Histopathology Handbook

Ipswich Hospital

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Summary of Changes:

- consultant list updated
- Broken hyperlink updated (to UKAS website and department schedule)
- ESNEFT website for consumables Added
- Cyted added
- Livers no longer sent to SBS

CONTENTS

1 INTRODUCTION

1.1 PURPOSE AND SCOPE

This User Guide has been produced to assist both hospital and community users of the Histopathology laboratory service at Ipswich Hospital. It deals with access to the Histopathology service, specimen requirements, information and labelling requirements. If this User Guide fails to provide information required, users are encouraged to contact relevant key personnel listed.

The Pathology Laboratory at Ipswich Hospital consists of Biochemistry, Haematology, Microbiology, Molecular, Histopathology/Cytopathology and Blood Transfusion and is the only pathology provision on-site. The service is provided by the East Suffolk and North Essex Foundation Trust.

Cervical Cytology screening is **not** contracted to ESNEFT. This service is directly contracted to Norfolk & Norwich Hospital. Any complaints, concerns or feedback must be communicated directly with the cytology service.

1.2 RESPONSIBILITY

It is the responsibility of management to effectively communicate information and sample requirements.

It is the responsibility of medical staff to give clinical advice where required.

It is the responsibility of senior technical staff to provide non clinical advice e.g. transport and packaging of samples.

It is the responsibility of clinical teams using the histopathology service to follow the requirements laid out in this document.

1.3 RELATED DOCUMENTS

CELL-IPS-LP-34: Collection of Urine Specimens for Cytological Investigations

CELL-ALL-GP-1: ESNEFT Cellular Pathology Quality Manual

1.4 REFERENCES

ISO15189:2012

1.5 DEFINITIONS

BMS: Biomedical Scientist

DPA: Data Protection Act

ESNEFT: East Suffolk and North Essex Foundation Trust

GDPR: General Data Protection Regulations

GP: General Practitioner

LBC: Liquid Based Cytology

MDT: Multi Disciplinary Team

1.6 HEALTH & SAFETY/RISK ASSESSMENT

CELL-IPS-RA-23: General Risk Assessment Histology

2 PROCESS

The service is managed by East Suffolk and North Essex Foundation Trust. Key contacts are:

Consultant Medical Staff	Email and Telephone
Dr J Wong Consultant Histopathologist Clinical Lead for Cellular Pathology	Jason.Wong@esneft.nhs.uk Contact via secretary 01473 703722 or 703733 Internal: 5722/5733
Dr J Orrell Consultant Histopathologist	Julian.Orrell@esneft.nhs.uk Contact via secretary 01473 703722 or 703733 Internal: 5722 / 5733
Dr Olga Gronowska Consultant Histopathologist	Olga.Gronowska@esneft.nhs.uk Contact via secretary 01473 703722 or 703733 Internal: 5722 / 5733
Dr Julian Ostrowski	Julian.Ostrowski@esneft.nhs.uk Contact via secretary 01473 703722 or 703733 Internal: 5722 / 5733

Biomedical Scientists	Email and Telephone
Ms Lynn Partridge Histopathology Service Lead	Lynn.Partridge@ esneft.nhs.uk Tel 01473 703227 (Internal ext 5227)
Ms Catriona Geekie Histopathology Operations Lead	Catriona.Geekie@ esneft.nhs.uk Tel 01473 703227 (Internal ext 5227)

Department Telephone Numbers

Department	Telephone	
Histopathology (Technical enquires) (telephone manned: 08.30 – 17.00 Monday – Friday)	External Internal	01473 703701 or 703227 5701 or 5227
Secretary to Medical Staff (09.00 – 17.00 Monday – Friday)	External Internal	01473 703722 or 703733 5722 / 5733

Location of Laboratory

The Histopathology Department is located in the Pathology Department, in the central zone, at Ipswich Hospital, Heath Road, Ipswich IP4 5PD.

