PRIMARY SAMPLE COLLECTION MANUAL (USER GUIDE)

Date of Issue: 29/07/2015 **Effective Date**: 29/07/2015

APPROVALS

	Name	**Date**
Written/Reviewed By	Grace Hanniffy	29/07/2015
Approved By	Dr. Susan Kennedy	29/07/2015

DOCUMENT REVIEW HISTORY

Reviewed by	**Date**	**Amendment Necessary** *(if yes, state sections changed)*	**Next Revision Date**
Grace Hanniffy	29/07/2015	1,4,5,6,7,8	29/07/2017

Applicable Change Control Number(s): 2015/40

1 QUALITY POLICY

The Laboratory is committed to providing a histopathology service of the highest quality where the needs and requirements of its users are always considered.
In order to ensure that the needs and requirements of users are met;
The department will comply with the requirements of:

- ISO 15189:2012 Medical laboratories – Particular Requirements for Quality and Competence
- INAB Terms, Conditions and Regulations; Current Editions
- ILAC and EA Documents
- Guidelines for the Implementation of a National Quality Assurance programme in Histopathology

The scope of tests with respect to accreditation with INAB is detailed in Appendix No. 1 of this document.

The department will commit to:

No	Quality Objective
1.	Provide an environment to ensure consideration of health, safety and welfare of its entire staff. Visitors to the laboratory will be treated with respect, and due consideration will be given to their safety while on site
2.	Operate a quality management system to integrate the organisation, procedures, processes and resources
3.	Set and review quality indicators, quality objectives and plans in order to implement and maintain this quality policy
4.	Ensure that all personnel are familiar with the quality manual and all procedures relevant to their work to ensure user satisfaction
5.	Uphold professional values and is committed to good professional practice and conduct, quality of examinations and compliance with the quality management system.

The department is committed to:

6.	Comprehensive orientation and induction programme for all new members of staff
7.	Staff recruitment, training, development and retention at all levels to provide a full and effective service to its users
8.	The proper procurement and maintenance of such equipment and other resources as are needed for the provision of the service
9.	The collection, fixation, transport, sample preparation, identification and handling of all specimens in such a way as to ensure the correct performance of laboratory examinations and ensure that all stages in the sequence are embedded in the QMS.
10.	Providing turnaround times within specified limits and ensuring critical and abnormal result notification.
11.	Providing clinically useful information through the laboratory examination of samples from patients and reporting of reliable results in a timely fashion.
12.	The assessment of user satisfaction, in addition to internal audit and external quality assessment in order to produce continual improvement
13.	The use of examination procedures that will ensure the highest achievable quality of all tests performed

14.	Compliance with relevant environmental legislation and all relevant national and international guidelines and legislation.

Signed: _____ Date:_____

Laboratory Director

2 INTRODUCTION

This manual is designed to give an overall view of the histology services available to customers of MC Pathology Group. It is intended as a quick reference guide for all our users.

The purpose of this manual is to provide the user with sufficient information to enable them to ensure the delivery of the highest quality pathological samples. This will in turn facilitate the laboratory in its efforts to deliver the most effective service to support good clinical decision-making. The manual lists the histology tests available within MC Pathology Group; details the request forms and specimen containers required; the information necessary in the labelling of forms and containers; the procedure for taking, packing, delivering, storing and transporting specimens; and the reporting of test results. This manual is intended for all staff involved in the collection, packaging and transportation of patient samples e.g. clinicians, nurses, etc.

MC Pathology Group is a privately owned histology laboratory that provides a high quality histopathology service to external customers.

All Histopathology services undergo continuous review through quality assurance and audit activities. The Laboratory is committed to performing its activities in accordance with the requirements of the following regulations, bodies and standards:-

- The **International Standard ISO 15189** (current version) "Medical Laboratories Particular Requirements for Quality and Competence"
- Irish National Accreditation Board Regulations "INAB R1 Regulations" (current version) and all INAB mandatory documents
- Relevant ILAC/EA Guidelines
- Guidelines for the Implementation of a National Quality Assurance Programme in Histopathology – Faculty of Pathologists, Royal College of Physicians of Ireland
- The Retention and Storage of Pathological Records and Archives (current edition), Royal College of Pathologists

3 GUIDE TO USING THIS MANUAL

A **controlled hardcopy** of this manual is provided to each customer, where requested, at their principal offices and other relevant locations as authorised by the Laboratory Director.
A **read only version** of the manual is stored on the Laboratory website.
All tests and special requirements for testing in MC Pathology Group are documented in Section 8 of this manual.

