

North Tees and Hartlepool  NHS Foundation Trust	File name: CP-UG-001-N	Revision: 5
	Current Author: Danielle Mead	Copy No:
Pathology Service, Department of Cellular Pathology	Approved by: See Q-Pulse Record	Page 1 of 16

Cellular Pathology User Guide

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Overview

This handbook has been provided to inform users of the Cellular pathology-Histology/cytology - Laboratory about which services are available and how to obtain the services required.

Also provided are lists of relevant telephone numbers to facilitate easy access to the appropriate Consultant and senior staff for advice, as well as numbers for general and results enquiries.

Any suggestions from users on how this guide could be improved would be welcome for inclusion in future editions. Please forward any suggestions onto Ann Wallis Pathology Quality Manager (Ann.Wallis1@nhs.net)

Our laboratory is based at University Hospital of North Tees - part of North Tees & Hartlepool NHS Foundation Trust. We provide an extensive histology and diagnostic cytology service, undertaking the examination of cells and tissues, including surgical specimens and biopsies from hospital and GP patients. There is participation in the cervical, breast and bowel screening programmes. The histology department provides a sub-regional HER2 testing service. The cytology section also provides a ROSE service for sample adequacy assessment.

Within this handbook there is a list of investigations, specimen containers and turnaround times. Certain investigations are referred to external laboratories.

All service areas participate in External Quality Assurance Schemes through UK NEQAS. The laboratory is accredited to UKAS ISO 15189:2022 standards. Quality is overseen by our Clinical & Quality Lead and the Cellular Pathology Department is subject to the Trust Clinical Governance structure.

A 6 day Monday to Saturday working arrangement is operational in Cellular Pathology, with no out of hours service provision.

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Departmental Telephone Numbers

General Pathology

Pathology Reception	24464
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Cellular Pathology

Secretaries (general/urgent enquires)	24123
Histology Lab (technical enquiries)	24446
Cellular Pathology screening room (technical enquiries)	83109
Dr Natu (Consultant Pathologist)	24123
Dr Dasgupta (Clinical Director and Head of Department)	24123
Dr Trigka (Consultant Pathologist)	24123
Dr Karpe (Consultant Pathologist)	24123
Dr Senina (Consultant Pathologist)	24123
Sharron Pooley (Cellular Sciences Service Manager)	24213
Sue Robinson (Operational Lead BMS)	24130
Danielle Mead (Lead BMS)	24130

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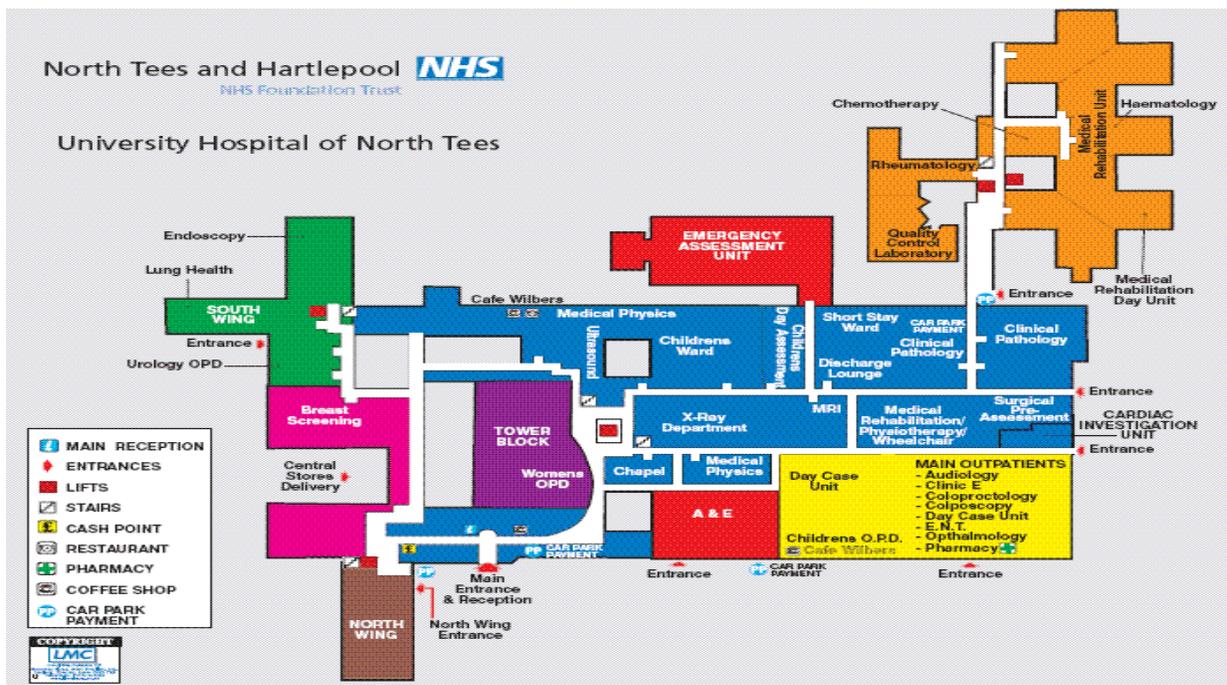
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Location and Map

