Vision | Openness | Integrity | Compassion | Excellence

NHS Bolton NHS Foundation Trust

Cellular Pathology

Histopathology, Non-Gynaecological Cytology, Andrology and the Mortuary

Laboratory Medicine User Handbook

... for a better Bolton

Document Control

Number of official printed copies of this document	0
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Copy 1	Electronic copy – Trust Intranet – Laboratory Medicine
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Contents

1. Introduction

This user guide details information for the requesting of investigations, specimen requirements and communication of results for the Cellular Pathology Department at the Royal Bolton Hospital NHS Foundation Trust. The department is structured operationally within the Laboratory Medicine Department of the Diagnostics and Support Services Division (DSSD).

The Cellular Pathology and Andrology department provides comprehensive services to primary and secondary care within Bolton, Greater Manchester. Gynaecological cellular pathology (including 'smear' testing) samples are handled and processed at the Manchester University NHS Foundation Trust (MFT) Cellular Pathology department.

The Mortuary provides services to Bolton and Greater Manchester.

This handbook aims to help our service users understand how the department's services are organised and hence to make the best use of the service by complying with necessary requirements.

There is a list of investigations, specimen containers and turnaround times. Certain investigations are referred to external laboratories, if further information regarding these laboratories or any other general information is required please contact the Laboratory Medicine Department Helpline on Tel 01204 390414.

Histology - The study of the structure of tissues and organs. This includes immunocytochemistry and a frozen section service.
Non-Gynae Cytology - The microscopic study of cells. Samples received include Non Gynae fluids and needle aspirates.
Andrology - The study of sperm to determine male fertility and confirm infertility following vasectomy.

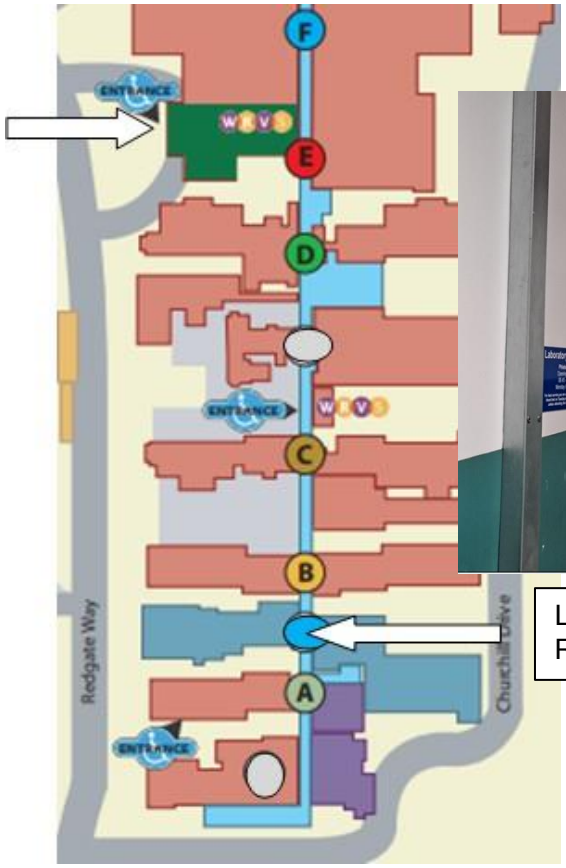
The department reports in the region of 19,000 surgical cases, 2,200 non-gynae cytology cases, 800 andrology cases annually. Approximately 500 post mortem cases are reported annually on behalf of the HM Coroner.

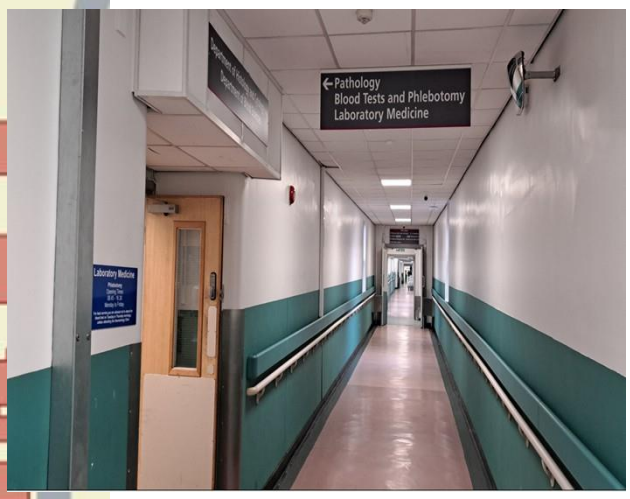
Staffing within the department consists of over 35 scientific, medical and ancillary staff. The department supports the Histopathology specialist training scheme of the North West Deanery with 2 candidates in rotation at any one time.

2. Address and Location

Location	Postal address
Laboratory Medicine is located just off the Main corridor in between A & B Block.	Cellular Pathology Laboratory Medicine Royal Bolton Hospital Minerva Road Bolton, Greater Manchester BL4 0JR

Bolton Hospital Main Entrance





Laboratory Medicine Main Reception

3. Opening Hours

Cellular Pathology Specimen delivery

Monday – Friday 8.45am – 16.30pm.

Cellular Pathology Opening hours

Monday – Friday 8.15am – 16.45pm.

- We currently do not operate an out of hours or bank holiday service.
- A labelled trolley is available out of hours, in the main Laboratory Medicine Reception, for samples to be left in and will be processed the following working day.
- Fresh (non-fixed) cytology fluid samples should be kept in a fridge at the source location to maintain cellular integrity and transported to the department within routine operating hours.

Andrology Specimen delivery

A patient's doctor will request an appointment for a semen test. An allocated appointment will be sent to patient. If the appointment is not convenient, please contact the laboratory on 01204 390513 to rearrange.

Patients should bring their labelled sample and your appointment letter to Laboratory Medicine (Pathology) at your allocated appointment time. The department is located between the A&B Block on the main hospital corridor.

Important: You must bring the sample as soon as possible after production and within 40 minutes.

Keep the sample warm, close to the body, under your clothes (armpit is ideal).
If there is any delay, you may have to repeat the test.

At reception, speak to a member of staff who will contact the Non-Gynae Cytology/Andrology team, who will come and speak to you about your sample and ensure everything is correct before you leave. Please make sure that the sample is handed directly to a member of the Non-Gynae Cytology/Andrology Team and not left at the reception or with a receptionist.

