University Hospitals of Leicester
NHS Trust

Caring at its best

Cellular Pathology User Handbook

A User Guide for Cellular Pathology Services

Contents

1.0 Introduction

The information contained in this guide has been developed in order to meet the needs and requirements of our users. This booklet provides detailed information about the Cellular Pathology services at the University Hospitals of Leicester NHS Trust and we hope that it will enable you to make the most efficient use of the service.

If you have any questions or require information about the service provided by a specific laboratory, please contact the laboratory directly and ask for advice from a Pathologist or a Senior Biomedical Scientist as appropriate. Alternatively please e-mail our generic mailbox; histopathology@uhl-tr.nhs.uk

2.0 Scope of the service

To ensure the highest possible standards of patient care we are accredited to ISO standard 15189 for Medical Laboratories (Laboratory reference 8608) and are licensed under the Human Tissue Act (HTA) (12337). Full details of our accredited tests is available on the UKAS website

The department provides a comprehensive range of diagnostic and mortuary services across the three acute sites. A range of specialised laboratory services are centralised on the Leicester Royal Infirmary site. These comprise immunocytochemistry, enzyme histochemistry, electron microscopy, and molecular pathology.

Discussion and advice on clinico-pathological correlation and therapeutic implications is readily available to all medical staff.

3.0 General Information

3.1 Location of services

There are laboratories at all 3 sites within the University Hospitals of Leicester NHS Trust but they are managed centrally from the Leicester Royal Infirmary site. They are comprised of the following:

- Histopathology / Diagnostic cytology laboratory
- Specialist services laboratory - Immunocytochemistry, electron microscopy, enzyme histochemistry, and molecular diagnostics
- Mohs laboratory
- Mortuary

Leicester Royal Infirmary site

Histopathology, diagnostic cytology and specialist services are located on level 3 of the Sandringham building. Mortuary services are located on the ground floor of the Windsor building. The Mohs laboratory is located in the corridor of clinic 3, Level 1, Balmoral Building.

Leicester General site

Histopathology specimen reception services only are located within the pathology department which can be found between OPD3 and the blood test room. Mortuary services are located in the PPD building.

Glenfield site

The Histopathology laboratory is located on the ground floor of the main hospital building. Mortuary services are located adjacent to the laboratory

3.2 Opening Hours - Laboratories

The laboratory on the Leicester Royal Infirmary site is open from Monday to Friday from 08:30 to 17:00 (excluding public holidays). Outside of this time, samples may be left according to the following procedure:

- Weekdays 17.00-18.00 – Level 2 Specimen Reception
- Weekdays 18.00-08.30 – Level 4 Specimen Reception
- Weekends – Level 4 Specimen Reception

Glenfield Hospital site is open from Monday to Friday from 08:30 to 17:00 (excluding public holidays). Outside of this time there is a designated specimen reception area in which fixed samples may be left.

The laboratory on the Leicester General site operates a specimen reception function only and is staffed from 8:30 to 11:30. Outside of this time there is a designated area in which samples may be left including a fridge for diagnostic cytology samples.

The Mohs laboratory is open on Tuesdays from 08:00-17:00. There is no out of hours service. Clinics which are going to overrun will need to be discussed by the laboratory team, consultant pathologist(s) and dermatology surgeons.

There is an on call service provided for native and transplant renal biopsy patients only. Please discuss any requirements with the on-call pathologist via the LRI switchboard (x17777 if calling from UHL phone / 0300 303 1573 if calling from external phone).

3.3 Opening Hours - Mortuary

University Hospitals of Leicester mortuaries are open from Monday to Friday (excluding public holidays).

The Leicester Royal Infirmary mortuary is staffed from 06:30hrs to 18:00hrs.

Glenfield Hospital mortuary has staff allocated from 09:30hrs to 11:30hrs although they will occasionally be required to go to Leicester General mortuary. During these absences the hospital duty manager will provide the necessary cover.

The Leicester General mortuary is staffed from 13:30hrs to 16:00hrs.

There is an on call service available outside these hours via LRI switch ext. 17777 or 300 303 1573.

On the rare occasions where a release needs to take place out of hours, there are 'Out of Hours' procedures available on UHL Connect for reference. This is performed by the hospital duty manager who can be contacted via LRI switch. The duty manager can contact on-call staff for advice where necessary.

3.4 Useful service contact numbers

Result enquiries	LRI / LGH	(0116 258) 6582
Result enquiries	GH	(0116 250) 2492

Enquiries about specimens from **Hinckley, Loughborough, Melton** or **Oakham** hospitals should be directed to the LRI site.

Medical advice can be obtained via the secretarial staff on the following numbers

	LRI / LGH	(0116 258) 6582
	GH	(0116 250) 2492
Frozen section requests	LRI / LGH	(0116 258) 6593
Frozen section requests	GH	(0116 258) 3571
Cellular pathology supplies (COD LRI) only		ext. 16576
Mortuary	LRI	(0116 258) 5596
Mortuary	LGH	(0116 258) 4914
Mortuary	GH	(0116 258) 3581