The postal address is:-

Clinical pathology- Histology/ Cytology (delete as appropriate)
 University Hospital of North Tees
 Hardwick
 Stockton On Tees
 TS19 8PE

Clinical Pathology is located just off the Main corridor in-between the cardiac investigation unit and the elderly care entrances.



Hours of Opening

Monday – Friday - 8.00am – 6.00pm
 Saturday – 8am – 4pm

Clinical pathology operates a six-day service Monday to Saturday excluding Sundays and bank holidays.

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Requesting Analyses

Reference should also be made to the [Trust policy C47 – Management of Diagnostic Testing Procedures](#).

ICE test requests are the preferred option; however, paper request forms are accepted. All specimens must be accompanied by a fully completed request form. The request form is available on the Histology-Cellular Pathology SharePoint site.

The patient must be uniquely identified on the form and on the specimen. For inpatients the form must show the patient's NHS or hospital number as well as the name and date of birth.

Failure to do so can cause results to be allocated to the wrong patient. The addressograph label should always be used for hospital patients. The sample itself must be labelled with the patient's first name, surname, date of birth, hospital or NHS number and the date and time of the specimen – this may be different to the time / date printed on the addressograph label.

Where space is limited it is acceptable to include 2 mandatory points of identification (full name and date of birth or NHS number) on prepared slides for cytology. This information should be included on all slides with an indication as to mode of fixation (F for alcohol fixed slides, AD for air dried slides).

The source of the specimen (ward or department and Consultant or GP) must be given.

The name of the requesting doctor and the doctor's bleep number (when indicated on the request form) must be clearly shown. This reduces delays when the laboratory needs to contact the clinician either because of a problem with the specimen or request or because of abnormal or unexpected results. All the data on the form and specimen must be legible.

Send the specimen and the request form together to the laboratory in the clear transparent plastic bags provided (sample within sealed zipper section and request form in separate outer pocket). It is essential that fresh cytology samples are submitted in a timely manner to the department in order to preserve the integrity of the cellular material. If any delay in transport is anticipated or encountered please refrigerate fresh cytology fluid samples. Cytology samples collected in CytoLyt® solution may be stored at room temperature.

Requesting Urgent Analyses

Please write clearly on the request form that the specimen is urgent and the date the result is required by, e.g. for a clinic date or MDT meeting. You can also telephone the laboratory and

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request a sample is processed urgently. All urgent work must be accompanied by a fully completed request form as described above.

Obtaining Specimen Containers and Supplies

All specimen containers and biopsy capsules can be obtained from the Cellular Pathology Department, North Tees and collected from Pathology Reception Hartlepool during normal opening hours. Please ring the histology laboratory at North Tees prior to collecting from the Hartlepool Pathology Reception to ensure that supplies can be transported across sites.

