

# Histopathology User Guide

Version number 12.1

# Author A Rice

Authorised by P Shah

Issued on 23/12/2024

Version Number	Change Details	Date
12	Synnovis template. Updates to Clinical Lead and Consultant Pathologists, plus changed 'Datix' to 'Radar'	19/07/24
12.1	Removed reference to UKAS Accreditation	23/12/2024



# Contents

1.	Introc	luction4	
1.1	Departmental Contact Details4		
1.2	Laboratory Hours		
1.3	Clinica	l advice and On Call Service5	
1.4	Histolo	gy and cytology specimens5	
	1.4.1	Minimum Specimen Requirement:5	
	1.4.2	Instructions for completing request forms5	
	1.4.3	Instructions for labelling pots5	
	1.4.4	Criteria for rejecting samples6	
	1.4.5	Storage conditions before collected samples are delivered to the laboratory	
	1.4.6	Transportation of Specimens from wards to the laboratory by Porters	
	1.4.7	Incident Reporting Procedure:7	
2.	Protoc	col for Urgent Specimens8	
2.1	Frozen	Sections	
2.2	Transp	ort of urgent specimen from HH to RBH - out of hours9	
3.	Histop	oathology9	
3.1	Scope	of Service9	
3.2	Results	59	
3.3	"Rapid	" Biopsy Service	
3.4	Surgical Reporting Service		
3.5	Molecular testing		
3.6	Predictive Immunohistochemical tests including PD-L1		
4.	Histology Service - Specimen Handling		
4.1	Core, E	Endobronchial and Transbronchial biopsies	
4.2	Surgica	al specimens 11	
4.3	Endomyocardial biopsies 11		
4.4	Transplant biopsies		
4.5	Non-thoracic Specimens12		
4.6	Amput	ation specimens12	
5.	Cytop	athology12	
5.1	Specim	nen Types 12	
5.2	Range	of Investigations13	
6.	Use of	f Cytology Service13	
6.1	Same	day cytology results13	
6.2	Sputum specimens		



9.	Laboratory's Policy on Protection of Personal Information. 16
8.	Complaint Procedure 16
7.	Turnaround Times15
6.8	Specimen Collection for Cytology14
6.7	Bronchial brushings14
6.6	Bronchial washings and trap specimens and Bronchio alveolar lavage (not for differential count)14
6.5	Bronchial lavage for differential counts14
6.4	Fine Needle Aspirates, including TBNAs13
6.3	Pleural/Serous fluids 13



### 1. Introduction

The Histopathology Department provides a comprehensive consultative, analytical and interpretive service to Royal Brompton and Harefield Hospitals and other hospitals. It is on both sites under a single management structure. The department includes a Histopathology and non-Gynaecological Cytology service and is an international referral laboratory for Thoracic (Lung, Pleura and Mediastinum), Cardiac and Cardiothoracic Transplant pathology. We provide a specialised service directed at the particular diagnostic needs of our patient groups.

Please note that currently, the RBHH Histopathology department is not UKAS accredited but its progressing merger with the St. Thomas' Histopathology department UKAS Accreditation number.

The postal addresses are:

Department of Histopathology	Department of Histopathology
Royal Brompton Hospital	Harefield Hospital
Sydney Street	Hill End Road
Chelsea	Harefield
London	Middlesex
SW3 6NP	UB9 6JH
Tel: 0207 351 8425	Tel: 01895 828 725

Each test request accepted by the laboratory constitutes an agreement between the laboratory and the service user.

