport of hospital specimens to the department is undertaken by the respective hospitals transport portering teams. Dependent on the site, dedicated transport boxes/packaging will be used to deliver the specimen pots to the laboratory. 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.

All specimen pots should be tightly sealed and transported using specimen bags, where appropriate. The request card if included 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 should be received with a documented tracking sheet detailing patient identifiable information such as specimen type and where the specimen has been taken. These tracking sheets are checked on arrival in the histology department and returned to the porter, department or area the specimen was taken from for staff to record that the specimen has been received safely in Histology.

There is also a transport pathway system for the transfer of specimens between MRI, Trafford General Hospital and Wythenshawe Hospital as well as Transport between Wythenshawe Histopathology, Withington Community Hospital, and Oxford Road Campus. These specimens should be sent via a packing list on Hive so they can be accepted by histology reception staff for audit and tracking purposes.

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 MFT 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.

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Samples from the GP surgeries within the South Manchester District are delivered to the main pathology reception area at Wythenshawe 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.

Any fresh specimens (not delivered in formalin) 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.

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.

Any 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, packaged and tracked.

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)

At ORC:

All requests for Formalin pots should be sent via the porter, the pneumatic tube or by email to our specimen reception using the appropriate request form available from the laboratory. MRI and Trafford theatres have separate request forms, as do GPs. Requests will be dealt with as soon as is practicable, however if you require the pots urgently please inform the laboratory by telephone on **68808**. Sufficient notice should be given.

At Wythenshawe:

We supply prefilled containers of all sizes to departments at Wythenshawe Hospital and empty buckets and prefilled biopsy pots to Tameside Hospital. please contact the laboratory on 0161 291 4800. 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

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

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. There are 3 suppliers of formalin Cell Solv, Genta and Cell path Cellsolv provides 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 – CellSolv Version 2 (Jan 2019) (external safety data sheet, contact laboratory if required)

Disposal of formalin depends on water board at laboratory location. Wythenshawe- formalin cannot be disposed of down the sink and is collected in waste containers and collected by a licensed waste disposal company. ORC-Formalin can be disposed of down a sink suitable for clinical waste with copious amounts of running water in a well-ventilated room.

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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:

- At ORC - contact the laboratory immediately on 0161 276 8808 during work hours only (9-5pm Monday to Friday) . Please give full details of your location and a fully trained member of staff will attend the spillage. Outside of these hours please provide hospital spillage protocols.
- At Wythenshawe - please follow local hospital spillage protocols. Or contact the laboratory for further information and advice Mon-Fri 09:00-17:30 on 0161 291 4800.

Our Formalin suppliers, Cell Solv and 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

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- Ensure all materials used to tackle the spillage are appropriately contained and disposed of
- If no protective equipment is available, phone the emergency number for your department (e.g. 2222) Inform them 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.
- 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.

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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
 - 1:5 tissue to Formalin ratio for very large specimens
 - 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 not 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 of infection 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, CJD, 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 TB MUST 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 not be performed on any high risk or potentially high-risk specimen.

5.4 Frozen Sections (5.4.2 d)

5.4.1 Booking other frozen section requests

All intra-operative frozen sections should be booked with the appropriate laboratory site at least 24 hours in advance, where possible. This is to ensure the availability of the appropriate scientific and consultant staff. Where this is not possible, the laboratory should be contacted at the earliest opportunity when theatre staff are aware a frozen section is required. Every attempt will be made to provide frozen sections during the laboratory opening hours, providing appropriate clinical and technical staff are available.

To book a frozen section please contact:

- **At Oxford Road – please ring the laboratory reception on 0161 276 8808**
- **At Wythenshawe – please ring the secretarial service on 0161 291 4800**

Frozen sections will not be performed on any high risk or potentially high-risk specimen.

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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 before 4.30pm. Formalin must not 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 the relevant site number as above. 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. Oxford Road and Wythenshawe frozen sections requests are delivered directly to the Histopathology department at the same site: 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 Immunofluorescence (5.4.2 d)

5.5.1 At Oxford Road:

All renal, skin, oral and conjunctiva specimens that require immunofluorescence investigation should be placed into Zeus transport medium or Michel's medium. These specimens should not be placed into Formalin as this technique cannot be performed on fixed tissue. Zeus transport medium is available on request from our specimen reception.

All Zeus pots should be labelled with the appropriate patient information as detailed in our specimen acceptance policy. Immunofluorescence will not be performed on high risk or potentially high risk specimens due to the health and safety risk it poses to staff.

5.5.2 Skin Immunofluorescence at Wythenshawe:

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

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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.

5.5.3 Oral Immunofluorescence samples at Wythenshawe:

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.

5.6 Renal Biopsy (5.4.2 d)

All renal biopsies should be transported to the laboratory immediately to enable urgent processing of the specimen. All specimens placed into Zeus for immunofluorescence should be left at room temperature prior to arrival in histology. Samples in other transport mediums such as Michel's medium or gel transport medium should be stored in the fridge especially if immediate transport to the laboratory is unavailable.

