




Pathology at Wigan and Salford				Cellular Pathology	
				Cellular Pathology User Manual	
<small>A joint venture between Salford Royal and Wrightington, Wigan and Leigh NHS Foundation Trusts</small>		Q-Pulse Ref: CP-Form.033	Q -Pulse Revision No: 10	Authorised By: David Muskett	Page 1 of 22

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1 Introduction

Welcome to the Pathology at Wigan and Salford User Manual. This document aims to provide service users with information they require to make the best use of services.

Specific and urgent enquiries should be directed to;

0161 206 5013 for reports, autopsies and clinical issues

0161 206 4075 for issues relating to specimens.

1.1 The location of the laboratory;

The laboratory is located on level 2 of the Turnberg Building at Salford Royal Hospital. All specimens should be delivered to the pathology specimen reception.

The postal address of the laboratory is

Cellular Pathology



Pathology at Wigan and Salford

Level 2, Turnberg Building

Salford Royal Hospital

Stott Lane

M6 8HD

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1.2 Contact details

Main Secretarial Enquiries	Telephone
All enquiries for urgent reports, PM's, clinical interpretation and consultant contact	0161 206 5013
Copies of reports, case reviews, audits, MDT's	
NHS.net email is the safest method of sending and receiving patient information. Please email: Srh-tr.Scmhisto@nhs.net	
The department has a secure fax (0161 206 4654) but faxes are discouraged.	
Cellular Pathology Service Manager	Telephone
David Muskett	0161 206 5011
Cellular Pathology Clinical lead	Telephone
Dr Luisa Motta	0161 206 4850
Clinical lead for Mortuary Services	Telephone
Dr Daniel du Plessis	0161 206 5020
Quality Manager	Telephone
Mrs Louise Bell	0161 206 5016
Cellular Pathology Operations Manager / Quality Lead	Telephone
Richard Mathias	0161 206 1875
Salford Mortuary Operations Manager	Telephone
Michael Coombes	0161 206 4484
Laboratory Sections (technical enquiries only)	Telephone
Histopathology/ Neuropathology	0161 206 5015
Cytopathology	0161 206 2012
Immunohistochemistry	0161 206 4910
Consumables (pots, slides, fixatives, request cards)	0161 206 5008 or 4075

1.3 Consultant Pathologists

1.3.1 Consultant Histopathologists

Dr. Gordon Armstrong



Dr. Shahid Bashir

Dr Mayuri Basnet

Dr Usha Chandran

Dr Kate Chillman

Dr. Jamil Choudhury

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Dr. Stephen McGrath

Dr. Stephen Hayes

Dr. Sangeeta Verma

Vacancy

1.3.2 Consultant dermatopathologists

Dr Ruth Green

Dr. Lynne Jamieson

Dr. Luisa Motta (Clinical Lead)

1.3.3 Consultant Neuropathologists

Dr. Daniel du Plessis (Clinical Lead for Mortuary)

Dr Federico Roncaroli

Vacancy



2 The departmental scope of practice

The department offers a comprehensive diagnostic histopathology service encompassing

- a) Routine Histopathology
- b) Dermatopathology
- c) Neuropathology
- d) Immunocytochemistry
- e) Special stains
- f) Muscle Histochemistry
- g) Electron Microscopy
- h) Breast Her-2 immunocytochemistry and bright field in-situ hybridisation
- i) Mortuary and post-mortem services for the Salford Royal Hospital site. (Wrightington. Wigan and Leigh Hospitals manage their own mortuary services. They may be contacted on 01942 822000)

3 Opening hours of the laboratory

The laboratory is fully open with consultant availability 8:30am to 5pm Monday to Friday. A BMS service is operated 8am to 1pm on Saturday.

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3.1 Consumable supplies

Specimen pots and request cards are available from the department within normal working hours either by pick up or to be ordered and sent out.

4 Sample requirements

4.1 Renal biopsies

Renal biopsies for cellular pathology analysis should contain at least 10 glomeruli for diagnosis. Laboratory staff are available to support renal biopsy adequacy assessment on Monday and Thursday mornings on the Salford Royal Hospital site.

4.2 Inflammatory skin samples for direct immunofluorescence studies


Skin biopsy samples for direct immunofluorescence studies should be placed in Michel's transport medium. This is available from the laboratory at Salford Royal Hospital into which the skin should be collected before being transported to the laboratory at the earliest opportunity. If there is a delay in transport to the laboratory then samples should be refrigerated.