A map of the hospital is embedded below:

Hospital Map.pdf

Services Offered by the Laboratory

The Histopathology Department offers the following services:

- Histopathology
- Diagnostic Cytology

Laboratory Opening Times

The Histopathology laboratory is open Monday – Friday 8.00am – 5.30pm. There is also a limited service running on Saturday mornings 8.15am – 12.15 pm.
Frozen sections 08:30 am – 4:00pm Monday - Friday

Clinical Advice and Interpretation

Medical staff are available on the telephone, and at MDT, to advise on:

- The choice of test and how to use the service including the type of sample that should be sent, whether or not a sample should be sent and the limitations of histology and diagnostic cytology.
- Individual cases including advice on the surgical report which contains the interpretation of the examinations.
- Ensuring the laboratory services are used effectively and efficiently e.g. if a specimen should be sent marked as urgent.

Please use the telephone numbers listed above.

Non Clinical Advice

Senior Biomedical Scientists are available to give advice on technical matters including the transport of specimens, the correct containers and fixatives to use, and the requirement s for acceptance criteria.

Please use the telephone numbers listed above.

1. TRANSPORT

All samples, unless stated, must be sent to the laboratory as soon as possible either in person or via a porter or transport system. The vacuum system should not be used for Histopathology samples. Unless stated, all samples are to be kept at ambient temperature. Consideration to confidentiality of patient details on samples and request forms should always be made when packaging samples.

Transport of Samples from GP Surgeries

The Pathology Department provides a daily collection service from all GP surgeries. Samples for collection should be individually bagged then placed in a large sealed plastic bag with sufficient wadding to absorb spills.

Transport of Samples from Wards, Theatres and Clinics

Histopathology samples are in the main not repeatable tests, the department recommends that samples are transported directly to the Histopathology service during opening hours, where a member of the Histopathology team will take receipt of samples. We strongly recommend that services operate a sample log, which the histopathology staff will sign to record full chain of custody.
Samples requiring frozen section must be transported immediately to the department.

2. STORAGE OF SAMPLES

If possible Histopathology samples should be delivered to the laboratory the same day. All theatre and clinic samples should reach the laboratory within a few hours of

collection. Samples from outside the hospital that cannot be delivered that day should be stored overnight and delivered the next morning. Histopathology samples do not require refrigeration. Diagnostic cytology samples should be stored in a refrigerator overnight with the exception of joint fluids which should never be refrigerated or the result could be compromised.

Delayed samples may result in over fixation, which can result in reduced sensitivity for a proportion of the diagnostic histopathology tests.