Mortuary

Opening Hours

Monday – Friday	8.00am – 1.00pm
	1.30pm – 4.00pm

4. Departmental Contact Details / Telephone Numbers

Laboratory Medicine Department Contacts:-

Name	Designation	Internal number	External number
General Helpline	Laboratory Medicine Office	5516	(01204) 390516
Carolyn Williams	Laboratory Medicine Clinical Lead	5172	(01204) 390172
Lewis Hurley	Service Manager	5088	(01204) 390088
Phil Henry	Operational Business Manager	5419	(01204) 390419
Imtiaz Wahid	Computer & IT Manager	5253	(01204) 390253
Barbara Y Colman	Administration & Support Services Manager	5437	(01204) 390437

Cellular Pathology (Histopathology, Non-Gynae Cytology and Andrology) Contacts:-

Name	Designation	Internal number	External Number
Cellular Pathology Secretariat		5534/4544	(01204) 390534
Cellular Pathology Enquiries – office hours only		5534	(01204) 390534
Cytology & Andrology Enquiries – office hours only		5513	(01204) 390534
Tracy Eastland	Histopathology, Cytology & Andrology Laboratory Manager	3606	(01204) 390534
Consultant Histopathologists:-			
Dr. Patrick Waugh	Consultant Histopathologist/Clinical Lead	3570	(01204) 390534
Dr. J Mark Pearson	Consultant Histopathologist	4586	(01204) 390534
Dr. Prabha Kushwaha	Consultant Histopathologist	4014	(01204) 390534
Dr. Ravindra Sawant	Consultant Histopathologist	144590	(01204) 390534
Dr. Foutoun Salim	Consultant Histopathologist	4587	(01204) 390534
Dr. Geetika Anand	Consultant Histopathologist	147455	(01204) 390534
Dr. Andrew Coates	Consultant Histopathologist	141810	(01204) 390534

Mortuary Contacts:-

Name	Designation	Internal number	External number
Mortuary	Office	5690	(01204) 390690
Danny Corry	Mortuary Manager	5690	(01204) 390690

4.1 Results and General Enquiries

Helpline for results and general Enquiries:

Histopathology Medical Secretaries: 01204-390534

Enquiries regarding frozen sections, specimen requesting, labelling and transportation:

Main Histopathology Laboratory: 01204-390390 Ext. 4588

4.2 Technical and Clinical Advice

Technical Advice:

Histology and non-gynae Cytology Technical Advice

- Mark Aylin – Histology Section Manager (ext. 4588)
- Pamela Hitchen – Non-Gynae Section Manager (ext. 5513)
- Tracy Eastland – Histology and Cytology Laboratory Manager (ext. 3606)

Andrology Technical Advice

- Pamela Hitchen – Andrology Section Manager (ext. 5513)
- Tracy Eastland – Histology and Cytology Laboratory Manager (ext. 3606)

Clinical Advice/Interpretation:

Histology and Non-Gynae Cytology Clinical advice

Clinical advice is available from Consultant Histopathologists between 08:45am-17:00pm. If you require clinical advice please contact 01204 390390 and ask for the pathologist required. If calling internally ring the telephone numbers listed in Section 4.

Clinical Interpretation of results can be given by the reporting pathologist and is also available at Multidisciplinary Meetings which are attended by a Histopathologist as per the schedule below:

MDT Meeting	Day	Designated Lead Histopathologist
Breast	Monday	Dr. Pearson/Dr. Salim
	Wednesday	Dr. Salim/ Dr. Pearson
	Thursday	Dr. Salim/ Dr. Pearson
Upper GI	Monday	Dr. Coates
Lower GI	Monday	Dr. Anand
Upper GI SMDT	Friday	Dr. Anand
Gynae	Tuesday	Dr. Sawant
	Friday	Dr. Sawant
Lung	Monday	Dr. Kushwaha
	Thursdays	Dr. Kushwaha
Skin	Alternate Mondays	Dr. Waugh
Urology SMDT	Friday	Dr. Waugh
Uro-radiological	Monday	Dr. Waugh

Andrology Clinical advice:
Clinical advice is available by contacting the Cellular Pathology department via emails to histopathology.medicalsecretary@boltonft.nhs.uk.

We will aim to response to all Andrology Clinical Advice enquiries within 7 days.

5. Complaints, Feedback and Compliments:

- The department is committed to fully investigating all complaints regarding the standard and quality of services that we offer. Please contact our Laboratory Manager via email on:

  Tracy.Eastland@boltonft.nhs.uk

- The Patient Advice & Liaison Service (PALS) is available in all NHS Hospitals and Primary Care Trusts for information, help, comments or complaints about

Patient Advice & Liaison Service (PALS)
Location: Royal Bolton Foundation NHS Trust, Hospital Main Entrance
Telephone: 01204 390193. An answer service is available
Email: pals@boltonft.nhs.uk

any aspect of the services provided at the hospital. Access to this service is detailed on the Bolton Foundation Trust Website: Your Views Matter page : Your views matter - Bolton NHS FT (boltonft.nhs.uk)

- Feedback on your experiences of the Cellular Pathology Service as a user are appreciated. This can be done via email to the Pathology Quality Manger on:

  Abigail.Giles@boltonft.nhs.uk

  Alternatively you can complete the online user feedback survey using the link below:
  Bolton Foundation Trust Laboratory Medicine - User Survey & Feedback Form (online)

- If you wish to provide a compliment on our service or any of its staff please do so via email to:

  Debra.Tyldsley@boltonft.nhs.uk

6. Quality

Quality is overseen by our Clinical Lead and Service managers with support from Laboratory Managers and the Quality & Service Improvement team. The Department of Laboratory Medicine is subject to the Trust Clinical Governance structure.

The Department of Laboratory Medicine aims to continually improve the repertoire of investigations, and co-operate in the formulation of guidelines, clinical pathways and protocols advising on the appropriateness of tests. The results which are issued are designed to be accurate, timely, and informative and quality assured. Quality assurance schemes such as EQA and IQA help make sure the department's high quality standards are maintained.

All practicing Biomedical Scientists and Clinical Scientists are registered with the Health and Care Professionals Council (HCPC). Training is accredited by the Institute of Biomedical Science (IBMS) for biomedical scientist specialist training, and by the Royal College of Pathologists for medical training.