3.5 Key staff contacts

Head of Service	Dr Cathy Richards E-mail: cathy.richards@uhl-tr.nhs.uk	ext. 16577
General Manager	Matthew Peatfield E-mail: matthew.peatfield@uhl-tr.nhs.uk	ext. 16591
Deputy Service Managers	Caroline Whiteley E-mail: caroline.whiteley@uhl-tr.nhs.uk Diana Cullen E-mail: diana.cullen@uhl-tr.nhs.uk	ext. 16591 ext. 16591
Clinical Mortuary Manager	Melissa Marmalade E-mail: melissa.marmalade@uhl-tr.nhs.uk	ext. 16101
Quality Manager	Diana Cullen E-mail: diana.cullen@uhl-tr.nhs.uk	ext. 16591
Specialist Scientific Lead for Electron Microscopy	Tracey de Haro E-mail: tracey.deharo@uhl-tr.nhs.uk Or ElectronMicroscopyUnit@uhl-tr.nhs.uk	ext. 16590

3.6 Protection of Personal Data & Patient Consent

All patient information is managed in accordance with the requirements of the Data Protection Act, Information Governance standards and Trust policies as detailed below

- Data Protection Policy
- Information Governance Policy
- Retention of Records Policy
- Protection and Use of Personal Information Policy
- Information Security
- Freedom of Information Policy

All staff undertake mandatory Information Governance/GDPR training.

In addition those staff members who are involved in NHS Screening Programmes undertake additional training in line with the NHS Cancer Screening Programmes Confidentiality & Disclosure Policy.

Due to the nature of procedures by which Cellular Pathology specimens are obtained, patient consent is obtained by the clinician, and is assumed when the sample presents in the laboratory with a correctly filled out request form. Full method of obtaining and recording patient consent is detailed in the following documents:

- Consent to Examination or Treatment Policy (B35/2024)
- Policy on Safety Standards for Invasive Procedures (B13/2016)
- Policy for the Sensitive Disposal of Feta Remains (B3/2007)

3.7 User Feedback

We appreciate any feedback you may have that will help us to improve the service we provide to our patients. Informal feedback can be provided via an online submission form: https://forms.office.com/e/Rwv5vL6zDt

The links to this form are available on the Trust Intranet (UHL Connect) and our external webpage. It can be completed by anyone who has contact with our services.

All responses will be logged and managed through our service improvement processes.

Formal concerns or complaints should be made through the Patient Advice and Liaison Service (PALS) who will liaise with the service directly. They can be contacted by patients, carers, friends and family members using the details below.

Freephone: 0808 178 8337

Email: **pals@uhl-tr.nhs.uk**

Online: **https://www.leicestershospitals.nhs.uk/patients/patient-welfare/patient-advice-and-liaison-service-pals/**

4.0 Histopathology Specimens

The quality of the information received by the laboratory directly affects the quality of the result provided to the requesting clinician. In order to help us provide the best possible service, it is essential to ensure that all specimens are collected properly, and that both the specimen and request form are labelled with the appropriate information. Please contact the laboratory if unsure of our requirements.

4.1 Sample collection

Where possible please confirm the identity of the patient with them.

The following samples either should **not** be sent in formalin **or** have specific instructions (see relevant entry):

- Multiple GI Biopsies using Multicassettes (see 4.7)
- Frozen sections (see 4.8)
- Muscle biopsies (see 4.9)
- Renal biopsies (see 4.10)
- Renal and skin samples for Immunofluorescence (4.11)
- Rectal biopsies for Hirschsprung's disease (see 4.12)
- Paediatric tumour specimens (see 4.13)
- Electron microscopy specimens (see 4.14)
- Hair specimens (see 4.15)
- Mohs specimens (see 4.16)

All specimens should be placed into appropriately sized containers. For smaller specimens use the pre-filled formalin pots. Larger, empty containers can be obtained from the laboratory at each site on request, and formalin for these should be purchased via NHS Supplies. (See Appendix 1 for more detailed instructions)

Specimens for routine histopathology (see exceptions list above) should be fixed, as soon as possible after removal, in 10% neutral buffered formalin. Wherever possible, the volume of fixative should be at least ten times the volume of the specimen. For large specimens where this is not possible the specimen must be, *at the very least*, totally immersed in neutral buffered formalin.

Certain types of large specimens may have specific instructions (e.g. breast, GI). If in doubt, please check with the laboratory beforehand.

Bowel resections require opening along the anti-mesenteric border but *DO NOT OPEN THROUGH TUMOUR*. The bowel should be cleaned of faecal material before placing in formalin as described above.

Please ensure that the lids of all specimen containers are correctly closed

Specimen pots must be placed in grip-seal specimen transport bags with the accompanying form either attached to the outside of the specimen bag or placed in a separate bag within the bag containing the specimen. Samples in formalin may be stored at room temperature overnight before transport if required.

4.2 Labelling of specimen containers

Please ensure that the specimen container, *not the lid*, is labelled with full patient identification details. Wherever possible, please use addressographs.

Essential information that is required:

- Date of birth
- Full name and address
- Unit number
- Specimen type

The following specimens also need to be clearly marked as such:

- Fresh specimens
- Urgent specimens
- Specimens with infection hazards - use a ‘DANGER OF INFECTION’ sticker.
- Radioactive specimens

4.3 Completion of request forms

Please use electronic requesting (ICM) wherever possible. The only exception to this is that at GH, a separate request form is available for Breast Non-Operative Diagnosis cases. This form is a paper document and is available from the Histology lab only.

