PATH LINKS NHS PATHOLOGY

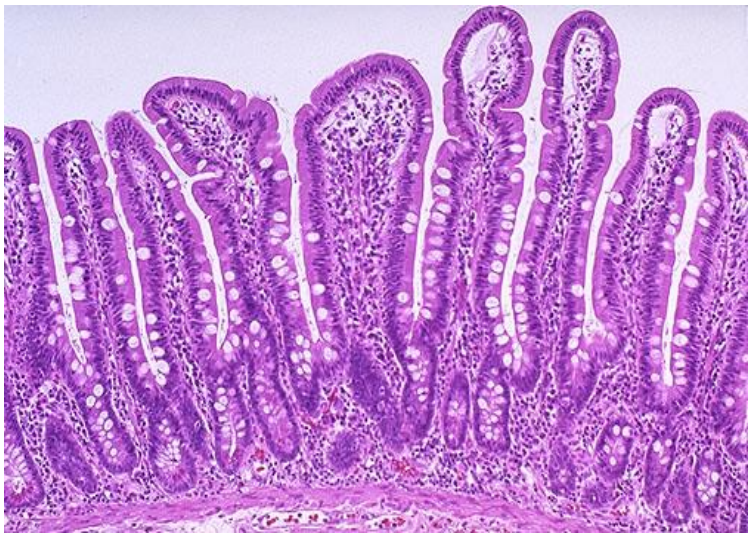
NHS Northern Lincolnshire and Goole NHS Foundation Trust

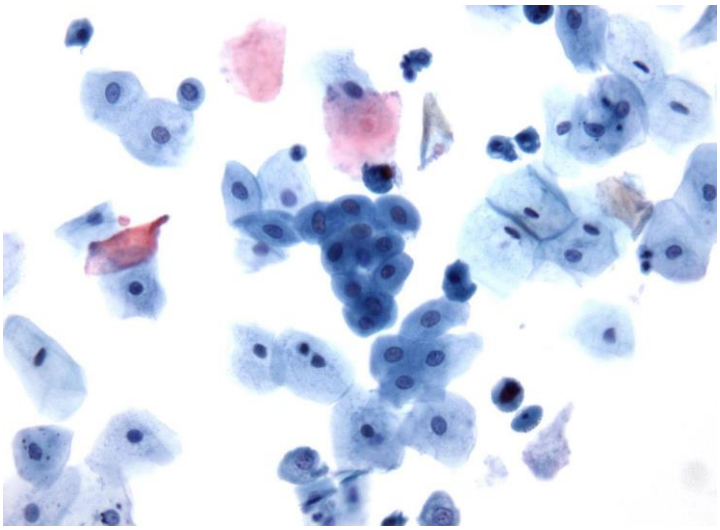
PATH LINKS

CELLULAR PATHOLOGY

USER GUIDE

Warning: Contains anatomical images
All images are from online sources





Contents

ABOUT CELLULAR PATHOLOGY

Path Links NHS Pathology Services is part of the Chief Operating Officer Division of Northern Lincolnshire & Goole NHS Foundation Trust (NLG). Path Links is a single managed pathology network providing a service across greater Lincolnshire (Lincolnshire, North Lincolnshire, and North East Lincolnshire) since 2001. This includes NLG, United Lincolnshire Hospitals NHS Trust (ULH) and local Integrated Care Boards or ICB's (formerly Clinical Commissioning Groups). The network incorporates a single governance and quality structure, Laboratory Information Management System and a consolidated budgetary arrangement.

Path Links laboratories are based at Diana Princess of Wales Hospital Grimsby, Scunthorpe General Hospital, Lincoln County Hospital, Boston Pilgrim Hospital and Grantham District General Hospital. There are further Front of House and Phlebotomy services at Goole & District Hospital and Louth County Hospital. A comprehensive courier service ensures that specimens and consumables are collected from and delivered to the appropriate hospital sites and Primary Care providers in a timely manner.

The Department of Cellular Pathology is centralised at Lincoln County Hospital. It is up to date, user focussed and offers a full range of laboratory and anatomical pathology facilities. Our principal aim is to deliver high quality diagnostic histopathology, non-gynaecological cytopathology and autopsies to all of our service users in support of patient care.

The department is clinically lead by Consultant Histopathologists covering a wide range of sub-specialties. The Consultants each have specialist areas of knowledge and expertise thus ensuring full support for cancer multi-disciplinary teams.

The wider Cellular Pathology team of Consultant Histopathologists, Biomedical Scientists, laboratory assistants and clerical support staff work to **ISO 15189:2012 Medical Laboratories – Requirements for quality and competence.** The scope of UKAS accreditation covers the histology and diagnostic (non-gynaecological) cytology services. Please see the UKAS Schedule of accreditation for further detail which can be found at **https://www.ukas.com/search-accredited-organisations/** by searching "8833".

Diagnostic (Non-Gynaecological) Cytopathology

Diagnostic Cytopathology is concerned with the examination of individual cells collected, either suspended in fluid or directly aspirated from a variety of anatomical sites where there is a clinical suspicion of disease. Cells are harvested, stained using Papanicoloau and Giemsa methods and examined microscopically.

Sampling is of particular importance in cytology and specimens must be sent to the laboratory as soon after collection as possible with all relevant information. There is no out-of-hours service so specimens should be received within normal working hours.

Histopathology

Histopathology is the examination of tissue samples from many clinical specialties, including Breast, Gynaecology, Gastroenterology, Dermatology, Urology and Head & Neck, to diagnose and assess the extent of disease. The department has a comprehensive test repertoire to deliver this service.

The predominant methodology utilised is formalin fixation and paraffin wax processing to facilitate the cutting of thin sections of tissue to be stained using the Haematoxylin & Eosin method. Thus general tissue structure is visualised which is then examined microscopically. Further ancillary tests, incorporating tinctorial dye methods, histochemistry and immunocytochemistry, are used to identify specific tissue components, tumour markers and infective agents.

Specialist Testing

The laboratory has a comprehensive repertoire of routine diagnostic tests. However, if specialist testing is required then these are referred to accredited external providers. The tests include Her2 and Gastric Her2, PDL-1 and molecular tests which cannot be completed in house including EGFR, POLE, PIK3CA and BRCA1 or 2.

These tests are requested by individual Consultant Pathologists in the course of their diagnostic work or following a clinical decision at Multi-Disciplinary Team Meetings. Any requests for additional tests which are made during a Multi-Disciplinary Team Meeting **must** be made via email to nlg-tr.histology@nhs.net.

When specimens are referred outside this department they are sent to accredited organisations. This will include genomics molecular testing and lymphoma diagnosis for example. A list of referral centres and individual experts is available on request

Specimen Turnaround Time for Histopathology & Non-Gynaecological Cytology

It is the aim of Cellular Pathology department's for 90% of specimens reported, electronically available to requestors within **10 working days from sample collection.** In addition, the department aims to meet Cancer Referral Pathway targets (31/62, 2 Week Wait) and Cancer Screening Programme standards (breast, bowel and cervical specimens).

Some specimens require more complex analysis or specialised testing outside the scope of this department's repertoire or referral for expert opinion. This may increase the turnaround time of the report. In such instances, a provisional report will be issued prior to the final report.

The departmental average Turnaround Time for 2023/2024 is:

Specimen Priority T	Average Turnaround Time (Calendar Days)
Urgent / Cancer Pathway	9.9
Routine	25.0

Anatomical Pathology

The Mortuary service provides a facility for the reception, examination, storage and release of bodies arising from the hospital service and within the community. There are five mortuaries operating within Path Links. The mortuary at Lincoln provides a comprehensive mortuary service, which includes post mortem investigations. Four other mortuaries, based at Boston, Grantham and Scunthorpe, offer storage and viewing facilities only.

OPENING HOURS AND CONTACTS

Cellular Pathology Laboratory opening hours

Lincoln site – A routine service is offered between the hours of 8.00am to 5.30pm Monday to Friday.

Sample reception facilities at Boston, Grantham, Grimsby, and Scunthorpe pathology sites are open between the hours 9.00am to 5.00pm Monday to Friday.

Contact details

Cellular Pathology Office for general enquiries, report enquiries or to speak to a Consultant Pathologist:
Tel: 01522 573755 (8:00am to 5.00pm Monday to Friday, answerphone available outside these hours)
Email: nlg-tr.histology@nhs.net

Cellular Pathology Laboratory for technical enquiries:
Tel: 01522 512512 Ext 582745
Email: nlg-tr.cellpathenquiries@nhs.net

Mortuary opening hours (Monday to Friday)

Lincoln County Hospital	8:00am to 5:00pm
Grimsby Diana Princess of Wales	8:00am to 5:00pm
Boston Pilgrim Hospital	10:15am to 2:00pm
Scunthorpe General Hospital	9:00am to 11:30am & 1:00pm to 4.30pm
Grantham & District Hospital	1:00pm to 4:30pm

Post Mortem Examination Requests

Post–mortems examinations are usually performed between 8:30 and 13:00 hours, Monday to Friday.

High risk cases **must** be brought to the attention of the duty Consultant Cellular Pathologist.

Out of hours arrangements

Please contact the relevant hospital switchboard should you need to contact a member of the Mortuary staff out of normal hours.

PATH LINKS PATHOLOGY HOSPITAL SITES

All Path Links Pathology Laboratories have reception points in which Blood sciences, Microbiology, Andrology and Cellular Pathology tests are received and distributed to the appropriate laboratories for testing. There are also reception points at Louth and Goole.

Cellular Pathology samples from primary and secondary care services are checked and booked into the laboratory information system at all sites and then transported to the Lincoln site for Histological and Cytological processing.

Northern Lincolnshire & Goole NHS Foundation Trust

Grimsby site
Address: Diana, Princess of Wales Hospital, Scartho Road, GRIMSBY, North East Lincolnshire, DN33 2BA
Contact: 01472 874111

Scunthorpe Site
Address: Scunthorpe General Hospital, Cliff Gardens, SCUNTHORPE, North Lincolnshire, DN15 7BH
Contact: 01724 282282

Goole Site
Address: Goole & District Hospital Woodland Avenue GOOLE North Humberside DN15 6RX
Contact: 01405 720720

United Lincolnshire Hospitals NHS Trust

Lincoln Site
Lincoln County Hospital, Greetwell Road, LINCOLN, Lincolnshire, LN2 5QY
Contact: 01522 512512

Boston Site
Address: Pilgrim Hospital, Sibsey Road, BOSTON, Lincolnshire, PE21 9QS
Contact: 01205 364801

Grantham Site
Address: Grantham District Hospital, 101 Manthorpe Road, GRANTHAM, Lincolnshire, NG31 8DG
Contact: 01476 565232

Louth Site
Address: County Hospital Louth High Holme Road LOUTH Lincolnshire LN11 0EU
Contact: 01507 600100

SERVICES EXTERNAL TO PATH LINKS CELLULAR PATHOLOGY

Cervical Screening

Path Links does not provide a NHS Cervical Screening Programme laboratory service. This is provided as follows.

University Hospitals of Derby and Burton NHS Foundation Trust
Cervical Screening for ULH Trust and Lincolnshire ICB along with Defence Medical Services and Family Planning/Sexual Health Clinics within the same geographical area is provided by the Cytopathology Department at Royal Derby Hospital.
Contact: dhft.cytology@nhs.net

Gateshead Health NHS Foundation Trust
Cervical Screening for NLG Trust, Humber and North Yorkshire ICB's, as well as Defence Medical Services and Family Planning/Sexual Health Clinics within the same geographical area is provided by the Cytology Department at Queen Elizabeth Hospital, Gateshead.
Contact: ghnt.neycervicalscreeningcentre@nhs.net

Placental Histology

Path Links does not provide a placental histology service. This service is provided by:

Sheffield Children's NHS Foundation Trust
Contact: Telephone: 0114 27 17247/17254; Histopathology Department, Sheffield Children's Hospital, Western Bank

For indications for referral of placentas for pathological examination please refer to: Tissue pathway for histopathological examination of the placenta, unique document number: G108. This document can be located on the Royal College of Pathologists website.

