Histopathology
Primary Sample Collection Manual

Change details

Change Description:
(i) Section 1: Reference to GDPR (Data Protection legislation) and HSE Data Protection Policy added (1.4 and 1.5)
(ii) Section 1: Reference to NQIPH added (1.5)
(iii) Section 1: Reference to related document LP-Histo-0021 removed (1.7)
(iv) Section 2: Number of staff grage medical scientists increased (2.2)
(v) Section 2: Histo CMS email address updated (2.3)
(vi) Section 3: ROS-1, PD-L1 and MSI by PCR added (3.5.5)
(vii) Section 4: Turnaround times amended to reflect NQIPH targets (4)
(viii) Section 12: Reference to PD-L1 being sent to SVH removed (12.2)

Reason for Change:
(i) Quality Improvement
(ii) Quality Improvement
(iii) Annual review
(iv) Quality Improvement
(v) Annual review
(vi) Quality Improvement
(vii) Quality Improvement
(viii) Annual review

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INTRODUCTION

1.1 Scope and purpose

This manual is designed to provide users of the Histopathology Service at Letterkenny University Hospital with information on the proper collection and handling of primary samples destined for examination in this laboratory or referral for specialist reporting elsewhere. The Histopathology Department is concerned with the diagnosis of abnormalities within tissues and cells by microscopic examination. It is used both by hospital clinicians and General Practitioners and is accredited to ISO 15189 standard (Registration number 210MT).

Please note that this manual is intended for use as a guide only; should you require any further information or clarification, please contact the relevant section of the Histopathology department prior to submission of the sample (see Section 2.3, Table 1).

1.2 Services offered

The Histopathology Laboratory at Letterkenny University Hospital offers the following services to users:

- Routine histological examination of biopsy and resection samples
- Frozen Section service if an urgent, intra-operative diagnosis is required
- Routine cytological examination of body fluids (excluding cervical cytology)
- Performance and reporting of Fine Needle Aspirate (FNA) procedures (excluding Transbronchial FNA)
- Forwarding of muscle and renal biopsy samples for specialist histological examination and reporting
- Forwarding of Transbronchial FNA and urine samples for specialist cytological examination and reporting
- Forwarding of tissue for Molecular Testing
- Forwarding of tissue for Oncotype DX breast cancer assay testing

1.3 Responsibility

The Chief Medical Scientist in charge of Histopathology is responsible for ensuring the implementation and maintenance of this procedure in conjunction with the Consultant Histopathologists.

1.4 Data Protection
All staff working in the HSE are legally required to comply with data protection legislation, namely the GDPR (General Data Protection Regulation (EU) 2016/679) which came into effect on 25th May 2018, and the Data Protection Act 2018. Data Protection is everyone’s responsibility and ensures that the personal data of service users, suppliers and employees is collected, processed, stored and disposed of as written in law. Data Protection rights apply whether the personal data is held in electronic format or in a manual or paper based form. Staff breaches of data protection legislation will result in disciplinary action.

1.5 References


[www.inab.ie](http://www.inab.ie)

International Standard ISO 15189 entitled “Medical Laboratories Particular Requirements for Quality and Competency” (current version).

“The Retention and storage of pathological records and specimens (5th Edition)”. Royal College of Pathologists and Institute of Biomedical Science. 2015.

HSE Data Protection Policy, 25th May 2018

“Guidelines for the Implementation of a National Quality Improvement Programme in Histopathology”, Faculty of Pathology, Royal College of Physicians of Ireland, Version 6.11 (2018)

1.6 Definitions

**Histopathology** – the microscopic examination of body tissues

**Cytology** – the microscopic examination of body cells

**Specimen** - any sample of tissue or fluid taken for diagnostic purposes

**Fixative** - a solution used to stabilize cellular components in preparation for histological examination.

**Fresh**: - no fixative has been used.

**Frozen** - specimens that are or have been frozen for rapid microscopic examination during an inter-operative consultation.

1.7 Related Documents

<table>
<thead>
<tr>
<th>Laboratory Procedure</th>
<th>Controlled copies on BLUE paper only</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample Acceptance Criteria</td>
<td>MP-GEN-0019</td>
</tr>
<tr>
<td>Packing Instruction 650</td>
<td>MP-GEN-0031</td>
</tr>
</tbody>
</table>

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Laboratory Procedure

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2 GENERAL INFORMATION

2.1 Hours of Operation

2.1.1 Laboratory Service

9am-5pm Monday-Friday (Frozen Section Service 9am-4.30pm)

The Histopathology Department is closed at weekends and on Public Holidays.

Outside normal working hours, the Consultant “on-call” can be contacted for advice via the main switchboard at Letterkenny University Hospital (Tel: 074 9125888).

2.1.2 Medical Advisory Service

Due to the difficulty in obtaining and often the unrepeatable nature of Histopathology/Cytology samples, users are strongly encouraged to contact an appropriate member of the Histopathology staff for advice and guidance, prior to taking the sample, if in any doubt as to the most appropriate sampling method to use.