Most histology specimens should be placed in formalin containers. The only exception is for pre-booked peri-operative tissue for frozen sections which should be placed in a sterile container.

Outpatient departments and clinics can collect formalin filled containers from the Histology department within normal opening hours. Please bring a box or trolley to carry them in.

Formalin filled containers will be delivered to North Tees Main Theatres and Day Case twice a day at approximately 9am and 1pm Monday to Friday. If a different sized container is required which is not available/present in theatres, then please telephone the histology laboratory stating what size you will need. If it is needed urgently before the next delivery at 9am or 1pm, then please come to the laboratory with a trolley to collect the container. Unfortunately, we cannot deliver containers outside of the twice daily visits.

GP surgeries can order from Pathology Reception on 01642 624464.

Cytology specimens are submitted as fresh samples collected into 25ml white topped universal containers, as prepared slides or collected into 30mls of CytoLyt[®] solution. Prefilled 50ml centrifuge tubes containing 30mls of CytoLyt[®] solution are available from cytology upon request.

Sputum samples are thought to be of limited or no clinical value, and hence should be rarely received. Where patients are unfit for bronchoscopy sputum samples should be sent fresh, in a plain, sterile sputum pot as supplied by pathology reception.

Breast aspirates requiring testing for Anaplastic Large Cell Lymphoma (ALCL) should be clearly noted as such on the request form within the clinical details section, and details given on the material submitted e.g. 20mls of fluid plus 1 fixed and 1 air dried prepared slides. All prepared slides should be submitted to cytology in separate mailers if the mode of fixation differs i.e. fixed slide(s) in one mailer and air-dried slide(s) in a separate mailer; to prevent any transfer of alcohol fixative. Prepared slides should have at least 2 points of patient identification (legible)

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and the mode of fixation included on the frosted end of each slide i.e. 'F' for fixed and 'AD' for air-dried. Slide mailers, glass slides and Cytotfixx are supplied by cytology.

Please note urine samples received in a red top universal containers (boric acid) are not eligible for diagnostic cytology analysis and hence WILL NOT BE PROCESSED.

Sample Size and Container Size

The larger the sample, the more tissue is available for analysis and the more likely the sample is suitable for histological diagnosis and further testing such as genetic tests. Small biopsies should be placed into biopsy capsules (sometimes called 'nets'). Breast screening use mesh biopsy capsules as these can be x-rayed; all other departments should use the plastic biopsy capsules.

Transport of Samples

GP Surgeries

The laboratory operates a transport system to deliver reports and collect specimens for analysis from GP surgeries in and around Teesside and east Durham. The service runs daily Monday to Friday. Contact Pathology Reception if you require further information.

Hospital Wards/Clinics/A&E

All samples should be delivered to Pathology Reception at either North Tees or Hartlepool the same day that they have been taken. During departmental hours, Cellular Pathology operates its own Pathology Reception and samples can be taken directly to the department. The earlier the sample is delivered to the laboratory, the earlier it can be processed and a result provided. The pneumatic pod system must not be used for histology samples.

Main Theatres/Day Case

Specimens will be collected from North Tees Main Theatres and Day Case at approximately 9am, 1pm and 4.45/5pm Monday to Friday. Pre-booked frozen sections should be delivered to Pathology Reception immediately and the reception staff should be informed that it is an urgent sample so that they can telephone Histology to collect it.

Hartlepool theatres should deliver Histology specimens to Hartlepool Pathology Reception the same day that they are taken.

Discrepancies/Errors

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Histology samples will not be discarded before analysis as they are not repeatable. Specimens which are unlabelled or where there is insufficient information to link the specimen specifically with the patient, will not be processed until the requestor attends the laboratory to label the specimen correctly.

Specimens without clinical details will not be processed until sufficient clinical details are provided – i.e. why has the specimen been removed and what are the clinical suspicions.