Skin specimens for direct immunofluorescence should not be placed in formalin.

Immunofluorescence is performed on 'unfixed' tissue. This test is therefore contraindicated in patients with certain conditions i.e. patients with blood borne viruses (for example, HIV, hepatitis B and C), suspected tuberculosis. For any specific queries, please contact the laboratory.

Depending on the underlying condition, specimens for normal, perilesional or lesional skin may be optimal for analysis. Please see table below:

Underlying condition	Optimal sample site
Pemphigus (all forms)	Perilesional
Pemphigoid (all forms)	Perilesional
Pemphigoid (herpes) gestationalis	Perilesional
Linear IgA bullous dermatosis	Perilesional or uninvolved (buttock)
Dermatitis herpetiformis	Uninvolved (buttock)
Lupus erythematosus	Lesional
Porphyria	Lesional

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Underlying condition	Optimal sample site
Vasculitis	Lesional

Samples for Epidermolysis bullosa investigations need to be sent with a St. John's Institute of Dermatopathology request for. Samples are forwarded via the Cellular pathology Department to St. John's.

4.3 Cerebrospinal fluid samples (CSF)

Cerebrospinal fluid samples should be transported urgently to the department and arrive no later than 4:30pm for same day analysis.

4.4 Neuropathology

CNS tissue usually gives good smear preparations, though frozen sections may be required if the tissue is too tough or assessment of tissue architecture is required.

A request card must be completed to the same standards as routine specimens, with the addition of a contact telephone number.

Specimens must be brought unfixed to pathology reception immediately and handed to a member of cellular pathology staff.

Do not leave at reception without notifying Cellular Pathology under any circumstances. Clinicians are encouraged to confirm receipt.

4.5 Neuropathology neurosurgical samples

Neurosurgical specimens e.g. tumours should be brought fresh to the cellular pathology laboratory and handed to a member of member of cell path staff. If they cannot be brought to the laboratory during opening hours, they must be placed into 10% neutral buffered formalin.


4.6 Neuropathology – muscle biopsy samples

Diagnosis of neuromuscular disorders relies on ultrastructural and/or enzyme histochemical studies. Careful and optimal handling is essential to preserve these features and avoid traumatic damage. Prompt submission of freshly excised tissue is vital.

The biopsy must not be placed into fixative, saline or any other liquid.

Biopsies can only be received between 08:30 and 16:30, Monday to Friday (excluding bank holidays), unless specifically agreed in advance. Biopsies should preferably arrive by lunchtime as they can then be dealt with the same day (optimal), but in any case before 16:30. Specimens should be handed directly to a member of the cellular pathology team and not left at specimen reception.

High Risk may require special handling and amended protocols.

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4.6.1 Muscle biopsies - SRFT on-site collection

- Notify neuropathology in advance if intending to send a muscle biopsy (0161 206 5015).
- Include all relevant clinical information, including any EMG results on the request card
- Specimens are delicate - handle with care to prevent damage
- Place on a piece of gauze swab dampened (not wetted) with isotonic saline
- Seal within a sterile, air-tight specimen container to minimise drying.
- Deliver to the laboratory as soon as possible after collection
- Biopsies should arrive by lunchtime as they can then be dealt with the same day (optimal), but in any case before 16:30
- Bring directly to Cellular Pathology. Do not leave at central reception without notifying Cellular Pathology under any circumstances.

4.7 Out of hours muscle specimens

- Out of hours biopsies are discouraged. If taken outside of laboratory hours then it must be refrigerated overnight and sent to Cellular Pathology at the start of the next working day so that it can be frozen. The laboratory is not open on Sunday.

4.8 Muscle biopsy specimens from distant sites:


- The department must be notified in advance – 0161 206 5015
- Biopsies sent from remote centres (where some time delay is inevitable) should be wrapped in gauze dampened (not wetted) with isotonic saline to maintain humidity. The procedure is otherwise as above for SRFT on-site collection.
- The biopsy must be taken and despatched in time so that it can arrive at the laboratory within the hours specified above.
- Ensure the driver/courier is instructed to bring the specimen promptly to cellular pathology reception

4.9 Renal biopsies

Renal biopsies collected on the ward can be supported by Biomedical Scientist staff. Support needs to be booked in advance.