A completed request form must accompany all specimens. Some forms have a bag attached into which the specimen should be placed. This form must contain full patient identification details and other relevant information, i.e.:

- S number (or NHS number if from a GP)
- Full name and address
- Date of birth
- Specimen type
- Date and time of collection
- Consultant and source of the request
- Adequate clinical information (the diagnosis may be compromised if relevant clinical details / history are not provided e.g. chemistry results with liver and thyroid specimens, or menstrual history with endometrial specimens.)
- Multiple samples from a single patient must be clearly labelled and differentiated with corresponding information provided on the request form.
- Destination for any copy reports
- ‘Required by’ date for urgent specimens
- The name of the person taking the sample
- Printed name of requesting clinician

4.4 Inadequately labelled specimens and forms

The following will be returned to source which may mean that results are delayed:

- Unlabelled specimens

- Inadequately labelled specimens
- Inadequately completed forms
- Samples for which the information on pots and forms does not match
- Large buckets which are labelled on the lid only
- POC specimens received without appropriate paperwork

A Datix incident report may be created against the relevant service if appropriate.

4.5 High risk specimens

Specimens from patients known or suspected to be high risk must be identified and sent in a biohazard bag in accordance with ACDP guidelines [HN(86)20] and Control of Infection – UHL guidelines (Document number 10840 22 April 2003).

Fresh (unfixed) specimens from high risk patients will not be examined *without prior agreement.* Please contact the appropriate consultant to discuss.

4.6 Urgent specimens

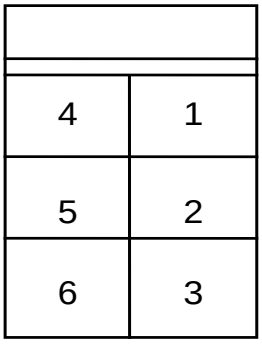
Specimens usually require overnight processing for optimal results. However, in exceptional circumstances, small urgent specimens may be processed on a shorter schedule. If a report is required urgently (i.e. within the same working day, or early the next working day) then please discuss this first with a Consultant Histopathologist.

Please:

- Indicate clearly on the form that the specimen is urgent - preferably with a red urgent sticker
- Record the time the specimen was taken
- Include a legible contact name and bleep number
- Indicate by when the report is required.

4.7 Multiple GI Biopsies using Multicassettes

The histology department will provide tissue cassettes with 6 numbered compartments. At endoscopy, the right side of the cassette, as viewed with the open compartments facing and the sloping edge at the top, should be labelled ***in pencil*** with the patient's surname. If it is a common name, add the initial:



Write the patients surname on this side of the cassette. Add the initial if it is a common name

Fig. 1 - Opened cassette viewed looking into compartments (1-6) with sloping side at top

Place the biopsies into the compartments in number order. The maximum number of biopsies permitted is 2 per compartment with a total of 12 / cassette. If there are more than six biopsies sites, a second cassette should be used and labelled as for the first.

Label the lid of the cassette with the contents of the compartments. This can be an abbreviation sufficient to relate each biopsy to the details on the request form. If a compartment is left empty it should be marked with an X.

When all the biopsies have been placed in the cassette, carefully secure the lid and place in a formalin pot with the sloping side uppermost.

Secure the pot lid and invert / gently shake to dislodge air from the cassette. If the cassettes do not sink to the base of the pot then shake again.

Fully label the pot and form as detailed above

For any queries or to obtain a set of instructions for endoscopy please contact a Senior Biomedical Scientist on ext. 16593 for further assistance.

4.8 Frozen sections

A diagnostic opinion can be given on fresh tissue to give a result within 30-35 minutes of it reaching the LRI laboratory. Please note that specimens from high risk patients will not be examined *without prior agreement.*

Frozen sections are normally carried out at LRI, although for certain operating lists, a service may be provided at GH and LGH depending on Consultant Histopathologist availability.

Owing to the limitations of the technique, there is a deferred diagnosis rate of 2-4% and diagnostic concordance with paraffin histology of 98%.

If a frozen section result is not received within the allotted turnaround time, then contact the laboratory on x16593 (LRI) or x13571 (GH) for further instructions.

To arrange a frozen section:

1) Contact the laboratory at LRI / LGH (ext. 16593) or GH (ext. 13571)
2) Provide the following information:
    - Patient details

- Surgeon
- Theatre
- Tissue to be sampled
- Estimated time of arrival

To send a frozen section

1) Place the specimen in a **dry** specimen pot. **DO NOT** use formalin
2) Ensure the pot is fully labelled with the patient details.
3) Place the labelled pot inside a red fresh/frozen tissue plastic transport bag.
4) Complete a histopathology request form including a contact telephone / bleep number for receipt of the report.
5) Arrange for immediate delivery to the histopathology laboratory. Please note that this is the responsibility of theatre staff.
6) If it is necessary to transport the specimen to a different site then it is the responsibility of theatre staff to organise taxis as appropriate

If a pre-booked frozen section is no longer required, please let us know.

4.9 Muscle biopsies

Please arrange in advance by contacting the laboratory on ext. 16590 or by e-mail to specialhistology@uhl-tr.nhs.uk). These contacts can also be used for advice on which tests are required and details as to how the specimen should be sent. A full clinical history should be provided as the result may be delayed if this is not received.

Please note that only in exceptional circumstances are we able to accept samples after 12pm on a Friday.

4.10 Renal biopsies

Special protocols apply for these specimens. Further details can be obtained from the laboratory on ext. 16590 or by emailing specialhistology@uhl-tr.nhs.uk

4.11 Renal and skin samples for Immunofluorescence

Samples must arrive in the laboratory before 16:30.