6.1 Accreditation

Cellular Pathology is a UKAS accredited Medical Laboratory (reference No. 9927). The department has been assessed by the United Kingdom Accreditation Service (UKAS) and is accredited to meet the requirements of the International Standard 15189.
Accredited Tests within the examination repertoire are available on the UKAS Schedule

of Accreditation for 9927 on the UKAS Website: Search UKAS accredited organisations

Non-accredited Tests provided by the department include:

Test Name	Quality Assurance Status
D2-40	Performance monitored through ongoing in-house control reviews at every use. UKAS accreditation being sought through an extension to scope.
Dual Staining P63/P504S	Performance monitored through ongoing in-house control reviews at every use. UKAS accreditation being sought through an extension to scope
HBME-1	Performance monitored through ongoing in-house control reviews at every use. UKAS accreditation being sought through an extension to scope
HAS (HEP PAR1)	Performance monitored through ongoing in-house control reviews at every use. UKAS accreditation being sought through an extension to scope
NAPSIN	Performance monitored through ongoing in-house control reviews at every use. UKAS accreditation being sought through an extension to scope
NKX3	Performance monitored through ongoing in-house control reviews at every use. UKAS accreditation being sought through an extension to scope
RCC	Performance monitored through ongoing in-house control reviews at every use. UKAS accreditation being sought through an extension to scope
Synaptophysin	Performance monitored through ongoing in-house control reviews at every use. UKAS accreditation being sought through an extension to scope
IMF	Performance is monitored through pathologist case reviews.

All requests received by Laboratory Medicine shall be regarded as a service agreement, in compliance with the international standard ISO 15189.

The Mortuary department is licensed by the Human Tissue Authority (HTA).

Please contact the Laboratory Manager(s) for any enquiries as to the accreditation of our laboratory activities.

The department is committed to ensuring the delivery of a high quality service to meet the needs of our users. The department utilizes a quality management system (QPulse) to ensure all processes are controlled and that the department is actively involved in continuous improvement of our services.
To ensure the continued provision of our tests, the department participates in the following External Quality Assurance (EQA) schemes in the following areas:-

UKNEQAS for Cellular Pathology Techniques (CPT)
UKNEQAS for Immunocytochemistry (ICC)
UKNEQAS for Andrology Reproductive science

Lab. Section/Technical EQA Scheme	Supplier	Participant No.	Accredited to ISO17034 Y/N
CPT: Tissue Diagnostics	UK NEQAS	15083	Y
CPT: Specialist techniques (Inc. Frozen Sections)	UK NEQAS	2295	Y
ICC: General pathology	UK NEQAS	187	Y
ICC Breast Cancer: ER & PgR	UK NEQAS	187	Y
ICC: Breast Cancer HER 2 protein Over Expression IHC	UK NEQAS	187	Y
ICC: Breast Cancer HER 2 protein LOW Over Expression IHC (PILOT)	UK NEQAS	187	Y
ICC: Lymphoid Pathology	UK NEQAS	187	Y
CPT: Diagnostic Cytology	UK NEQAS	5052	Y
CPT: Diagnostic Cytopathology Cell Block	UK NEQAS	20046	Y
Reproductive Science: Concentration & Morphology	UK NEQAS	4629	Y
Reproductive Science: Sperm Motility	UK NEQAS Using Gamete-expert website		Y
Reproductive Science: Interpretive Morphology	UK NEQAS Using Gamete-expert website		Y

6.2 Confidentiality and Data Protection

Information is an essential for the clinical management of individual patients. The quality of the data supplied with a specimen determines the accuracy of the subsequent examination result and the timely return of the report.

Personal information is strictly confidential and will not be disclosed without the patients'

consent. Exceptional circumstances included where national reporting is a statutory legal requirement, such as where there would be a risk to public health.

All staff 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.

The department will:

- Only ask for the information that we need to allow appropriate interpretation of results
- Protect the information we receive to ensure that only those staff who need access to it can access it.
- We store data in accordance with the documented departmental policies and for no longer than is necessary.

6.3 Requirements for Patient Consent

It is the responsibility of the requesting clinician (doctor or GP) to obtain appropriate informed consent for all investigations from the patient. It is their responsibility to ensure that any consent is disclosed, along with appropriate clinical information and family history to the department at the time of requesting of the test.

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

Patient material will not be submitted to clinical trials without the express documented consent of the patient. A copy of the consent documentation, along with that of the trials ethical approval documentation should be sent to the department at the time of the request.

6.4 Result Uncertainty / Uncertainty of Measurement

In clinical laboratory testing there are potential uncertainties that can affect test results, such as poor specimen collection or transport, patient related factors or other interfering factors.

The laboratory examination process itself is subject to some degree of variability and our department regularly monitors this by the use of internal quality control and participation in external quality assurance schemes.

In accordance with the RCPath guidance, an assessment of the uncertainty of measurement will be carried out for any measurement that is included in the diagnostic report if it is deemed to have actual or potential "direct clinical impact." Where weights and measurements are part of an overall description and do not impart prognostic or predictive value, an assessment will not be carried out.

Any comparability studies between methods, where appropriate, are available to all users upon request. Please contact the laboratory if in there are any concerns regarding the validity of results.

7. Requesting examinations for Cellular Pathology

The sample and the request form must be appropriately labelled and placed into a sealed plastic 'biohazard' bag ensuring that the form and sample are in separate sections of the bag. This will prevent contamination of the request form if the sample container leaks. Ensure all sample pots and container lids or screw tops are tightly closed before transporting to avoid leakages and/or loss of specimen tissue. The Cellular Pathology Dept. does not accept any telephone requests. Requests for further testing on a previously received sample should be made to the dept. via email to (histopathology.medicalsecretary@boltonft.nhs.uk) or at MDT. Histopathology samples are disposed of 4 weeks after the authorisation of the initial report. Therefore additional tests cannot be requested after this time.

Each patient's samples should be placed into their own specimen bag (multiple samples from the same procedure on the same patient can be placed into separate pots but put into the same specimen bag-each pot must be uniquely identified with the site of the specimen). Samples from the same procedure for different disciplines should be placed into their own containers and be submitted to Pathology in separate request bags with

their corresponding discipline specific request card.

Please Note: Incorrectly labelled samples or incomplete request forms will be delayed until the sample and/or request form is completed or amended satisfactorily by the sending department following contact by the receiving section of the laboratory.

7.1 Specimen Containers, Request Forms and Formalin

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

- Request cards are ordered direct from the Printing Department quoting R18.
- Formalin is sourced by the sending department.
  If clinicians are uncertain how to send a specimen then please contact the laboratory.