4 GENERAL INFORMATION

4.1 Laboratory Location

The laboratory services are located at MC Pathology Group, Northbrook Clinic, 15A Northbrook Road, Ranelagh, Dublin 6.
The laboratory is located on the first floor of this building. The laboratory consists of the specimen reception and cut-up area, microtomy room, immunohistochemistry room, laboratory office, consultant office, reporting room and the store room. The reporting office is located on the ground floor of the Northbrook Clinic.

4.2 Laboratory Opening Hours

Specimen Reception: Monday - Friday from 08.00 - 17.30hrs
Routine Laboratory Diagnostic Service: Monday to Friday 08.00 - 17.30hrs
Emergency Out of Hours Service (on call diagnostic service): By arrangement.

4.3 Contact Information

The Histology Laboratory welcomes your queries. The contact details for the Laboratory are as follows:
Tel: +353 1 478 2274
Fax: +353 1 478 2733
Email: lab@mcpathology.ie
Contact can also be made using the 'Contact' tab on the MC Pathology Group website at www.mcpathology.ie

4.3.1 Key Staff Members

Position	**Name**	**Contact No.**
Laboratory Director	Professor Susan Kennedy	086 8387313
Consultant Histopathologist	Dr. Eoghan Mooney	01-4782274
	Dr. DS O'Briain	01-4782274
Senior Medical Scientist	Ms. Lisa Jaynes	01-4782274
Quality Manager	Ms. Grace Hanniffy	087 2512391
Administration / Enquiries	Laboratory Office	01-4782274

4.4 Service Description

MC Pathology Group provides a service in the discipline of Histopathology. Where **medical and scientific advice is required** on medical indications and appropriate selection of available procedures please contact the laboratory. For **telephone queries** use the list provided in Section 4.3 of this manual above. The Laboratory has a complaints system to facilitate the reporting of any unsatisfactory product or service by users and/or patients. Refer to Section 10 of this document.

The Laboratory, located at Northbrook Clinic, provides a comprehensive Histology Service across a wide range of specimens including gastrointestinal biopsies, skin lesions, surgical resections, gynaecologic specimens and a wide range of other tissue types. The department further provides a referral service for cytology samples including urine, cyst fluid, and fine needle aspirates and also a referral service for immunohistochemical techniques and molecular testing.

4.5 Accreditation

The Histology Laboratory is committed to achieving and maintaining accreditation under ISO 15189 for medical testing through the Irish National Accreditation Board (INAB).

4.6 Staffing

The laboratory team consists of:-

Management Team

- Laboratory Director
- Consultant Histopathologists
- Quality Manager
- Senior Medical Scientist(s)

Technical Staff

- Medical Scientist(s)
- Laboratory Aide(s)
- Support Services - Secretarial/Administration Staff

5 LABORATORY REQUEST FORMS & SPECIMEN CONTAINERS

5.1 General Information

This section details the information that must be documented on the laboratory request form and the specimen container, prior to sending for analysis. For accurate identification of specimens and patients, it is essential that specimens are labelled properly and that request forms are completed fully and accurately.

The laboratory has a standard request form which is used to request histopathology examinations by customers. These request forms are available on request from the Laboratory. Customers may use their own request forms provided the necessary criteria for completing the request form as listed below are adhered to.

Note: Please ensure the request form is completed in a clear, legible manner to ensure the prompt processing of specimens.

Note: Where changes are made to the request form, resulting in the issuing of a new version, the customer is notified and the new request form is sent to service users. A copy of the laboratory request form is also available on the MC Pathology website.

5.1.1 Specimen Acceptance Criteria

The information on the request form must be sufficient to identify the patient and the authorised requester. The following essential information must be documented in **a legible manner** on the request form:

1. Patient's Surname
2. Patient's Forename
3. Patient's Date of Birth
4. Patient's unique identification number
5. Patient's gender
6. Date of specimen collection (see special requirements in Section 5.3); collection time is not critical to specimen processing.
7. Patient's location / source, and the postal address of the location
8. The name and location of requestor
9. Specimen type and anatomical site
10. Examination(s) required
11. Relevant clinical details appropriate to the test(s) requested must be supplied e.g. history of previous histopathology, administration of drugs etc.
12. Patient's full home address
13. A clear indication as to whether the tests requested are urgent or routine
14. The signature of the requesting person completing the form.