Specimens from high risk patients will not be examined *without prior agreement.*

1) Place the specimen in saline solution in a specimen pot.
2) Ensure the pot is fully labelled with the patient details.
3) Complete a histopathology request form.
4) Arrange for immediate delivery to the histopathology laboratory.

4.12 Rectal biopsies for Hirschsprung's disease

Please contact the laboratory (ext. 16590) *before* sending the specimen.

Specimens from high risk patients will not be examined *without prior agreement.*

1) Place the specimen in a dry specimen pot.
2) Ensure the pot is fully labelled with patient details.
3) Put the labelled pot inside a blue 'Fresh Tissue for Histology' transport container.
4) Complete a histopathology request form including a contact telephone / bleep number for receipt of the report if necessary.
5) Arrange for immediate delivery to the histopathology laboratory.

4.13 Paediatric tumour specimens

Please contact the LRI laboratory on ext. 16593 *before* sending the specimen

These must arrive in the lab before 16:30.

Specimens from high risk patients will not be examined *without prior agreement.*

1) Place the specimen in a dry specimen pot.
2) Ensure the pot is fully labelled with patient details
3) Put the labelled pot inside a blue 'Fresh Tissue for Histology' transport container.
4) Complete a histopathology request form
5) Arrange for immediate delivery to the histopathology laboratory.

4.14 Samples for electron microscopy

The quality of electron microscopy results is affected by tissue handling procedures as sub-optimal tissue preservation may place limitations on the ultrastructural interpretation of the sample. To prevent this all samples should be

- No larger than 2mm in size. (Strips or cores of tissue up to 2mm thick/diameter are acceptable).
- Placed into an appropriate sealed pot (such as a 30ml universal container) containing glutaraldehyde fixative immediately upon removal from the patient.

For further information on Electron Microscopy, please see section 7.0

4.15 Hair specimens

Hair specimens should be sent in a sealed dry pot of appropriate size – they **should not** be sent in formalin. Ensure that the pot is fully labelled with patient details.

4.16 Mohs specimens

- Specimens must be brought directly to the lab by the surgical team.
- They must be put in a petri-dish with a closed lid, labelled with the corresponding number on the mohs map.
- A mohs map and request form with patient identifiers must be brought with the specimen to the mohs laboartory

5.0 Cervical Cytology

Following the changes to the national screening programmes in 2019 the cervical screening service relocated to University Hospitals of Derby & Burton.

Samples taken in primary care or from within the hospital should still be sent to us as we have daily courier collections to Derby.

Results enquiries should be directed to the Derby laboratory on 01332 789307 or 789311

6.0 Diagnostic Cytology

6.1 Sample collection

It is important that cytology specimens are delivered promptly to the laboratory to avoid problems associated with deterioration of the sample. Wherever possible, the specimen should be taken on a weekday and delivered the same day, before 16.00. If this is not possible, it is vital that the specimen is refrigerated until it can be transported to the laboratory.

6.2 Completion of request forms

A completed request form must accompany all samples and contain full patient information i.e.:

- S number or NHS number if from a GP surgery
- Full name and address
- Date of birth
- Source of the request
- Date and time of collection
- Adequate clinical information (diagnosis may be compromised if relevant clinical details / history are not provided)
- Destination for any copy reports
- Name of requesting clinician

The following specimens must be clearly marked:

- Urgent cases
- Cases where there is a risk to lab staff of infection
- Multiple samples from a single patient must be clearly labelled and differentiated with corresponding information provided on the request form.

Urgent and/or high risk samples should be clearly labelled on sample and request form. If specimens are not correctly labelled they may be rejected. The requesting clinician may need to come to the laboratory to verify the request form and specimen.

6.3 Procedures for different samples

6.3.1 Urine

A 20ml sample of clean urine should be sent to the laboratory within a few hours of production. Please note that:

- The initial voided urine is required.
- Epithelial cells are usually passed at the beginning and end of voiding, so mid-stream specimens may give unsatisfactory cytology.
- Early morning urines are also unsatisfactory as the cells may have been in the bladder for several hours, and thus may show degenerative changes.

This test is not appropriate for the investigation of urinary tract infections.

Please indicate on the request form if the sample was taken via a catheter or after recent instrumentation of the urinary tract as this may cause problems in interpretation.

6.3.2 Serous effusions

A minimal volume of 50-75ml of fluid should be drained into a clean container and sent directly to the laboratory. For pericardial fluid the minimal volume is 60ml. Please note that specimens from drains are usually too degenerate for reliable cytology.

Where a repeat serous fluid is being taken after a previous suspicious one this must be indicated on the form, and the repeat specimen taken to allow prompt delivery to the laboratory

6.3.3 Respiratory samples

Sputum cytology is no longer taken as an open access procedure in cases of suspected malignancy. Any patients in whom malignancy is suspected should be referred to the Rapid Access Lung Clinic at Glenfield Hospital in accordance with local guidelines.

The rapid referral lung clinic coordinator can be contacted on (0116 258) 2616

Sputum cytology should not be used as an indiscriminate screening test such as in smokers and COPD patients with a chest infection and no other features to suggest malignancy, as the diagnostic yield is extremely low.

Sputum cytology is generally only merited if the patient is regarded as unfit for / refuses further investigation such as bronchoscopy. Please contact Dr Cathy Richards for further advice, on ext. 16577.