7.2 Specimen Acceptance Policy

7.2.1 Completing the Request Form

A request form that is completed legibly and accurately must accompany all samples.

The request form **must** include the following details:

- Patient Forename and Surname
- Date of Birth
- NHS/RMC number
- Specimen type and site (ie. Left breast, chest, D2 etc.) For multiple specimens for a single patient, ensure that the specimen type is labelled with a prefix such as
  A-Left colon, B-Right colon and so on.
- Clinical details
- Time and date the sample was collected
- Full name of requesting Clinician/Consultant/GP **(clearly printed)** and signed
- Requesting Department/GP practice
- Specimens from High Risk patients MUST be identified

Restricted use of specimen: Consent for Research
It is the responsibility of the person taking the sample to identify whether a patient has placed any restriction on the use of the tissue sample for research. This must be

relayed to the Cellular Pathology department by completion of the Consent for Research information on the Histology Request card.

7.2.2 Labelling the specimen container with 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
- Specimen origin of each tissue must also be clearly stated on the pot label as well as on the request form.

NB.

The request card forms a contract between the clinical team and the Cellular Pathology department and as such, an error on the request card/pot cannot be amended by the Cellular Pathology team.

Errors/omissions on the request card will therefore require correction/amendments to be made by the clinical team prior to processing of the sample. The time taken to obtain this prior to our ability to process a sample, will result in delays to the clinical team in the availability of a final report. It is therefore imperative that double checks are made by the clinical team on the accuracy of completion of the request card and between the patient/sample details on the request card and pot prior to submission for analysis.

Request Form Diagram

Tick which request type is required

Date and time specimen collected

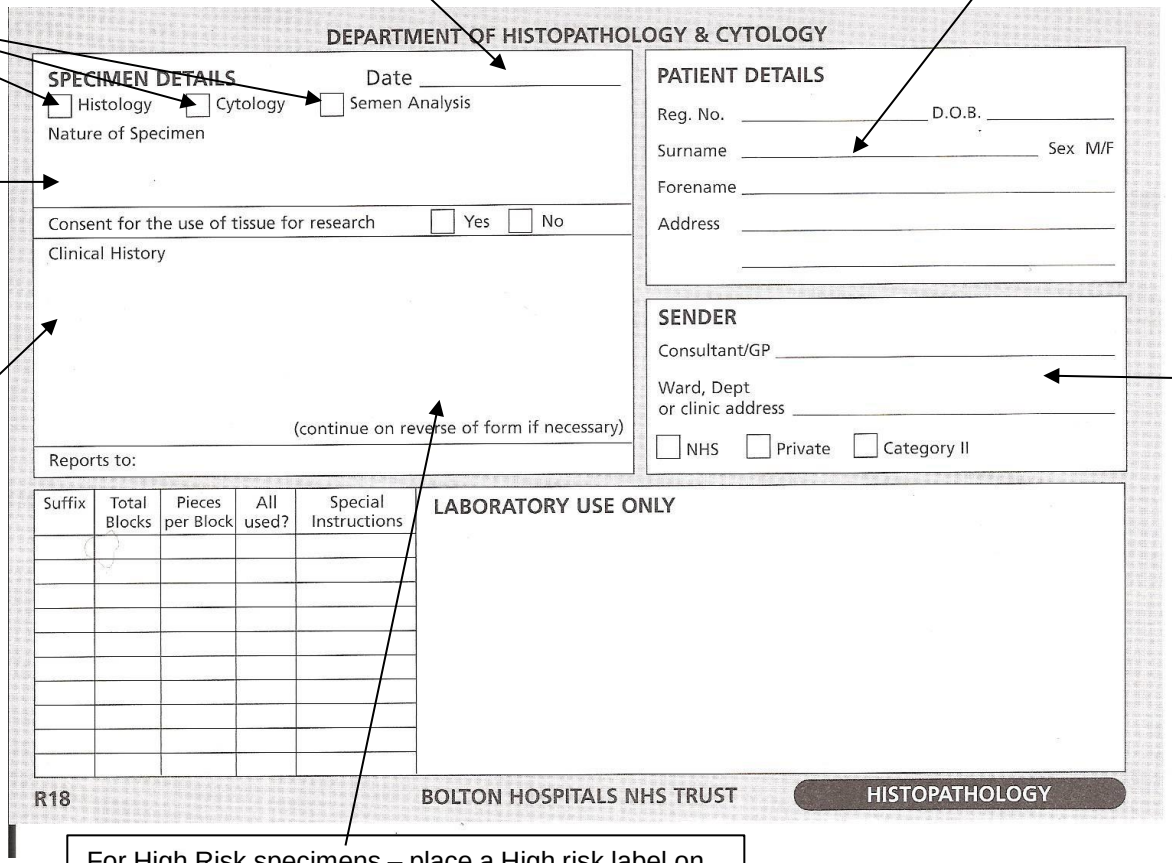
Enter RMC/NHS number, date of birth, Surname, Sex, Forename and address

Enter tissue specimen type/origin – for multiple specimens list for each specimen type.

e.g.

A) Punch Bx – Skin left Breast

B) Excision – Skin Right upper thigh


DEPARTMENT OF HISTOPATHOLOGY & CYTOLOGY

SPECIMEN DETAILS Date _____

☐ Histology ☐ Cytology ☐ Semen Analysis

Nature of Specimen

Consent for the use of tissue for research ☐ Yes ☐ No

Clinical History

(continue on reverse of form if necessary)

Reports to:

PATIENT DETAILS

Reg. No. _____ D.O.B. _____

Surname _____ Sex M/F

Forename _____

Address _____

SENDER

Consultant/GP _____

Ward, Dept or clinic address _____

☐ NHS ☐ Private ☐ Category II

Suffix	Total Blocks	Pieces per Block	All used?	Special Instructions

LABORATORY USE ONLY

R18 BOLTON HOSPITALS NHS TRUST HISTOPATHOLOGY

Consultant/Clinician /GP name, and department requested from and patient category (NHS/Private

Write the clinical history in this area or any special tests required

For High Risk specimens – place a High risk label on form and add details in the clinical history box

7.3 Potentially Infective and High Risk or Radioactive Specimens

Although a 'Universal Precautions' policy is adopted in the laboratory, specimens taken from patients known or suspected to present a health hazard to laboratory staff e.g. TB, typhoid and paratyphoid, brucellosis, Creutzfeldt-Jakob Disease CJD and variant CJD, should be clearly labelled "DANGER OF INFECTION" on both the form and specimen. This is especially important when sending specimens of tissue, blood, feces, CSF or other body fluids - such specimens will require a further 24 hours' fixation in 10% formalin, therefore, a delay in reporting. This should be taken into account when booking return appointments.