4.10 Cytology samples

Cytology samples should be collected into cytolyt collection media. Syringes used for samples should be flushed through with collection fluid to ensure maximum cellular yield. Samples should be transferred to the department at the earliest opportunity.

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4.11 Placenta samples for cytogenetics

Placenta samples for cytogenetics should be no more than 1cm³ and placed in cytogenetics transport media. Samples should be transferred directly to St. Mary's.

5 Specimen pot instructions

Please ensure that lids are firmly fixed to the specimen pots before transferring samples. Specimen pots are either screw tops or snap fix lids.

5.1 Screw tip lids

Please ensure the lids are sealed tight and not cross threaded.

5.2 Snap fit lids

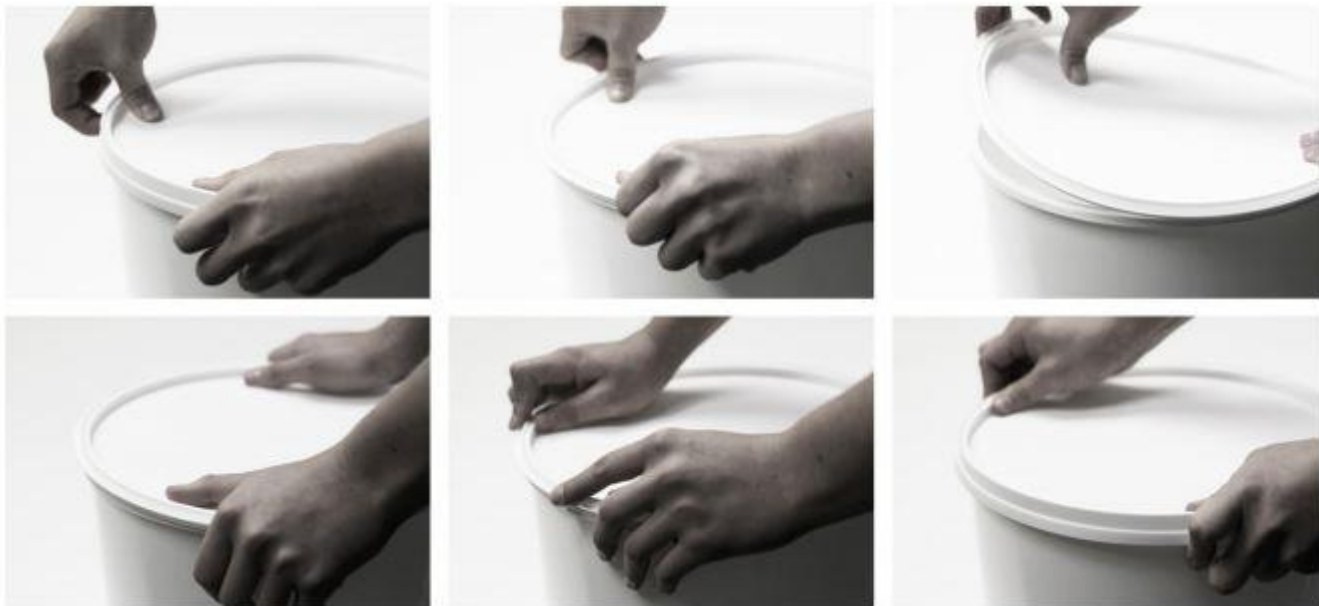




Figure 1 - Instructions for sealing niftilid pots. The lids have a 2 part snap and seal design. The outer rim needs pushing down to complete the pot seal.

5.3 Patient details

It is mandatory that all requests contain 3 matching, legible patient identifiers between the request and each pot. They are:

- Unique identification number (hospital or NHS number, both if available)
- Full name i.e. Surname (Family Name) and Forename (First Name)
- Date of birth

Please check the details on the label are correct and legible. Use a ballpoint pen on handwritten labels, or use an ICE/HIS/PAS label.

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5.4 Routine cellular pathology requests

Specimen pots should be large enough to easily accommodate the specimen and labelled as specimens are collected. It is poor practice to label pots in advance. There should be 10x the amount of fixative to specimen

5.5 Primary sample volume for histology

Specimen pots should be large enough to easily accommodate the specimen and labelled as specimens are collected. It is poor practice to label pots in advance.