2.2 Histopathology Staffing

The Histopathology Laboratory is staffed by:
- Consultant Pathologists (3)
- Chief Medical Scientist (1)
- Senior Medical Scientist (1)
- Staff Grade Medical Scientists (5)
- Departmental Secretaries (2)

2.3 Contact Details

The postal address for the Histopathology Laboratory is:

Histopathology Laboratory,
Department of Pathology,
Letterkenny University Hospital,
Letterkenny,
Co. Donegal,
Ireland.
The contact details for the Histopathology department staff are as follows:

<table>
<thead>
<tr>
<th>Contact</th>
<th>Position</th>
<th>Telephone</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td>Letterkenny University Hospital</td>
<td></td>
<td>074 91 25888</td>
<td></td>
</tr>
<tr>
<td>Dr. G.M. O’Dowd</td>
<td>Consultant Pathologist</td>
<td>Ext. 3545</td>
<td><a href="mailto:gerry.odowd@hse.ie">gerry.odowd@hse.ie</a></td>
</tr>
<tr>
<td>Dr. K.M. Dillon</td>
<td>Consultant Pathologist</td>
<td>Ext. 3546</td>
<td><a href="mailto:katrina.dillon@hse.ie">katrina.dillon@hse.ie</a></td>
</tr>
<tr>
<td>Dr. H. Gyorffy</td>
<td>Consultant Pathologist</td>
<td>Ext. 4469</td>
<td><a href="mailto:hajnalka.gyorffy@hse.ie">hajnalka.gyorffy@hse.ie</a></td>
</tr>
<tr>
<td>Departmental Secretaries</td>
<td></td>
<td>Ext. 3579/4468</td>
<td></td>
</tr>
<tr>
<td>Histopathology–Technical Advice</td>
<td>Chief Medical Scientist</td>
<td>Ext. 8896</td>
<td><a href="mailto:kerry.alcorn@hse.ie">kerry.alcorn@hse.ie</a></td>
</tr>
</tbody>
</table>

2.4 User Satisfaction and Complaints

All complaints, either verbal or written, regarding any aspect of the service provided by the Pathology department should be directed to the Quality Manager. All complaints will be raised as a non conformance on Q-Pulse. In all cases, it is department policy to respond in an open, positive and professional manner to issues raised. Where necessary, adjustment to process may ensue.

The laboratory performs annual surveys of user satisfaction. Results of user surveys are reviewed and if deemed appropriate, quality improvements may be implemented based on the information provided by the users.
3 PATHOLOGY SERVICES AVAILABLE

3.1 Routine Histopathology

Routine histopathological examination is performed on all biopsy samples including core biopsies, endoscopic biopsies, small resection specimens and bone marrow biopsies. It is also carried out on surgical resections removed in theatre.

All specimens must be in the laboratory by 4.00pm to facilitate optimal fixation and standardisation of results.

3.2 Frozen Section

Frozen sections should only be requested if the immediate management of the patient is likely to be altered as a result. Requests for frozen section **MUST** always be discussed with a Consultant Pathologist. Planned frozen sections should be pre-booked with a Consultant Pathologist at least 24hrs in advance, to ensure the availability of medical and technical staff. In cases where an unplanned frozen section is required, as much warning as possible should be given to the laboratory as the equipment used requires appropriate preparation.

If the operation is delayed, or if it is subsequently found that the frozen section is not required, please notify the Histopathology Department without delay.

High TB risk, known HIV, Hepatitis B or C are contraindications to frozen section. If such a specimen is inadvertently processed, full decontamination of the equipment used will be required, and during this time no further frozen sections can be performed for at least 24hrs. Such instances will be recorded as clinical incidents.

3.3 Routine Non-gynaec Cytology

Routine cytopathological examination is performed on all fluids, sputa and bronchial washings/brushings/lavages received within 24 hrs (ideally, as promptly as possible) of sample collection. Samples taken and refrigerated may be examined within 72 hours at the discretion of the reporting pathologist; **samples outside of these time-frames will not be processed for cytopathological examination**.

Please note that all requests for gynaecological cytology are now handled through the National Cervical Screening Program.
3.4 Fine Needle Aspiration (FNA)

Consultant Pathologists will perform Fine Needle Aspiration (FNA) procedures ONLY by prior arrangement. (Please refer to section 2.3, Table 1 for contact details).

3.5 Histological/Cytological samples requiring specialist reporting

Some histological/cytological samples received by the Histopathology Department LGH are forwarded to specialist centres for examination and reporting.

3.5.1 Renal Biopsy
Renal biopsies performed for medical diagnosis are examined and reported by the Pathology Department, Beaumont Hospital, Dublin. Renal biopsies for primary/secondary tumours are processed at Letterkenny University Hospital.

3.5.2 Muscle Biopsy
Muscle biopsies for diagnosis of Neurodegenerative disorders and metabolic studies are examined and reported by the Neuropathology Department at the Beaumont Hospital, Dublin.

3.5.3 Transbronchial FNA (TBNA)
Transbronchial FNA (TBNA) samples are examined and reported at the Cytology Department, Central Pathology Laboratory, St. James’s Hospital, Dublin.