#### **1.1 Departmental Contact Details**

	Contact No.
Consultant Histopathologist & Clinical Lead: Dr Jan	Ext 88424
Lukas Robertus	
Consultant Histopathologist: Prof. Andrew	Ext: 88661
Nicholson	
Consultant Histopathologist: Dr Cecilia Brambilla	Ext: 88423
Consultant Histopathologist: Dr Yu Zhi Zhang	Ext 82104
Consultant Histopathologist: Dr Lauren D'sa	Ext: 88409
Service Manager: Pratibha Shah	Ext: 88427 & 85871 (HH)
General Office Enquiries, Histology/Cytology	Ext: 88425 and 82073
Reports - RBH	
General Laboratory enquiries - RBH	Ext: 82101
Cytology Laboratory - RBH	Ext: 82104



#### 1.2 Laboratory Hours

Monday-Friday 9.00am-5.30pm

#### 1.3 Clinical advice and On Call Service

Clinical advice on ordering tests and interpretation of results is available from a Consultant Histopathologist during working hours from Monday to Friday.

Consultant Histopathologists are available for advising on individual clinical cases, professional judgments on the interpretation of the results of examinations and consulting on scientific and logistic matters. Consultants are also available in support of the trust Medical Examiners to discuss any deaths within the Trusts, this being co-ordinated by the PALS team with a daily rota for the on-call pathologist for such discussions.

In addition, the department provides an out of hours on-call service for urgent biopsies. Please contact laboratory staff via switchboard. They will then contact the on-call BMS and pathologist as appropriate.

#### 1.4 Histology and cytology specimens

All details should be filled in on Epic Beaker or specimens must be accompanied by fully completed legible request forms. Failure to do so will cause delays in diagnosis, as specimens and request will be returned to source for completion before acceptance.

#### **1.4.1 Minimum Specimen Requirement:**

#### Histopathology:

All formalin fixed specimens should be placed in an adequate volume of formalin; ideally the specimen to formalin ratio should be 1:10.

#### Cytopathology:

The minimum requirement of Cytology specimens is 2 to 10ml of fluid but if this is not possible, please let laboratory know on ext: 82103 and send us whatever is possible.

#### **1.4.2 Instructions for completing request forms**

All details should be filled in on Epic Beaker or a request form must accompany all specimens to the laboratory. This should clearly show the patient's details, including:

- Name i.e. first name and surname
- Hospital number/NHS number
- Date of birth
- Ward/GP name and number
- Type of specimen
- Date and time of sample
- All relevant clinical data including any infection risk
- Previous sample test date and any relevant history/treatment

#### 1.4.3 Instructions for labelling pots

QMUG00014 Histopathology User Guide



- The specimen pot must be labelled identically with the form including type of specimen.
- The minimum data set such as the patient's name, date of birth, the hospital number and the type of specimen must be included on all specimen containers.

#### 1.4.4 Criteria for rejecting samples

Mismatched or inappropriately labelled specimens or request forms will not be processed, as this constitutes a clinical risk.

Hospital clinicians will be informed to visit the laboratory and identify the mistakes and make necessary amendments. They are requested to sign the disclaimer form and take responsibility for any amendments.

If the cytology specimen does not conform to the requirements as given below in section 6.8 Specimen Collection for Cytology - a note will be made on the patient records as the diagnosis may be compromised. This will be done in the form of coded comments.

#### Coded comments

INSU	Insufficient material for diagnosis
XTYP	Incorrect specimen type
AIR	Air-drying artefact (poor fixation) - impaired assessment
XDIF	Inappropriate specimen container for Diff Counts – Use polypropylene
	containers
INAD	Inadequate smear
THIK	Smear too thick- impaired assessment
CLOT	Clot forwarded to Histopathology
LEAK	Specimen Received Leaking

#### **1.4.5** Storage conditions before collected samples are delivered to the laboratory

Please read section 4 for Histology Service – and section 6 for Use of Cytology Service

#### 1.4.6 Transportation of Specimens from wards to the laboratory by Porters

Specimens being transported to the laboratory must be contained in a robust leak-proof container in accordance with <u>UN3373 transport regulations</u> for Biological substances category B and diagnostic specimens. They must be easily disinfected if they become contaminated. Large Histopathology specimens, in their plastic buckets, should be transported in an opaque plastic bag, which is to be discarded into a clinical waste bin after use, or transported in a large ridged transportation carrier.