5.1.1.1 Minimum Requirements for Histology Request Forms

- Include specimen type and anatomic site on both request form **and** specimen container.
- Include all clinical details.
- Include date specimen taken.
- Prior to dispatch by service user, each specimen is recorded on the relevant chain of custody form. This form must be signed for by personnel involved in collection and dispatch of the specimen. Upon receipt in the logistics company the chain of custody form is date and time stamped prior to dispatch. This form is then signed for by a medical scientist/laboratory aide upon receipt and verification that each specimen is present according to chain of custody form.
- Cervical cytology (not performed by MC Pathology but can be outsourced to an approved referral laboratory on request): include last menstrual period (LMP).
- Cervical cytology specimen request form and/or label **requires** the patient's address.

5.1.2 Labelling the Sample Container

The following information must be documented in a **legible manner** on all sheets of the request form.
Items marked with an * are minimum identifiers and failure to provide the minimum data required will delay processing of the sample.

1. *Patients' Full Surname
2. *Patients' Full Forename
3. *Hospital number
4. *Date of birth
5. *Specimen Type / Anatomic Site - Containers must be individually labelled with specimen type/description if more than one specimen is provided with a single request form

5.1.3 Key Points

- Prior to sending specimen check the completion of the Request Form. Always confirm the identity of the patient as per your establishments labelling and consent policy.
- Check the specimen pot is correctly labelled, sealed and not leaking.
- Ensure that the specimen is in an adequately sized specimen pot and determine if specimen should be sent with or without fixative (see Appendix No. 1).
- Minimise the risk of specimen interchange by not pre-labelling pots and double checking request forms prior to sending.

5.1.4 Specimen Rejection

Specimens are rejected where they cannot be processed for histology, although it is the policy of MC Pathology Group to make every effort to avoid rejection. Specimens for histology are rejected where no tissue is present in the specimen container. The source of the specimen is contacted as soon as possible and advised that no specimen is present in the container.

5.1.5 Scope of Service and Specimen Requirements - Routine Histology

All specimens for routine histology must be fixed in 10x formalin. Histology specimens need to be placed into a container at least 3 times the size of the specimen and fully covered with formalin. All specimens must be accompanied by a fully completed MC Pathology request form (or alternative as detailed in Section 5.1 of this document). Relevant clinical details are essential. (Clinical details where relevant, medical history, symptoms and/or possible diagnosis). Samples without clinical details or with insufficient or incorrect patient and specimen details must be verified with the sample taker prior to processing. This may result in a delay in reporting.

- **Skin biopsies for direct immunofluorescence** – These specimens must not be placed in formalin and should be placed in saline dampened gauze. **Immediate delivery to the Cellular Pathology department is vital.**
- **Non-Gynaecological Cytology** - Cervical cytology samples must be sent via the laboratory. Slides, spatulas, brushes, thin prep, fixative and mailing containers are not available from the laboratory. Reports are usually issued in 3-4 weeks of receipt. Refer to Section 5.1.1.1 for specific requirements for request forms.
- **Cytology** - please send to laboratory in universal container as soon after collection as possible, with an appropriate request form detailing relevant clinical details. If this is not possible the specimen must be refrigerated to prevent degradation.

Note: Non-Gynaecological specimens must be delivered to the laboratory in cytofix solution provided. Please notify the laboratory if stocks are low.

5.2 Computer Generated Specimen and Addressograph Labels

Computer generated addressograph labels may be used on all samples and request forms. Please check all details are correct on labels at patient's bedside before labelling specimens and forms. **Ensure all copies (including back copy) of request form are labelled.**

5.3 Histology/Cytology Specimen Containers

Type of Container	Special Requirements
Histology Biopsy Formalin Pots (pre-filled)	Adequate volume of formalin is essential for proper fixation. The recommended volume of fixative (formalin) is ten times the volume of the tissue to be fixed.
Theatre Pots or Buckets containing Formalin	Adequate volume of formalin is essential for proper fixation. The recommended volume of fixative (formalin) is ten times the volume of the tissue to be fixed.
Sterile Dry Containers	Fresh specimens requiring special analysis. Any unfixed tissue should be transported to the laboratory urgently in refrigerated transport container and laboratory staff alerted immediately.
Saline Soaked Fine Gauze	Use to gently wrap specimen inside a sterile dry specimen pot for skin specimens requiring direct immunofluorescence. **DO NOT add formalin**.
ThinPrep Pap Test PreservCyt Solution (White lid, 20 ml)	Use for cervical cytology smear specimens (Referral service only). Any unfixed tissue should be transported to the laboratory urgently in refrigerated transport container and laboratory staff alerted immediately.
Sterile Universal Container (20 ml) Prefilled with cytofix solution	Use for urine, cyst, synovial fluid, bronchial washings or other fluid specimens for cytology specimens. <u>If retaining overnight, ensure specimen refrigerated</u>. If cytofix (green or red) solution added, DO NOT refrigerate, and indicate original volume of fluid. DO NOT ADD formalin.