3. HEALTH AND SAFETY

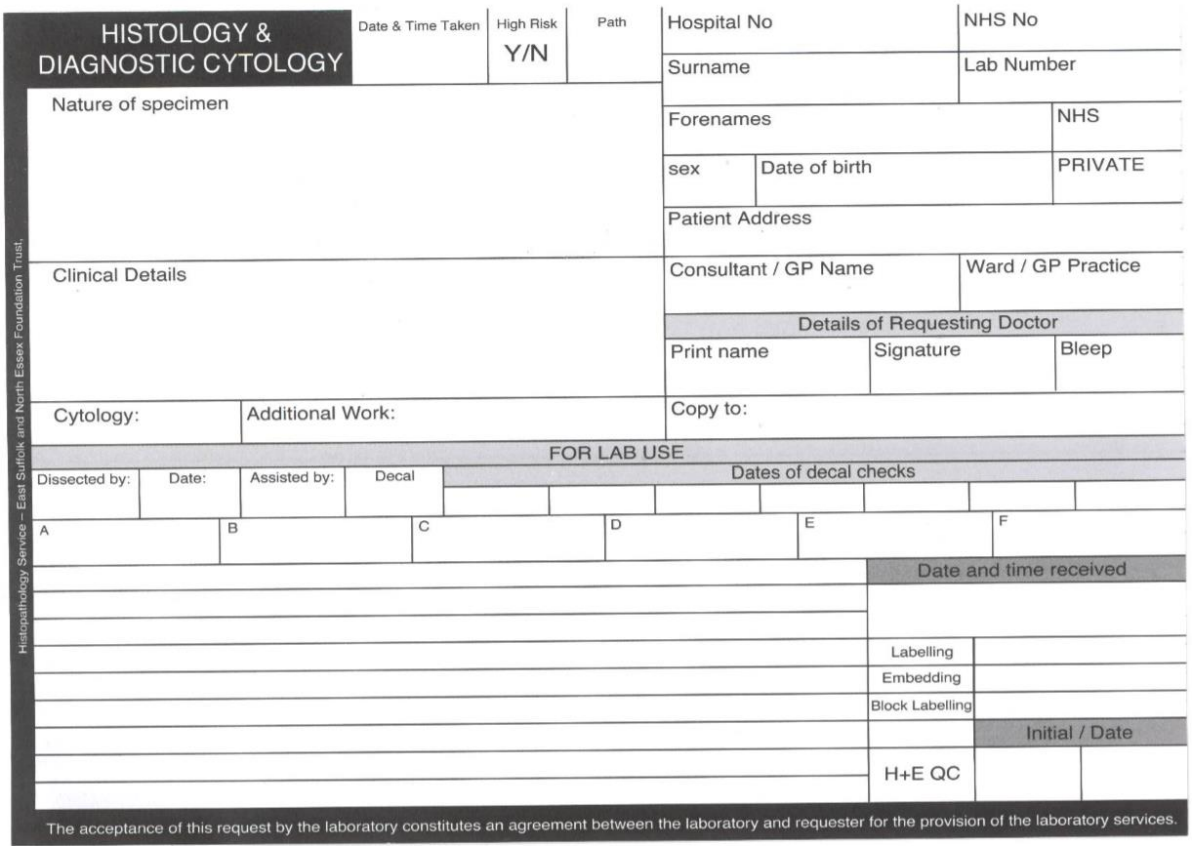
Histopathology – formalin fixative is classified as a class 1B carcinogen and should be handled within a controlled environment with minimum exposure. Any spillages should be absorbed using formaspill granules to neutralise the formaldehyde, prior to scooping and disposal into clinical waste. Frozen section samples are unfixed and pose a biological hazard, and should be handled according to local protocol (clinic/theatre guidelines) to safeguard the health and safety of the individual. Spilt samples should be decontaminated according to local protocol (clinic /theatre guidelines) to safeguard the health and safety of the individual.

Diagnostic Cytology – these samples pose a biological hazard, and should be handled according to local protocol (clinic/theatre guidelines) to safeguard the health and safety of the individual. Spilt samples should be decontaminated and discarded according to local protocol (clinic /theatre guidelines) to safeguard the health and safety of the individual.

4. COMPLETION OF PATHOLOGY REQUEST FORMS AND LABELLING OF SAMPLES

It is the responsibility of the requesting clinician and the sample taker to ensure that request forms and samples are correctly and identically labelled. It is essential that the risk of mis-reporting pathology results is minimised to ensure patient safety and to this end accurate identification of the patient from whom the specimen/ sample was obtained is of paramount importance.

Each request accepted by the Histopathology service is considered to be an agreement between the laboratory and the requestor. An image of the correct request form is shown below:



HISTOLOGY & DIAGNOSTIC CYTOLOGY

Date & Time Taken | High Risk Y/N | Path

Hospital No | NHS No

Surname | Lab Number

Nature of specimen

Forenames | NHS

sex | Date of birth | PRIVATE

Patient Address

Clinical Details

Consultant / GP Name | Ward / GP Practice

Details of Requesting Doctor

Print name | Signature | Bleep

Cytology: | Additional Work: | Copy to:

FOR LAB USE

Dissected by: | Date: | Assisted by: | Decal | Dates of decal checks

A | B | C | D | E | F

Date and time received

Labelling

Embedding

Block Labelling

Initial / Date

H+E QC

Histopathology Service – East Suffolk and North Essex Foundation Trust.