It is mandatory that all requests contain 3 matching, legible patient identifiers between the request and each pot. They are:

Unique identification number (hospital or NHS number, both if available)

Full name i.e. Surname (Family Name) and Forename (First Name)

Date of birth

Please check the details on the label are correct and legible. Use a ballpoint pen on handwritten labels, or use an ICE/HIS/PAS label.

5.6 Sample fixation

Correct fixation of specimens is vital to ensure the quality of the diagnosis. 10% neutral buffered formalin is supplied by the department or from Wigan Theatres. The working solution is neutral buffered formal saline and is bought from Genta. 10% neutral buffered formalin should be used at a volume of 10x that of the sample. Specimens should be stored in fixative at room temperature.

Information on specific specimen types can be found below. For further advice, please ring 0161 206 5015

Do not use fixative beyond its expiry date.

For further information please see their website: <http://www.mangen.co.uk/lab-services/GeneralDiagnosticGenetics.php>



5.7 Special precautions

5.7.1 10% Neutral Buffered Formalin

10% Neutral Buffered Formalin is a liquid based fixative used to preserve tissue samples.

Description of First Aid Measures

First Aid

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Eye contact: Immediately flush eye with water for at least 15 minutes while lifting the upper and lower lids. Get immediate medical attention.

Skin contact: Remove contaminated clothing. Wash thoroughly with soap and water. Get medical attention if irritation persists. Launder before reuse.

Inhalation: Remove victim to fresh air. If breathing is difficult have qualified individual administer oxygen and get immediate medical attention. If breathing stops, give artificial respiration. Get immediate medical attention.

Ingestion: Do not induce vomiting unless directed to do so by medical personnel. If the victim is conscious and alert, have them rinse their mouth with water. Never give anything by mouth to an unconscious or drowsy person. Get immediate medical attention.

5.7.2 Cytolyt collection fluid

Cytolyt is a methanol based, buffered preservative solution used to support cells during transport and slide preparation.

It is toxic if swallowed or comes into contact with the skin. Safety gloves should be worn when cytolylt is handled.

Description of first aid measures

General advice immediate medical attention is required. In case of accident or being unwell, seek medical advice immediately (show directions for use or safety data sheet if possible).

Inhalation Immediate medical attention is required. Remove to fresh air. If not breathing, give artificial respiration. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation.



Skin contact Wash off immediately with plenty of water.

Eye contact immediately flush with plenty of water. After initial flushing, remove any contact lenses and continue flushing for at least 15 minutes. Keep eye wide open while rinsing. Call a doctor immediately.

Ingestion Do NOT induce vomiting. Call a doctor or poison control centre immediately. Never give anything by mouth to an unconscious person. Drink plenty of water

5.7.3 Michel's Transport media

Michel's transport media is available for transporting skin samples for immunofluorescence studies. Samples should be sent in the supplied 30ml universal bottles and transferred to the laboratory at the earliest opportunity

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Michel's transport media can cause irritation to skin and eyes.

Skin contact (or hair): Remove/Take off immediately all contaminated clothing.

Rinse skin with water/shower. Wash with plenty of soap and water. Wash contaminated clothing before reuse. If skin irritation occurs: Get medical advice/attention.

In case of eye contact

Eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists get medical advice/attention.

5.8 Electron Microscopy

Electron microscopy is carried out on renal specimens as per clinical need.

For further information about electron microscopy please contact the laboratory on 0161 206 5015

6 .Instructions for completion of the request form

Cellular Pathology provides a consultant led clinical consultation service. All opinions are based on interpretation of specimens in the context of clinical history.



ALL requests should be accompanied by clear documentation indicating the nature and anatomical site of the material, clinical indications for biopsy, specific clinical issues to be addressed and any other relevant clinical information including previous biopsies. It is the responsibility of the requesting clinician to provide ALL relevant information including full patient identification and clinical history.

Reports will be made available electronically via EPR and in paper form in some cases. Cellular Pathology medical staff will contact requesting clinicians in cases of unexpected clinically significant results but this cannot be guaranteed and it is the responsibility of the requesting clinician to review all results.

The department accepts paper histology request forms and electronic requested forms with specimens. The request form constitutes an agreement between the service user and the laboratory. Any changes required to a request form by service users will need to be documented in writing.