5.4 Non-Conforming Specimen Containers, Forms or Specimen Quality Issues

It is the policy of MC Pathology Group to accept specimens only if they meet the requirements set out in Section 5.1. Laboratory staff will inform the originator immediately on receipt if the sample is inadequately labelled and/or otherwise unsuitable. Given the invasive nature of histology specimens, every effort will be made to ensure the specimen can be examined. In some instances it may be necessary to hold the specimen prior to processing for clarification of patient identifiers etc. resulting in a delay in examination/diagnosis for the patient.

5.4.1 Sample Volume

Adequate Fixative - (10x formalin) is required for optimised tissue preservation. Refer to Section 8 for test specific sample volumes.

5.5 Further Additional Testing

If further additional testing is required on a specimen submitted to MC Pathology Group, contact the senior medical scientist to investigate the feasibility of using the initial specimen for analysis, since the age or remaining quantity of the specimen may impact on the validity of test results or preclude further testing.
Ideally, a request form must accompany such a request, but the lack of the request form will not impede the processing of an urgent request. A record of the name and status of the person requesting the test will be entered on the original request form.
All requests for additional histology or cytology testing and/or examination must be forwarded (by FAX if necessary) in writing and signed by the requestor. All additional histology tests/examinations are subject to authorisation by the Consultant Histopathologist at MC Pathology Group.

6 DELIVERY, PACKING, TRANSPORT AND POSTAL REQUIREMENTS FOR SPECIMENS

6.1 General Information

It is the policy of the laboratory to treat all specimens and samples as potentially infectious or high risk. Therefore, it is advised to take universal precautions in the collection, packaging and the delivery of specimens being sent to the Laboratory for analysis. Transport all specimens to the laboratory with minimal delay.

6.2 Specimen Delivery

- Place all specimens being sent to the laboratory in a plastic specimen transport bag attached to the request form or containing the request form in the outer sleeve of the bag. The "Gard" specimen bag is slightly larger and should be used for larger histology specimens.
- Specimen containers that are contaminated externally or leaking in any way **must not be** sent to the laboratory. The contamination or leak must be rectified prior to sending.
- High risk specimens (i.e. specimens from a patient with a known infectious disease) must be identified by attaching a RED STICKER to the request form and to the sample with an indication in the clinical details as to why the specimen is high risk. However all specimens must be treated as high risk and appropriate health and safety precautions taken.

6.3 Procedure for the Out of Hours Delivery and Storage of Specimens

Store **non-urgent** specimens as follows:-

1. Non-gynaecologic cytology – if fixative has not been added, then refrigerate prior to transport and indicate on request form that specimen has been refrigerated.
2. Routine Cellular Pathology specimens must be stored in appropriate containers with fixative at room temperature until the next available delivery time to MC Pathology Group. Keep these containers up-right while being transported to the laboratory.
3. Specimens for cytology or fresh tissue for histology must be stored in a refrigerated environment until the earliest available delivery to MC Pathology specimen reception. If any fresh specimens, including non-gynaecological cytology samples, for non-urgent reporting for Cellular Pathology cannot be delivered during working hours, they **MUST** be kept refrigerated, then collected and delivered on the 'first' following weekday. Containers and request form must be labelled with full patient details and specimen details.

6.3.1 Urgent Specimens

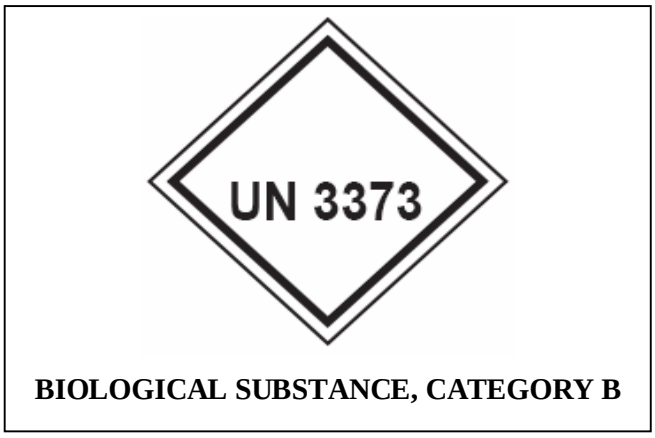
Mark the request form 'Urgent'. Send all urgent specimens for delivery to Specimen Reception area. The senior medical scientist will follow up where necessary.
In some cases Urgent specimens may be processed by prior arrangement after consultation with the laboratory director or senior medical scientist.