The acceptance of this request by the laboratory constitutes an agreement between the laboratory and requester for the provision of the laboratory services.

The laboratory will refuse to accept samples that do not comply with the following criteria:

LABORATORY CRITERIA FOR THE ACCEPTANCE OF PATHOLOGY REQUESTS/ SAMPLES - GENERAL INFORMATION

All samples **must** arrive at the Pathology Department accompanied by a laboratory request form containing relevant information. Patient demographics on the sample and request form **must** be clearly annotated and identical. If samples have a discrepancy, the requesting consultant will be contacted to amend the discrepancy, this will cause a delay to the issue of the report.

Minimum Sample Labelling Criteria

Histopathology samples must be clearly identified with a minimum of three points of identification which must include the first name and surname plus as a minimum of one other identifier, ie. date of birth, hospital number or NHS number. Where there is more than one sample for a patient request each sample must be clearly labelled as to the sample site of origin. This is important to enable samples to be clearly distinguished from each other.

The following information should be provided:

Request Form	**Patient Sample**
Surname	Surname
Forename(s)	Forename(s)
Date of Birth	Date of Birth/ Hospital/ NHS Number/
Hospital/ NHS Number/ Unique patient identifier	Unique patient identifier
Date and time sample taken	Sample type (if more than one pot)
Ward/ Location/ Consultant	
Clinical Details	
Specimen type	

Histology specimens sent in neutral buffered formalin must have a hazard warning label.

Radioactive specimens must be clearly labelled as such.

Priority Status
Requests are assumed routine unless marked Urgent, 2WW, BCSP, or ?malignancy. Clinically urgent samples that require a faster turnaround above the published 7 days service must be discussed with a consultant histopathologist to ensure these samples are identified and managed effectively.

High Risk Samples
High Risk samples can pose a risk to laboratory staff and should be clearly labelled as high risk on both the request card and the sample.

Frozen sections
Samples requiring frozen sections must be pre-booked and transported to the department immediately. The extension number of the theatre where the operation is taking place must be stated on the request card so the report can be phoned through as soon as available. Frozen sections may only be booked Monday to Friday 08:30 – 16:00 only. High risk samples cannot be accepted for frozen section.

Products of Conception
Where histology is required on products of conception, or ectopic pregnancies, a fully completed patient consent form must be sent in addition to the histology request card (Consent for histological or cytogenetic examination of pregnancy loss specimen). If specimens are for disposal only, please contact the mortuary directly on 01473 703580 (internal extension 5580).

5. FACTORS AFFECTING LABORATORY TESTS

Histopathlogy

Multiple specimen pots **must** be easily distinguishable from each other and **must** be numbered/lettered in the same order as they appear on the request card. Failure to do so will result in the specimen being rejected and returned to the sender.

All specimens **must** be sent in formalin fixative unless prior arrangements have been made with the Laboratory or require a frozen section and has been pre-booked. Fresh specimens received without prior arrangements **will be** challenged.

Specimens from known TB patients **must** always be sent in formalin fixative unless prior arrangements and notification are made with the laboratory.

Where investigations for gout are required, samples must be sent in 70% alcohol.

The quality of the results obtained can be affected by the quality of the sample received. Histopathology samples must be transferred promptly to the formaldehyde fixative solution. Delays in fixation can affect the morphology of the tissue sample and also impact on the quality of some diagnostic tests. This can have a negative impact on the quality of the diagnostic result.

Histology samples should be transferred to the histopathology service as soon as is possible, ideally on the same day. Delays in transfer result in prolonged fixation which can be detrimental to the quality of some diagnostic tests.

Unlabelled histology specimens **will be** returned with the request form to the clinician requesting the test, or the clinician **will be** given the opportunity to visit the laboratory and identify the specimen him/ herself. A legal disclaimer form must be completed by the clinician to enable the department to process the specimen.