Bronchial washing: Wash / trap specimens should be collected into a universal container without fixative and be sent straight to the laboratory

Bronchial brushing: Please ensure the cut end of the brush is placed in the collection fluid

6.3.4 Fine Needle Aspirates (FNA)

FNA's are primarily used as a safe and relatively rapid method of diagnosis for tissues such as lymph nodes, salivary glands and other easily reached sub-cutaneous lumps.

Equipment required:

- 21g (green) or 23g (orange) needle
- 10 or 20 ml syringe
- Syringe holder (optional)
- Alcohol swab to disinfect skin
- Cytology collection fluid (available from cellular pathology department)
- Gauze swab or cotton wool ball

Procedure:

1) Explain the procedure to the patient and gain verbal consent
2) Locate lesion and stabilise area of insertion between thumb and finger
3) Disinfect skin surface
4) With the needle in the lesion, apply suction and make several passes
5) Release the suction, withdraw the needle and wash in in the collection fluid
6) Label the container and the form

Label any air dried slides from direct preparations with the patient's name and S number. Place in a slide transport box and send to the laboratory with the sample and request form.

The FNA report:

Like most cytopathology reports, FNA samples will be reported as:

Malignant; benign; suspicious; or inadequate/unsuitable, with a more specific or probable diagnosis added if appropriate.

A report of **malignant** cells is not conventionally made, unless there is certainty about the diagnosis and the cytopathologist is happy for treatment decisions to be made based on the report.

A report of **benign** should be taken in conjunction with other clinical information, and not taken as a definitive diagnosis. There are a small but significant number of false negative diagnoses using FNA cytology – most often due to sampling. For this reason, a benign cytology report should not override other worrying clinical investigations and the lesion should be investigated further, if only by re-aspiration.

A report of **suspicious** implies the presence of some worrying features, but the stringent criteria for malignancy have not been met. In most cases, further effort to reach a definitive diagnosis is probably mandatory and in the absence of other clinical information, surgical biopsy will be required.

The commonest cause of an **inadequate or unsuitable** sample is an inadequate yield of cells. This can be minimised by ensuring correct siting of the needle within the lesion, and by making several passes through it. Benign breast lesions are often hypocellular, with few epithelial cells present. Thus, if the aspirator is convinced the

lesion was adequately sampled, the report may be taken as supporting evidence of a benign nature, but should never be used to contradict the overall clinical impression.

6.3.5 Other Cytology

The following specimens are also routinely examined;

- CSF for neoplastic cells; send the fresh sample to the laboratory immediately
- Joint fluid for crystals and cells; send the sample fresh and promptly
- Hydrocoele and spermatocoele fluids (but not routine semen analysis)
- Cytological samples taken at bronchoscopy or endoscopy; send the sample promptly

We are happy to undertake, and are equipped to examine, most cytological samples. However, experience may be limited for those samples, which are not routinely examined. Please contact Dr Catherine Moreman, Consultant Cytopathologist on ext. 16582 for further advice (catherine.moreman@uhl-tr.nhs.uk).

7.0 Electron Microscopy

7.1 Accepted Sample Types for Electron Microscopy

The electron microscopy unit will accept the following tissue types;

- Renal biopsy – diagnostic and transplant
- Muscle biopsy
- Nerve biopsy for semi-thin or ultrastructural examination
- Cornea samples for semi-thin or ultrastructural examination

Other tissue types such as GI biopsies and pituitary biopsies will be accepted after discussion with the specialist Scientific Lead for Electron Microscopy (see contact information)

Cilia samples / nasal tissue for evaluation of primary cilia dyskinesia will not be accepted directly into the electron microscopy service. These samples are evaluated in this unit but only as part of the NHS commissioned diagnostic specialist centre pathway. If you are aware of a need for primary cilia dyskinesia evaluation please contact kellychamberlain@nhs.net before samples are taken.

7.2 Sample Requirements for Electron Microscopy

Samples requiring electron microscopy should be less than 2mm in any dimension, and ideally fixed in a glutaraldehyde-based fixative immediately after removal from the body (gold standard). However if this is not possible the following tissues can be examined accepting that there will be a variable loss of ultrastructural detail;

- Formalin fixed tissue
- Paraffin wax embedded tissue (please send the whole block)

All samples for Electron Microscopy should be adequately identified and must contain as a minimum:

i. NHS number (if allocated)

ii. Patient's full name or unique coded identifier

iii. Date of birth

iv. Referral laboratory sample number (where appropriate)

Failure to follow these requirements will mean rejection of the sample

All samples should be accompanied by a request card or copy of histology report giving the above patient information and full clinical details. Further information from the pathologist detailing specific areas of interest for ultrastructural evaluation is beneficial.

Please contact the Electron Microscopy Unit for specific advice about these pre-analytical requirements if unsure. (see contact information)

7.3 Specimen Transport – External Cases

Samples for electron microscopy from sources external to UHL should be sent via courier or secured postal services. This will be the responsibility of the originating trust. Samples must be transported in approved transport boxes labelled in accordance with UN3373 regulations.

8.0 Transport of specimens to the Laboratory

The transport of specimens to the laboratory must be done in such a way as to minimise the potential exposure to formalin and the risk of infection to those who may come in contact with them - e.g. taxi drivers, porters, and laboratory staff.

Please ensure that the container is appropriate for purpose, that the lid is properly closed and sealed, and that it is not contaminated on the outside.

Specimens must be placed in a grip-seal bag. This bag must then be sealed. In order to avoid accidental contamination, please do not place request forms in the same bag as the specimen pots.