3.5.4 Urine Cytology
Urine samples requiring cytopathological examination are examined and reported by the Cytology Department, Central Pathology Laboratory, St. James’s Hospital, Dublin.

3.5.5 Molecular Testing
Requests for KRAS, NRAS, ALK FISH, BRAF, EGFR, ROS-1, PD-L1 and MSI (by PCR) Molecular Testing of archived Histopathology blocks are prepared in the Histopathology Department and sent to the Molecular Histopathology Laboratory, Department of Pathology, R.C.S.I. Education and Research Centre, Beaumont Hospital, P.O. Box 9063, Dublin 9. Requests for MSI Testing by immunocytochemistry are performed at Letterkenny University Hospital.

3.5.6 Oncotype DX Breast Cancer Assay
Requests for Oncotype DX Breast Cancer Assay testing of archived Histopathology blocks are prepared in the Histopathology Department and sent to Genomic Health Inc., 301 Penobscot Drive, Redwood City, CA 94063, USA for analysis.
3.6 TSE patients

Tissue samples from patients with known or suspected new variant Creutzfeldt–Jakob disease (nvCJD), or any other Transmissible Spongiform Encephalopathy (TSE), **MUST NOT BE SENT TO THE HISTOPATHOLOGY LABORATORY AT LETTERKENNY UNIVERSITY HOSPITAL UNDER ANY CIRCUMSTANCES.** The clinical team **MUST** liaise directly with the Neuropathology Department at Beaumont Hospital, Dublin, who have the necessary facilities and expertise for dealing with such cases. They can be contacted directly on 01-8092633.
4 TURNAROUND TIMES

Turnaround time is defined as the number of working days from the date that the specimen is received in the Histopathology laboratory until the time an authorised report is available. The time taken for a result to be available depends on the type, size and complexity of the specimen.

4.1.1 Small biopsy specimens (e.g. endoscopic biopsy, core biopsy)
The majority (>80%) will be reported within 5 working days of receipt.

4.1.2 Large and unfixed specimens (e.g. surgical resections)
These will require additional fixation. The majority (>80%) will be reported within 7 working days of receipt.

4.1.3 Non-gynae Cytology specimens
The majority (>80%) will be reported within 5 working days of receipt.

4.1.4 Urgent Samples
Specimens requiring urgent reporting must be discussed and pre-arranged with the Consultant Pathologist covering "cut-up", ideally PRIOR to submitting the specimen to the lab. Urgent requests must be made by the Consultant in charge of the patient.

The request for urgent analysis must be used appropriately. Abuse of the urgent request facility will have an adverse effect on the turnaround times of genuinely urgent requests.

4.1.5 Exceptions
In the following situations the final report may be delayed. In such cases, an interim report may be issued, or the Consultant Pathologist may discuss the case with the referring doctor:

- Specimens where the tissue requires decalcification e.g. bone
- Specimens requiring lengthy and involved procedures, particularly those requiring immunocytochemistry or special stains
- Specimens where the pathologist feels a second opinion may be of benefit to the patient
- High risk specimens (Category 3)
5  ISSUING OF RESULTS

The Department of Histopathology, Letterkenny University Hospital is accredited to ISO 15189 to give assurance to users and to safeguard the quality of the results obtained. The registration number is 210MT and the full scope of accreditation can be examined on www.inab.ie

5.1 Samples examined ‘on-site’

Hardcopy written reports will be issued, once the case has been authorised by a Consultant Histopathologist. Where necessary, paper copies may be obtained by arrangement with the Histopathology secretaries. In some cases, where further work is being performed on the sample, an addendum report may be issued when all investigations are complete.

Pending reports can only be discussed with the relevant Consultant Histopathologist.

In accordance with INAB Accreditation recommendations, reports will not be communicated verbally by Secretarial Staff.

**For all enquiries relating to the reporting of Histopathology/Cytology requests, please contact the Pathology Secretaries (see Section 2.3, Table 1).**

5.2 ‘Copy to’ Reports

There is no facility on the laboratory information system to automatically generate copies of reports. Reports will be sent to the person and location stated on the Histopathology request form. It will be the responsibility of the requestor to inform the ‘copy to’ person of the result. Copies of reports will not be issued to Primary Care, these should be obtained through the relevant Hospital Consultant.

5.3 Samples forwarded elsewhere

Reports on samples forwarded to specialist centres will be issued directly by the reporting laboratory to the requesting clinician.

**Please do not contact the Histopathology Department, LGH to request copies of these reports as the secretarial staff do not have access to these results.**
6 LABORATORY REQUEST FORM

6.1 General Information

All requests for Histological/Cytological examination must be made using the correct version of the blue, controlled Histopathology/Cytology request card (MF-0370). Supplies of these forms are available from Pathology Reception. The General Laboratory request form MUST NOT be used.

Requests made on unapproved forms will not be processed.

Histopathology do NOT accept verbal requests for examinations.

The specimen type and anatomical site are particularly important in Histopathology where specimens may be multipart or left or right etc. Failure to submit essential information will result in a delay in specimen processing pending amendments being made to request forms or specimens. This may cause unnecessary delays in issuing reports.