5.6.1 Native Biopsies

Where possible, two cores of native renal tissue should be obtained to enable investigation into native renal disease. A good quality core of renal tissue is required for routine histology investigations and should be placed in an appropriately labelled container of 10% Formalin. The second core should be placed into I transport medium for immunofluorescence medium, however if there is any uncertainty regarding the adequacy of the sample then both cores should be placed in Formalin.

5.6.2 Transplant Biopsies

Patients who have had their transplant for less than 3 months:

- Two cores, if possible, and both placed into 10% Formalin.

Patients who have had their transplant for more than 3 months:

- Treat as native biopsy (see above).

5.7 Pregnancy Remains (5.4.2 d)

The emergency gynaecology unit is based at Wythenshawe. However, pregnancy remains for Adult Histology will be accepted from MFT patients admitted to St Mary's and triaged as appropriate. 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.

Pregnancy remains from Tameside locations are also accepted at Wythenshawe. Specimens for cytogenetics should NOT be sent to cellular pathology from any site. These should be sent directly to cytgenetics.

Manchester Centre for Genomic Medicine

Division of Laboratory Medicine

6th Floor
St Mary's Hospital
Oxford Road
Manchester
M13 9WL

Telephone: 0161 276 6506

Requests for Post Mortems (PM) on pregnancy remains that are over 12 weeks gestation should be sent to Paediatric Mortuary with consent and clinical history. All pregnancy remains sent to Adult Histopathology must have an accompanying **fully completed PS1 form**.

5.8 Endobronchial ultrasound guided aspirate specimens (EBUS) (5.4.2 d)

These should be delivered to the Histology department at Oxford Road 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.

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).

5.9 Limbs (5.4.2 d)

Please notify the laboratory of all limb amputations at the earliest opportunity on:

- At Oxford Road - 0161 276 8808.
- At Wythenshawe - 0161 291 4800

Amputated limbs for disposal at Wythenshawe 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

5.10 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 must be sent directly to Central Specimen Reception (CSR) on the ground floor of the Clinical Sciences Building, ORC.

5.11 Ophthalmic Pathology (5.4.2 d)

Ophthalmic pathology forms part of Adult Histopathology and provides a diagnostic service in Ophthalmic Histopathology and Cytopathology. It is one of four laboratories within England making up the National Specialist Ophthalmic Pathology Service (NSOPS).

The laboratory aims to provide a high quality and timely service with provision of expertise in diagnosis using an appropriate range of techniques including histology, cytology, immunofluorescence, immunohistochemistry, and electron microscopy. Specimen requirements differ depending on the investigations required.

More information can be found in the Ophthalmic Histopathology user guide:

<https://mft.nhs.uk/the-trust/other-departments/laboratory-medicine/histopathology/>

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5.12 Biobank and Cellular Pathology Research (5.4.2 d)

Research and Innovation at MFT offers a biobank and cellular pathology research service. The biobank and research teams provide a high quality and not-for-profit sourcing, storage, preparation and analysis of human biological samples service. We support clinical trials and research projects led by the NHS, universities and commercial partners. As part of the NHS, the biobank and research teams aim to improve people's health by providing a valuable resource to researchers wanting to understand the development and genetic links of disease.

The biobank offer the following services:

- Banked samples
- Sample collection
- Pre-analytics and storage services
- Extraction and analysis

Cellular pathology research offers the following services:

- Processing, paraffin embedding and sectioning of fixed tissue
- Electron microscopy (subject to requirements)
- Frozen sectioning of fresh tissue samples
- Immunohistochemistry (IHC) including single and dual staining
- Antibody optimisation for IHC
- Chromogenic in-situ hybridisation (CISH)
- Silver in-situ hybridisation (SISH)
- Standard H&E and special staining techniques
- Pathological review

More information can be found at:

<https://mft.nhs.uk/the-trust/other-departments/laboratory-medicine/histopathology/>

All biobank and research requests require a formal application. For more information please contact the relevant department.

Biobank	0161 701 1890
Histology Research	0161 276 8814

5.13 Immunohistochemistry (5.4.2 d)

The Adult Immunohistochemistry Laboratory are found at both sites. At ORC this is situated on the ground floor of the Cadet building, in clinical sciences. At Wythenshawe it is located on the ground floor of the clinical sciences building. IHC service provides IHC testing for both our ISO accredited histology and cytopathology services. We currently house eight automated Ventana BenchMark Ultra Plus staining machines and one automated Ventana Benchmark Ultra staining machine which we use to carry out our routine clinical work. We currently hold a repertoire of over 150 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.

The laboratory is the regional referral centre for Diagnostic Mismatch Repair (MMR) testing, working alongside the genetics department in St Mary's Hospital for genetic testing referrals.

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Requests should be directed to the IHC laboratory. Clinical trial material requests and research projects are also processed in the department.