6.4 Specimen Delivery when Referring Specimens

All specimens transported by road must comply with the European Agreement concerning the International Carriage of Dangerous Goods by Road (UNADR). Package all specimens as per the ADR P650 Packaging Instruction. It is the responsibility of the sender to ensure that specimens are transported in accordance with current regulations. A copy of this regulation is available at:
www.izvg.co.uk/regulations.pdf
To meet the requirements of P650, there are 3 levels of packaging for diagnostic liquid and solid samples.

1. The primary receptacle – containing the sample.
2. This secondary containment receptacle - containing the primary sample/s and sufficient absorbent material to soak up any spillage that occurs.
3. The outer packaging, which is seen by delivery or postal staff.

At least one of the above packages must be pressure resistant to 56 kPa.
The outer packaging must be marked with UN 3373 and Biological substances, Category B marked adjacent to the diamond shaped mark as overleaf.



Jiffy bags **do not** meet the criteria in relation to the outer packaging.
All specimens referred for external testing are packaged using an UN approved packaging system. The system used incorporates a triple packaging system and is fully P650 compliant. It is based on the provision of a 95kPa leak proof bag and an outer study card-board box offering physical protection during transport. The outer boxes are labelled in-compliance with ARD 2007 requirements.

6.5 Disposal of Waste Material used in Specimen Collection

Treat all materials used in specimen collection as potentially hazardous and discard using sharps containers and other appropriate colour coded bags. Refer to your establishment waste disposal policy.

6.6 Storage of Examined Specimens (Minimum Retention Times)

6.6.1 Clinical Specimens

Clinical material is stored to facilitate repeat and further examination of material.
The retention times in this document refer to retention time for specimens post results being issued and are determined by the nature of the material and the type of analysis required.
Specimens are stored for a minimum of 4 weeks but may be stored for longer until the report is authorised. Specimens are retained in accordance with the following guidelines:

- The Royal College of Pathologists 'The Retention and Storage of Pathological Records and Specimens' (current edition)
- ISO 15189:2012 'Medical Laboratories-Particular Requirements for Quality and Competence
- Statutory Instruments, S.I. 360 of 2005 and S.I. 547 of 2006 transposing the above directives into Irish Law
- Irish National Accreditation Board, Document 'INAB Terms and Conditions' (TC)

The minimum retention times for the most common specimens are detailed in the Table below. Refer directly to the Cellular Pathology Laboratory for further details of minimum retention times for Cellular Pathology specimens. Additional testing of specimens may be possible during this time. Contact the laboratory for confirmation:

CELLULAR PATHOLOGY		
1.	Paraffin blocks, slides and Cytology slides/preparations	Held for a minimum of 30 years
2.	Cytology Specimens: Non-Gynae	Processed, blocked and kept for 30 years
	Gynae	Sent to external location- Slides kept for 10 years. Thin prep vials kept for 4 weeks post report authorization.
3.	Frozen Sections	Permanent tissue blocks held for a minimum of 30 years
4.	Surgical Specimens	Four Weeks† *following authorisation of final report*
5.	Stained Slides including controls	Held for 30 years

The laboratory participates in relevant available external third party assessment schemes. This includes schemes operated by:-

- NEQAS (UK, National External Quality Assurance Scheme)
- UK National Hospital Services(National Liver Pathology , Breast Pathology and National Ophthalmic Pathology EQA Scheme)
- Faculty of Pathology, RCPI, (Irish General Histopathology EQA Scheme)

The laboratory is committed to participating in other schemes as they become available to ensure comprehensive assessment of the test repertoire. Where EQA schemes are not available, the laboratory participates in inter-laboratory comparisons where possible.

7 PATHOLOGY SERVICES AVAILABLE

7.1 Clinical and Scientific Advice

Consultant Pathologists provide advice to customers on appropriate investigations, interpretation of laboratory results and patient management. Medical Scientists are responsible for carrying out the cellular pathology techniques. The Consultant Pathologists are responsible for providing interpretative comments and advice. MC Pathology Group consultant histopathologists are involved in continuous medical education. If clinical or scientific advice is required contact the laboratory and you will be directed to the appropriate staff member.

7.2 Service Description

SERVICE	DESCRIPTION
Consultant Service	There are Medical Consultants available in Cellular Pathology. The Laboratory Director/deputy will consult a Consultant on clinician request. Refer to section 4.3 of this document for contact details.
Cellular Pathology	All Histology specimens and Body Fluids for Cytology received in MC Pathology are processed. Cervical Cytology specimens are referred to external location.