Specimens are collected from the wards by the porter at the following times:

Harefield Hospital

Monday to Friday:

06:00hrs (ITU and Recovery)



09:00hrs	(Phlebotomy room, ANZAC Centre, except
	Tuesday &Friday)
09:30hrs	All wards and departments
10:30hrs	All wards and departments
11:30hrs	All wards and departments
13:30hrs	All wards and departments
15:30hrs	All wards and departments
17:00hrs	All wards and departments

During normal working hours, all specimens must be delivered to Specimen Reception via the rear entrance of the Laboratory Medicine building. Out of hours, all specimens are placed in the Specimen Reception fridge.

Royal Brompton Hospital	
Sydney Wing	<u>Fulham Wing</u>
09.00hrs*	08.30hrs*
10.00hrs*	09.30hrs*
11.00hrs*	10.30hrs*
12.00hrs*	11.30hrs*
13.00hrs*	12.30hrs*
14.00hrs	13.30hrs
15.00hrs	14.30hrs
16.00hrs	15.30hrs
17.00hrs	16.30hrs
18.00hrs	17.30hrs

All collections are completed on normal working days.

\*Sample collections in **bold** are completed on weekends and bank holidays.

On the Brompton site, during normal working hours, all specimens should be delivered to the Histopathology Specimen reception area in Laboratory Medicine, Sydney Wing. Out of hours, all Cytology specimens should be placed in the refrigerator in the Histology corridor and Histology specimens in formalin should be placed in the Histology cupboard, under the fridge in the Histology corridor.

#### 1.4.7 Incident Reporting Procedure:

Any received samples whose integrity has been compromised, incorrect patient error (specimen pot contains a specimen from a different patient to the one whose details appear on the pot and accompanying request form), specimens placed into incorrect (fixative) solution or left dry in the pot or no specimen found in the specimen pot, specimen mislaid in theatre/ward or en-route to the laboratory will be reported back to the clinicians. They will be requested to make corrections appropriately and also sign



the disclaimer form. Repetition of such incidents may be reported via using Radar incident reporting procedure.

## 2. Protocol for Urgent Specimens

To make an urgent request you will require the following information:

- Patient's Name
- Hospital Number
- Nature of specimen
- Name and bleep number/mobile number for further contact
- Location of specimen for collection

You must contact the laboratory (82101 (RBH). Also, the on-call pathologist must be contacted so that the case can be prioritised accordingly. An on-call rota is held by switchboard out of hours and can be accessed via the histopathology office during hours (ext. 88425 and 82073).

#### NOTE:

# Specimens marked urgent but not sent via this procedure will not be given priority.

If the consultant/clinician requiring urgent results will not answer their bleep then they will be contacted on their mobile number (if given) and if still not contactable then the "on-call" pathologist will request them to contact on his/her mobile number for the results.

#### 2.1 Frozen Sections

Requests for rapid diagnosis frozen sections **must** be booked in advance, at least 24 hours in advance by calling **on ext: 88425 or 82101 (RBH) or emailing** <u>HistopathologyTests@rbht.nhs.uk</u>

#### NOTE:

<u>Please do not call HH pathology as the Histology laboratory is not permanently staffed.</u> The Laboratory must be notified of any cancellations as soon as possible.

Tissue should be placed into a suitably labelled dry container and sent to the laboratory by vacuum tube (RBH site) or special porter (HH site). The accompanying form <u>must</u> detail patient ID, site of specimen, clinical details, Consultant Surgeon, theatre and phone number to communicate the result. Cases are reported by pathologists. Frozen sections at Harefield are usually reported remotely using a digital pathology system from the RBH site, unless a consultant is on-site at Harefield.

#### NOTE:

It is essential to detail any infectious hazards such as HIV, Hepatitis C or tuberculosis.