Cytogenetics

Path Links does not provide a cytogenetics testing service. This is provided as follows.

Nottingham University Hospitals NHS Trust
For ULH Trust and primary care within the same geographical area.
Contact: nuhnt.cytogenetics@nhs.net

Sheffield Children's NHS Foundation Trust
For NLG Trust and primary care within the same geographical area.
Contact: sheffield.diagnosticgenetics@nhs.net

Bone Marrow Trephines

Path Links does not provide a bone marrow trephine testing service.

GENERAL INFORMATION

Any non-repeatable sample which has not met Path Links Policy, EXT-STD-9 Expected Standards of Pathology Request Form Labelling, which is available via the link https://www.nlg.nhs.uk/services/ and selecting Pathology, will be retained by the laboratory and a disclaimer form will be issued to the department to authorise further testing.

Reports

All reports are available via Web V and System One as soon as they are authorised. This is the preferred method of checking if a specimen report is available. The current status of specimens is displayed within Web V and advice regarding specific samples and their report availability can be obtained by contacting the Cellular Pathology Office on 01522 573755 or email nlg-tr.histology@nhs.net

A hard copy of the report can be generated, as appropriate, and sent via internal mail / post to requesting clinician plus copies to, as requested, at location indicated on the sample request form.

Urgent  Specimens

Urgent specimens are those where the patient requires urgent clinical intervention based on histopathological diagnosis whether or not the patient is on a cancer pathway. If a report is required urgently this must be clearly stated on the request form and, ideally, discussed with the appropriate Consultant Histopathologist where MDT meetings are scheduled.

Clinical advice regarding urgent biopsies can be obtained from a Consultant Pathologist, by contacting the Cellular Pathology Office (see page 4).

Cancer Priority Referral: 31/62 or 2 Week Wait cancer pathway patients

Specimens from patients being tracked on the cancer pathway must have this stated clearly on the sample request and other associated paperwork such as endoscopy reports. Please use a blue sticker or stamp (whichever is relevant to local clinical policy) to clearly identify the request form and if possible specimen pots. Failure to do this may result in an unnecessary delay in producing a timely report on these samples.

High risk  samples

High Risk specimens are those from patients known to have, or suspected of having, an infection due to a Category 3 organism (Advisory Committee on Dangerous Pathogens classification), e.g. Mycobacterium tuberculosis, Hepatitis B virus, Human Immunodeficiency Virus.

Specimen container and request form must be labelled with Danger of Infection. Techniques requiring fresh tissue, i.e. not formalin-fixed, cannot be performed on high risk specimens. This includes Direct Immunofluorescence and direct air-dried smears. High risk specimens that are not appropriately labelled will be incident reported.

Request forms, pots and vials; reordering consumable stock

Request forms, specimen pots/vials and preservative solutions such as 10% Neutral Buffered Formalin, Michel's medium and Cytospin are available on request at each of the Path Links reception points at Lincoln, Boston, Grantham, Scunthorpe and Grimsby.

Complete a requisition form (available from Pathology Departments) to order the amount required and collect from your onsite pathology reception point. Please allow 5 working days for delivery to Primary Care locations.

Please ensure that any consumables or reagents supplied by Cellular Pathology are returned for safe disposal where required, e.g. for exceeded expiration dates.

Specimen/Consumables Transport

Transport for the Path links area is provided by a combination of Path Links' own drivers plus NLG and ULH Trust drivers which ensures a comprehensive and robust service.

Most primary care facilities receive two specimen pick-up / consumable drop-off visits per day. In addition there are several transports between hospitals throughout the day and into the evening.

Information regarding transport times are available from each of the hospital site pathology departments.

Data Protection and Confidentiality

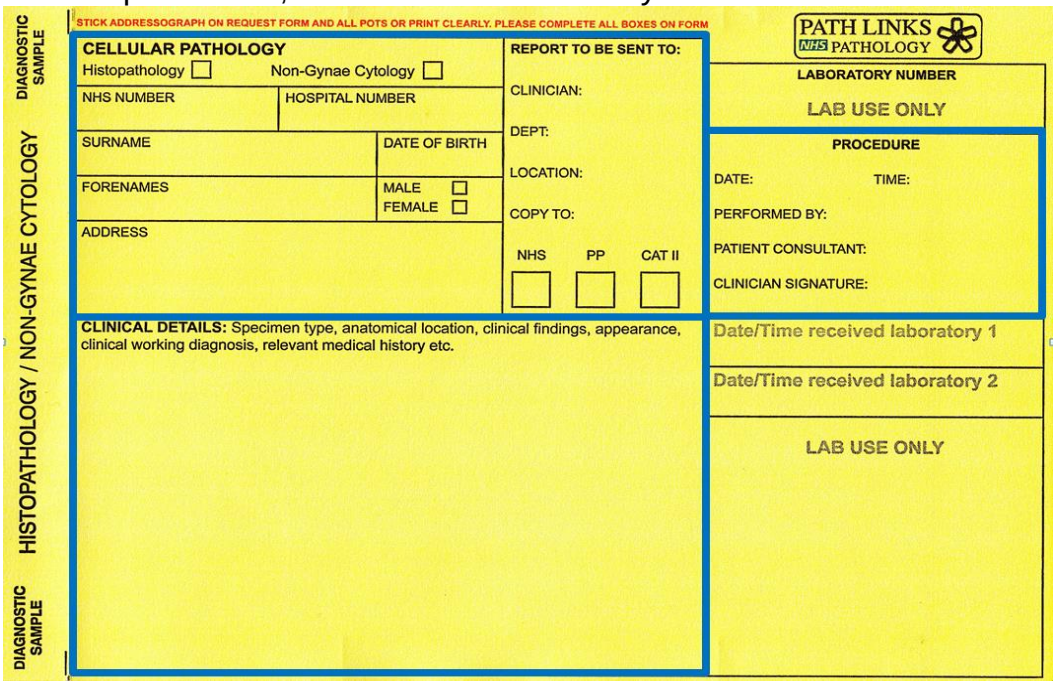
All patient information within Cellular Pathology, Path Links, is processed in accordance with the principles and legal obligations outlined in the Data Protection Act (2018), General Data Protection Regulation and common law duty of confidentiality. For further information please refer to the NLAG policy DCP332 Data Protection and Confidentiality Policy.

NON-GYNAECOLOGICAL CYTOLOGY

Request forms and labelling

- ***All Specimens must adhere to the Path Links Policy, EXT-STD-9 Expected Standards of Pathology Request Form Labelling, which is available via the link https://www.nlg.nhs.uk/services/ and selecting Pathology.***
- ***Requests and labelling must be completed at the time of specimen collection, not prior to the collection or remotely from the patient.***
- ***Non-Gynaecological Cytology requests must be made using a yellow Cellular Pathology request form.***
- ***It is preferable that non gynaecological and histology specimens are submitted on separate request forms that reference each other.***
- ***Separate forms for Biochemistry and/or Microbiology investigation should be generated and wherever possible separate samples should be sent.***
- ***Do not use Dart OCM or WebV to make non-gynaecological cytology requests, including when requesting crystal analysis.***

Requirements for request forms; blue fields are mandatory.



- **NHS Number *(if unavailable use A&E, Hospital number or other unique identifier)***
- **Full Surname**
- **Full Forename *(initials are not sufficient)***
- **Date of Birth *(not age)***
- **Date & Time of Collection**
- **Consultant / GP name *(clinician code is preferred)***
- **Source of collection *(Ward / Department / Surgery)***
- **NHS or Private Patient**
- **Type of Sample and Site of collection**
- **Patient's clinical details**
- **Patient's address and postcode**
- Gender
- Name of the requesting clinician (*clinician code is preferred*

- Signature of requesting person
- 'Copy to' *(provide clinicians name & location if a copy report is required)*

Labelling requirements for containers:

- **Surname**
- **Forename**
- **DOB**
- **NHS Number**
- **Specimen site and type**

Labelling requirements for glass; must be labelled in PENCIL with:

- **Surname**
- **Forename**
- **DOB**
- **Fixed or Unfixed status**
- **NHS Number**

If slides are sent they must be labelled on the frosted end and placed in a slide carrier for protection. A delay will be incurred if fixation status is unknown.

All specimens are processed at the Lincoln site. The department does NOT operate an out-of-hours service.

Sample Collection Requirements

- ***Specimens submitted diagnostic cytology must be sent to the laboratory as soon after collection as possible. This is because the majority of them are fresh/unfixed and liable to rapid deterioration.***
- ***Unfixed specimens collected at sites other than Lincoln must meet transport deadlines (contact your local laboratory for details). Alternatively, they should be refrigerated between 2-8˚C until the next available transport.***
- ***Unfixed specimens collected outside of normal laboratory opening hours (see page 4) should be stored at source and refrigerated 2-8˚C suitable refrigeration until the next available transport.***
- ***Prior to submission to the laboratory ensure that the exterior of the container is cleaned of any contamination by specimen or fixative.***

Urine/Urinary tract washings

Representative sample in a 25ml white topped universal container.
As cells deteriorate rapidly the sample should be sent as soon as possible. The manner of collection should be stated in the clinical details i.e. voided urine or catheter sample. Voided samples should be taken as the first part of the stream of urine and NOT be the first urination of that day.

Sputum

A "deep cough" sample collected into a clean wide mouthed sterile container which should be submitted on the day of collection
Sputum specimens are only appropriate where there is a clinical suspicion of malignancy and the patient is unfit for bronchoscopy.

Sputum pots can be requested and distributed from pathology reception points.

Body cavity fluids i.e. Pleural, Ascitic, etc

DO NOT use formalin or Cytospin transport medium

Representative fresh fluid in a 25ml white topped universal container.
When malignancy is **highly** suspected in ascitic and pleural fluid specimens **at least 75ml** of fresh fluid is required, in separate white topped 25ml universal containers. It is important to state the exact site of the sample origin in the clinical details.

Bronchial Washings

Representative sample in a 25ml white topped universal container.

Endoscopic Brushings

Endoscopic brush tip in a white topped universal containing 5ml Cytospin fluid (green transport medium)

DO NOT DIRECTLY PREPARE ONTO SLIDES EITHER AIR-DRIED OR FIXED.

Cerebrospinal Fluid (CSF)

Representative sample in a 25ml white topped universal container.
A sample should only be sent to cytology if there is a significant suspicion of malignancy. If clinically suspicious of infectious meningitis send the sample to microbiology using the appropriate request form.

Cells in CSF are prone to rapid degeneration. Despatch as soon as possible after collection taking note of transport times to reach Cellular Pathology in Lincoln before 16:30. The department does not run an out of hours' service.

Synovial Fluid

Representative sample of aspirated fluid for crystal analysis in a 25ml white topped universal container.