Specimens that leak inside the plastic specimen bag may be delayed until the container/request form has dried.

Where the time of sample collection, the method of collection, the patient preparation for the test does not conform to the requirement for the investigation it may not be possible to complete the analysis fully, e.g. genetic testing. Advice should be sought from the laboratory about the conduct of special investigations.

Cytology samples received with insufficient patient identification, discrepant or absent mandatory points of patient identification (between request form and sample container), samples significantly leaking or urine samples in red topped boric acid container, **will not be processed**. An audit form will be sent to the requester and where possible, a report issued on the specimen indicating why the sample was unable to be processed. Any cytology samples received into the department where the discrepancy is classed as minor may still be processed, the requester will be notified of the discrepancy via a returned audit form or by telephone to request a representative to attend the department and make relevant amendments. A note will be made in the final report of any discrepancies and/or amendments.

Results

Electronic Transmission of Results

Almost all GP Practices receive their pathology results via the ICE system. Contact the Pathology IT & Information Manager for further details. Results for hospital wards and out patients are also reported via the Trusts ICE system.

Direct Access to Results

Wards and GPs have access to results via the ICE web browser. Where available, this enquiry system, based on the NHS or hospital number, should be used rather than telephoning the Cellular Pathology secretarial team. GP's and hospital users can view results can view all results on ICE. All tests can be ordered using electronic requesting. Sunquest ICE is now used by most GP Practices. All results are sent to ICE. This improves result retrieval as pathology reports become part of the electronic patient record.

Telephoning for Results

Please use the ICE web browser rather than telephoning for results, this reduces the following risks:-

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1. Giving patient information to someone not authorised to receive it. This might include the patients themselves who may not identify themselves as such and for whom results should only be given by their treating clinician in the context of all the clinical information.
2. Transcription errors. These occur if the person taking the results does not hear properly what is said over the telephone, does not write the results down properly having heard them or writes them in such a way that they are subject to misinterpretation by another person when reading them. This is most likely to occur when given results to those least familiar with their use and meaning.

Turnaround Times

The turnaround times stated in the table below are in calendar days from the date the specimen is received to the authorisation date.

Specimen Type	Turnaround Time
Band A (diagnostic biopsies 2WR)	80% reported within in 10 calendar days
Band B (urgent biopsies not 2WR)	80% reported within in 10 calendar days
Band C (Resection Specimens)	70% reported within in 10 calendar days
Band D (Insourced specimens – non-cancer resections & biopsies with previous pathology)	70% reported within in 10 calendar days
Band E (Outsourced specimens – non-cancer biopsies)	70% reported within in 10 calendar days
Bowel screening	Acceptable \geq 90% in 7 calendar days Achievable \geq 95% in 7 calendar days
HER2 IHC (breast)	100% in 7 calendar days
Molecular tests	90% in 21 calendar days
Cytology (first actionable report)	80% of cases reported within 7 calendar days 90% of cases reported within 10 calendar days

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* The above information is correct as of 01/05/2025. Please contact the Service Manager or Operational Lead BMS should further information be required.

Our current turnaround times for Bands A to E are as follows:

Specimen Type	Turnaround Time
Band A (diagnostic biopsies 2WR)	65% reported within 10 calendar days 80% reported within in 21 calendar days
Band B (urgent biopsies not 2WR)	42% reported within 10 calendar days 80% reported within in 28 calendar days
Band C (Resection Specimens)	42% reported within 10 calendar days 80% reported within in 28 calendar days
Band D (Insourced specimens – non-cancer resections & biopsies with previous pathology)	42% reported within 10 calendar days 80% reported within in 28 calendar days
Band E (Outsourced specimens – non-cancer biopsies)	42% reported within 10 calendar days 80% reported within in 28 calendar days

Safety Information

Potentially Infective Specimens

All specimens should be treated as if potentially infective, but specimens suspected or known to have certain infectious diseases constitute a hazard. Specimen containers and request forms from patients known to be Hepatitis B Surface Antigen (HBsAg) carriers, cases of suspected acute hepatitis, patients with Tuberculosis (TB), patients known or at risk of being HIV positive, Hepatitis C (HCV), Creutzfeldt-Jakob Disease (CJD) and variant CJD must be labelled with a “**Danger of Infection**” sticker. Any samples from suspected or known COVID-19 positive patients must be clearly indicated on the sample request form (this is a mandatory question field on Web ICE requests).