More information can be found at:

<https://mft.nhs.uk/the-trust/other-departments/laboratory-medicine/histopathology/>

5.14 Electron Microscopy (5.4.2 d)

The Cellular Pathology Electron Microscopy (EM) Service is situated on the Ground Floor of Clinical Sciences Building 1 at Manchester Royal Infirmary. It provides a high quality adult and paediatric diagnostic transmission electron microscopy service for MFT and for several external Trusts nationwide. The unit is open and staffed from 08:00 – 17:15 Monday to Friday (except bank holidays).

Approximately 90% of the samples handled are renal. Electron microscopy is routinely carried out on both native renal biopsies and longstanding renal transplant biopsies. For all other specimen types, electron microscopy will be undertaken at the specific request of the reporting Consultant Histopathologist. If the user would specifically like to request electron microscopy on a specimen, an appropriate Consultant Histopathologist must be contacted prior to biopsy. For any other information please contact the Lead Biomedical Scientist for Electron Microscopy on 0161 701 0795 or 0161 276 8806.

Current or prospective service users external to the Trust can find more information in the Cellular Pathology Electron Microscopy User Guide for External Service Users available on the Laboratory Medicine area of the Trust Website (Histopathology section) at: <https://mft.nhs.uk/the-trust/other-departments/laboratory-medicine/histopathology/>

5.15 Referrals (4.5)

5.15.1 Referrals at Oxford Road

The department regularly receives requests for expert/second opinion from other hospitals. Similarly, the department also refers cases to other services for expert opinion, diagnostic services and in response to service pressures. The following are the most commonly used.

Type	Address
Lymphomas	Via the HCD partnership with The Christie.
Reporting/Vacancy cover	Source LDPATH 1st Floor, Cornwell House 21 Clerkenwell Green London EC1R 0DX Source BioScience 1 Orchard Place Nottingham Business Park Nottingham NG8 6PX
Reporting/Vacancy cover	Diagnexia Exeter Science Park Centre, 6 Babbage Way,

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	Exeter EX5 2FN
Laboratory services	Cellular Pathology Services 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

5.15.2 Referrals at Wythenshawe

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:

Type	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 may request the return of tissues following a surgical procedure. This could be for various reasons such as cultural or religious and 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 the Laboratory Manager (or deputy) within Histopathology at Oxford Road (for Oxford Road samples) and Wythenshawe hospital (for Wythenshawe samples).

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.

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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 contact the department 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.

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. Reports are only made available when the necessary tests have been completed, reviewed and authorised by a Consultant Pathologist. Verbal reports are not routinely provided by the Consultant however, on occasion, when there is a clear benefit or risk to the patient verbal reports or clinical discussions can only be provided to identified and qualified medical staff by Consultant Pathologists only. All report enquiries should be directed to the secretarial office in the first instance. The scientific staff in the laboratory cannot give out any information regarding results/reports. To support timely release of results, third party agencies may be used to produce the report issued – this will be specifically referenced on the report issued if applicable.

Histology Reports

Generic contact details	Location	Extension	Information
Report enquiries – ORC	Office	0161 701 1615	At times, this number may have an answering machine: please leave a clear request and a number for us to call you back
Report enquiries - Wythenshawe	Office	0161 291 4813	
Departmental nhs.net email address	ORC		mft.adult.histosecs@nhs.net
	Wythenshawe		mft.wythenshawe.histosecs@nhs.net

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

6.2 Turnaround Times (TAT's) (5.4.2 d)

The department works to RCPATH Key Performance Indicators (KPI). The target is to report all diagnostic cases within 10 days. Complex cases requiring additional processing steps such as decalcification or cases which require additional tests will have extended TAT's. Turnaround times are monitored by the department and reported both internally within the Trust and externally to organisations such as NHS England.

The up to date TAT information can be found on the trust webpage which is updated as a minimum bi annually.

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. 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 must 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)

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

Regarding complaints, our department is dedicated to thoroughly investigating all issues related to the quality and standard of our services. Complaints may be directed to the laboratory manager using the contact information listed below.

Gajan Sivarajah Lead BMS – ORC	ORC	0161 276 5806	Gajan.sivarajah@mft.nhs.uk
Catherine McNulty Lead BMS - Wythenshawe	Wythenshawe	0161 291 4804	Catherine.mculty@mft.nhs.uk

7.1 Errors

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:

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- Make sure that both digital and paper 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

7.2 Complaints

Cellular pathology at MFT is always striving to improve but acknowledge there are times when the department has not got things right. There is a complaints process, and details are found below.

Complaints are made via PALS (Patient Liaison service). Please contact PALS via email PALS@mft.nhs.uk or phoning **0161 276 8686**.

Patients can also make complaints via the PALS office.

- **Oxford Road site-Ground Floor, Entrance 2, Manchester Royal Infirmary**
- **Wythenshawe site-Ground Floor, Entrance 5, Wythenshawe Hospital**