8 LABORATORY TESTS/ PROFILES AVAILABLE

8.1 List of Laboratory Tests / Profiles

A list of all tests available from the Laboratory is available in Appendix No. 1 of this document. Each laboratory test will be described under the following headings:-

- Test Name
- Specimen type/ site
- Specimen requirements, required specimen volume and container type
- Special requirements
  The special requirements column defines for each diagnostic test if (applicable) the following:-
  - Patient preparation
  - Consent form
  - Special timing for collection of samples
  - Any special handling needs between time of collection and time received by the laboratory (transport requirements, refrigeration, warming, immediate delivery etc.)
- Test Frequency
  A test frequency which is stated as "daily" means that the test is available on each working day (i.e. Monday to Friday). A Turnaround Time (TAT) described as "same day" means that the result is available on the day that the sample was processed, provided that it was received in time for a process run that day. If not, the sample is held over until the next process run unless it is considered urgent.
  Referral of samples for diagnostic tests to external referral laboratories may also extend the turn-around-time. Please take the time to read any special instructions included under the test you are looking for.
- Turnaround time
  - Turnaround time is given as the maximum number of working hours/days between **specimen receipt** in the laboratory and issuing a report under normal operating conditions. Working days denotes Monday to Friday and does not include out-of-hours including weekends and bank holidays.
  - In addition to the routine service the laboratory operates an "URGENT" system whereby the target turnaround time is shorter. If tests are "Clinically Urgent" please flag/stamp as urgent on the request form. If results are "extremely" urgent please contact the senior medical scientist to discuss your requirements.
  - Cellular Pathology (Histology and Cytology) reports are usually available within 7 - 10 working days, depending on the specimen size and complexity and **unless extra tests are pending**.
  - Samples that need to be referred to outside institutions **may take 10 -14 days for a report to be available**.
  - Some specialised tests are not performed daily; if such tests are required urgently please phone the appropriate laboratory to discuss the request.
  - Please see relevant column in Appendix No. 1 of this manual for specific Turnaround Times for individual tests.

8.1.1 Tests Not Listed

If a diagnostic test is required that is not listed below, contact the laboratory for a list of approved Referral Laboratories and Referred Pathology Tests. Refer Appendix No. 2 Tests Referred to External Laboratories

8.2 Repeat Examination due to Analytical Failure or Further Examination of the Primary Specimen

8.2.1 Repeat Examination due to Analytical Failure

It is the policy of the laboratory in the event of an analytical failure to:-

- Repeat the test using a back-up instrument or
- Store the specimens in appropriate conditions until the cause of the analytical failure is identified and corrected and then repeat the test. The urgency of the outstanding specimens is reviewed by the Consultant Pathologist or nominee.
- To refer out any urgent samples during this period to an approved referral laboratory.

8.2.2 Further Examination of the Primary Specimen

1. Where further testing is relevant to the investigation or diagnosis of the condition or symptoms which gave rise to the original test request then it is the policy of the laboratory to pursue a diagnosis by performance of additional tests using the primary specimen.
2. Users may request additional examinations on specimens already sent to the laboratory. All requests for additional Cellular Pathology testing and or examination must be forwarded in writing (FAX) and signed by the requesting clinician. All additional Cellular Pathology tests/examination requests are subject to authorisation by the Consultant Histopathologist. The analysis will be performed provided the specimen has been stored appropriately and there is sufficient specimen remaining to perform the additional tests. There are time limits for additional tests – please phone the laboratory to enquire.

8.3 External Laboratory Testing / Referral Laboratories

Some specimen / samples are referred to external laboratories for testing – for specialised tests not performed in house at MC Pathology Group. A detailed list of tests referred and referral laboratories used is available in Appendix No. 2 of this document. Specimen handling and sample type necessary for each test is detailed here, along with any special requirements. Please refer to this before contacting the laboratory as they may answer any queries you may have in relation to the required test.

Ref.: Appendix No. 2: Tests Referred to External Laboratories

8.4 Factors known to Affect Examination Performance or Result Interpretation

Inadequate formalin / fixation can affect examination performance. Please ensure the specimen fully immersed for all histology specimens. Ensure pot is large enough to hold the specimen in 10x formalin.

Timely transportation of specimens is also recommended.