Any samples taken where the patient is suspected of having TB MUST be divided within theatre so as to provide sufficient samples for Histology (sent in formalin) and Microbiology (sent in an empty sterile container). Each sample should be sent in a separate Specimen bag with its own departmental specific request card.

Specimens that may be radioactive, for example, Sentinel Lymph nodes, should be marked with a radioactive label on the request form and specimen container/pot.

7.4 Urgent requests

Quick Turnaround for urgent cases are still dependent on adequate fixation and are required to be brought to the laboratory **by 16:30pm** on the day of specimen collection.

All samples from patients on the 'Faster Diagnosis Pathway (aka Two Week Wait Pathway), **must** be clearly marked on the request form with the phrase 'FDP or TWW'. Clinically urgent requests, 62-day target, MDT and 18-week treatment cases should be marked as 'URGENT' on the request form. The status should be written at the top of the request form in capital letters and not within the clinical information.

7.5 Examination Tests Referred Externally

The department refers cases to other services for expert opinion, diagnostic services and in response to service pressures. The following are the most commonly used. Please contact the Cellular Pathology department for further information.

Type	Address	Accreditation Status
Lymphoma referrals	HMDS St James's Institute of Oncology Level 3 Bexley Wing St James's University Hospital Beckett Street Leeds LS9 7TF	A UKAS accredited medical laboratory No. 9305
Various Genomic tests	NW Genomic Laboratory Hub Manchester Centre for Genetic Medicine 6th Floor St Mary's Hospital Oxford Road Manchester M13 9WL	A UKAS accredited medical laboratory No. 9865 Please contact Cellular Pathology for information on specific tests
Diagnostic Mismatch Repair - MMR (Colorectal Cases) **Jaw Cyst Second Opinions**	Immunohistochemistry Laboratory Dept. of Adult Histopathology Manchester Royal Infirmary Oxford Road Manchester M13 9WL	A UKAS accredited medical laboratory No. 8648
Gastric Her2 / FISH **2nd Opinions** **PD-L1** √ **P16 FISH**	Histopathology, Christies Hospital, Wilmslow Road, Manchester, M20 4BX	A UKAS accredited medical laboratory No. 8697
Dermatopathology 2nd Opinions **Urology 2nd Opinions** **+ve bowel screening reviews**	Northern Care Alliance Cellular Pathology Dept. Level 2 Turnberg Building Stott Lane Salford M6 8HD	A UKAS accredited medical laboratory No. 9902
Multi Disciplinary Team (MDT) Review	Northern Care Alliance Cellular Pathology Department Rochdale Road Oldham OL1 2JH	A UKAS accredited medical laboratory No. 9880

Lung Pathology 2nd Opinions **Breast Pathology 2nd** **Opinions Alk-1 testing** **PD-L1 testing**	Manchester University NHS Foundation Trust Department of Histopathology University Hospital of South Manchester Southmoor Road Whythenshawe Manchester M23 9LT	A UKAS accredited medical laboratory No. 9083

Oral pathology 2nd Opinions **MDT review**	Department of Histopathology East Lancashire Hospital NHS Trust Haslingden Road Blackburn BB2 3HH	A UKAS accredited medical laboratory No. 8136
Oncotype DX testing Breast	Genomic Health Inc Clement Odoom 351 Galvaston Dr 94063-4736 Redwood City Ca USA	Accredited to ISO 15189:2022
Immunohistochemistry **multiple antibodies/stains	HSL-Advanced Diagnostics Groundfloor 60 Whitfield St London WT1 4EU	A UKAS accredited medical laboratory No 9007 Please contact Cellular Pathology for information on specific tests
Andrology 2nd Opinions	Manchester University NHS Foundation Trust Department of Reproductive Medicine, Andrology Laboratories Oxford Road Manchester M13 9WL	A UKAS accredited medical laboratory No. 8228
Hydatid/Molar Pregnancy	Department of Histopathology, Sheffield Teaching Hospitals NHS FT Royal Hallamshire Hospital Glossop Road Sheffield S10 2JF	A UKAS accredited medical laboratory No. 8509
Asbestos Fiber Counts	Cellular Pathology Dept. Cardiff & Vale University Health Board Heath Park Cardiff CF14 4XW	A UKAS accredited medical laboratory No. 8987
Oral pathology Second Opinions **MDT review**	Histopathology Dept. East Lancashire Hospital NHS Trust Haslingden road Blackburn BB2 3HH	A UKAS accredited medical laboratory No. 8136

Upper GI PD-L1 testing **Bladder PD-L1** **Breast PD-L1**	The Molecular Pathology Diagnostic Service Clinical Laboratory Services Level 1 Queen Elizabeth Hospital Birmingham Mindelsohn Way Edgbaston Birmingham B15 2WB	A UKAS accredited medical laboratory No. 8759

8. Specimen Transport Requirements

Formalin Fixed Histopathology Samples/Fixed Non-Gynae Samples: Should be transported to the department as soon as possible. Delays in receipt will impact trust Turn around times and may impact fixation for larger resection samples. Transport is undertaken by Porters/Clinical teams/IFM transport services, with the exception of samples which are taken in the main surgical theatres. Histopathology Staff will collect samples from theatres at 08:00am (Monday- Friday) and samples will be delivered to Cellular Pathology from theatres by theatre staff at 15:30pm (Monday- Friday). Any URGENT theatre samples should be transferred to the department by the porters/theatre staff ASAP.

Frozen Sections/IMF Samples: Should be transported to the department immediately (we do NOT offer an out of hours or weekend service). Transport is undertaken by porters/clinical teams.

Fresh Histopathology Specimens/Unfixed Non-Gynae Samples: Should be taken to the department immediately if within working hours. We do NOT offer an out of hours or weekend service and these samples should NOT be transported to the laboratory out of hours. If they cannot be transported to the Cellular Pathology department within working hours, then they should be refrigerated by the clinical teams overnight between **4-7°C** and promptly transferred to the Cellular Pathology Dept. the next working day (Monday-Friday). Transport is undertaken by porters/clinical teams.

All samples: should be transported to the laboratory in sealed bags/transport boxes/tins.