6.2 Legally changed surnames

Where a patient surname has changed e.g. marriage, the Medical Records department must be provided with written confirmation. This should be done with the next sample sent to the Pathology Department (any laboratory) so that the Laboratory Information System (LIS) is updated accordingly.

Specimens will not be processed until written confirmation is received and the IPMS and LIS are updated. Written confirmation must include; Previous full name, current full name, DOB, PCN, and address, on GP headed notepaper, signed by GP/ patient’s Consultant/ Secretary.

6.3 Completing the Request Form

Note: Failure to provide the minimum data required on the Histopathology/Cytology Request form will result in a delay in processing the sample.

The following ESSENTIAL information MUST be documented, in a legible manner, on the request form. An addressograph label if available, should ideally be attached. The request form SHOULD also contain the following DESIRABLE information.

<table>
<thead>
<tr>
<th>Laboratory Procedure</th>
<th>Essential Information</th>
<th>Desirable Information</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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6.4 Responsibility

Responsibility for full and correct completion of the Histopathology/Cytology request form lies solely with the requesting clinician (Hospital or GP based). Incomplete, or incorrectly completed, request forms will not be accepted under any circumstances and will not be processed until the discrepancy is amended. This, in turn, will cause a delay in sample reporting.

<table>
<thead>
<tr>
<th>Request Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Patient’s Hospital Number (PCN) (patient’s full address if PCN not available)</td>
</tr>
<tr>
<td>• Patient’s Full Name</td>
</tr>
<tr>
<td>• Patient’s Date of Birth (DOB)</td>
</tr>
<tr>
<td>• Ward/Practice location</td>
</tr>
<tr>
<td>• Consultant/GP in charge of patient</td>
</tr>
<tr>
<td>• Requesting Doctor/Nurse name and/or MCRN</td>
</tr>
<tr>
<td>• Signature of requesting clinician</td>
</tr>
<tr>
<td>• Date of request</td>
</tr>
<tr>
<td>• Specimen nature/site, including side, for each sample being submitted</td>
</tr>
</tbody>
</table>

| Clinical Details, including procedure indicators and any previous Histopathology/Cytology reference numbers |
| Patient’s Gender |
7 SAMPLE COLLECTION

7.1 Medical indications and appropriate selection of available procedures

Certain clinical indicators will dictate the most appropriate sampling method to use when submitting tissue/fluid for histological/cytological examination. Where any doubt exists, it is advisable to contact one of the Consultant Pathologists prior to performing the biopsy, who will be pleased to offer help and advice.

7.1.1 Histopathology

<table>
<thead>
<tr>
<th>Sample</th>
<th>Clinical indicator</th>
<th>Appropriate action/recommendation</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin lesion</td>
<td>Pigmented</td>
<td>Punch biopsy NOT recommended; excise in full</td>
<td>Risk of sampling error</td>
</tr>
<tr>
<td>Lymph Node</td>
<td>? lymphoma</td>
<td>Core biopsy/FNA of lymph node NOT recommended</td>
<td>Excision-biopsy of an entire lymph node is investigation of choice</td>
</tr>
<tr>
<td>Any</td>
<td>? malignant</td>
<td>Biopsy specimen recommended over cytology sample</td>
<td>Immunocytochemistry difficult to perform on cytology samples and often gives unsatisfactory results</td>
</tr>
</tbody>
</table>

7.1.2 Cytology

<table>
<thead>
<tr>
<th>Sample</th>
<th>Clinical indicator</th>
<th>Appropriate action/recommendation</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>CSF</td>
<td></td>
<td>Routine cytological examination of CSF is inappropriate. Discuss individual case with Consultant Pathologist before taking sample</td>
<td>Minimal cellular yield</td>
</tr>
<tr>
<td>Breast Cyst Fluid aspirate</td>
<td></td>
<td>Do NOT submit fluid aspirated from breast cysts for cytology; refer to Breast Care North West</td>
<td>As per National Cancer Control Programme (NCCP) guidelines</td>
</tr>
</tbody>
</table>
7.2 General information

All samples sent for histological/cytological examination **MUST** be submitted to the laboratory in the appropriate manner.

### 7.2.1 Routine Histopathology

All specimens for routine histological examination **MUST** be collected into containers of 10% neutral-buffered formalin solution. There **MUST** be sufficient formalin in the container to completely cover the specimen. (Ideally there should be at least 3 times the volume of fixative in ratio to the size of the specimen to ensure adequate fixation). Specimens **MUST NOT** be placed into any other solution or into a dry container (except frozen section requests), as irreversible deterioration of the specimen will take place, making accurate microscopic interpretation impossible. Large surgical resection specimens should not be sliced or opened by the surgeon, but sent directly to the laboratory without delay.

### 7.2.2 Frozen section

Specimens for frozen section **MUST** be placed in a suitably-sized **DRY** specimen container and transferred immediately to the Histopathology Department by hand.

**Tissue for frozen section must be handed directly to a Medical Scientist or Consultant Pathologist.**

### 7.2.3 Routine Non-Gynae Cytology

A separate sample, specifically for cytological analysis, **MUST** be submitted with the approved request form.