To maintain confidentiality, specimen request forms may be sent in their plastic specimen bag inside an envelope. Delays may occur in processing these samples. Some investigations may not be possible owing to hazard to laboratory staff. For further advice, contact the laboratory.

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Chemical hazards

Formalin is a hazardous chemical – it is carcinogenic, mutagenic, toxic and harmful. Please see the latest material safety datasheet which can be found on the Histology-Cellular Pathology sharepoint site, which gives advice on first aid measures and how to deal with a spillage. Please telephone the laboratory if further help is required.

CytoLyt® is a methanol-based preservative used to support cells during transport, it is toxic and flammable. Please see the latest material safety datasheet which can be found on the Cellular Pathology sharepoint site, which gives advice on first aid measures and how to deal with a spillage. Please telephone the laboratory if further help is required.

Specimens Referred to External Laboratories

All samples will be dissected and processed at North Tees. However, further work may be required such as immunohistochemistry, fluorescent in situ hybridisation, genetic testing and specialist expert pathologist second opinions. External IHC requests are referred to laboratories for which the tests are UKAS accredited, where possible. Please contact the laboratory for specific details of which reference laboratories individual specimens are sent to.

Referral laboratories used are as follows:

Laboratory	UKAS accreditation
Backlogs	https://www.ukas.com/download-schedule/21408/Medical/
RVI Newcastle	https://www.ukas.com/download-schedule/8534/Medical/
Newcastle Genetics Laboratory	https://www.ukas.com/download-schedule/9028/Medical/
QE Gateshead	https://www.ukas.com/download-schedule/9133/Medical/
Source Bioscience	https://www.ukas.com/download-schedule/9571/Medical/
QE Birmingham	https://www.ukas.com/download-schedule/10141/Medical/
South Tees Hospitals	https://www.ukas.com/download-schedule/9210/Medical/
HSL	https://www.ukas.com/download-schedule/9706/Medical/ https://www.ukas.com/download-schedule/8059/Medical/ https://www.ukas.com/download-schedule/9007/Medical/
HMDS Leeds	https://www.ukas.com/download-schedule/9305/Medical/
Exact Sciences, USA	https://precisiononcology.exactsciences.com/
Guy's and St. Thomas Genetics	https://www.ukas.com/download-schedule/9295/Medical/
Synnovis	https://www.ukas.com/download-schedule/8818/Medical/
Leeds Teaching Hospitals	https://www.ukas.com/download-schedule/9862/Medical/
North Bristol Genetics	https://www.ukas.com/download-schedule/9307/Medical/
North Bristol	https://www.ukas.com/download-schedule/8130/Medical/
Medica	8311 Medical Single
Source Bio Science	9571 Medical Multiple
Manchester Christie	https://www.ukas.com/download-schedule/8648/Medical/
Sheffield Teaching Hospitals	https://www.ukas.com/download-schedule/8509/Medical/
Norfolk and Norwich Hospitals	https://www.ukas.com/download-schedule/8405/Medical/

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Factors Known to Affect Histological Examination

- Delay in fixation time – the specimen must be placed into formalin as soon as possible as otherwise cell degradation may occur and affect the result
- Not enough formalin for fixation – choose a pot size that covers the specimen fully in formalin so that the specimen can be fixed correctly. If in doubt, choose the larger sized pot.
- Lack of clinical details – this may lead to incorrect processing of the specimen or a delay in the reporting due to incorrect triage of urgency
- Opening a specimen prior to receipt – if a specimen has been sliced/opened prior to receipt in the department, it can be difficult to correctly assess margins etc.
- Not enough tissue – if a sample is very small or scanty, it can be difficult to make a diagnosis based on just a few cells, and it is unlikely that there will be enough tissue left for further in-depth investigations such as immunohistochemistry.