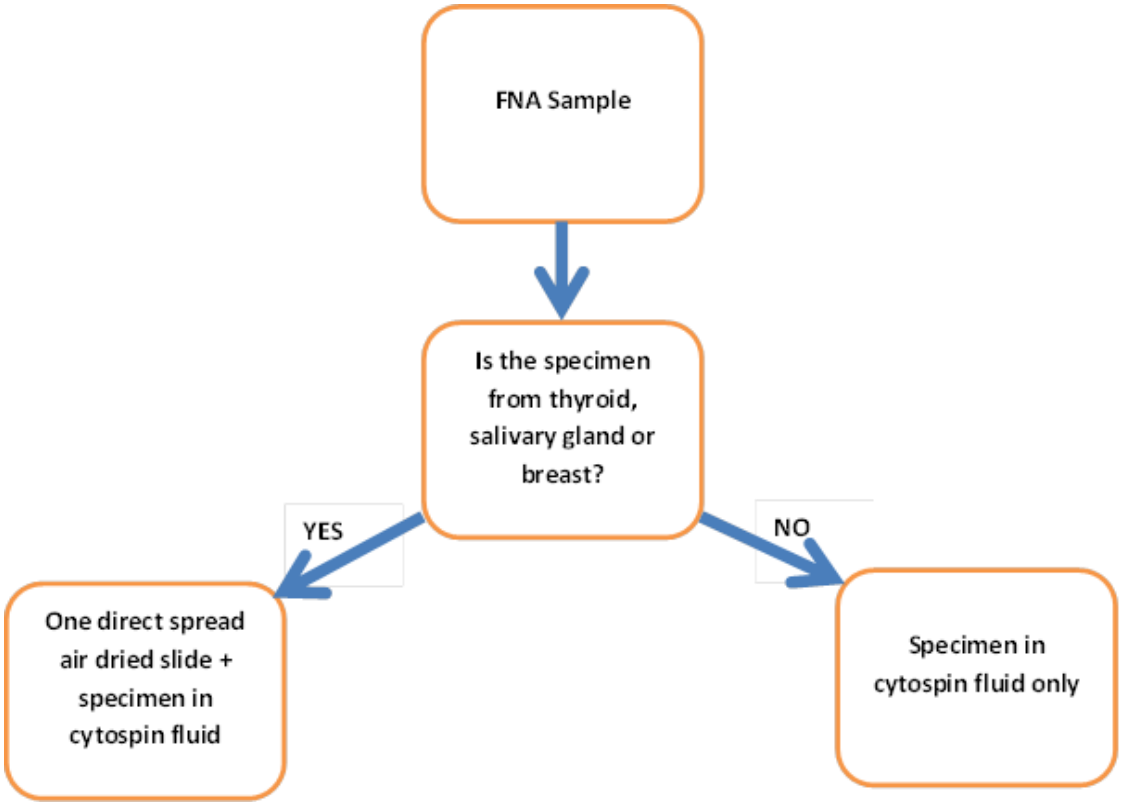
Ovarian Cyst Fluid

Representative sample in a 25ml white topped universal container.

Ovarian cyst fluid received with an oophorectomy specimen is **not** processed. If no histological specimen is sent for diagnosis, cytological examination of ovarian cyst fluid may be helpful.

Fine Needle Aspirates (FNA)

Follow the guide and submit samples as seen below.
Aspirated samples are placed in a white topped universal containing 5ml Cytospin fluid (green transport medium). Specific specimens (as below) may benefit from clinic prepared slides.



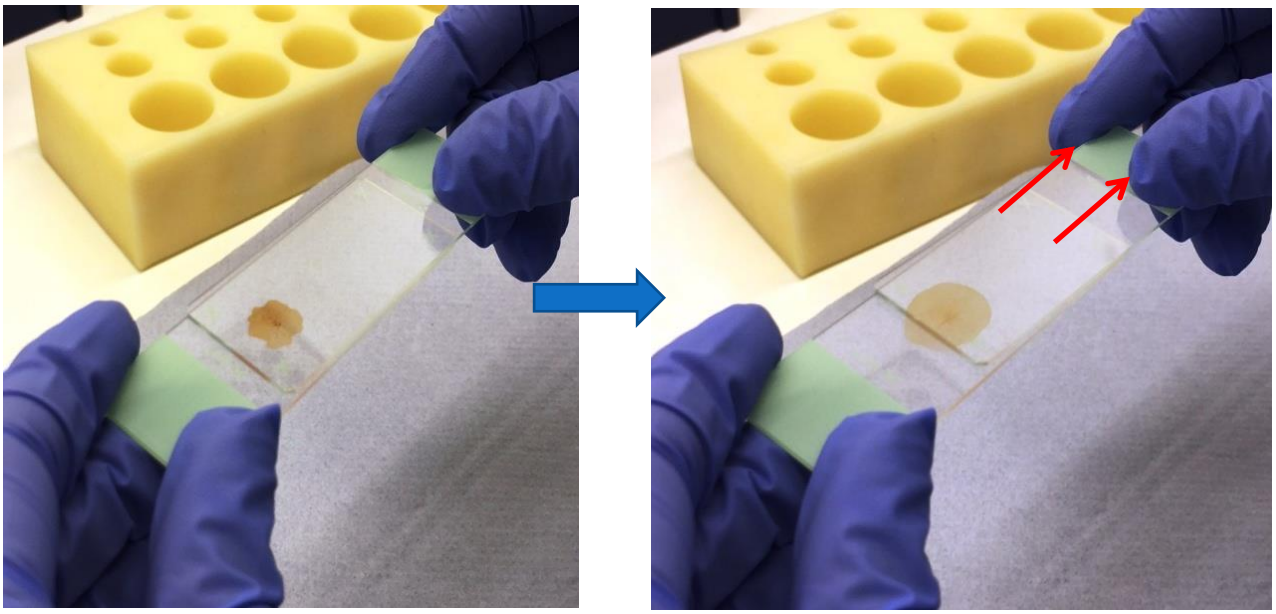
Important – Air dried slides must not be prepared from respiratory samples or high risk cases.

Do not submit multiple spread slides - this is not required. Using a large proportion of the specimen on slides will be detrimental to diagnosis as this reduces the material available for potential immunohistochemistry (tumour marker identification).

Once an FNA has been performed a single air dried direct spread slide can be made in clinic as in the recommended guide above. Use the following method.

A small amount of material is aspirated from the FNA needle onto a glass slide a third of the way from the frosted end. A second slide is used to spread the material. The spreading slide is placed with the short edge resting between the frosted end and the aspirated specimen and brought gently down, parallel to the specimen slide, until just touching the wet specimen. As soon as the specimen is touched, quickly move the spreading slide, keeping it parallel with the specimen slide, to spread the material across the length of the slide. Take care not to use pressure which will cause trauma

to the cellular content of the sample. Quickly air dry the slide by moving it rapidly side to side to create airflow across the sample.



If further information/advice/recommendations are required about FNA samples/technique, please contact Cellular Pathology (see page 5).

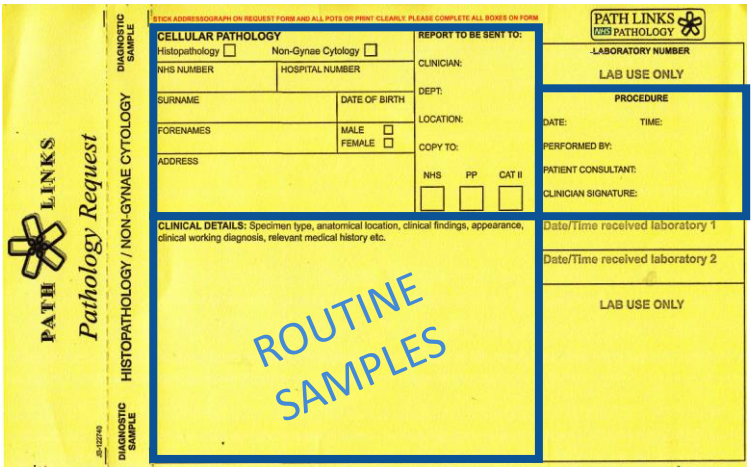
HISTOLOGY

Request forms and labelling

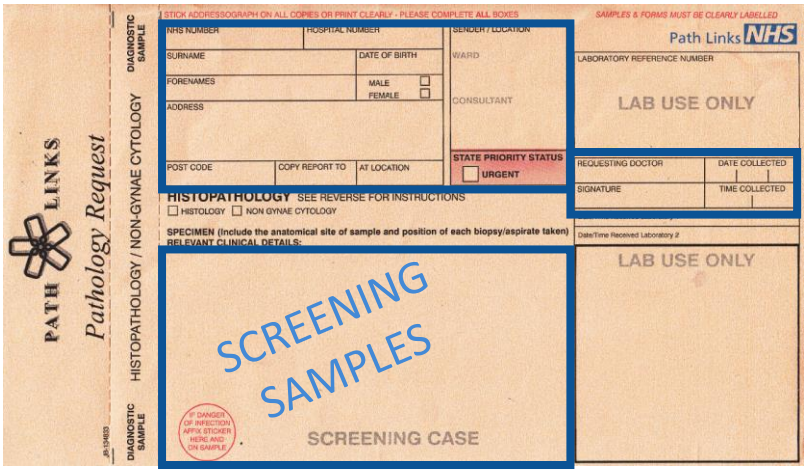
- ***All Specimens must adhere to the Path Links Policy, EXT-STD-9 Expected Standards of Pathology Request Form Labelling, which is available via the link https://www.nlg.nhs.uk/services/ and selecting Pathology.***
- ***Requests and labelling must be completed at the time of specimen collection, not prior to the collection or remotely from the patient.***
- ***Histology requests must be made using a yellow Cellular Pathology request form.***
- ***It is preferable that non gynaecological and histology specimens are submitted on separate request forms that reference each other.***
- ***Separate forms for Biochemistry and/or Microbiology investigation should be generated and wherever possible separate samples should be sent.***
- ***Do not use Dart OCM or WebV to make histology requests.***

Requirements for Histology forms: Blue fields are mandatory

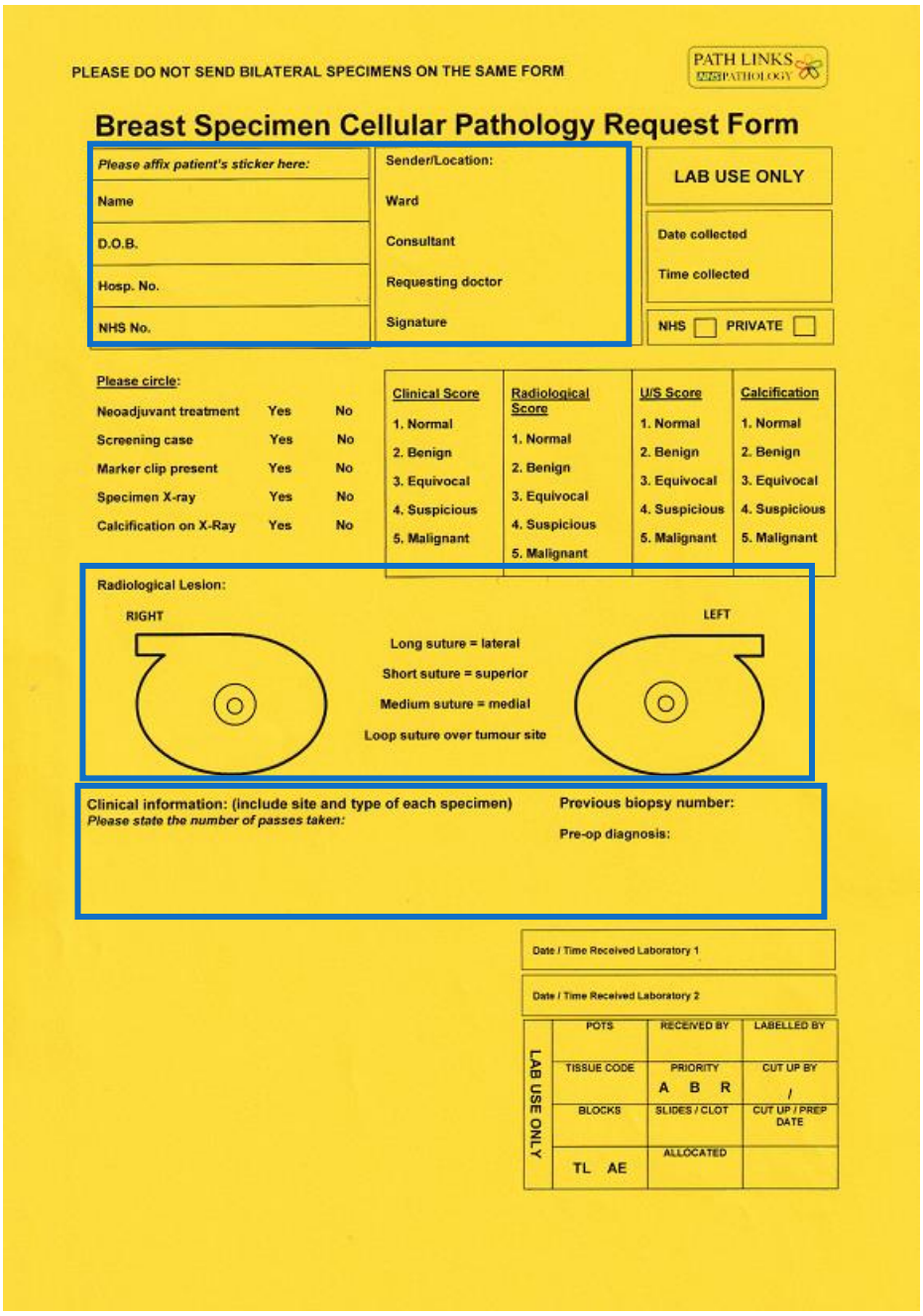
Routine specimens:



Bowel Cancer Screening specimens (endoscopic biopsies, polypectomies) and Cervical Screening specimens (punch and LLETZ biopsies):



All Breast Screening specimens (needle core biopsies, mammotome biopsies, wide local excisions, mastectomies):



PLEASE DO NOT SEND BILATERAL SPECIMENS ON THE SAME FORM

PATH LINKS NHS PATHOLOGY

Breast Specimen Cellular Pathology Request Form

Please affix patient's sticker here:	Sender/Location:
Name	Ward
D.O.B.	Consultant
Hosp. No.	Requesting doctor
NHS No.	Signature

LAB USE ONLY

Date collected

Time collected

NHS ☐ PRIVATE ☐

Please circle:

Neoadjuvant treatment	Yes	No
Screening case	Yes	No
Marker clip present	Yes	No
Specimen X-ray	Yes	No
Calcification on X-Ray	Yes	No

Clinical Score	Radiological Score	U/S Score	Calcification
1. Normal	1. Normal	1. Normal	1. Normal
2. Benign	2. Benign	2. Benign	2. Benign
3. Equivocal	3. Equivocal	3. Equivocal	3. Equivocal
4. Suspicious	4. Suspicious	4. Suspicious	4. Suspicious
5. Malignant	5. Malignant	5. Malignant	5. Malignant

Radiological Lesion:

RIGHT

LEFT

Long suture = lateral

Short suture = superior

Medium suture = medial

Loop suture over tumour site

Clinical information: (include site and type of each specimen)
Please state the number of passes taken:

Previous biopsy number:

Pre-op diagnosis:

Date / Time Received Laboratory 1

Date / Time Received Laboratory 2

LAB USE ONLY

POTS	RECEIVED BY	LABELLED BY
TISSUE CODE	PRIORITY A B R	CUT UP BY /
BLOCKS	SLIDES / CLOT	CUT UP / PREP DATE
TL AE	ALLOCATED	

NB: Where **bilateral** breast samples are taken it is important to use **two** request forms: one for right breast and one for left breast. This acts as a failsafe to ensure the correct location is recorded.

Request form requirements:

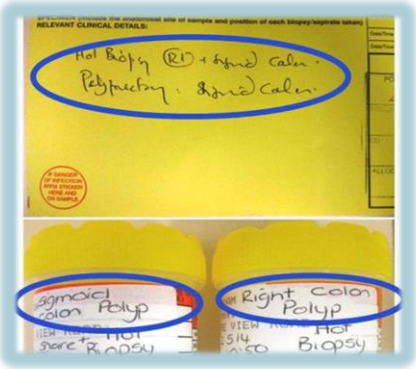
- **NHS Number *(if unavailable use A&E, Hospital number or other unique identifier)***
- **Full Surname**
- **Full Forename *(initials are not sufficient)***
- **Date of Birth *(not age)***
- **Date & Time of Collection**
- **Consultant / GP name *(clinician code is preferred)***
- **Source of collection *(Ward / Department / Surgery)***
- **NHS or Private Patient**
- **Type of Sample and Site of collection**
- **Patient's clinical details**
- **Patient's address and postcode**

- Gender
- Name of the requesting clinician (*clinician code is preferred*
- Signature of requesting person
- 'Copy to' *(provide clinicians name & location if a copy report is required)*
- Number of tissue cores / biopsies / pieces per specimen container.

Labelling requirement for containers:

- **Surname**
- **Forename**
- **DOB**
- **NHS Number**
- **Specimen site and type**

Addressograph labels may be used but the correct information must be present i.e. specimen details must be written on the pot



Where multiple specimens are collected at the same time, e.g. GI biopsies, the Site of collection on the specimen pot and the request form **MUST** match. Numbering the pots and stating the order on the request form is preferred to ensure the correct diagnosis is given to each sample area.

Please Note: Samples will not be accepted at handover from clinics and theatres or the sample register signed if any discrepancies in sample labelling or tissue sample identification are apparent.

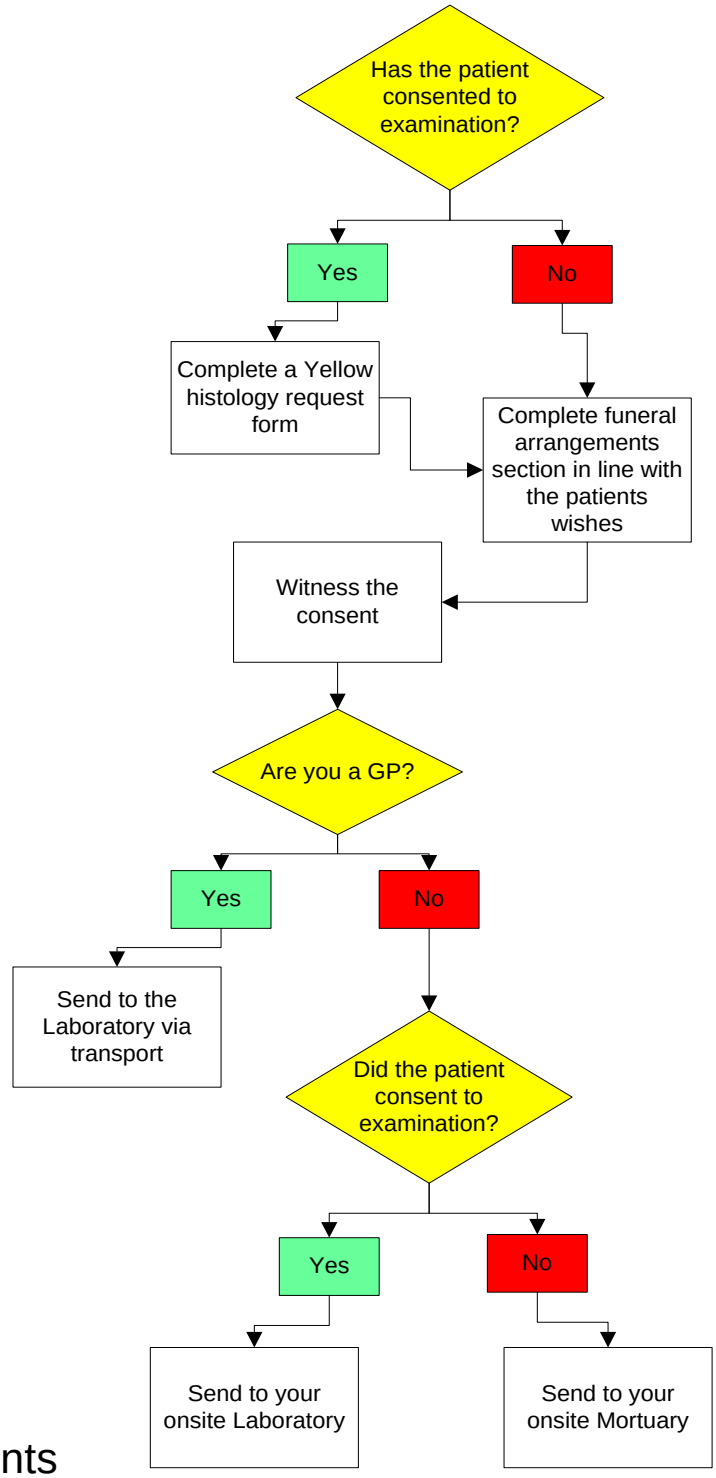
Consent for examination: Products of Conception (POC)

All products of conception samples **MUST** be accompanied by a consent form signed by the patient and witnessed accordingly, as per *Human Tissue Authority (HTA) Codes of Practice, Code A: Guiding principles and the fundamental principle of consent*. Incomplete or incorrect consent and request forms will be returned to the sender for correction which will incur unnecessary delays. Where a patient (mother) has terminated or miscarried during pregnancy or believed to have miscarried the laboratory requires consent to **examine** and **dispose** of the tissues retained.

Products of Conception specimen flowchart

To Include Sample Types:
?POC, Products of Conception, ERPOC, Ectopic Pregnancy, Tubal Ectopic, Molar Pregnancy, MTOP, STOP

IF CONSENT IS NOT GIVEN FOR HISTOPATHOLOGICAL EXAMINATION THEN **DO NOT COMPLETE** A CELLULAR PATHOLOGY REQUEST FORM



Specimen Collection Requirements

Histology specimens are placed in 10% neutral buffered formalin. This is a fixative which prevents the tissue from degenerating by autolysis and kills the bacteria which cause putrefaction; this known as fixation.

Fixation is a chemical reaction so there are some important factors common to most chemical reactions which affect good fixation, including quantity of reagent, temperature as well as the type of tissue. Poor fixation will adversely impact on the subsequent laboratory processing techniques and the microscopic appearance of tissue which will make accurate diagnosis difficult or impossible. This is especially the case if tumour molecular markers are to be investigated.

- Formalin must be stored and used at room temperature (15-30°C); colder conditions will impede fixation.
- Check expiry date before use.
- Place the specimen in 10% neutral buffered formalin as soon as possible following removal from the patient.
- Ensure there is a sufficient amount of formalin. The general rule is the volume of fixative should be between 5 and 10 times the volume of the specimen so that it floats freely. If not, the specimen will be irreversibly distorted so that orientation will be difficult and architectural structure lost.

- Use an appropriately sized container so that the entire specimen is submerged.

- Large resection specimen contents such as faecal material and cyst contents will also inhibit fixation. It is important to deliver these large resection specimens promptly to the laboratory so that preliminary dissection can be undertaken to open the specimens and remove the contents.

- The nature of the tissue itself may be a barrier to fixation. Dense tissue such as lymphoid tissue (lymph nodes, spleen) need to be delivered promptly so that they can be sliced to enable adequate fixation.
- Occasionally, large resection specimens will not fit into a 10 litre container. For these infrequent instances an extra-large container can be requested from the laboratory by ringing 01522 573755. If possible give 24 hours' notice to enable laboratory reception staff to source a suitable container and arrange transportation to the Lincoln County Hospital Site.

Under no circumstances are clinical waste containers to be used due to the associated risks of inadvertent sample disposal.

- Prior to submission to the laboratory ensure that the exterior of the container is cleaned of any contamination by specimen or fixative.

10% FORMALIN
CAUTION: CONTAINS FORMALDEHYDE
Toxic by inhalation and if swallowed. Irritating to the eyes, respiratory system and skin. May cause sensitization by inhalation or skin contact. Risk of serious damage to eyes.