Requests for Cytology made on the General Laboratory request form, or without a separate sample for cytology, will not be processed.

The method of submission of non-gynae cytology samples depends on the sample type. These samples **must be forwarded to the laboratory without delay (less than 24 hours)**; if a delay cannot be avoided, the sample may still be accepted if kept refrigerated, up to a maximum of 72 hours.

The main sample types are detailed below:

- **Pleural, Peritoneal and Cyst Fluids:** Up to a maximum of 25ml of fresh fluid should be sent to the laboratory in a white topped, sterile, universal container.
Drainage bags of fluid MUST NOT be sent to the laboratory. Transport of such bags poses a serious infection risk to staff and public within the hospital.

- **Sputum**: Use a white topped, sterile, universal container to collect the first deep cough specimen produced in the morning, or a sample taken after physiotherapy. The sample should be collected before breakfast or teeth cleaning. Samples comprising predominantly saliva are inadequate for cytological investigation of the lower respiratory tract. Sputum cytology should not be used as a screening investigation. It should be limited to individuals in whom a histological or cytological diagnosis is desired but in whom bronchoscopy is inappropriate or unsuccessful. Ideally, the test should be carried out on three consecutive days, with each specimen being delivered to the lab as soon as it is taken. For other suspected pathology, discuss with a Consultant Pathologist in advance.

- **Bronchial Brushings**: Collect brushings and brush tip into a 30ml Cytolyt® collection cup (available in the Endoscopy Unit).

- **Bronchial Washings**: Collect washings into a 30ml Cytolyt® centrifuge tube (available in the Endoscopy Unit).

- **Bronchoalveolar Lavage (BAL)**: Collect into sterile, screw-top container. Do NOT add any fixative/preservative.

- **FNA (excluding TBNA – see Section 7.2.6)**: Consultant Pathologists prepare FNA slides at the clinic or in the radiology department by prior arrangement, and return the sample(s) to the Histopathology laboratory for processing. Wash needle into sterile white-topped universal containing Cytolyt® solution (obtain from Histopathology laboratory).

### 7.2.4 Muscle Biopsy

Muscle biopsy procedures MUST be performed as early in the day as possible to ensure that the sample is delivered to the Histopathology Laboratory LGH by 11am sharp the same day. This is to facilitate the specialist reporting centre in Dublin, who require that the biopsy arrives with them no later than 4pm on the same day. The specimen should ideally measure 15x10x10mm and be wrapped in saline dampened gauze before being placed into an empty white topped Universal container. **Do not over soak the gauze as this causes problems with ice crystal artefact formation during subsequent processing.** Make sure the specimen is reasonably loose within the container. Take care not to squash the specimen. **Do not send the sample on ice.**

Please refer to Appendix A for ward instructions on the collection of muscle biopsies.
7.2.5 Renal Biopsy (for medical diagnosis)

Two specimens should be taken: one into 10% buffered formalin and the other into Zeus fluid. Both fixatives are available for collection by prior arrangement from the Histopathology Department at Letterkenny University Hospital. Renal biopsies should be received in the Histopathology Department before 11am to ensure next-day delivery to the specialist reporting centre via the Biomnis Courier service. The Histopathology Laboratory MUST be informed if a sample is clinically urgent so that it can be sent by taxi the same day, and the specialist centre informed.

7.2.6 Transbronchial FNA (TBNA)

TBNA specimens are collected directly into Cytolyt® fluid by the Bronchoscopy Team at the time of the procedure, and dispatched for specialist reporting.

7.2.7 Urine

20ml of urine in a white topped, sterile, universal container will be sufficient. For best cell yields the sample should be collected at the beginning or end of voiding urine. The first morning sample is less suitable than other times as cells in the low pH and hypertonic environment undergo degenerative changes making cytologic assessment difficult. It is extremely important that no alcohol or any other fixative is added to the specimen.

7.3 Summary of Appropriate Sample Collection Methods

All requests, and the appropriate submission method for each, are summarised in Table 2 below:

(Table 2)

<table>
<thead>
<tr>
<th>Request</th>
<th>Appropriate submission state</th>
<th>Specimen example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routine Histopathology</td>
<td>10% Formaldehyde (Formalin)*</td>
<td>Endoscopic biopsy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Core biopsy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Surgical resection</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bone marrow biopsy</td>
</tr>
<tr>
<td>Frozen Section</td>
<td>Dry: hand-delivered direct to lab immediately</td>
<td></td>
</tr>
<tr>
<td>Routine Non-gynae Cytology</td>
<td>Max. 25ml fresh i.e. unfixed: delivered to lab without delay</td>
<td>Pleural fluid</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sputum</td>
</tr>
</tbody>
</table>

Laboratory Procedure

Controlled copies on BLUE paper only

This document is designed for online viewing. Printed copies not distributed by the Quality Manager are deemed UNCONTROLLED.
Collect into 30ml Cytolyt® solution***

Bronchial Brushing/Washings

Collect into sterile, screw-top container. Do NOT add fixative/preservative.