Fresh or frozen tissue - Red plastic transport bags have been provided to theatres and fresh tissue should be transported between sites in these when being transferred via taxi or courier.

8.1 Transport services

The transport of specimens to the laboratory from on-site locations is by the use of the portering services or the pneumatic air tube system (GH site only). The following guidelines for sending samples internally must be followed.

8.1.1 Portering services

Laboratory specimens are routinely collected from wards, theatres and clinics by clinical distributors at regular intervals throughout the day. Ideally, specimens should be taken to coincide with collection times.

The collection of urgent or out-of-hours samples must be organised at ward / theatre level by paging the porter on duty.

- All specimens should be carried upright in trays (contained within a secondary bag) or in individual sealed leak proof bags.
- Under no circumstances should anyone transport specimen containers in their hands or pockets.
- All specimens should be transported on / in an appropriate trolley and tray or receptacle that will contain leaks and spills. It is recommended that all trolleys used for conveyance of specimens have available spill kits, including an approved disinfectant and absorbent mopping up material.
- Specimens should be transported in such a way as to maintain patient confidentiality.
- All specimens that are to be taken directly from source to the laboratory should be delivered in a timely manner.

8.1.2 Dealing with spillages

Human tissue specimen containers may contain varying quantities of formalin.

If a specimen leaks into the tray or box, report for assistance (if required) to the nearest pathology laboratory reception

In the event of a spillage which is not contained, wearing gloves, clear the contaminated area and if safe to do so, mop with absorbent material and wash down with copious water.

For major spills (> 250 ml); evacuate the immediate area and contact the laboratory on ext. 16591, 16592 or 16593 for advice and assistance, as Personal Protective Equipment and formalin spill kits may be required for clean-up.

Please do not leave leaking specimens in specimen reception areas.

All spillages must be reported as an incident using the Datix reporting system

8.1.3 Pneumatic air tube system (GH only)

The air tube systems in UHL are maintained by the local facilities departments and may only be used by authorised members of staff.

It is the responsibility of the ‘sender’ to operate the system correctly, and to have back-up systems in place for when the system is unavailable, or not functioning normally. Steps must be taken to ensure the health and safety of the recipient and anyone who works on the system.

- Glass containers or damaged / contaminated containers must not be used

- All specimens must be placed into a sealed plastic bag (specimen bag) before placing in the air tube carrier
- The carrier lid must be secure before sending
- Leaking samples must not be sent

If there are any concerns about biological specimen contamination of the actual air tube, then Interserve/facilities engineers must be immediately contacted.

8.2 Pathology transport services

All biological specimens transported to and from the pathology laboratories are considered to be **Cat B** status or below

All diagnostic specimens must be enclosed in the appropriately labelled bags and transport boxes - these must not be opened unnecessarily by the driver. The laboratory follows UN 3373 (P650 packaging instruction) as per the European Agreement Carriage of Dangerous Goods by Road (ADR) as regulated by the Carriage of Dangerous Goods Regulations 2007.

Specimens are delivered periodically throughout the day to Sandringham level 2 during standard working hours (Monday-Friday, 8.30-17.00) and Sandringham level 4 outside of working hours, and they are sent to histopathology staff via the hoist system.

8.3 Taxi services

Specimens sent to the laboratory must be packaged correctly according to guidelines for sending of samples through the normal post. Alternatively, special transport boxes may be used.

The transport box must be made of smooth impervious material such as plastic or metal which can easily be disinfected or cleaned.

- The transport box must be secured with a fastenable lid.
- The box must retain liquid in the event of leakage of a specimen.
- The box must clearly labelled with the UN 3373 diamond shaped mark and the proper shipping name ‘Biological substance, Category B’ for new type transportation boxes and ‘Diagnostic Specimen-Fragile with Care’, for the older transportation boxes.

9.0 Mortuary Services

9.1 Requesting an Autopsy

Clinical staff are encouraged to seek consent for autopsy examination of patients dying in hospital. Autopsies are valuable even in cases where the clinical cause of death is thought to be obvious. In addition to clarifying the cause of death, they may provide useful information about disease progression and the effect of treatment.

Consent should be sought from the next of kin and the detailed forms available in the Patient Affairs Office should be completed in full. A death certificate may be issued with an indication that further information may be available after the autopsy.

The consent form deals with the extent of the autopsy and the sampling and retention of tissues and other material for diagnosis, teaching, and research. The method of disposal of any samples taken must also be discussed and indicated on the form.

It may be helpful to discuss the case with one of the Consultant Histopathologists (LRI – ext. 16582; GH – ext. 12492) before seeking consent in order to clarify any practical issues relating to the autopsy.

When the autopsy is complete, the requesting doctor will be paged and offered the opportunity to see and discuss the findings.

9.2 Examination of products of conception

All fetal remains irrespective of origin will be managed in a respectful and dignified manner and in accordance with Human Tissue Authority guidance; no fetal tissue will be disposed of as clinical waste. Any sample which definitely or possibly contains products of conception therefore requires consent for histological examination and notification of the mother's wishes as to the preferred route of disposal. Consent forms can be found in the UHL Policy for the Sensitive Disposal of Fetal Remains (DMS No.35054).

Histological examination is usually required (the exception is in surgical termination of pregnancy with no obvious complication) and therefore consent for it must be documented on the form. For *every* case the mother's wishes with regard to disposal must also be noted on the form. The options are for a communal cremation according to Trust policy or for private disposal following collection by the patient or an undertaker working on their behalf. The consent form must be countersigned by a medical or nursing practitioner. Please refer to UHL Policy for the Sensitive Disposal of Fetal Remains (as above).