HAZARD

Formaldehyde is a dangerous substance. Please observe the precautions with respect to Formaldehyde indicated on the containers supplied. Care must be taken when filling empty specimen containers due to vapours released. Where possible this should be done over an extraction bench or in a fume cupboard. A spillage policy must be in force. It is the responsibility of the clinic, ward or area using the substance to conform to the policy. However, the Lincoln laboratory is happy to advise on recommended safety measures by telephoning **01522 512512 Ext 582745**

Formalin must not be used for specimens requiring Direct Immunofluorescence investigations (see p21)

Dermatology

Skin samples should not be labelled as urgent, unless they are reconstructions from the Head & Neck

Multidisciplinary Team Meetings (MDT)

MDT	Day	Frequency		Time	MDT Coordinator	Lead Pathologist
ULH Dermatology	Thursday	Weekly	1st, 3rd weeks	09:00	gill.rayney@ulh.nhs.uk	Dr Willey
			2nd, 4th, 5th weeks	16:00		
NLG Dermatology	Friday	Fortnightly	2nd, 4th, 5th weeks	11.30	Stephen.dyer@nhs.net	Dr Willey

Routine Skin Specimens

Skin samples for routine histological examination must be placed, free-floating, into 10% neutral buffered formalin.

Orientated Skin Specimens

Sutures may be used to enable orientation of a specimen and identification of specific resection margins. The location of the suture(s) must be clearly stated on the request form, preferably using clock-face terminology.

Direct Immunofluorescence (DIF)

These cases are referred to a specialist pathology provider namely, Synnovis which is a London-based collaboration between Guy's & St Thomas' NHS Foundation Trust, King's College Hospital NHS Foundation Trust and SYNLAB UK & Ireland

Specimens must be placed in **Michel's transport medium and NOT** 10% neutral buffered formalin; DIF testing cannot be performed on formalin-fixed tissue. Sterile saline is also unsuitable. Pre-filled containers of Michel's medium can be obtained by contacting the Histology laboratory.

MICHEL'S TRANSPORT MEDIUM
CAUTION: CONTAINS N-ETHYLMALEIMIDE
Toxic if swallowed. Irritating to the eyes, respiratory system and skin.


Toxic


Corrosive

If the specimen will not reach the local laboratory before 16:30 then refrigerate overnight / over the weekend (including bank holidays) and send the next working day.

Specimens for DIF **must not** be taken from High Risk patients.

Head & Neck

Multidisciplinary Team Meetings (MDT)

MDT	Day	Frequency	Time	MDT Coordinator	Lead Pathologist (cover)
ULH Thyroid & Endocrine	Thursday	Weekly	13.00	kristina.noonan@ULH.nhs.uk nick.mcandrew@ULH.nhs.uk	Dr Bhobe (Nottingham)
ULH Head & Neck	Thursday	Weekly	14.00	nick.mcandrew@ULH.nhs.uk	Dr Hamilton (Dr Bhobe)

Skin Specimens for the investigation of Alopecia and related conditions

In such cases, it is essential that two 4mm diameter punch biopsies are provided. It must be stated explicitly in the clinical details on the request form that **Alopecia is suspected** to ensure that the correct technical protocol is followed in the laboratory for histological examination.

Skin Specimens from patients scheduled for subsequent reconstructive surgery

Cellular Pathology must be contacted (01522 309396) 72 hours prior to the surgical procedure as a minimum. The availability of a reporting Pathologist cannot be guaranteed where limited notice is given.

On contacting the laboratory to notify a specimen where subsequent reconstruction is required, the following information will be required:

- Date and time of initial surgery
- Date and time report required for reconstructive surgery
- Hospital site and surgeon
- Contact telephone number
- Patient name
- Patient NHS number
- Patient date of birth
- Specimen type and location

The availability of a Pathologist will be confirmed in a return telephone call.

The sample must be placed in 10% neutral buffered formalin. The request form must be highlighted as **urgent for reconstruction** along with the time and date the report is required. It is essential that these cases are taken to the on-site Pathology Specimen Reception as soon as possible in order for the turnaround requirements to be met.

Gastrointestinal

Multidisciplinary Team Meetings (MDT)					
MDT	**Day**	**Frequency**	**Time**	**MDT CoordTinator**	**Lead Pathologist (cover)**
ULH Colorectal	Friday	Weekly	09:00	joshua.pearce@ulh.nhs.uk jackie.turner@ulh.nhs.uk	Dr Sheth Dr Weerasinghe Dr Oliver
NLG Colorectal	Wednesday	Weekly	08.30	victoria.horsfall1@nhs.net m.camps@nhs.net rachael.douglass-jacklin@nhs.net	Dr A Coup (Dr Weerasinghe) (Dr Bhobe)
ULH Upper GI	Monday	Weekly	16.15	ulhcancerservicesupperGI@ulh.nhs.uk	Dr Weerasinghe (Dr Sheth)

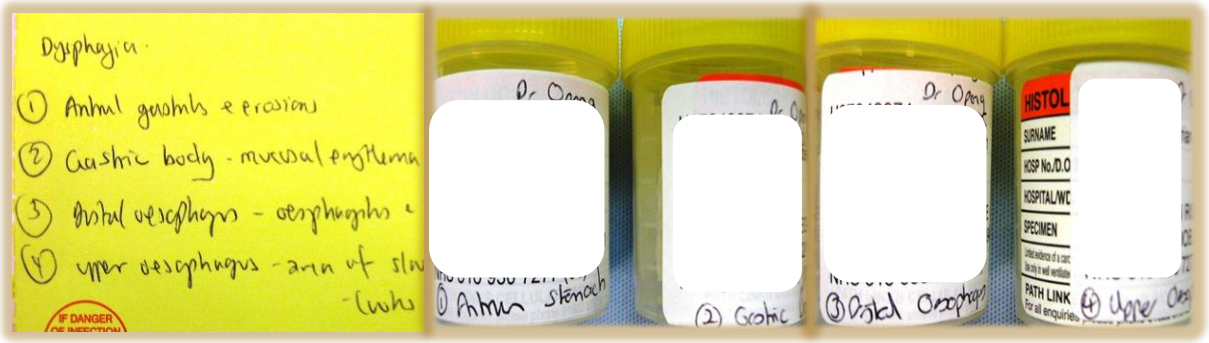
Specimens form the Bowel Cancer Screening Programme

Path Links is committed to meeting UK Cancer Screening Programmes guidelines and continues to deliver Bowel Cancer Screening reports within 7 calendar days from receipt.
Ensure that the orange Screening Case request form is used (see p15).

Biopsies and polypectomy specimens

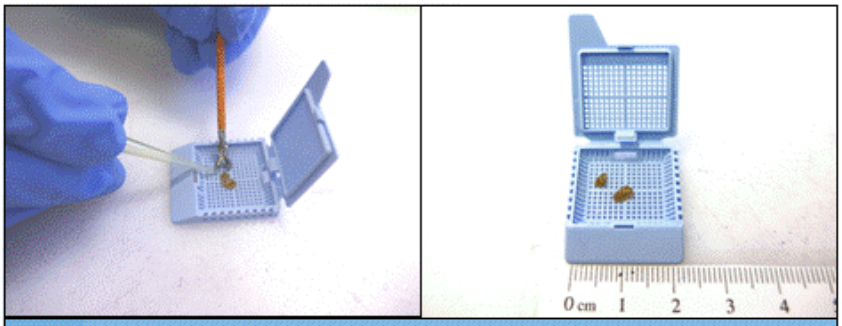
Preferred method of collection for standard grab biopsies or small polyps **up to 4mm** is to use blue mini-cassettes (see guide on p25).
Biopsies or polyps **greater than 4mm** must be placed 'free floating' into a formalin pot; forcing a specimen of this size into a mini-cassette will result in distortion / loss of tissue architecture.

Where multiple GI tract samples are taken, ensure the pots and request form match, e.g. use a numbering system and anatomical site as in the following example:



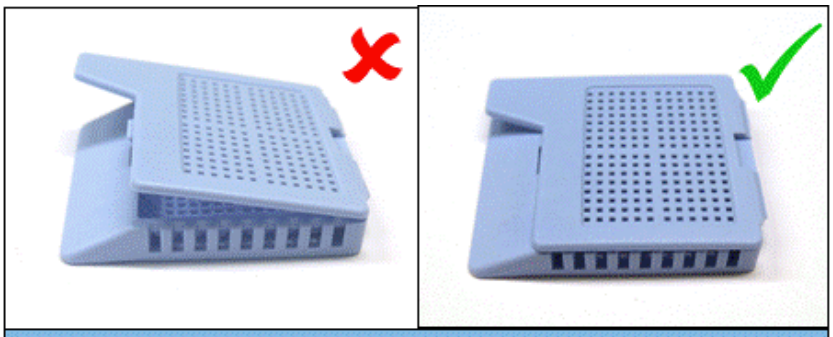
Where no number system has been used multiple pots will be reported in the anatomical order of the GI Tract, proximal to distal. We encourage submission of Endoscopy reports with samples wherever possible, in order to maximise clinical information provided.

Using mini-cassettes for biopsies and small polyps up to 4mm diameter:-



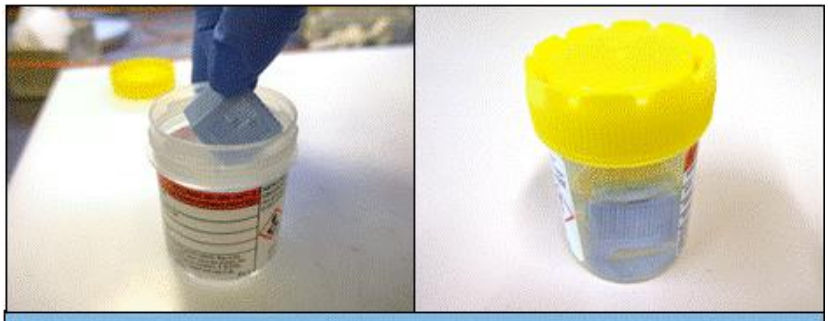
Step 1

Open the mini cassette and place the tissue biopsies into the centre of the mini cassette using a pipette tip.



Step 2

Carefully close the mini cassette, ensuring all tissue remains inside and is not trapped between the lid and the base. The mini cassette should 'click' closed.



Step 3

Place the mini cassette into a formalin pot as soon as possible, replace yellow lid securely and label as per sample labelling policy. Include anatomical site of the biopsy.

Breast

Multidisciplinary Team Meetings (MDT)					
MDT	**Day**	**Frequency**	**Time**	**MDT Coordinator**	**Lead Pathologist (cover)**
ULH (Lincoln & Grantham) Breast	Monday	Weekly	08:15	ULHCancerServicesBreast@ULH.nhs.uk	Dr Sheeran (Dr Bhobe)
ULH (Boston) Breast	Tuesday	Weekly	12:45	ULHCancerServicesBreast@ULH.nhs.uk aileen.routledge2@ULH.nhs.uk	Dr Pigera (Dr Bickers) (Dr Sheeran) (Dr Sevilla)
ULH (Lincoln & Grantham) Breast	Wednesday	Weekly	13:15	david.warman@ULH.nhs.uk	Dr Bickers (Dr Sheeran) (Dr Sevilla)
NLG Breast	Tuesday	Weekly	08:30	n.tew@nhs.net claire.over@nhs.net	Dr Sevilla (Dr Bickers) (Dr Sheeran)

Specimens from the Breast Screening Programme

Path Links is committed to meeting UK Cancer Screening Programmes guidelines and aims to deliver Breast Screening histology reports within 5 working days from receipt. The department aims to provide an initial report on urgent Breast core biopsies within 24Hrs following receipt.

Needle Core Biopsies

The number of breast cores taken must be recorded clearly on the request form.

Where **BILATERAL** breast samples are taken, it is important to use **TWO** request forms; one for the right and one for the left breast. This acts as a failsafe to ensure the correct location is recorded. Make sure as much clinical information is recorded as possible, including biopsy site or sites or if areas of calcification are included.

For best results; obtain cores using a long throw gun (23 mm) and 14G Needle. Breast biopsies and cores need to be fixed in 10% neutral buffered formalin for a minimum of **six hours**. Please bare this in mind when requesting results.

Vacuum Assisted Biopsies

State on the request form whether it is a diagnostic or excision sample. Where possible please leave the tissue in the vacuum capture device and place directly in to a Formalin pot.