Accurate and complete clinical history is very important to help the pathologist order appropriate tests to help make their diagnosis.

Laboratory staff **will not** intervene in the labelling and identification process.

Diagnostic Cytology

Delays in transportation of cytology samples to the laboratory **must** be avoided.

Unlabelled cytology samples **will be** returned with the request form to the clinician requesting the test, or the clinician **will be** given the opportunity to visit the laboratory and identify the specimen him/ herself, with the exception of urine samples which will discarded and a repeat requested.

Laboratory staff **will not** intervene in the labelling and identification process.

6. OUTLINE OF TESTS PROVIDED

Histopathology
The service offers a routine Histopathology service including, H+E, Immunohistochemistry, HER2 immunohistochemistry and frozen sections.

Diagnostic Cytology
The service offers a diagnostic service for most types of diagnostic cytology samples, including, Serous fluids, respiratory samples, cyst fluids, joint fluids, urines and Fine needle aspirations.

7. SAMPLE REQUIREMENTS

Histopathology samples for routine histology should be placed into formaldehyde fixative, in a container that provides sufficient volume to allow the sample to move freely suspended within the formaldehyde solution. Containers are available of varying sizes, (60ml to 25litre).

Histology samples requiring gout crystal investigations must be sent in 70% alcohol.

Skin samples for immunofluorescence should be collected into specialised transport media obtained from the Histopathology laboratory.

Histology samples requiring frozen sections (pre-booked) should be delivered to the department fresh and as quickly as possible.

Diagnostic cytology samples should be collected into the following containers

- Samples of fluid from body cavities, cysts, and joint fluids should be collected into clean plain universal containers, please do not use containers with preservative. Where there is more than one universal of fluid the laboratory recommends a representative sample is taken from the fluid, and collected into one universal.
- EBUS samples should be collected into Hologic ThinPrep LBC sample vials.
- Urine cytology samples should be collected into urine cytology containers which contain a preservative solution. These containers are available, by request, from the Histopathology service. The patient should collect one complete voided urine, which should **not** be the first of the day. A copy of the instructions for urine collection should be distributed with the container for patients information.
- Fine needle aspirates can be spread onto clean glass slides and fixed using spray fixative or left to air dry (slides must be clearly labelled to indicate if fixed or air dried). The laboratory recommends that both spray fixed and air dried

slides are prepared. Slides should be sent in a plastic slide container. For samples where there is a large volume, the sample can be placed into a clean universal and delivered to the laboratory. Patient details must be written on the slides in **Pencil** only**. *Do not use pen or labels.***

- Bronchial washing should be suspended in saline in a plain specimen container. Do not use trap bottles as these use pose a health and safety risk due to leaking.
- Bronchial brushings should be collected in a LBC vial or spray fixed on a glass slide. Do not leave the brush head in the vial or this could result in a low cell yield.

All consumables are available from the ESNEFT pathology website: ESNEFT Pathology Service

8. TURNAROUND TIMES

Cellular Pathology samples are provided by East Suffolk and North Essex Foundation Trust. Turn around times are as follows:

- 80% of samples reported within 7 days of receipt in the laboratory.
- 90% of samples reported within 10 days of receipt in the laboratory.
- 95% of samples reported within 21 days of receipt in the laboratory.

Turnaround time information is published on the Ipswich Hospital internet site, under Pathology.

Reports may be viewed electronically from within the hospital using the Pathology Results software. In addition a hard copy is sent to all clinicians including GPs.

9. SUMMARY OF TESTS REFERRED TO OTHER LABORATORIES

Tests not available at Ipswich are referred to other laboratories which have their accreditation to UKAS assessed by the Ipswich Laboratory. This is not a complete list of tests; some complex cases may be sent at the pathologists discretion to a nationally recognised expert in the area of interest.