There are separate paper request forms for:-

- a) Histopathology
- b) Cytopathology

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- c) Dermatopathology
- d) Oaklands private hospital

Cellular Pathology will accept no responsibility for specimens analysed which initially failed to meet the Specimen acceptance criteria. The need for correction of Specimen/Patient data will result in the delay of a report being issued.

6.1 Completion of paper request forms

When completing any handwritten form, all of the following must be included:

- Patient's Full Name (PRINTED)
- Hospital (District) Number or NHS Number (NOT PWI numbers)
- Consultant (FULL name, Clearly printed)
- Date Of Birth
- Location for reports
- Relevant clinical details
- Number of pots being sent
- Date and time of sample collection (important for sample quality)

6.2 Procedure for changing the patient details following submission of a specimen

The requesting clinician must sign to confirm that he/she has checked that the written details are complete and correct on the request form and specimen. If errors are detected at a later date they will be reported as adverse incidents and the medical director may be informed

If a specimen is submitted correctly for histopathology and then at a later point the patient details are found by the clinician then the following procedure is followed

- a) A letter must be submitted to the cellular pathology laboratory with the incorrect and correct patient ID on.

6.2.1 ICE Order Comms for Salford CCG Users:

Select "Histology/Cytology request" from the Cell Path tab. You must then complete the information at each prompt.

Accepting the histology/cytology request prints an A4 form with patient details and labels for the pots. The clinician accepting the request takes full responsibility for the accuracy of the information.

6.2.2 Order Comms for WWL and Wigan Borough CCG Users:



Requests should be made using ICE or HIS. There are two requests available:

Histology (tissue) - for solid tissue - biopsies, resections, etc.

Cytology (fluid) - for fluids, aspirates, FNA, urine, EBUS, etc.

An explanation of the details required can be found below:

1	Consent to use tissue: please confirm whether or not the patient/consenter has placed any
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	restriction on the use of their tissue. If they have, you must select "yes" and a separate box will appear for you to enter their wishes.
2	Number of pots: select between 1 and 10.
3	Histology - Clinical details: (Type/paste 350 characters which then prints on a custom form in the lab as well as the user form/label) Specify the contents of each pot. For multiple pots, label the first as A), the second as B), etc. Include all relevant symptoms, history and suspicions in this text box. Urgency for a reason other than cancer tracking should be included here.
4	Cancer tracking: Choose Yes if the patient is on a 62-day/2WW cancer pathway. If yes, you should also select Urgent in the priority option.
5	Select the correct entries: Requestor, location and category
6	Global Clinical details: as the information should already in Histology Clinical Details, type "see form" to move past this box
7	Priority: Select "Urgent" if the patient is on cancer tracking. Urgency for other reasons should be included in the Histology clinical details.
8	Accept the order and print the label.
9	Place the printed label onto a Cellular Pathology form. You do not need to write anything else on this form.
10	Do not reprint the request multiple times to obtain more labels - each print automatically generates a request form in lab reception at Salford which increases the risk of specimen errors.

6.2.3 Hand-written requests for Cellular Pathology

Users may still make paper requests using the forms.


There are separate request forms for histology, non-gynae cytology and dermatology these are stock items and can be ordered from Supplies using the code on the card.

When completing any handwritten form, please include:

- Patient's Full Name (PRINTED)
- Hospital (District) Number or NHS Number (NOT PWI numbers)
- Consultant (FULL name, Clearly printed)
- Date Of Birth
- Location for reports
- Relevant clinical details
- Number of pots being sent
- Date and time of sample collection (important for sample quality)
- Please sign and date the request to confirm it is accurate

7 Transport of specimens to the laboratory

Formalin fixed samples should be transported to the department on the same day where possible. If this is not possible then arrangement should be for samples to be transported the next day.

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Specimens sent in formalin or cytology collection fluid may be left at room temperature.

Fresh specimens should be transported immediately or refrigerated prior to prompt transfer.

7.1 Salford GP specimen transport

GP samples should be placed in the transport area in each practice for pick up by the Salford van driver.

7.2 Salford hospital transport

Salford Hospital specimens should be transferred by each department directly to the laboratory. Fresh specimens or those requiring urgent handling should be handed directly to a member of Cellular Pathology staff.