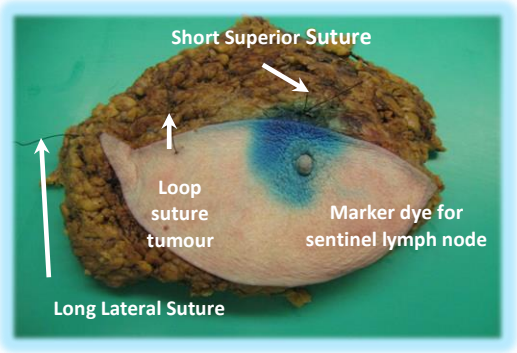
Large Excision Specimens:

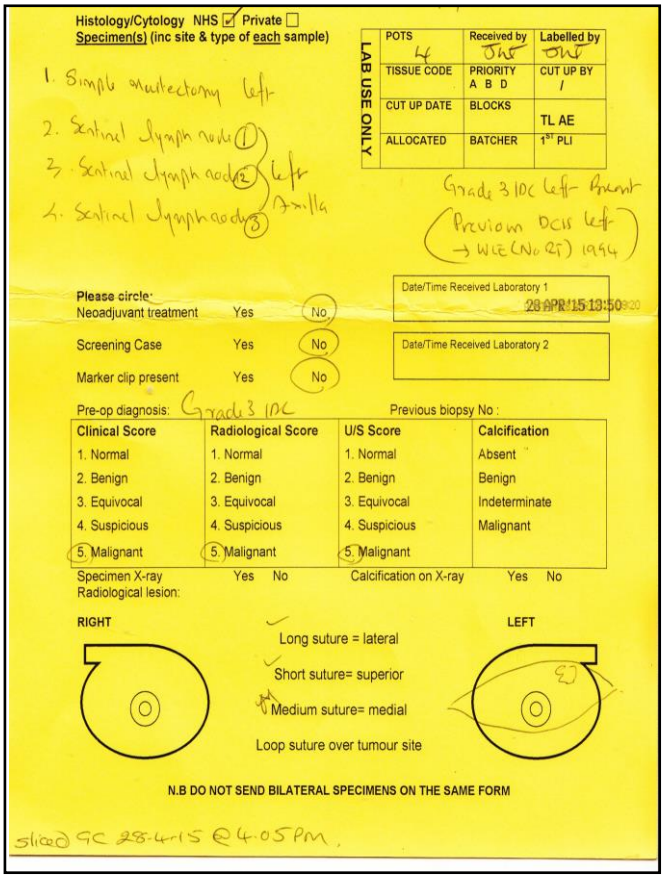
These specimens should be delivered to the laboratory as soon as possible so that they can be opened to facilitate adequate fixation.
Sutures, guide wires/clips and internal markers must be indicated on the request form to facilitate orientation of the specimen and location of the tumour.

The recommended and agreed suture markers for specimen orientation are as follows:

Short= Superior
Medium= Medial
Long= Lateral
Loop = Tumour or nipple (state)

For Example:





Bilateral specimens **MUST** be submitted on separate request forms, as with biopsies, in order to eliminate risk of confusion.

Patients who have had a radioisotope or blue dye administered for sentinel node sampling **MUST** have their specimen transferred to pathology reception points at the earliest opportunity. Delays in order to allow radioactive decay may compromise Histological examination, and sufficient decay will have occurred before the sample is handled in the laboratory.

Gynaecology

Multidisciplinary Team Meetings (MDT)					
MDT	**Day**	**Frequency**	**Time**	**MDT Coordinator**	**Lead Pathologist (cover)**
ULH Gynae Cancer	Monday	Weekly	08:30	ULHCancerServicesGynae@ULH.nhs.uk	Dr Sheth / Dr Sekhri / Dr Oliver
NLG Gynae Cancer	Tuesday	Weekly	12:00	joanne.palmer@nhs.net	Dr Sheth / Dr Sekhri / Dr Oliver
ULH Colposcopy	Monday	Fortnightly	12:00	kim.bradley@ULH.nhs.uk	Dr Sheth / Dr Sekhri / Dr Oliver
NLG Colposcopy	Friday (3rd)	Monthly	14:00	sarah.britteon@nhs.net rachel.templeman@nhs.net	Dr Sheth / Dr Sekhri / Dr Oliver

Specimens from the Cervical Screening Programme (CSP)

Path Links is committed to meeting UK Cancer Screening Programmes guidelines and aims to deliver gynaecological Histology results within 10 calendar days to aid the patient pathway.

Cervical Biopsy

Use an orange Screening Case request form if the patient has been referred from the CSP
Biopsies should be free-floating in the specimen container.

Large Loop Excisions of Transformation Zone (LLETZ), Loop and Cone biopsies

Use an orange Screening Case request form if the patient has been referred from the CSP
It is preferable that LLETZ, loop and cone biopsies are submitted as one piece as this enables accurate assessment of resection margins. However, it is acknowledged that this is not always possible for clinical reasons.

Urology

Multidisciplinary Team Meetings (MDT)

MDT	Day	Frequency	Time	MDT Coordinator	Lead Pathologist (cover)
ULH Urology	Thursday	Weekly	14.00	ULHCancerServicesUrology@ULH.nhs.uk	Dr Coup (Dr Oliver)
NLG Urology	Friday	Weekly	08.15	jamie.brumby@nhs.net	Dr Coup (Dr Oliver)

Prostatic Biopsies (Cores)

These are usually multiple specimens from several sites; it is particularly important that the number of cores and their site of origin is carefully identified on the request form and each specimen pot. Numbering the pots is helpful.
Clinical information should also include PSA value and any therapy as this may affect the significance of Gleason grading.

Transurethral Resection of Prostate and Bladder Tumour (TURP, TURBT)

Due to the fragmented nature of these specimens it is easy to overfill specimen pots; use larger containers if necessary.

Respiratory

Multidisciplinary Team Meetings (MDT)

MDT	Day	Frequency	Time	MDT Coordinator	Lead Pathologist (cover)
ULH (Lincoln) Lung	Tuesday	Weekly	08.30	emma.livingstone@ULH.nhs.uk ULHcancerserviceslung@ulh.nhs.uk	Dr Bhobe (Dr Sheth)
ULH (Boston & Grantham) Lung	Wednesday	Weekly	12.00	ulhcancerserviceslung@ulh.nhs.uk	Dr Borg Grech (Dr Bhobe)
NLG Lung	Wednesday	Weekly	14.00	samantha.oakton@nhs.net amy.billings@nhs.net sally.brockbank@nhs.net	Dr Peters (Dr Bhobe)

Respiratory specimens

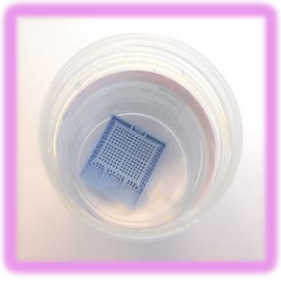
Path Links will aim to deliver a patients result from urgent respiratory biopsies within 48 hours**.**

Lung Biopsy

Respiratory specimens are low volume in nature; wherever possible obtain multiple cores which can then be separated in the laboratory to maximise diagnostic material especially as molecular testing is an integral to determining personalised treatment plans.

Bronchial Biopsy

It is preferable for Bronchial Biopsies to be placed in blue mini-cassettes which are suitable for tissue biopsies up to **4mm**. (See p22)



Endobronchial Ultrasound Guided Specimens (EBUS):

Tissue and fluid sampled during the EBUS procedure is placed, as soon as possible, into a white topped universal containing 5ml of Cytospin fluid. The use of this alcohol based transport medium enables specimens to be processed for both Histological and Cytological assessment.
Site of specimen sampling must be included on the form and pot.

Cancer of Unknown Primary

Multidisciplinary Team Meetings (MDT)

MDT	Day	Frequency	Time	MDT Coordinator	Lead Pathologist (cover)
ULH CUP	Tuesday	Weekly	13:00	laura.humphreys@ULH.nhs.uk ULHCancerServicesUnknownPrimary@ULH.nhs.uk	Dr Bickers (Dr Bhobe)

In House Molecular Testing

Background Information

Please note that this test is not currently within the scope of accreditation for UKAS (ISO 15189 standards)

In house molecular testing is performed on the Biocartis Idylla System.

The Biocartis Idylla System covers the entire process from sample to result with fully integrated preparation followed by PCR amplification and detected of the targeted sequences.

The Assay procedure and data analysis have been optimised for FFPE tissue sections.

All sections are assessed for suitability for testing to ensure testing requirements are met and where appropriate macro-dissection is performed to enrich for tumour content.

Molecular Testing in Colorectal Cancer

MSI (Microsatellite Instability) Testing

The Idylla MSI Assay detects a novel panel of seven monomorphic biomarkers:

MSI Biomarkers	
Biomarker	Reference Sequence
ACVR2A	NC_000002.12
BTBD7	NC_000014.9
DIDO1	NC_000020.11
MRE11	NC_000011.10
RYR3	NC_000015.10
SECS1A	NC_000004.12
SULF2	NC_000020.11

Where mutations are found in 2 or more of these biomarkers, the results is MSI-H (Microsatellite Instability – High). Otherwise the result will be MSS (Microsatellite Stable).

NRAS / BRAF

The Idylla NRAS-BRAF Mutation Test detects mutations in codons 12, 13, 59, 61, 117, 146 of the NRAS gene and in codon 600 of the BRAF gene.

Nomenclature of BRAF mutations detected by the Idylla NRAS-BRAF Mutation test: (Reference sequence: LRG_299t1/NM_004333.4)						
Gene	**Exon**	**Codon**	**Mutation**	**Protein**	**Nucleotide Change**	**Genetic Call**
BRAF	15	600	V600E	p.Val600Glu	c.1799T>A	V600E/D
					c.1799_1800delinsAA	
			V600D	P.Val600Asp	c.1799_1800delinsAC	
			V600K	p.Val600Lys	c.1798_	V600K/R

Nomenclature of BRAF mutations detected by the Idylla NRAS-BRAF Mutation test: (Reference sequence: LRG_299t1/NM_004333.4)						
					1799delinsAA	
			V600R	p.Val600Arg	c.1798_1799delinsAG	

Nomenclature of NRAS mutations detected by the Idylla NRAS-BRAF Mutation test: (Reference sequence LRG_92t1/NM_002524.3)						
Gene	**Exon**	**Codon**	**Mutation**	**Protein**	**Nucleotide Change**	**Genetic Call**
NRAS	2	12	G12D	p.Gly12Asp	c.35G>A	G12D
			G12C	p.Gly12Cys	c.34G>T	G12C
			G12S	p.Gly12Ser	c.34G>A	G12S
			G12A	p.Gly12Ala	c.35G>C	G12A/V
			G12V	p.Gly12Val	c.35G>T	
		13	G13D	p.Gly13Asp	c.38G>A	G13D
			G13R	p.Gly13Arg	c.37G>C	G13R/V
			G13V	p.Gly13Val	c.38G>T	
	3	59	A59T	p.Ala59Thr	c.175G>A	A59T
		61	Q61K	p.Gln61Lys	c.181C>A	Q61K
			Q61R	p.Gln61Arg	c.182A>G	Q61R
			Q61L	p.Gln61Leu	c.182A>T	Q61L
			Q61H	p.Gln61His	c.183A>C	Q61H
					c.183A>T	
	4	117	K117N	p.Lys117Asn	c.351G>C	K117N
					c.351G>T	
		146	A146T	p.Ala146Thr	c.436G>A	A146T/V
			A146V	p.Ala146Val	c.437C>T	

KRAS

The Idylla KRAS Mutation Test, performed on the Biocartis Idylla System, is an *in vitro* diagnostic test for the qualitative detection of mutations in codons 12, 13, 59, 61, 117 or 146 of the *KRAS* oncogene.