Examination	Turnaround time	Requirements and safety precautions (Fixative, Pot/Container)	Temperature interval	Accreditation
Surgical histopathology requests	**7-10 days**	Grey and White histopathology form (with black bar) (R18) Appropriately sized container containing 10% Formalin	Room temperature	A UKAS accredited medical laboratory No. 9927 (see section 6.1 for specific non-accredited tests)
Frozen section requests	**Same day**	Grey and White histopathology form (with black bar) (R18) No fixative – use a 70 ml histology container **By prior arrangement with the laboratory only**	Room temperature	A UKAS accredited medical laboratory No. 9927

Immunofluorescence requests	**7 days**	Grey and White histopathology form (with black bar) (R18) 0.9% Neutral Buffered Saline (Collected from Histology Laboratory in advance)	Room temperature	NOT ACCREDITED

8.1 Specimen containers

Specimen pots/containers should be large enough to easily accommodate the specimen and to allow sufficient formalin to be added to the specimen (if required). The pots should only be labelled at the time the specimens are collected. It is poor practice to label pots in advance, as it can potentially lead to a sample being placed in a container that is labelled with another patient's details.

8.2 Formalin Fixed Specimen / Fixation instructions

All samples for Histology should be placed in a suitably sized pot (please take the size of the tissue specimen into consideration) in 10x the volume of 10% neutral buffered formalin UNLESS a frozen section or Immunofluorescence test is required (SEE BELOW).

Please ensure that lids are firmly fixed to the specimen pots before transferring samples. Specimen pots are either screw tops or snap fix lids. Ideally specimens should be received with 10x the amount of formalin to specimen. For large specimens this is not always possible. For advice please contact the laboratory.

8.3 Frozen Sections/IMF Samples

Frozen Sections:

A frozen section service is available at the Royal Bolton Hospital. The service operates between 08:45am and 16:30pm Mon to Fri. Surgical staff should contact the histology laboratory on extension 4588 for booking in the frozen section at least 48 hours prior to the surgery taking place.

Full name of patient, date of birth, RMC/NHS number, specimen type and approximate time of specimen delivery must be given when booking in. Please contact the laboratory to cancel the frozen section if no longer required. Allow 30 minutes from receipt for a frozen section

report to be issued by telephone.

Samples should be sent immediately to the department in a dry specimen container with an appropriately labelled request card with 'FROZEN SECTION' written at the top of the card.

NB: Frozen sections are not performed on known high risk specimens.

Immunofluorescent samples:

An IMF service is offered on Dermatology cases. This non-accredited test is available at the Royal Bolton Hospital, operating between 08:45am and 16:30pm Mon to Fri.

The sample should be placed in 0.9% NBS in a screw topped appropriately labelled sterile container (available from the laboratory by prior request) and be sent immediately to the department with an appropriately labelled request card with 'IMF' written at the top of the card.

8.4 Performance Influence Factors

The following is a list of factors known to significantly affect the performance of examination and interpretation of results:

- Failure to follow the specimen acceptance policy will result in a delay to specimen processing and reporting.
- Failure to supply adequate clinical information may result in a delay to requesting of specimen investigations and reporting.
- Failure to label requests as urgent will result in a delay to specimen processing and reporting.
- Failure to fix specimens appropriately and in a timely manner will adversely affect specimen integrity and subsequent histological examination.
- Failure to follow instructions for the specific specimen requirements will prevent necessary examinations from being performed.
- Failure to disclose high risk status of the specimen will put staff at unnecessary risk of infection.
- Specimens for frozen section placed in 10% neutral buffered Formalin will result in a frozen section not being performed and therefore a rapid report would not be possible.
- Failure to contact consultant/laboratory in advance for a frozen section may result in a delay or even a scenario where it cannot be performed, due to a lack of availability of technical staff and/or Consultant staff.
- Specimens for immunofluorescence placed in 10% neutral buffered Formalin will prevent necessary immunofluorescence examinations.

9. Health and Safety - Spillages

If specimens are sent in appropriately-sized containers with secure lids, spillages should be minimal. Specimen containers should be placed in a sealable bag with a separate pocket for any request forms.
Each sender must have their own local spillage policy or procedure which covers procedures in their area. There should be suitable materials for dealing with the samples you routinely handle.

Spillages must be dealt with as soon as is safely practical. Saving the specimen, which may not be repeatable, must be the primary concern. It is as important as protecting the staff from possible infection. Specimens must not be discarded. Cellular pathology must be informed of cases where the spillage may have resulted in a diagnostic specimen being lost, partially lost or had its fixation compromised – This will need to be recorded on the request form. A safeguard incident must be completed and the sending clinician should be informed as soon as possible.

9.1 Dealing with a formalin spillage

Formaldehyde is a severe skin irritant and sensitizer. Exposure to vapor can cause reddening/burning sensation in the eyes, irritation of the upper respiratory tract, allergic asthma or shortness of breath. Any spillage may require ventilation of the immediate area.

1) If formaldehyde has been spilled inform anyone in the vicinity.
2) Use PPE e.g. goggles, gloves, apron
3) Check any containers for damage and re-seal the container if safe to do so. Ventilate or evacuate the area if necessary.
4) Contain the spill using absorbent materials (or spillage kit if large)
5) Check the request card for details and attempt to locate any specimen.
Where possible this should be returned to the original container and a note made on the request card. Please contact the laboratory on 4588 if you feel you need advice or assistance
6) Seal saturated/contaminated absorbent materials used in the cleaning process in a clinical waste bag, double bag this and then ensure it is sent for incineration
7) Wash the area with detergent and cool water.
8) Dry area thoroughly

There is now a **Trust Heavy Duty Cleaning Team** for dealing with Spillages in non-clinical areas such as corridors. Please contact switch board if required.

Cellular Pathology can be called to any area to check Air levels (Monday-Friday 08:30:

16:30) after the clean-up if required by contacting the department by telephone on 01204-390390 Ext. 4588.

9.2 Health & Safety - Sharps

Every year numerous staff working in Healthcare sustains injuries from sharps. These injuries pose a significant risk to the physical and mental health of the staff member.

All members of staff have a responsibility to:

- Familiarize themselves with the guidance regarding the safe use and management of sharps.
- Adhere to safe working practice in order not to harm either themselves or others.
- Familiarize themselves with the necessary action to take in the event of injury and unsafe disposal.
- Report any incidents or unsafe practice

Managers must ensure that:

- The management of sharps is incorporated into the risk assessment process
- Suitable sharp containers are readily available and located in agreed areas.
- All personnel are informed of the correct and safe procedures for the management of sharps both at induction and during refresher training.
- All personnel are made aware of the action to take should a needle stick injury or sharps spillage occur, including appropriate reporting of the incident.
- A risk assessment is immediately undertaken if a member of staff reports a sharps injury.
- The incident is reported in line with the Trust Incident Reporting Procedure.