7.3 WWL GP specimen transport

Wigan district GP samples are collected as per the WWL hospital pick up schedule

7.4 WWL Hospital pick up

The last pick up times for same day delivery to Salford from each of the Wigan sites are:-

Leigh infirmary	16.45 hrs	arrive at RAEI	17.45
Wrightington	14.30 hrs	Arrive at RAEI	15.15
TLC	16.50hrs	Arrive at RAEI	17.15


Fresh specimens from the Salford site need bringing down between 8:30am and 17:00pm and handed directly to a member of staff. Outside this time then samples need to be refrigerated in the local department until transfer to cellular pathology on the next working day. For further information please contact the department

Specimens should be transferred to the laboratory at the earliest opportunity.

7.5 Specimen drop off points

Specimens from Wigan, Wrightington and Leigh should be delivered to one of the specimen drop off points:

- a) Pathology Lab – Royal Albert Edward Infirmary, Wigan
- b) Leigh Hospital
- c) Wrightington Hospital
- d) Thomas Linacre Centre, Wigan

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The specimens are collected periodically throughout the day and transferred to Salford. The last specimen pick up of the day to Salford is from the RAEI at 6pm, Monday to Friday. There are specimen pick up over the weekend as well.

7.6 Audit trails for specimens / specimen tracking

Specimen / theatre books where used should be presented and signed by cellular pathology staff on receipt of the specimens within the department during opening hours. Specimens sent from departments who do not deliver specimens directly are encouraged to use specimen tracking sheets. Templates can be supplied by cellular pathology. Tracking sheets should be sent with the specimens and the department will fax back sheets acknowledging receipt of specimens.

7.7 Specimen leaks prior and during transport to the laboratory.

If a specimen pot leaks a small amount (<250ml) of formalin prior to or during transport then service users are advised to wear protective gloves and wipe up using absorbent towels. Formalin contaminated absorbant towels can be discarded as clinical waste. If larger spills (>250ml) occur please contact the department for advice.

8 Specific sample requirements - Instructions for patient-collected samples

8.1 Urine samples

Collect a mid-morning sample in a dry container (Early morning specimens are less suitable as the exfoliated cells are more degenerate.



If possible, submit the whole specimen for analysis as this increases the cell content.

Deliver to the laboratory as soon as possible on the day of collection or keep the specimen refrigerated around 4°C until delivery.

8.2 Sputum samples

Please note that sputum is not recommended for investigation of pulmonary neoplasia as the diagnostic yield is very low.

- Collect in a dry container
- Specimen should be obtained by deep coughing in the morning, before eating, drinking or cleaning of teeth.
- Saliva or nasal secretions are NOT suitable.
- Deliver to the laboratory as soon as possible on the day of collection. If there is likely to be a delay, the specimen can be kept refrigerated around 4 C.

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9 High risk specimens

Specimens potentially infected with hazard group 3 organisms must be clearly marked as such, and the nature of the risk described. Laboratory staff do need to work safely and process the specimen appropriately.

High risk specimens are not suitable for frozen section examination. Specimens received without prior notification will not be processed. If clinicians consider that a frozen section is imperative for immediate patient management this **MUST** be discussed with a consultant pathologist who may suggest other options for achieving a rapid diagnosis.

It is mandatory to discuss specialist high risk specimens e.g. muscle, immunofluorescence before they are taken. Specimens from high risk patients may require special handling or amended protocols which could limit the amount of diagnostic information from the specimens.

High risk specimens for routine histology must be fixed in 10% Neutral Buffered Formalin for at least 24 hours in the laboratory prior to processing. As a result, there may be a delay in reporting and this should be taken into account for return appointments.


Specimens with radioactive dyes e.g. sentinel nodes must be labelled as radioactive with the correct hazard labels in addition to the required formalin hazard

10 Urgent requests

All urgent requests must be clearly marked on the request form, including two week wait (2WW), 62-day target, MDT and 18-week treatment cases. ICE, HIS, GI reporting tool all have options to submit urgent requests electronically. Handwritten forms must have “Urgent” or a prominent sticker.

It is advisable to discuss requirements for urgent diagnosis influencing immediate patient management with a pathologist at the time of submission. All relevant clinical information should also be included.

Results in urgent cases still depend on adequate fixation and the complexity of the pathology. Additional technical work and external opinion may be needed

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10.1 Rapid intraoperative diagnoses

A frozen section service is available to both Salford and Wrightington, Wigan and Leigh Trusts, though the arrangements are different. The service operates routinely between 9.00am and 4.30 p.m. on weekdays and can only be offered outside this time by prior agreement with a consultant pathologist.