Nomenclature of KRAS mutations detected by the Idylla KRAS Mutation test: (Reference sequence LRG_344t1/NM_004985.5)						
Gene	**Exon**	**Codon**	**Mutation**	**Protein**	**Nucleotide Change**	**Genetic Call**
KRAS	2	12	G12A	p.Gly12Ala	c.35G>C	G12A
			G12C	p.Gly12Cys	c.34G>T	G12C
			G12D	p.Gly12Asp	c.35G>A	G12D
			G12R	p.Gly12Arg	c.34G>C	G12R
			G12S	p.Gly12Ser	c.34G>A	G12S
			G12V	p.Gly12Val	c.35G>T	G12V
		13	G13D	p.Gly13Asp	c.38G>A	G13D
	3	59	A59E	p.Ala59Glu	c.176C>A	A59T/E/G

Nomenclature of KRAS mutations detected by the Idylla KRAS Mutation test: (Reference sequence LRG_344t1/NM_004985.5)						
			A59G	p.Ala59Gly	c.176C>G	
			A59T	p.Ala59Thr	c.175G>A	
		61	Q61H	p.Gln61His	c.183A>C	Q61H
			Q61H	p.Gln61His	c.183A>T	
			Q61K	p.Gln61Lys	c.181C>A	Q61K
			Q61K	p.Gln61Lys	c.180_181delinsAA	
			Q61L	p.Gln61Leu	c.182A>T	Q61L/R
			Q61R	p.Gln61Arg	c.182A>G	
	4	117	K117N	p.Lys117Asn	c.351A>C	K117N
			K117N	p.Lys117Asn	c.351A>T	
		146	A146P	p.Ala146Pro	c.436G>C	A146P/T/V
			A146T	p.Ala146Thr	c.436G>A	
			A146V	p.Ala146Val	c.437C>T	

Molecular Testing in Melanoma

BRAF

The Idylla BRAF Mutation Test, performed on the Biocartis Idylla System, is an in vitro diagnostic Test for the qualitative detection of V600E/E2/D and V600K/R/M mutations in codon 600 of the BRAF gene.

Nomenclature of BRAF mutations detected by the Idylla BRAF Mutation test: (Reference sequence LRG_299t1/NM_004333.4)		
Mutation Group	**Mutation Type**	**Details**
V600E/E2/D	**V600E**	Base Change: c.1799T>A Amino Acid Change: p.(Val600Glu)
	V600E2	Base Change: c.1799_1800TG>AA Amino Acid Change: p.(Val600Glu)
	V600D	Base Change: c.1799_1800TG>AT, c.1799_1800TG>AC Amino Acid Change: p.(Val600Asp)
V600K/R/M	**V600K**	Base Change: c.1798_1799GT>AA Amino Acid Change: p.(Val600Lys)
	V600R	Base Change: c.1798_1799GT>AG Amino Acid Change: p.(Val600Arg)
	V600M	Base Change: c.1798G>A Amino Acid Change: p.(Val600Met)

Molecular Testing in Non-Small Cell Lung Carcinoma (NSCLC)

EGFR

The Idylla EGFR Mutation Test, performed on the Biocartis Idylla System, is an in vitro diagnostic test for the qualitative detection of exon 18 (G719A/C/S), exon 20 (T790M, S768I), exon 21 (L858R, L861Q) mutations, exon 19 deletions and exon 20 insertions of the *EGFR* gene.

Nomenclature of EGFR mutations detected by the Idylla EGFR Mutation test: (Reference sequence LRG_304t1/NM_005228.3)					
Gene	**Exon**	**Mutation**	**Protein Change**	**Nucleotide Change**	**Genotype Call**
EGFR	18	G719A	p.Gly719Ala	c.2156G>C	G719A/C/S
		G719C	p.Gly719Cys	c.2155G>T	
		G719C2	p.Gly719Cys(2)	c.2154_2155delinsTT	
		G719S	p.Gly719Ser	c.2155G>A	
	19	Deletion 9	p.Leu747_Ala750delinsPro	c.2238_2248delinsGC	Exon 19 Deletion
				c.2239_2248delinsC	
			p.Leu747_Ala750delinsSer	c.2240_2248del	
			p.Leu747_Glu749del	c.2239_2247del	
		Deletion 12	p.Leu747_Thr751delinsPro	c.2239_2251delinsC	
			p.Leu747_Thr751delinsSer	c.2240_2251del	
		Deletion 15	p.Glu746_Ala750del	c.2235_2249del	
				c.2236_2250del	
			p.Leu747_Thr751del	c.2239_2253del	
				c.2240_2254del	
				c.2238_2252del	
			p.Glu746_Thr751delinsAla	c.2237_2251del	
			p.Glu746_Thr751delinsIle	c.2235_2252delinsAAT	
			p.Glu746_Thr751delinsVal	c.2237_2252delinsT	
			p.Lys745_Ala750delinsThr	c.2234_2248del	
			p.Glu746_Thr751delinsLeu	c.2236_2253delinsCTA	
			p.Glu746_Thr751delinsVal	c.2237_2253delinsTA	
			p.Glu746_Thr751delinsAla	c.2235_2251delinsAG	
			p.Glu746_Thr751delinsGln	c.2236_2253delinsCAA	
			p.Ile744_Ala750delinsValLys	c.2230_2249delinsGTCAA	
		Deletion 18	p.Leu747_Pro753delinsSer	c.2240_2257del	
			p.Glu746_Ser752delinsVal	c.2237_2255delinsT	
			p.Leu747_Ser752del	c.2239_2256del	
			p.Glu746_Thr751del	c.2236_2253del	
			p.Leu747_Pro753delinsGln	c.2239_2258delinsCA	
			p.Glu746_Ser752delinsAla	c.2237_2254del	

Nomenclature of EGFR mutations detected by the Idylla EGFR Mutation test: (Reference sequence LRG_304t1/NM_005228.3)					
			p.Glu746_Ser752delinsAsp	c.2238_2255del	
			p.Glu746_Pro753delinsValSer	c.2237_2257delinsTCT	
			p.Glu746_Ser752delinsIle	c.2236_2255delinsAT	
				c.2236_2256delinsATC	
			p.Glu746_Ser752delinsVal	c.2237_2256delinsTT	
				c.2237_2256delinsTC	
				c.2235_2255delinsGGT	
		Deletion 21	p.Leu747_Pro753del	c.2238_2258del	
			p.Glu746_Ser752del	c.2236_2256del	
		Deletion 24	p.Ser752_Ile759del	c.2253_2276del	
	20	T790M	p.Thr790Met	c.2369C>T	T790M
		S768I	p.Ser768Ile	c.2303G>T	S768I
		InsG	p.Asp770_Asn771insGly	c.2310_2311insGGT	Exon 20 Insertion
		InsASV(9)	p.Val769_Asp770insAlaSerVal	c.2307_2308insGCCAGCGTG	
		InsASV(11)	p.Val769_Asp770insAlaSerVal	c.2309_2310delinsCCAGCGTGGAT	
		InsSVD	p.Asp770_Asn771insSerValAsp	c.2311_2312insGCGTGGACA	
		InsH	p.His773_Val774insHis	c.2319_2320insCAC	
	21	L858R	p.Leu858Arg	c.2573T>G	L858R
				c.2573_2574delinsGT	
				c.2573_2574delinsGA	
		L861Q	p.Leu861Gln	c.2582T>A	L861Q

Genefusion

The Idylla Genefusion Panel, performed on the Biocartis Idylla System, is an in vitro diagnostic test for the qualitative detection of specific gene fusions for ALK, ROS1, RET and MET exon 14 skipping and expression imbalance for ALK, ROS1 and RET.

Gene rearrangements detected by the Idylla Genefusion Panel:
(Reference sequence: ALK: LRG_488t1; NM_004304.3; ROS1: LRG_997t1; NM_002944.2; RET: LRG_518t1; NM_020975.4: MET exon 14 skipping: NM_000245.4)

List of Detected Gene Rearrangements		
ALK fusions (17)	EML4-ALK	EML4 exon 2; ALK exon 20
		EML4 exon 6a; ALK exon 20
		EML4 exon 6b; ALK exon 20
		EML4 exon 13; ALK exon 20
		EML4 exon 15; ALK exon 20
		EML4 exon 17; ALK exon 20
		EML4 exon 18; ALK exon 20
		EML4 exon 20; ALK exon 20
	KIF5B-ALK	KIF5B exon 15; ALK exon 20

List of Detected Gene Rearrangements		
		KIF5B exon 17; ALK exon 20
		KIF5B exon 24; ALK exon 20
	HIP1-ALK	HIP1 exon 28; ALK exon 20
		HIP1 exon 30; ALK exon 20
	KLC1-ALK	KLC1 exon 9; ALK exon 20
	TPR-ALK	TPR exon 15; ALK exon 20
	TFG-ALK	TFG exon 4; ALK exon 20
		TFG exon 6; ALK exon 20
ROS1 fusions (13)	CD74-ROS1	CD74 exon 6; ROS1 exon 32
		CD74 exon 6; ROS1 exon 34
	SDC4-ROS1	SDC4 exon 2; ROS1 exon 32
		SDC4 exon 4; ROS1 exon 32
		SDC4 exon 4; ROS1 exon 34
	SLC34A2-ROS1	SLC34A2 exon 4; ROS1 exon 32
		SLC34A2 exon 4; ROS1 exon 34
		SLC34A2 exon 13; ROS1 exon 32
	EZR-ROS1	EZR exon 10; ROS1 exon 34
	TPM3-ROS1	TPM3 exon 8; ROS1 exon 35
	GOPC-ROS1	GOPC exon 4; ROS1 exon 36
		GOPC exon 8; ROS1 exon 35
	LRIG3-ROS1	LRIG3 exon 16; ROS1 exon 35
RET fusions (7)	KIF5B-RET	KIF5B exon 15; RET exon 11
		KIF5B exon 15; RET exon 12
		KIF5B exon 16; RET exon 12
		KIF5B exon 22; RET exon 12
		KIF5B exon 23; RET exon 12
		KIF5B exon 24; RET exon 11
	CCDC6-RET	CCDC6 exon 1; RET exon 12
MET exon 14 skipping	MET-MET	MET exon 13; MET exon 15

Expression Imbalances detected by the Idylla Genefusion Panel. Only reported in case no specific fusion is detected.

List of Detected Expression Imbalances		
Biomarker	Kinase Gene	Biomarker Call
ALK Expression Imbalance	ALK	ALK Expression Imbalance
ROS1 Expression Imbalance	ROS1	ROS1 Expression Imbalance
RET Expression Imbalance	RET	RET Expression Imbalance

NRAS/BRAF

The Idylla NRAS/BRAF Mutation Test is performed on the Biocartis Idylla System for NSCLC mutation testing. Full details are included on Pages 31 and 32.

KRAS

The Idylla KRAS Mutation Test is performed on the Biocartis Idylla System for NSCLC mutation testing. Full details are included on Page 32.

MORTUARY

Post-Mortems; Death Certification

It is the statutory obligation of a doctor who has attended a patient who dies to issue a Death Certificate unless the death falls within the following categories requiring it to be reported to HM Coroner:

- Deaths from unknown causes
- All cases seen only after death
- Deaths which occur within 24 hours of an anaesthetic or operative/investigative procedure. The Coroner wishes to be informed about such deaths although he may authorise the reporting doctor to issue a death certificate.
- All violent or unnatural deaths related to:
    a. Poisoning or drug mishap
    b. Criminal abortions
    c. Assault or accident – irrespective of time interval between the event and the death
    d. Want, exposure or neglect
    e. Industrial diseases e.g. pneumoconiosis
    f. Inmates of prisons or police custody
    g. If there is any known suggestion of allegations of neglect or malpractice against hospital medical or nursing staff.

Post- Mortems; Coroner

If the cause of death is not known and falls within one of the above categories, HM Coroner **must** be informed.