The use of sharps should be avoided where possible. When their use is essential, particular care is required in handling and during the disposal process:

Sharps **must** always be handled carefully, and in accordance with the following principles;

1. Do not re-sheath used needles, scalpel or sharp objects.
2. Never pass sharps from person to person by hand.
3. Never walk around with sharps in your hand.
4. Never leave sharps lying around – always dispose of them yourself.

9.3 Use of Sharps Bins

1. Sharps must only be disposed of, in designated sharps bins that meet the requirements of the British Standard: BS 7320 (1990) UN3291

2. The correct size plastic container must be assembled correctly prior to use and staff must ensure the lid is secure.
3. The person assembling the sharps container must complete the relevant sections on the label before putting it into use. Site/date in use etc…
4. When placing the used sharps into the container, staff must ensure that all contents actually pass the plastic flap and enter the container.
5. The sharps container must be used and discarded as per the Trust Policy Safe Management of Sharps.

10. Non-Gynaecological Cytology Test Repertoire

Unfixed specimens need to be submitted promptly before degeneration of the cells occurs. If this is not possible, ensure the specimen is kept refrigerated between 4-7°C. Contact the laboratory if any advice is required (01204 390390 ext. 4588) Please ensure that the date and time of collection is given on all cytology requests. Please contact the laboratory to request supplies of cytology collection fluids, slides, fixatives and FNA kits. 48-hour advance notice will need to be given to the laboratory to ensure that the requests can be prepared and ready for collection.

Examination	Turnaround time	Requirements and safety precautions (Fixative, Pot/Container)	Temperature interval	Accreditation
Synovial Fluids	**7 days**	Collected into a 2ml paediatric lithium heparin tube.	Room temperature	NOT UKAS ACCREDITED TO ISO 15189
Body Cavity Fluids (Pleural, ascitic, pericardial, peritoneal) cyst, seroma fluids and bronchial washings	**7 days**	No fixative – use a 25ml universal container If cannot send before 1645 keep in a refrigerator between 4-7°C **Please note**: A bronchial washing specimen is not a BAL (See BAL sample below) and therefore a differential cell count will not be performed on this type of sample. However, presence of eosinophils can be confirmed if required.	Room temperature if sending same day or at 4°C if stored overnight.	A UKAS accredited medical laboratory No. 9927 (see section 6.1 for specific non-accredited tests)
Fine Needle Aspiration (FNA) Cytology	**7 days**	FNA kit for Direct smears – placed in 95% industrial methylated spirit. Smears must be fixed immediately and labelled in pencil for patient identifiers. **THEY MUST NOT BE ALLOWED TO AIR DRY.** Rinse the needle out into the small container (bijou) containing cell collection fluid for optimal cell preservation of residual material.	Room temperature	A UKAS accredited medical laboratory No. 9927 (see section 6.1 for specific non-accredited tests)
		For ENT specimens - Universal containers with green Cytological fixative or CytoRich® Red for bloodstained specimens should be used and available from Cytology.		

Urine	**7 days**	Collected in urine bottles containing cell collection fluid, which are obtainable from the Cytology Laboratory on request. If the specimen is collected out of normal laboratory opening hours it can be stored at room temperature. 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. State the collection method i.e. voided, catheter specimen, ileal conduit.	Room temperature	A UKAS accredited medical laboratory No. 9927 (see section 6.1 for specific non-accredited tests)
Broncho-alveolar lavage specimens (BAL) **Used mostly to diagnose infections (such as *Pneumocysti s jiroveci/carini* – and for differential cell counts for interstitial lung disease.**	**7 days**	No fixative; transport to the lab as soon as possible within normal working hours on ice. Sample needs to be received **by 15:00** at the latest and prior notice given to Cytology laboratory. **Please note** that a differential cell count can only be done on a BAL (Not for bronchial washings)	4-7°C (on ice)	NOT UKAS ACCREDITED TO ISO 15189

Brushings - Bronchial or Biliary	**7 days**	Direct smears – placed in 95% industrial methylated spirit. Smears must be fixed immediately and labelled in pencil. **THEY MUST NOT BE ALLOWED TO AIR DRY**. Brush head is detached and placed in a bijou of cell collection fluid.	Room Temperature	A UKAS accredited medical laboratory No. 9927 (see section 6.1 for specific non-accredited tests)
Cerebrospinal Fluids (CSF)	**7 days**	Collect 1-2 ml in a universal bottle and deliver to the lab as soon as it is taken and by 1500 at the latest. CSF specimens can degenerate rapidly, compromising diagnostic interpretation. Specimens taken after 1500 should not be taken. If there is likely to be a delay, the specimen can be kept refrigerated around 4 C overnight.	Room temperature on day of collection or at 4°C if stored overnight.	NOT UKAS ACCREDITED TO ISO 15189
Sputum	**7 days**	• 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. Patient may be induced to provide a deep cough sample. To maximise detection of pulmonary malignancy; 3 separate samples collected on consecutive days should be sent. • 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 4C	Room temperature on day of collection or at 4°C if stored overnight	A UKAS accredited medical laboratory No. 9927 (see section 6.1 for specific non-accredited tests)

		overnight.		
Cervical Cytology Smears for Manchester University NHS Foundation Trust (MFT)	**Not performed in Bolton. Please contact CMFT Lab for current turnaround time**	Please place these samples in a lilac coloured bag – do **not** place in any other colour bag under any circumstances. Also do not place any other samples in these bags as samples placed incorrectly in the lilac coloured bag will be delayed and patient will need to have repeat samples done. LBC kits are available from Manchester Cytology Laboratory Tel: 0161 276 8817.	Room temperature	A UKAS accredited medical laboratory No. 8648

11. Andrology (Fertility and Post-Vasectomy services) Test Repertoire

For full details on Male Fertility / Post vasectomy services and specimen collection see Patient leaflet(s) – these will be sent to patients upon doctor appointment request.