Surgical staff should make requests prior to the operation wherever possible. Without advance arrangement, the laboratory cannot guarantee to provide the service. Please contact the laboratory to cancel the biopsy if no longer required.

Please allow at least 20 minutes from receipt for a frozen section report to be issued by telephone. Please note: frozen sections are never performed on high risk specimens

10.1.1 Salford cases

Specimens must be brought unfixed to pathology reception immediately and handed directly to a member of Cellular pathology staff. Do not leave at reception without notifying Cellular Pathology under any circumstances. Clinicians are encouraged to check receipt. A histology request card must be completed to the same standards as routine specimens, with the addition of a contact telephone/bleep number.

Please allow 20 minutes from receipt for a frozen section report to be issued by telephone.

10.1.2 WWL cases

The unfixed specimen must be securely packaged and clearly labelled with the same minimum data as a routine sample. A histology request must be completed and a contact telephone number must be clearly stated. Please contact the laboratory at Salford as the specimen leaves Wigan sites to ensure that the lab is expecting the sample.


It is the responsibility of the requesting clinician to arrange transport to the Cellular Pathology department at Salford e.g. taxi.

11 Examinations referred to other laboratories

For further information contact the cellular pathology office on 0161 206 5013

Or by e-mail to srh-tr.scmhisto@nhs.net

A range of examinations are referred to other laboratories. The list of referral laboratories and consultants is extensive and is available on request and is reviewed on a regular basis.

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Due to the reporting capacity shortfall within the department remote reporting services are used for reporting specimens. Specimens are triaged within the laboratory and urgent specimens are retained within PAWS. The preferred supplier of remote reporting services is Backlogs limited.

www.backlogs.co.uk

12 Requirements for patient consent

Any objections or restrictions that a patient expresses regarding the use of their tissue must be recorded.

It is not necessary to ask the patient explicitly for consent for each of the purposes listed, merely to confirm whether or not they have expressed any objection, having been given adequate opportunity to do so.

12.1 Consent to disclose clinical information and family history to relevant healthcare professionals, where referral is needed

Consent for genetic testing (e.g. BRCA-1, MMR) will need to be agreed in advance with the patient by the requesting clinician

12.2 Clinical trials

Patient material will not be submitted to clinical trials without the express documented consent of the patient.

13 Use of surplus sample for quality assurance, teaching and research



Surgical consent to take specimens for cellular pathology implies consent to handle the tissue for diagnostic purposes and to store fixed material as part of the medical record.

It is the responsibility of the requesting clinician to inform the laboratory if a patient has refused consent for scheduled purposes. It is not sufficient to state that the matter has not been discussed. Patients should be consulted about the use of surplus diagnostic tissue, and it is recommended to advise patients to agree to the use of surplus tissue for quality control, ethically approved research and audit. The use of tissue for these purposes assists in the maintenance of quality within the department.

13.1 Post-mortem samples

The department operates under the legal framework of the Human Tissues Act 2004.

The Human Tissue Act 2004 requires consent for storage and use of surplus tissue for purposes of education, quality control, audit, public health monitoring and anonymised and ethically approved research. All patient information within the trust should carry a statement advising this

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potential use which allows implied consent but all patients should have an opportunity to refuse or withdraw consent.

14 Turnaround time

The department recognises and aspires to the Royal College of Pathologists recommendations regarding turnaround times. 80% of cases reported within 7 calendar days of collection

90% of cases reported within 10 calendar days of collection

The department is currently unable to achieve these standards but work is actively underway to improve the situation.

14.1 Specific specimen types

The department is unable to achieve the desired turnaround times for the following specimens

Lung Biopsy – target all reported within 3 calendar days of receipt (currently 80% within 7 calendar days)

Breast biopsy all reported within 7 calendar days of receipt (currently 95% within 7 calendar days)

Cervical biopsy and cervix specimens all reported within 20 days (currently 82% within 20 days)



This data is continually monitored.

The department operates a triage system to expedite specimens on cancer tracking targets and those identified as clinically urgent. Currently 30% of our workload is classified as urgent which largely represents cancer tracking cases. In cases of clinical urgency please ensure that the clinical information is clear and comprehensive and contact the department for advice (0161 206 5013).