Bronchoalveolar Lavage

FNA
Prepared by Consultant Pathologist at clinic/radiology department;
Wash needle into Cytolyt® solution**

Muscle biopsy
Fresh: wrapped in saline-moistened gauze

Renal biopsy
One sample in 10% Formaldehyde plus one sample in Zeus Fluid**

Transbronchial FNA
Cytolyt® fluid***

Urine
20ml Fresh (beginning or end of second morning voiding)

*40ml pre-filled, red-topped formalin pots, suitable for small biopsy samples, are available to all wards from the Pharmacy Department, Letterkenny University Hospital. Theatres acquire their own supply of formalin and specimen containers for use in the submission of large surgical resections. It is the responsibility of individual GP Surgeries to supply their own formalin and specimen containers.

** Available direct from the Histopathology Laboratory by prior arrangement.

*** Sourced direct by Bronchoscopy Unit.

Please ensure that all specimen container lids are securely fastened before forwarding to the Histopathology Laboratory.

7.4 Labelling the sample container

Specimen containers MUST be labeled in such a way as to provide an unequivocal link to the patient. Best practice dictates that labeling should take place in the presence of the patient, immediately after sample collection.

The following essential information MUST be documented, in a legible manner, on the specimen container(s). An addressograph label, if available, may be used. Large sample containers MUST be labelled on the pot AND on the lid.
Specimen container

- Patient’s Hospital Number (PCN) and/or Date of Birth (DOB)
- Patient’s Full Name
- Specimen nature/site, including side, for each sample being submitted

Note: Failure to provide the minimum data required on the Histopathology/Cytology sample container(s) will result in a delay in processing the sample.

7.5 Responsibility

Responsibility for full and correct labelling of any Histopathology/Cytology sample submitted to the laboratory for testing lies solely with the requesting clinician (Hospital or GP based). Unlabelled, or incorrectly labelled, samples will not be accepted under any circumstances and will not be processed until the discrepancy is amended. This, in turn, will cause a delay in sample reporting.

7.6 Category 3 Samples

A “BIOHAZARD” sticker:

**MUST** be placed on Histopathology / Cytology sample containers and request forms of any specimen from a patient who is known to have, or is being investigated for, any of the following:

- Undiagnosed jaundice
- HIV
- Hepatitis B or C
- Tuberculosis
- Viral Haemorrhagic Fever
- History of I.V. drug abuse
- Severe Acute Respiratory Syndrome (SARS)

It is desirable that the nature of the infection be stated in the clinical information section of the blue Histopathology/Cytology request form.

The sample **MUST** undergo a minimum of 24 hours fixation before cut-up and processing.
Unlabelled high risk samples will **NOT** be processed as they pose a serious health and safety risk to laboratory staff.

<table>
<thead>
<tr>
<th>Laboratory Procedure</th>
<th>Controlled copies on BLUE paper only</th>
</tr>
</thead>
<tbody>
<tr>
<td>This document is designed for online viewing. Printed copies not distributed by the Quality Manager are deemed <strong>UNCONTROLLED</strong>.</td>
<td></td>
</tr>
</tbody>
</table>
8 SAMPLE QUALITY

Laboratory Personnel inspect all samples received into the laboratory for adequate fixation (if appropriate) and proper labelling of both the request form and the specimen container. **Failure to comply with any of the submission and/or labelling requirements of the Histopathology Laboratory will result in a delay in sample processing.**

8.1 Unlabelled and inadequately completed samples and request forms

Acknowledging the unrepeatable nature of many Histopathology samples, the clinical team/GP will be given the opportunity to amend any unlabelled or inadequately completed samples or request forms.
9 PACKAGING, DELIVERY AND TRANSPORT OF DIAGNOSTIC AND INFECTIOUS SAMPLES TO THE LABORATORY

9.1 General Information

It is the policy of the Pathology Department to treat all specimens and samples as potentially infectious or high risk. Therefore, it is essential that precautions in the collection, packaging and the delivery of specimens are undertaken when preparing and sending specimens to the Laboratory for testing (as detailed in MP-GEN-0060).

9.2 Sample Packaging

Sample packaging is dependent on a number of factors. Please refer to Table 3 for full details:

(Table 3)

<table>
<thead>
<tr>
<th>Sample being sent</th>
<th>Requestor Location</th>
<th>Method of delivery</th>
<th>Packaging Instruction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biopsy (inc. frozen section)</td>
<td>Within hospital</td>
<td>By hand</td>
<td>Biohazard bag, with completed request form in separate pocket</td>
</tr>
<tr>
<td>Biopsy</td>
<td>Within hospital</td>
<td>Pneumatic chute</td>
<td>Directly into pod, with completed request form; pad out pod if necessary</td>
</tr>
<tr>
<td>Surgical resection</td>
<td>Within hospital</td>
<td>By hand</td>
<td>Directly into steel trolley, with completed request form</td>
</tr>
<tr>
<td>Biopsy</td>
<td>GP Surgery</td>
<td>Routine GP Transport</td>
<td>Biohazard bag, with completed request form in separate pocket</td>
</tr>
</tbody>
</table>
9.3 Specimen delivery from within the hospital

All samples from within the hospital being sent for histological and/or cytological examination must be delivered directly to the Histopathology Laboratory and NOT to Pathology Central reception. Specimens can be transported to the Histopathology laboratory via any of the following methods:

- Hand-delivered by hospital portering staff
- Hand-delivered by nursing or medical staff
- Pneumatic chute system

Please note that samples for frozen sectioning MUST be hand-delivered to a member of Histopathology laboratory staff immediately after removal.