Each case must be accompanied by both consent for examination and a disposal form.

9.3 Examination of fetuses and infants over 16 weeks gestation

Fetuses over 16 weeks gestation (or over 10cm in length if there is doubt about the gestational age), and babies should be sent to the mortuary at the LRI with appropriate consent and pregnancy loss forms. Clinical information must be provided to the pathologist via the Mortuary before an examination can proceed. This may be in the form of;

- A computer print-out (e.g. from labour ward computer records)
- Patients' notes
- A handwritten post mortem information form.

Reports will be sent within 6 weeks to the relevant Consultant and a copy is also sent to the mother's GP.

9.4 Referral to the Coroner

Some deaths are required by law to be reported to H.M. Coroner. These include deaths that may be unnatural - such as trauma, intra/post-operative death, overdose or patient receiving disability pension for an industrial disease. In addition, many doctors follow a rule of thumb that any death occurring within 24 hours of admission should at least be discussed with the Coroner's officer even though many such deaths are natural.

If an unnatural death can reasonably be excluded, even though the exact cause of death may not be known, a Coroner's autopsy is not strictly necessary. However, consideration should be given to requesting a 'hospital' post-mortem.

Details about Coroner's cases and how to contact the Coroner's office can be obtained from the Patient Affairs Office.

Professor C.E. Mason, H.M. Coroner for Leicester City and South Leicestershire District, or her officers can be contacted on (0116) 225 2534 or (0116) 225 2535

9.5 Death Certificates

Department of Health guidance states that certificates should be completed within 24 hours of death. Advice on death certification is available if required. Please contact any Consultant Histopathologist (ext.16582).

10.0 Availability of Results

Results are available via the iLab system or ICE. Please check for the results on iLab or ICE *before* telephoning the relevant office. All Histopathologists and Cytopathologists are happy to discuss individual cases with hospital clinicians and General Practitioners.

10.1 Histopathology

Paper copies of reports will be issued to the source identified on the form so please bear this in mind when completing request forms. The reporting pathologist may be contacted via the secretaries (ext. 16582 for LRI /LGH, and ext. 12492 for GH).

Tissue preparation generally takes 24 to 72 hours before it is available for examination and if specialised investigations are required this will take longer and a preliminary report will usually be given. Please allow adequate time before making enquiries to the relevant office.

Specimen Type	Earliest Time Report Available
Urgent Specimens	Lunchtime of next working day
Small Biopsies	No earlier than 48hrs after receipt
Large Specimens	No earlier than 72hrs after receipt

Turnaround time targets are currently set at:

- 95% in 7 days for 2 week wait samples (2023 average 74%)

- 90% in 7 days for Diagnostic biopsies (2023 average 49%)
- 90% in 7 days for all Histology samples (2022/23 average 40%)

10.2 Diagnostic Cytology

We aim to issue a report on 90% of samples within 7 (calendar) days of receipt of the specimen. Average turnaround time for 2023 was 85%.

10.3 Electron Microscopy

90% of Electron Microscopy samples are reported within 10 working days.

All samples are examined ultrastructurally by trained staff. A suitable set of images and an ultrastructural descriptive report is produced which outlines the features seen, or not seen, on examination in the electron microscope. This will include relevance to the clinical details received and any communications with the reporting pathologist. This ultrastructural descriptive report is only issued once it has been checked for accuracy and suitability by the senior staff (Band 7 and above)

For referred cases, images and a copy of the final ultrastructural descriptive report will be emailed to the requesting pathologist via an agreed email address that complies with information governance requirements.

11.0 Referral of Work Outside of UHL

11.1 Specialist Opinions

Specialist opinions may be requested on complex or unusual cases. These are sent, at the pathologist's discretion, to nationally or internationally recognised experts in the area of interest. A full list is available from the laboratory on request.

11.2 Referral Laboratories

Referral laboratories are used for services / tests that are outside of our current repertoire. Tests which are currently referred for analysis and details of where they are sent are given below;

Laboratory	Address	Test referred
Department of Cellular Pathology	University Hospitals of Birmingham NHS Trust, Edgbaston, Birmingham, B15 2TT	Molecular analysis for KRAS (non-GI), EGFR, ALK, ROS-1, CTNNB1, NTRK PD-L1 IHC - other than lung
Histopathology Department	Cambridge University Hospital, Histopathology, Box 235, Addenbrookes Hospital, Hills Road, Cambridge, CB2 0QQ	EGFR, NTRK
North West Genomic Laboratory Hub	Manchester Centre for Genomic Medicine, Saint Marys Hospital, Oxford Rd, Manchester. M13 9WL	BRCA, NTRK, NGS on TP53, Lymphoreticular panel
Molecular Diagnostics	Histopathology Department, City Hospital, Nottingham. NG5 1PB,	Molecular analysis for KRAS (GI), BRAF, Human Herpes Virus 8, DDIT3, Clonality Studies