9 REPORTING OF TEST RESULTS

The main method of reporting results is by the production of a printed report and MC Pathology Group issues its own distinctive report.
The laboratory ensures that tests are performed to the highest possible standard and reported in the time specified within this User Manual. It is the responsibility of the requesting clinician to follow up on the test results.

9.1 Reporting of Results

All results, once released, are available on the laboratory information system. Hard copy reports are printed as reports are authorised. Reports are dispatched by post to their destination daily, if results are available before 15:30 hours, otherwise they are dispatched on the first working day after authorisation.

9.2 Telephoned Results

- It is the policy of the laboratory to telephone reports if the report is marked urgent or an unexpected result is obtained.
- Requests for verbal reports are not accepted except in urgent cases.
- Verbal/unscheduled reports are recorded on the Laboratory Information System (LIMS).
- The method by which results are phoned is clearly defined to ensure the results only reach an authorised receiver and that results are clear and unambiguous. The security of the patient records is ensured and the risk of error reduced.
- Results provided verbally are followed by a written report.

9.3 Faxed Reports

Reports may be faxed following authorisation by the Consultant Pathologist. In such instances, the confidentiality of the patient results must be ensured.
Faxed reports are sent only to secure locations and when the reporting administration staff is satisfied that the report is to be received immediately.

10 CUSTOMER COMPLAINTS

MC Pathology Group operates a complaint system. The objectives of the complaints handling system are as follows:-

- That all complaints are rapidly and effectively handled
- Customer/patient difficulties are alleviated as soon as possible
- The same problem will not occur again as following identification of the cause appropriate corrective actions will be put in place
- That customer confidence is restored in the service
- That the relevant information is formally recorded and reported to the Laboratory Director, as soon as possible.

If the service provided by the laboratory is not satisfactory, contact the Laboratory Director / Quality Manger to process the complaint. Refer to Section 4.3 of contact details.

11 DATA PROTECTION POLICY

MC Pathology Group complies with all legislation pertaining to the rights of the patient and staff and to act in an ethical and responsible manner in maintaining the security and integrity of all personal information.

12 APPENDICES

Appendix No. 1: Repertoire of Tests Provided by The laboratory
Appendix No. 2: Tests Referred to External Laboratories
Appendix No. 3: Sample Packaging Instruction P650
Appendix No. 4: Document Reading Record
Appendix No. 5: Amendment Proposal Record

Appendix No. 1: Repertoire of Tests Provided by the Laboratory

Test/ Profile/ Product	Sample Type	Sample Requirements			Special Requirements	Turnaround Time Routine/ Urgent
		Additive /Fixative	Volume Required mL	Test Frequency		
Cytology/FNA (Non-cervical)	Body Fluids/Fine Needle Aspirates	Fresh/Equal volume of Cytofix fluid	N/A	Daily	N/A	7-10 working days
Routine Histology	Any	Formalin at Room Temperature	10x volume formalin for at least 24 hours (appropriate to size of specimen)	Daily	Cellular Pathology request form. Do not store in fridge as formalin is inactivated below room temperature.	7-10 days (varies with nature of tissue and extent of investigations) 24-48 hrs if urgent/discuss with Cellular Pathology laboratory staff.

Appendix No. 2: Tests Referred to External Laboratories

Investigation	Address	Telephone No.	Contact	Sample	Specimen Handling Comments
FISH Analysis	Histopathology Laboratory, RCSI, Beaumont Road, Dublin 9	01 8093726	Tony O'Grady	Breast & Gastric Biopsies	Contact Cellular Pathology Laboratory before sending. Test is requested by Pathologists.
HER2	Histopathology Laboratory, RCSI, Beaumont Road, Dublin 9	01 8093726	Tony O'Grady	Breast & Gastric Biopsies	Contact Cellular Pathology Laboratory before sending.
Immunostains / Molecular Testing	Histopathology Laboratory, RCSI, Beaumont Road, Dublin 9	01 8093726	Tony O'Grady	Unstained tissue section	Contact Cellular Pathology Laboratory before sending.
Immunostains	Immunohistochemistry Laboratory, National Maternity Hospital, Holles Street, Dublin 2	01 6373180	Mary Hunter	Unstained tissue section	Contact Cellular Pathology Laboratory before sending.
EGFR Mutation Studies	Histopathology Laboratory, RCSI, Beaumont Road, Dublin 9	01 8093726	Tony O'Grady	Unstained tissue section	Contact Cellular Pathology Laboratory before sending.
KRAS Mutation Studies	Histopathology Laboratory, RCSI, Beaumont Road, Dublin 9	01 8093726	Tony O'Grady	Unstained tissue section	Contact Cellular Pathology Laboratory before sending.