Test / Sample Type	Sent To
Lymphoma Histopathology samples.	HODS, Addenbrookes
Renal biopsy samples – transplant patients	Histopathology, Addenbrookes
Molecular test - KRAS	Source Bioscience, Nottingham
Molecular test – BRAF/ KIT / PDGFRA	The Royal Marsden, London

Molecular test – EGFR / ALK	University Hospital Birmingham.
Molecular test - MMR	Source Bioscience, Nottingham
Histopathology Skin for Immunoflourescence	St Johns Institute of Dermatology, London
Bile Duct Brushings.	Histopathology, Addenbrookes
Her2 ISH	Source Bioscience, Nottingham
ISH (EBV, Kappa, Lambda)	Histopathology, Addenbrookes
IHC not in repertoire	Histopathology, Addenbrookes
OncoDX	Genomic Health, CA, USA
Medical Liver Biopsies	Cyted
Non urgent histology if departmental capacity exceeded	Cyted
Rarely requested Molecular Tests	Eastern Genomics Hub, Addenbrookes

10.DATA PROTECTION AND PATIENT CONFIDENTIALITY

The Data Protection Act 2018 is the UK's implementation of the General Data Protection Regulation (GDPR).It is closely linked to the Freedom of Information and Human Rights Acts. Its focus is on promoting the rights of individuals in respect of their privacy and the right to confidentiality of their data.

It is the policy of East Suffolk & North Essex Foundation Trust (ESNEFT) that the eight principles underpinning the DPA are fulfilled. The eight Principles are:

1. Personal data shall be processed fairly and lawfully.
2. Personal data shall be obtained for one or more specified and lawful purpose(s) and shall not be further processed in a manner incompatible with that purpose(s).
3. Personal data shall be adequate, relevant and not excessive in relation to those purposes.
4. Personal data shall be accurate and where necessary kept up-to-date.
5. Personal data shall not be kept for longer than is necessary for that purpose.
6. Personal data shall be processed in accordance with the rights of the data subject under the Act.
7. Appropriate technical and organisational measures shall be taken against unauthorised or unlawful processing of personal data and against accidental loss destruction or damage.

8. Personal data shall not be transferred to countries outside the European Economic Area (EEA) without adequate protection.

11.ESCALATION IN CASE OF FAILURE

In case of failure, refer to the Business Continuity Plan for Pathology

12.FEEDBACK/ COMPLAINTS

The service works closely with users to ensure the service provided meets the needs of the users. This is achieved through discussions at MDT meetings and user surveys.

User surveys are issued to primary and secondary care, results are reviewed and feedback provided. Where concerns are raised these are considered by the service management and where relevant taken into account to improve the service.

The results of the most recent users surveys are included at the end of this document.

If users would like to feedback comments to the laboratory, please contact the Histopathology Service Lead or Operations Lead. All complaints should be referred to the ESNEFT complaints team who can be contacted at: complaints@esneft.nhs.uk.

13. MONITORING COMPLIANCE AND EFFECTIVENESS

The User Guide is reviewed once every two years and is controlled by quality management software. The Quality lead for Histopathology at Ipswich Hospital is responsible to ensure this is monitored.

14.QUALITY STANDARDS AND CONFIDENTIALITY

The Histopathology Department has attained accreditation from the following professional bodies:

UKAS(15189:2012) reference number: 9316.
Please note some tests may be outside of the scope of accreditation to ISO15189:2012. Individual tests should be checked to confirm their accreditation status using the UKAS website: **9316 Medical Single (ukas.com)**

The department has recently benefited from purchasing a new H&E staining machine which has been fully verified by the department and clinically signed off. This has not yet been added to the accredited schedule of tests with UKAS under ISO15189:2012 and

H&E stains are therefore not currently accredited. This is an entirely normal process and any questions should be directed to the laboratory managers whose contacts are listed in this document.

IBMS (Institute of Biomedical Sciences)
(http://www.ibms.org/)

The department is approved for pre-registration and post-registration BMS training and support staff training. Approval expires June 2023.