		Melanoma Sentinel Lymph Nodes Sural nerve biopsies
Regional Genetics Laboratory	City Hospital, Nottingham. NG5 1PB,	MLH1 MDM 2
Histopathology Department	Royal Hallamshire Hospital, Glossop Road, Sheffield. S10 2JF	ALK1, PDL1
National Specialist Ophthalmic Pathology Service	Dept. of Histopathology, E-Floor, Royal Hallamshire Hospital Glossop Road, Sheffield. S10 2JF	Eye Histology
National Amyloidosis Centre	Cellular Pathology, Royal Free London NHS Foundation Trust , Pond St, London NW3 2QG	Amyloid
Health Services Laboratories	Advanced Diagnostics, The Halo Building, 1 Mabledon Place, London, WC1H 9AX	IHC - Androgen Receptor HPV Genotyping
Genomic Laboratory	Royal Surrey County Hospital, Egerton Rd, Guildford GU2 7XX	Prosigna
Genomic Laboratory	Royal Marsden Hospital, 203 Fulham Road, Chelsea, London, SW3	BRAF NTRK

11.3 External suppliers

External suppliers may be used as a contingency for outsourcing because of capacity or resource issues within the service. Details are given in the table below

Supplier	Address	Contingency
Backlogs Limited	Silvaco technology Centre, Compass Point, St Ives. Cambs PE27 5JL	Histology
Source Bioscience	1 Orchard Place, Nottingham Business Park, Nottingham, NG8 6PX	Breast Histology Herceptin FISH Analysis
University Hospital Southampton NHS Foundation Trust	Tremona Rd, Southampton SO16 6YD	Paediatric post mortems

12.0 Quality Assurance

The service is accredited to ISO15189 however there are some tests that are outside of our scope of accreditation. A full list of these can be found in Appendix 3.

The Mortuary is licensed under the Human Tissue Authority (HTA).

The laboratories participate in national and local external quality assurance (EQA) schemes for diagnostic histopathology, immunocytochemistry, immunofluorescence, renal biopsies, electron microscopy, molecular pathology and Herceptin testing.

All Consultant Histopathologists take part in EQA schemes that are appropriate to their speciality. Regular MDT and clinico-pathological meetings are held with clinicians from many different specialties where cases are discussed and reviewed.

13.0 Appendices

Appendix 1 – Sample Container Types

Sample Type	Container	Units of Supply	Order from:
Small routine histology sample 3x3 cm	60ml Pre-filled 10% formal saline pots. Yellow lid.	Tray of 25	LRI Pathology Stores - ext. 15968
Medium routine histology sample 7x7 cm	300ml single use pot	Box of 60	
Large routine histology sample more than 7 cm Large fresh tissue resections – Breast, paediatric tumour specimens etc.	Appropriate sized single-use bucket. Sizes currently available = 1L, 2.5L, 5L, and 10L.	As per request	LRI Pathology Stores - ext. 15968 GGH – collect from histology laboratory LGH – collect from specimen reception
Cytology sample - urine, csf, joint aspirate, serous fluids	Plain universal container – approx. 25ml	As per request	
Abnormally large samples for histopathology e.g. limb	> 25 litres	Single	Histology - ext. 16593
Frozen section pots – for all small fresh tissue samples including frozen section, muscle biopsy, Hirschprungs, lymphoma etc.	Blue fresh tissue transporting vial containing a plain 60ml pot for the sample	Box of 50	Histology - ext. 16576
FNA cytology	Universal container pre-filled with approx. 3ml Cytorich red preservative	Tray of 12	
Electron Microscopy	Universal container pre- filled with approx. 3ml Gluteraldehyde fixative	As per request	LRI laboratory – ext. 16590 GGH – histology laboratory

Appendix 2 - Medical Staff Specialties and Contacts

Dr L. Adamczyk	Dermatopathology, Gastrointestinal, Head and Neck	16594
Dr M. Bamford	Dermatopathology	16587
Dr R. Bishop	Urology, Renal, Gynae	16582
Dr K. Clarkson	Breast	13567
Dr P. DaForno	Dermatopathology, Head and Neck	16588
Dr J. Dormer	Urology, Renal	17472
Dr L. Hatsell	Breast, Gynae	15902
Dr R. Hew	Lymphoreticular, Gynae, Cytopathology	17259
Dr H. Martin	Dermatopathology, Urology, Lymphoreticular	17473
Dr G. Matthews	Gastrointestinal, Renal	16579
Dr C. Moreman	Cytopathology, Gynae, Head and Neck	16582
Dr M. O'Riordan	Dermatopathology, Gastrointestinal	16596
Dr E. Pointen	Lymphoreticular, Gynae	16589
Dr D. Purnell	Cytopathology, Breast, Respiratory	13195
Dr H. Rashed	Lymphoreticular, Urology	16582
Dr C. Richards	Gastrointestinal, Soft tissue, Respiratory, Hepatobiliary	16577
Prof. G. Saldanha	Dermatopathology	16582
Dr E. Stannard	Gynae, Genomics, Respiratory	16582
Dr H. Uraiby	Dermatopathology	16581
Dr E. Webb	Respiratory, Soft Tissue, Head and Neck	16582
Trainee SpR, ST	LRI	16583
Trainee SpR, ST	GGH	13566

Appendix 3 – Non-Accredited Tests

- Skin Immunofluorescence
- Renal Immunofluorescence
- Gastric Her-2 FISH (OMNIS)
- Tinctorial stains:
    - Hamperls
    - Von Kossa
    - Victoria Blue B
- Immunocytochemistry tests for
    - Factor XIII
    - Langerin
    - INI-1
    - Mast Cell Tryptase
    - P40
    - PD-1
    - Prostein
    - HHV8
    - PRAME
    - Napsin A

NB: Details of our scope of accreditation can be provided on request.