Appendix No. 3: Sample Packaging Instruction P650

This packing instruction applies to UN No. 3373 (Diagnostic Specimens)

1. The packaging shall be of good quality, strong enough to withstand the shocks and loadings normally encountered during carriage, including transhipment between vehicles or containers and between vehicles or containers and warehouse as any removal from a pallet or over pack for subsequent manual or mechanical handling. Packaging shall be constructed and closed to prevent any loss if contents that might be caused under normal conditions of carriage by vibration or by changes in temperature, humidity or pressure.
2. The packaging shall consist of three components
   a) a primary receptacle;
   b) a secondary packaging; and
   c) an outer packing.
3. Primary receptacles shall be packed in secondary packaging in such a way that, under normal conditions of carriage, they cannot break, be punctured or leak their contents into the secondary packaging. Secondary packaging shall be secured in outer packaging with suitable cushioning material. Any leakage of the contents shall not compromise the integrity of the cushioning material or of the outer packaging.
4. For carriage, the mark illustrated below shall be displayed on the external surface of the outer packaging on a background of a contrasting colour and shall be clearly visible and legible. The width of the line shall be at least 2mm; the letters and numbers shall be at least 6mm high.

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5. The completed package shall be capable of successfully passing the drop test in 6.3.2.5. as specified in 6.3.2.3. and 6.3.2.4. except that the height of the drop shall not be less that 1.2m. The smallest external dimension of outer packaging shall be not less than 100mm. (See note).
   (Note: This condition has been removed in a corrigendum issued by the UN dated, December 2004).
6. For **liquid substance**:
   a) The primary receptacle(s) shall be leak proof;
   b) The secondary packaging shall be leak proof;
   c) If multiple fragile primary receptacles are placed in a single secondary packaging, they shall be either individually wrapped or separated to prevent contact between them;
   d) Absorbent material shall be placed between the primary receptacles(s) and the secondary packaging. The absorbent material shall be in quantity sufficient to absorb the entire contents of the primary receptacle(s) so that any release of the liquid substance will not compromise the integrity of the cushioning material or of the outer packaging;
   e) The primary receptacle or the secondary packaging shall be capable of withstanding, without leakage, and internal pressure of 95 kPa (0.95 bar).
7. For **solid substances**:
   a) The primary receptacle(s) shall be sift proof;
   b) The secondary packaging shall be sift proof;
   c) If multiple fragile primary receptacles are placed in a single secondary packaging, they shall be either individually wrapped or separated to prevent contact between them.
8. **Refrigerated** or **frozen** specimens: **Ice, dry ice and liquid nitrogen**
   a) When dry ice or liquid nitrogen is used to keep specimens cold, all applicable requirements of ADR shall be met. When used, ice or dry ice shall be placed outside the secondary packaging or in the outer packaging or an over pack.
   Interior supports shall be provided to secure the secondary packaging in the original position after the ice or dry ice has dissipated. If ice is used, the outside packaging or over

pack shall be leak proof. If carbon dioxide, solid (dry ice) is used, the packaging shall be designed and constructed to permit the release of carbon dioxide gas to prevent a build up of pressure that could rupture the packaging and the package (the outer packaging or the over pack) shall be marked "Carbon dioxide, solid" or "Dry ice".
b) The primary receptacle and the secondary packaging shall maintain their integrity at the temperature of the refrigerant used as well as the temperatures and the pressures, which could result if refrigeration were lost.

9. **Infectious substances** assigned to UN No. 3373 which are packed and packages which are marked in accordance with this packing instruction are not subject to any other requirement in ADR.
10. Clear instructions on filling and closing such packages shall be provided by packaging manufacturers and subsequent distribution to the consignor or to the person who prepares the package (e.g. patient) to enable the package to be correctly prepared for carriage.
11. If any substance has leaked and has been spilled in a vehicle or container, it may not be reused until after it has been thoroughly cleaned and, if necessary, disinfected or decontaminated. Any other goods and articles carried in the same vehicle or container shall be examined for possible contamination.

Appendix No. 4: Document Reading Record

Print Name	Signature	Date

Appendix No. 5: Amendment Proposal Record

No.	Date	Page. No	Amendment	Authorised By
1.				
2.				
3.				
4.				
5.				
6.				
7.				
8.				
9.				
10.				

NOTES:

- The amendment must be authorised by the author of the procedure.
- The amendment must be underlined and the corresponding number from this form written in the margin alongside the change with an asterisk – correction fluid must not be used.
- Major changes must result in the immediate review of the procedure.