9.3.1 Instructions for use of the pneumatic chute system

- Place the sample to be transported into the carrier bottle.
- Pack out carrier with tissue paper or similar to avoid damage to specimen containers while in transit
- Dial the POD number of the Histopathology laboratory - 3561.
- Place carrier bottle into the sending funnel.

9.3.2 Instructions for pneumatic tube fault reporting

- Call APT (company responsible for chute system) on speed-dial 173-503 or direct 01-8413005 to report fault.
- This is a 24 hour call centre.
- APT will investigate the problem remotely and attempt to fix it.
- In the event that the problem cannot be fixed remotely, APT will contact the hospital on-call maintenance team.

9.4 Specimen delivery from outside the hospital

Histological and/or cytological specimens from community GP surgeries must be packaged and transported in accordance with the European Agreement concerning the International Carriage of Dangerous Goods by Road (UNADR). Pathological specimens are classified as diagnostic specimens and must be packaged in accordance with the ADR packaging instruction P650 (MP-GEN-0031). The package must be clearly labelled “DIAGNOSTIC SPECIMENS”. The UN Number 3373 must be shown.

All samples from GP Surgeries are delivered to the Laboratory Central Reception area for sorting. Any Histopathology/Cytology samples are subsequently hand-delivered to the Histopathology laboratory by Central reception staff.
10 STORAGE OF SAMPLES, REQUEST FORMS & REPORTS

The Histopathology department retains all specimens, blocks, slides and associated documentation in accordance with Royal College of Pathology guidelines. Dedicated space is available for archiving tissue blocks, slides, request forms and reports. All unprocessed tissue is retained in formalin fixative in the ‘cut-up’ room, off the main Histopathology lab. Non-gynae cytological samples are stored at 2-4°C in the Histopathology laboratory fridge. After the storage period, specimens are disposed of according to HSE procedure for the disposal of clinical waste.

The period of time that all histological and cytological material must be retained for is detailed in Table 4:

(Table 4)

<table>
<thead>
<tr>
<th>Item</th>
<th>Retention time</th>
<th>Storage Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Histological Tissue Block</td>
<td>(Permanently) Min 30 years</td>
<td>Histopathology laboratory &amp; store</td>
</tr>
<tr>
<td>Histological Slide</td>
<td>(Permanently) Min 10 years</td>
<td>Histopathology laboratory &amp; store</td>
</tr>
<tr>
<td>Unprocessed Tissue</td>
<td>28 days after report issued</td>
<td>Histopathology laboratory</td>
</tr>
<tr>
<td>Cytological sample</td>
<td>14 days after report issued</td>
<td>Histopathology laboratory</td>
</tr>
<tr>
<td>Cytological slide</td>
<td>(Permanently) Min 10 years</td>
<td>Histopathology laboratory &amp; store</td>
</tr>
<tr>
<td>Cytological block</td>
<td>(Permanently) Min 30 years</td>
<td>Histopathology laboratory &amp; store</td>
</tr>
<tr>
<td>Histo/Cyto request form</td>
<td>Min 30 years</td>
<td>Histopathology office &amp; store</td>
</tr>
<tr>
<td>Histo/Cyto report</td>
<td>Min 30 years</td>
<td>Histopathology office &amp; store</td>
</tr>
</tbody>
</table>
11 QUALITY CONTROL

11.1 Internal Quality Control

The department employs rigorous internal quality control procedures to all stages of the process to ensure a high level of quality is always maintained.

11.2 External Quality Control

The Histopathology Service is committed to participating in available External Quality Assurance schemes to maintain and improve staining quality. To this end, the department partakes in the:

- NordiQC Scheme for Immunocytochemistry
  - General Pathology Module
  - Breast Cancer IHC Module
- National External Quality Assessment Scheme (NEQAS) for Cellular Pathology Technique (CPT)
- National External Quality Assessment Scheme (NEQAS) for Diagnostic Non-gynaecological Cytology
- Irish EQA Scheme in General Histopathology
- Histopathology National Quality Improvement Programme (NQIP)

11.3 Patient Consent

Patients consent to the use of their tissue as potential quality control material at the same time as consenting to their surgical procedure. The paragraph, contained within the Letterkenny University Hospital "Consent by Patient" form, reads as follows:

"Once the Pathologist has made a diagnosis on my tissue sample, I consent to any remaining tissue being utilised to assist with other similar diagnoses."