15 The laboratory's criteria for accepting and rejecting samples

The majority of Cellular Pathology specimens cannot be easily repeated. Any specimen that does not meet the minimum data requirements should be considered unacceptable. These specimens should be returned to their point of origin for the fault to be rectified. Under no circumstance should laboratory staff identify/amend the specimen details. These cases should be error logged and AIRs submitted prior to their return to source (CP-ADMIN.004).



A comment is added to the Macro report field as this will appear on the final report and will highlight errors to the senders directly.

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'Cellular Pathology will accept no responsibility for specimens analysed which initially failed to meet the Specimen acceptance criteria. The need for correction of Specimen/Patient data will have resulted in the delay of a report being issued. Specimen returned to [LOCATION] on [DATE] due to the following error:-'

The table below shows the criteria for rejection and follow up action.

Mandatory Labelling Requirement	Action taken by Laboratory if requirement not met
<p>Specimens MUST be labelled with 3 unique identifiers from:</p> <ul style="list-style-type: none"> Unique identification number (e.g. hospital or NHS number) Patient's full name i.e. Forename and Surname Date of birth 	<p>No analysis will be performed until provided</p> <p>Where the specimen is repeatable/ reproducible, no analysis will be performed and the specimen will be held for up to one week.</p> <p>Where the specimen is unrepeatable / un-reproducible, the risk to the patient of rejection of the specimen must be weighed against the risk of acceptance of a wrongly labelled specimen, local procedures will be followed.</p> <p>Pathology will accept no responsibility for specimens analysed which initially failed to meet the acceptance criteria and will issue a disclaimer on such reports.</p>
<p>The request form data MUST match the above information on the specimen.</p>	
<p>Request forms SHALL also contain:</p> <ul style="list-style-type: none"> the patient's location/destination for the report (or a location code) Specimen Type Name of Consultant or GP Name of the requester and contact number (bleep or extension) Patient gender Date and time of specimen collection Anatomical site and type of specimen (where relevant) All relevant clinical information Patient address for GP requests 	<p>Samples will not be processed unless accompanied by a request form.</p> <p>A lack of patient or specimen information may result in the laboratory not conducting the analysis / examination or result in a significant delay.</p> <p>Examples could include:</p> <ul style="list-style-type: none"> No consent information given no dates and times of sampling no clinical details given <p>It may not be possible to issue a report or to interpret results.</p> <p>Appropriate comments will be made on the report where this can be issued.</p>

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16 Factors known to significantly affect the performance of the examination or the interpretation of the results

Fresh samples must be transferred to the laboratory immediately and handed to a member of cellular pathology staff.

Fixed Breast core samples should be placed in fixative for no more than 36 hours and should be transferred to the laboratory for delivery the next day.

17 Availability of clinical advice on ordering of examinations and on interpretation of examination results

Clinical advice is available from our consultant Histopathologists via the cellular pathology office.

18 The laboratory's policy on protection of personal information

Information is a vital asset for the clinical management of individual patients. The quality of the data supplied with a specimen determines the accuracy of the subsequent diagnosis and the timely return of the report.

Both SRFT [document Inf4(06)] and WWL [document TW11/011] have policies which underline each trust's commitment to data quality. All staff should have an understanding of risks and responsibilities associated with incorrect data and the impact this can have on patient care.

The laboratory has policies covering the acceptance of samples to ensure safe diagnosis and treatment, and that we act with the patient's consent. Specimens cannot be processed until any errors or omissions have been corrected and results will be delayed.

NHS standards and guidelines state that all clinical records (including pathology requests):


- Must be written clearly, legibly and in such a manner that cannot be erased;
- Must be accurately dated, timed and signed with the full name printed alongside each entry;
- Should be completed with minimal abbreviations.

Quality and patient safety starts from the moment the sample is taken. Delivering a quality result for the patient starts with **you**

The only secure way of transferring data between trusts/ healthcare organisations is via nhs.net e-mail accounts. The department will only send patient related data outside the trust via this mechanism.

19 The laboratory's complaint procedure.

The laboratory welcomes feedback from service users, whether suggestions, compliments or complaints. Complaints about the service should be made in the first instance to David Muskett,

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Cellular Pathology Service Manager on 0161 206 5011 or by e-mail to david.muskett@srft.nhs.uk as soon after the incident has happened. Please include full details of any patients affected.