If the coroner requires an autopsy to be done, his officer will make the necessary arrangements. Preparation of a short clinical summary is of great assistance to the pathologist. The clinical notes, if requested by the coroner's office, should be dispatched to the Mortuary as soon as requested.

Clinicians wishing to see copies of post mortem reports must contact the relevant Coroner's office.

Post-Mortems; Hospital

If a consent post-mortem is required by the clinical team the following steps must be taken:

- Provide the relatives with the death certificate (NB if the cause of death is not known, the case **must** be referred to the coroner)

- Where a hospital post mortem examination is indicated, the clinician will seek permission for the autopsy from the bereaved relatives after completion of the death certificate.

All Adult post mortems must be consented using the appropriate Trust consent form. The post-mortem will not proceed if the form is not completed fully and appropriately signed. The clinician responsible for taking consent will be offered a short training session or alternatively they will be accompanied by a trained member of mortuary or bereavement staff.

Adult post mortems need to be consented by the person ranked highest in a qualifying relationship or the deceased during life. As part of the consent process a ***'Hospital post mortem consent form'*** must be completed, signed and any restrictions in the autopsy procedure (eg no examination of the head) must be indicated clearly. (Consent forms can be requested via telephone from the Mortuary)

- A clinical summary should be provided for the pathologist, outlining the case and the questions to be addressed by the post mortem. Ideally the case should be discussed with the Consultant Pathologist concerned, ***and at least one member*** of the clinical team should be available to attend the mortuary and see the findings of the examination.
- The consent form should be taken immediately with the case notes to the Mortuary.
- A post mortem examination on a baby or child will be performed by a Paediatric Consultant Pathologist and will require transfer of the body to a specialist centre. As arrangements differ between Trusts, please contact the Mortuary if further information is required.

Prior to post-mortem; examination*:*

If it is known that there is going to be a Coroner's post mortem, for example a post-operative death, all such objects must be left in situ.

These items along with others should be left in situ as the position of these may have a direct bearing on the cause of death.

- catheters
- cannulas
- nasogastric tubes
- endotracheal tubes
- drains
- pacemaker wires etc

If such an object interferes with the viewing of the body and it is known that there is not going to be a Coroner's post mortem, then these objects can be removed. Where there is a possibility of a Coroners post mortem or if any doubt arises about the correct action to be taken, then contact the mortuary staff before removal.

Cremation Forms:

If a cremation form is required, the doctor completing part 4 should ensure that they are available to discuss the case with the Medical Examiner.

Please endeavour to complete the cremation forms as promptly as possible in order to facilitate bereaved relatives.

Funeral Directors:

Collection of bodies can be arranged by telephoning the mortuary staff. Afternoon collections are preferred.

Bodies will only be released on production of a release form signed by the relative or executor, a coroners release form or on evidence of the ‘green’ Disposal Certificate.

QUALITY CONTROL & QUALITY ASSURANCE

Path Links is accredited under Medical laboratories - Requirements for quality and competence (ISO 15189:2012) by the United Kingdom Accreditation Service (UKAS). Therefore Cellular Pathology is subject to compliance inspections by UKAS and other regulatory bodies including Human Tissue Authority and Screening Quality Assurance Service for NHS Cancer Screening Programmes.

Path Links has a culture of continuous improvement embedded within the service, the foundation for which is a processed based quality management system. All data associated with non-conformity is captured through Q-Pulse industry standard compliance management software. This supports the quality management team in the identification of trends, root cause, improvement opportunities and objective setting.

Improvement work concentrates on improving the efficiency and safety of the service in which all staff are regarded as stakeholders. Lean thinking and methodology, incorporating a variety of tools such as value stream mapping and 5S system of workplace organisation, have been instrumental in establishing the centralized Cellular Pathology Department at Lincoln and to maintain continuous improvement.

Internal quality control (IQC)

Sample registers are utilised for the handover and receipt of all histology specimens taken at hospital sites including operating theatres and out-patient departments.

Specimens will not be accepted unless they are compliant with the Path Links policy EXT-STD-9 Expected Standards of Pathology Request Form Labelling, which is available via the link https://www.nlg.nhs.uk/services/ and selecting Pathology.

Sample tracking arrangements are in place for all samples transported between Path Links sites to/from the central laboratory at Lincoln County Hospital.

All cancer specimens, biopsies and resections, are dissected and prepared according to the Royal College of Pathologists (RCPath) guidelines and are reported in accordance with the RCPath Minimum Datasets. Data are submitted to relevant Cancer Registries.

All screening specimens are prepared and reported according to NHS Cancer Screening Programmes guidelines (NHSCSP, NHSBS, and BCSP).

All staining methods (morphology, histochemistry and immunocytochemistry tests) are performed alongside known IQC material confirmed as positive. Slides are subjected to a microscopical check against NEQAS standards prior to submission for reporting.

External Quality Assurance (EQA)

Medical Quality Assurance Schemes participated in are as follows:

- National Breast NHSBSP Pathology EQA
- Yorkshire Histopathology EQA
- East Midlands Histopathology EQA
- National Uropathology EQA
- National Gastrointestinal Pathology EQA
- National Bowel Cancer Screening Pathology EQA
- National Gynaecological Pathology EQA
- National Dermatopathology EQA
- National Renal pathology EQA

Technical External Quality Assurance Schemes participated in are as follows:

- UK NEQAS Cellular Pathology Technique (CPT) modules:
  - Tissue Diagnostics
  - Specialist Techniques (including mega-block and frozen section)
  - Non-gynae Cytology
  - Bone Marrow Trephine
- UK NEQAS Immunocytochemistry, General, GIST and Breast Hormone Receptor Modules.
- NordiQC Immunocytochemistry
- RCPA-QAP Synovial fluid
- UK NEQAS Interpretative Digital Diagnostic Cytopathology

Compliance with national standards for sample and record storage and disposal as specified by the RCPath Storage and Retention guidelines are in place and followed. Mortuary and laboratory protocols also include requirements as specified under the Human Tissue Authority regulations.

Continuing Professional Development (CPD)

Consultant Medical Staff

CPD is a necessary component for Consultant Pathologists' Trust annual appraisal and 5-yearly revalidation with the General Medical Council. All consultant pathologists participate in external quality assurance schemes relevant to their scope of practice as detailed above.

Technical Staff

All Biomedical Scientist staff are registered with the Health and Care Professions Council and are required to participate in regular CPD activity. On rotation, all BMS staff (with guidance from Path Links Quality Management Team) are required to undertake internal audit of processes throughout Path Links directorates and take ownership of actions

COMPLAINTS, CONCERNS, COMMENTS AND COMPLIMENTS

Cellular Pathology would encourage all service users to provide feedback, both positive and negative as this will inform our continuous improvement programmes.

Path Links adheres to Northern Lincolnshire & Goole NHS Foundation Trust complaints policies and procedures, as such please refer to the Trust policy which is available on the NLG Hub - POLICY AND PROCEDURE FOR THE MANAGEMENT OF FEEDBACK FROM COMPLAINTS, CONCERNS, COMMENTS AND COMPLIMENTS (DCP07

MEDICAL, TECHNICAL AND CLERICAL STAFF CONTACT DETAILS

All Cellular Pathology telephone Enquiries: **01522 375755**

Dr A Willey *MB, ChB, FRCPath*
CLINICAL LEAD
CONSULTANT PATHOLOGIST
anu.willey@ulh.nhs.uk
Dermatopathology

Dr N N Arsenovic *SPEC PATH*
CONSULTANT PATHOLOGIST
nebojsa.arsenovic@ulh.nhs.uk
Dermatopathology

Dr R Bhobe *MBBS, MDPath, FRCPath*
CONSULTANT PATHOLOGIST
r.bhobe@nhs.net
Gastroenterology, Head & Neck, Breast, Diagnostic Cytology

Dr A Bickers *BM, FRCPath*
CONSULTANT PATHOLOGIST
adam.bickers@ulh.nhs.uk
adam.bickers@nhs.net
Breast, Urology, Gynaecology, Gastroenterology, Autopsy Pathology

Dr A Borg Grech *LRCP, MRCS, FRCPath, FRCPC*
CONSULTANT PATHOLOGIST
anthony.grech@ulh.nhs.uk
Gynaecology, Breast

Dr A Coup *MBChB, FRCPath*
CONSULTANT PATHOLOGIST
andrew.coup@nhs.net
Urology, Gastroenterology

Dr J Hamilton *BSCi (physiology), BMedSci, MBBS, FRCPath*
CONSULTANT PATHOLOGIST
Joey.Hamilton@ULH.nhs.uk
Dermatopathology, Head & Neck, Diagnostic Cytology

Dr H Hellquist MB, PhD, SAPath, FCAP
CONSULTANT PATHOLOGIST

henrik.hellquist@ulh.nhs.uk
Head & Neck

Dr C Oliver ***FRCPath, CHAT***
CONSULTANT PATHOLOGIST
Charlotte.Oliver@ULH.nhs.uk
Gynaecology, Urology, Gastrointestinal, Diagnostic Cytology, Autopsy Pathology

Dr W M Peters ***MBChB, FRCPath***
CONSULTANT PATHOLOGIST
martin.peters1@nhs.net
Gastroenterology

Dr M Pigera ***MB, ChB, FRCPath***
CONSULTANT PATHOLOGIST
marian.pigera@ulh.nhs.uk
Breast

Dr F Sevilla ***MD, Histopathology Specialist, PhD***
CONSULTANT PATHOLOGIST
Francisco.SevillaChica@ULH.nhs.uk
Breast, Skin, Gynaecology

Dr P Sekhri ***MBBS, MD, FRCPath***
CONSULTANT PATHOLOGIST
priti.sekhri@ulh.nhs.uk
Gynaecology

Dr R Sheeran ***MB, ChB, FRCPath***
CONSULTANT PATHOLOGIST
rachael.sheeran@ulh.nhs.uk
Breast

Dr A A Sheth ***MBBS, MDPath, FRCPath***
CONSULTANT PATHOLOGIST
anuradha.sheth@ulh.nhs.uk
Gynaecology, Gastroenterology, Non-gynaecological Cytology
Service Lead for Cervical and Bowel Screening Programmes

Robert Hughes ***BSc, CSci, FIBMS***
Directorate Operational Manager & Lincoln Pathology Site Manager
robert.hughes@ulh.nhs.uk
robert.hughes1@nhs.net
01522 308830

Louise Shaw ***BSc, MSc, MIBMS***
Laboratory Manager
louise.shaw@ulh.nhs.uk
louise.shaw12@nhs.net
01522 308761

Andrew Milner ***DAPT, FAAPT***
Mortuary Manager
andy.milner@ulh.nhs.uk
Andrew.milner@nhs.net
01522 573711

Suzanne Laver
Directorate Office Manager
suzanne.laver@ulh.nhs.uk
suzanne.laver@nhs.net
01522 308748

Catherine Brown ***MSc, LIBMS***
Deputy Laboratory Manager
catherine.brown@ulh.nhs.uk
01522 309396

Louise Dolan ***BSc, MSc, FIBMS***
Deputy Laboratory Manager
louise.dolan@ulh.nhs.uk
01522 309396

Susan Smith ***BSc Hons, PgD, MSc, FIBMS***
Reporting Biomedical Scientist
sue.smith2@ulh.nhs.uk
01522 308760

Hannah Drury ***BSc Hons, MIBMS***
Advanced Practitioner
hannah.drury@ulh.nhs.uk
01522 309396

Joanne Godfrey ***BSc, MSc, CSci, FIBMS***
Advanced Practitioner
joanne.godfrey@ulh.nhs.uk
01522 309396

Louise Greenhalgh ***BSc, CSci, FIBMS***
Advanced Practitioner

louise.greenhalgh@ulh.nhs.uk
01522 309396

Nicole Hayward ***BSc Hons, PgD, FIBMS***
Advanced Practitioner
nicole.hayward@ulh.nhs.uk
01522 309396