When a specimen that would be suitable for use as control material is identified, if possible, a copy of the consent form is received from the ward/Medical Records, and filed in the Histopathology laboratory. A full list of all control blocks taken is also maintained.
12 EXTERNAL LABORATORY TESTING

12.1 Referral for Quantitative Analysis

Tissue from patients with equivocal Her2 results on immunocytochemistry are forwarded for quantitative analysis by in-situ Hybridisation (ISH) to:
   Source Bioscience Healthcare Ltd.
   Nottingham
   UK

An addendum report will be issued by the Histopathology Department to the requesting clinician when the result of ISH testing becomes available. Referrals for ISH Testing routinely take 7-10 days until a result is returned.

12.2 Molecular Testing

Requests for KRAS, NRAS, ALK FISH, BRAF, EGFR, ROS-1 and PD-L1 Molecular Testing of archived Histopathology blocks must be submitted to the laboratory on the appropriate Histopathology Molecular Testing Request Form (MF-0559). These requests are then prepared in the Histopathology Department and forwarded to the Molecular Histopathology Laboratory, Department of Pathology, R.C.S.I. Education and Research Centre, Beaumont Hospital, P.O. Box 9063, Dublin 9. Results are communicated back via secure email to the Histopathology Department, who in turn forwards the original report to the requesting clinician.

Requests for c-MYC analysis are submitted to the laboratory on the appropriate Histopathology Molecular Testing Request Form (MF-0559) and forwarded to Tallaght Hospital, Dublin.

Requests for MSI Testing by immunohistochemical methods are performed at Letterkenny University Hospital and an addendum report issued when results are to hand. MSI Testing by PCR is performed in the RCSI Laboratory at Beaumont Hospital, Dublin.

12.3 Oncotype DX testing

Requests for Oncotype DX Breast Cancer Assay to be performed on archived Histopathology blocks must be submitted to the laboratory on the appropriate Genomic Health Inc. International Requisition form. A supply of these forms is available in the Histopathology Laboratory, complete with shipping kits and air-way bills. Results are communicated directly from the testing laboratory to the requesting clinician.
13 MULTI-DISCIPLINARY MEETINGS (MDM)

Consultant Pathologists from the Histopathology Department attend regular multi-disciplinary meetings (MDMs) to discuss individual cases. Also present at these meetings are members of surgical, radiological, oncological and nursing staff from within Letterkenny University Hospital, as well as staff from specialist centres via video-conferencing. The schedule is as follows:

(Table 6)

<table>
<thead>
<tr>
<th>MDM</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local Breast</td>
<td>Weekly (Wednesday)</td>
</tr>
<tr>
<td>Breast</td>
<td>Weekly (Thursday)</td>
</tr>
<tr>
<td>GI</td>
<td>Weekly (Friday)</td>
</tr>
<tr>
<td>Respiratory</td>
<td>Weekly (Monday) on request</td>
</tr>
<tr>
<td>Colposcopy</td>
<td>Monthly (Thursday)</td>
</tr>
</tbody>
</table>

Slides will be referred to outside institutions for MDM discussion at the request of the clinical team, upon completion of MF-0399 Request for Pathology Material review (Histopathology/Cytology).
14 FURTHER EXAMINATION OF SAMPLE

14.1 By Reporting Pathologist

Consultant Pathology staff may refer cases to colleagues, both on-site and elsewhere, when they feel that a second opinion or further stains may be of benefit to the patient. All cases of equivocal Her2 results will also be referred for quantitative Her2 analysis by \textit{in-situ} Hybridization (ISH). In any such instance, a final report will be issued, with an addendum report following once all investigations are complete.

14.2 By Requesting Clinician

All requests for further examination of the primary sample, by the requesting clinician, \textbf{MUST} be made directly to the reporting Primary Pathologist (see Section 2.3, Table 1 for contact details) by the Consultant in charge of the patient and on completion of the appropriate request form (MF-0399 Request for Pathology Material review (Histopathology/Cytology)).
15 HEALTH & SAFETY ADVICE

15.1 General

- Treat all biological samples as potentially-infectious and wear proper protective equipment.
- Ensure that all lids are securely attached to specimen containers to minimise spillages.
- Dispose of excess cytological fluid in a safe and responsible manner.
- Clean up all spillages immediately and disinfect the area.

15.2 Formalin/Formaldehyde

- Avoid skin contact as sensitization may occur.
- Always wear proper protective equipment when handling as there is a possible risk of irreversible effects.
- Avoid breathing in fumes.
- Ensure container is always properly labelled with formalin hazard labels.
16 APPENDIX A

Ward Information for collection of Muscle Biopsies

1. Muscle biopsies should be performed as early in the morning as possible as they must arrive at the Beaumont Hospital in Dublin before 4.00pm.

2. Check that both specimen containers and request form are correctly labelled.

3. The specimen should ideally measure 15x10x10mm.

4. Wrap the specimen in saline dampened gauze and place into an empty white topped Universal container. **Do not over soak the gauze as this causes problems with ice crystal artefact formation during subsequent processing.**

5. Make sure the wrapped specimen is reasonably loose within the container. **Take care not to squash the specimen.**

6. **Do not send the samples on ice.**

7. Send the sample to the Histopathology Department at Letterkenny University Hospital, to arrive by 11:00am at the latest.