Instructions for patients – Male fertility: CY-AND-SW-2
Instructions for patients providing a PVSA sample: CY-AND-SW-11
Instructions for patients providing a 1 Hour PVSA sample: CY-AND-SW-11

Examination	Turnaround time	Requirements and safety precautions (Fixative, Pot/Container)	Temperature interval		**Accreditation**
Fertility Semen Analysis	**7 days**	No fixative. A fresh semen sample is required in a specimen container which has been pre-weighed and tested for spermicidal properties by the laboratory. This will be issued to the patient together with an appointment and instructions on how to collect the sample and transport to the laboratory. Criteria for the test as per the WHO 6 Laboratory Manual: Sampled adequately labelled. Sexual abstinence of between 48 hours to 7 days before the test. The entire ejaculate collected. Sample collected in the container provided. Sample brought to the laboratory as soon as possible so that critical tests can be performed within 60 minutes. Samples which do not adhere to the criteria will	Sample must be kept close to body temperature 37°C during transportation e.g. under clothes and under the armpit.	Semen analysis is carried out via appointment with the Laboratory. The request form is sent to the laboratory by the requesting clinician and an appointment is made and sent to the patient.	A UKAS accredited medical laboratory No. 9927 (observational tests are not accredited)

		be rejected as this will affect the results of the test.			
Routine Post Vasectomy Semen Analysis	**7 days**	No fixative. A fresh semen sample is required in a sample container pre-weighed and tested for spermicidal properties by the laboratory. This is provided to the patient by the clinician performing their procedure. Criteria for the test as per the 2016 Post Vasectomy Guidelines: Sampled adequately labelled. Sexual abstinence of between 48 hours to 7 days before the test. The entire ejaculate collected. Sample collected in the container provided. Samples which do not adhere to the criteria will be rejected as this will affect the results of the test.	Sample must be kept close to body temperature 37°C during transportation. e.g. under clothes and under the armpit.	Post vasectomy semen analysis is carried out by appointment only. The first appointment is allocated to the patient by the clinician following the procedure. The laboratory will send the report to the consultant who performed the vasectomy surgery.	A UKAS accredited medical laboratory No. 9927 (observational tests are not accredited)

1 Hour Post Vasectomy Semen Analysis	**7 days**	No fixative. A fresh semen sample is required in a sample container pre-weighed and tested for spermicidal properties by the laboratory. Sample must be received within 40 minutes of collection to allow time-critical tests to be performed within 60 minutes.	Sample must be kept close to body temperature 37°C during transportation. e.g. under	1 Hour PVSA samples are by appointment only by contacting the laboratory. The laboratory	A UKAS accredited medical laboratory No. 9927 (observational tests are not accredited)

		Criteria for the test as per the 2016 Post Vasectomy Guidelines: Sampled adequately labelled. Sexual abstinence of between 48 hours to 7 days before the test. The entire ejaculate collected. Sample collected in the container provided. Sample must be received with sufficient time to assess for motility within 60 minutes of collection. Samples which do not adhere to the criteria will be rejected as this will affect the results of the test.	clothes and under the armpit.	will send the report to the consultant who performed the vasectomy surgery.	

12. Communication of Results

12.1 Reporting Results

Electronic results:

Cellular Pathology reports are issued electronically to electronic patient record systems (EPR) and ICE immediately on reporting for Royal Bolton Hospital Patients - This improves result retrieval as pathology reports become part of the electronic patient record. The issue of reports to the correct location is subject to the correct location details being supplied on the specimen request card.

Paper results:

Cellular Pathology will distributed paper reports on all cases. For RBH clinics this is done via the internal post, for external locations this will be via recorded delivery or courier. Paper results will incur a degree of delay in their receipt by the clinical teams when compared to electronic copies.

When an unexpected abnormal result has been confirmed the Consultant Histopathologist will contact the requesting Clinician or member of the clinical team directly to discuss the findings.

12.2 Turnaround Times

The department is working to RCPath Key Performance indicators (KPI). The target is to report 80% of diagnostic biopsy cases within 7 days, and 90% of all specimens within 10 days.

Whilst we maintain our turnaround times regularly if you need our current turnaround times please contact the laboratory manager.

The complexity of a case will increase the time taken to report it. Complex cases or bone samples may require extensive laboratory work up or referral to outside departments; large specimens require adequate time to fix before investigations can be started in order to provide optimum accuracy. The department urges users to take this into account when booking follow up appointments or MDT discussions.

Frozen sections are reported on the day and a verbal report is usually given by telephone within 30 minutes.

13.0 Mortuary Services

13.1 Mortuary Location and Contact information

The Mortuary is situated in the Department of Laboratory Medicine at the Royal Bolton Hospital. Visitors are asked to proceed along the main hospital corridor to A Block square and press the intercom button at the opening to the Mortuary corridor to gain access.

Telephone Enquiries (01204) 390690 **Internal** 5690

Hours of Opening

Monday – Friday 8.00am – 1.00pm
1.30pm – 3:45pm

The on call mortuary technician can be contacted via switchboard outside of these hours.

13.2 Staff attending the Mortuary

Hospital medical staff and other staff may need to attend the mortuary for the following:

- Identification of bodies for cremation certificates or occasionally to certify death.
- Attendance at post mortems.

Please note that when attending the mortuary that other persons such as the deceased patient's relatives, funeral directors and the police may be attending for other reasons.

13.3 Post Mortem

Post mortem (PM) examination is crucially important in understanding the cause of death, and in telling bereaved families (who wish to know), about the possibility of acquired and genetic diseases which might need care and treatment. More widely, it is vitally important in advancing our understanding of disease.

Histopathologists at Royal Bolton Hospital NHS Trust perform adult Post Mortem examinations, requested by either the Coroners Office or Hospital/Voluntary.

Paediatric and Perinatal Post Mortem examinations require referral to the Paediatric Mortuary at Royal Manchester Children's hospital with consent and clinical history.

13.3.1 Requesting a Hospital/Voluntary Post Mortem

If a post mortem has been requested, either by the hospital clinician or a relative, then consent from a person of qualifying relationship is required, unless the deceased explicitly

gave their permission to a post mortem before they died. Please refer to the Trust Informed Consent for Post Mortem Policy available on the Trust Staff Intranet.

13.3.2 Coroner Requested Post Mortem

A Coroner is an independent judicial officer of the Crown who is under a statutory duty to investigate all sudden, violent or unexplained deaths. The Coroner will enquire into any reported deaths and request a Post Mortem.

An Inquest will be held in circumstances where the cause of death cannot be clearly established following a post mortem. Trust Inquest Policy available on the Trust Staff Intranet.