Factors Known to Affect Cytological Examination

- Prepared slides
 - Slides utilised in the procedure
 - Grease and products transferred from human skin can affect adhesion of material to the surface of a glass slide-handle by frosted/blue end only
 - Use of incorrect slides i.e. those not provided by the cytology department may not result in optimum adhesion of material to the glass slide during processing procedures
 - The volume of material placed onto the slide
 - Too little/spread too thin can render slides insufficient
 - Too much/spread too thick can affect interpretation/staining
 - How slide the is spread
 - Too much pressure can cause trauma artefacts/pooling of the sample at one end of the slide
 - Uneven distribution of material over the slide can affect interpretation/staining
 - Inadequate labelling of slides
 - Unprocessed slides if the correct identity of the patient cannot be ascertained
 - Incorrect stain procedure applied for mode of fixation, if not identified as fixed or air-dried
 - Air-drying of prepared slides
 - Slow air drying can lead to drying artefacts
 - Thickness of preparation can cause uneven staining/ drying artefacts
 - Alcohol fixation of prepared slides
 - Insufficient alcohol fixative can cause air drying and therefore staining artefacts

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- Fixative not applied to slide in a timely manner can also produce the above effect
- Fresh fluid samples
 - Delay in sample submission, without appropriate storage, can result in sample deterioration and may result in a loss of integrity of the cellular material.
- Voided urine
 - Delay in sample submission, without appropriate storage, can result in sample deterioration/cellular degeneration and may result in a loss of integrity of the cellular material.
 - Samples collected into boric acid (red topped universal containers) will render the sample unsuitable for cytological assessment and the sample will be discarded.
- EBUS and bronchial samples
 - If samples are not collected into CytoLyt® transport medium, specimens can deteriorate and may not be optimally preserved resulting in a loss of sample integrity.

Consent

Trust consent forms for specific procedures include awareness that pathology specimens are primarily for diagnostic purposes but may be used for clinical audit, teaching, quality assurance and performance assessment in accordance with the Human Tissue Act 2008 and for public health surveillance or medical research.

Pathology receives specimens from many sources and does not have access to the patient to demonstrate consent has been given. The referral of a specimen into Pathology is a 'request for a consultation' relating to the specimen and the indications for the request given on the form / electronic request accompanying the specimen. As such, the Pathology service may amend the request if a different test would be more appropriate, add or delete tests as required. Clinical protocols relating to this practice must be available to the requesting clinician if required.

A 'sensitive handling of pregnancy loss remains' consent form must be used for all confirmed/suspected pregnancy remains (<24 weeks). This is available on the Histology sharepoint site.

Complaints

Minor complaints can be telephoned to the laboratory and we will attempt to immediately resolve the problem. If an InPhase event is required, please telephone the laboratory to discuss the issue and to assign the correct investigating manager.

Serious complaints about the service delivered or other issues should be sent by letter or email to the Head of Department and a formal response will be made. Serious complaints may also be sent directly to the PALs Team or to the Chief Executive for the Trust

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Confidentiality

All patient information is protected within the department and will not be issued to third parties outside the NT&H NHSfT or requesting practitioner except when required for referred tests or statutory notification.

Accreditation

All service areas participate in External Quality Assurance Schemes through UKNEQAS. The laboratory is accredited to UKAS ISO 15189:2022 standards. A Rapid On-Site Examination (ROSE) service is offered by the Cytology section of the department, this is an unaccredited element of the service.

Our accreditation is limited to those activities described on our [UKAS schedule of accreditation \(9587 Medical Multiple \(ukas.com\)\)](#).

Quality is overseen by our Clinical & Quality Lead and the Cellular Pathology Department is subject to the Trust Clinical Governance structure.

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