#### **COVID 19 infection:**

The department is NOT accepting any fresh specimens from COVID 19 positive patients.



#### 2.2 Transport of urgent specimen from HH to RBH - out of hours

- The Requesting doctor will provide the on-call RBH Histopathology BMS with patient's name and hospital number together with details of investigation(s) they require.
- The RBH on-call Histopathology BMS will inform the requesting doctor to place the sample at the Main Reception, Harefield Hospital and also to inform the main reception staff to place in a red despatch box addressed "Main Reception, Royal Brompton Hospital: Please contact the RBH Switchboard to call the RBH On-call Histopathology BMS on arrival of this Urgent Sample". The despatch box is situated in the post room adjacent to main reception. Collection will be arranged by the on-call RBH Histopathology BMS.

## 3. Histopathology

#### 3.1 Scope of Service

This department has, over many years, built up an international reputation in the field of cardiac, respiratory, mediastinal and transplant pathology. Highly trained staff handle and process material for diagnosis, teaching and research. We are an international referral centre for cardiac and pulmonary pathology and, as such, we offer a unique service geared to the needs of the trust and other prospective users.

The service is centred on the RBH site, with a satellite laboratory on the HH site dealing with submission of samples from the HH site, including frozen sections, and a minor proportion of specimen processing.

#### 3.2 Results

Reports are available in the Electronic Patient Record as soon as approved by pathologists. Please check the system prior to making telephone enquiries. If an urgent verbal report is required, please contact the reporting pathologist.

#### 3.3 "Rapid" Biopsy Service

Routine small biopsies are normally reported the next working day unless specified as urgent (see section 2), in which case a same-day service may be provided. The laboratory (ext 82101 (RBH) and reporting pathologist must be informed as soon as possible if a same day service is required. Please call the laboratory on 82101 to arrange transport of urgent specimens.



#### 3.4 Surgical Reporting Service

- Thoracic resections (Lung and mediastinum)
- Mediastinoscopy Specimens (e.g. Lymph nodes)
- Surgical Lung Biopsies
- Cardiac valves and vascular disease
- Other surgical excisions
- Cell blocks from cytology specimens such as EBUS-TBNA
- Others (including non-cardiothoracic specimens)

For the diagnosis of tumours and interstitial lung disease, vascular disease and cardiac disease, we employ a wide range of special histochemical staining techniques to provide a definitive diagnosis as well as immunohistochemistry.

Fixed specimens received before 3.00pm will normally be reported the following day. Large specimens received fresh will require fixation before processing, typically overnight. Reports will therefore not be available for at least 48 hours after receipt on these specimens. Specimens requiring decalcification (e.g. chest wall resections) may take up to 3 weeks.

#### 3.5 Molecular testing

Molecular tests are undertaken by the North Thames Genomic Hub at the Molecular Diagnostics Department, Royal Marsden Foundation Trust, Sutton, Surrey SM2 5NG. For NHS patients this is requested reflex tests by the pathologist. For private patients the clinician must confirm which tests they require.

If the clinician wishes to send the samples to a different laboratory, they need to inform the pathologist on-call and send the appropriate request form. These can be emailed to HistopathologyTests@rbht.nhs.uk or sent to the department.

If samples have been sent to the Marsden, the phone number for results is 0208 915 6565.

A copy of the RMH form is attached below.



#### 3.6 Predictive Immunohistochemical tests including PD-L1

These tests are not funded by NHSE so it is essential to add the Oncologist's name and address (for the billing purposes) on the PD-L1 test request form. The request will not be accepted without these details. A copy of this form is attached below.





# 4. Histology Service - Specimen Handling

#### 4.1 Core, Endobronchial and Transbronchial biopsies

Biopsies should be placed into formalin-filled pots, clearly labelled with patient's details and sent, together with a completed specimen request form, to the laboratory. If a patient is being considered for multiple molecular tests, cases should be indicated on the request form or discussed in advance with the pathologist on-call so that appropriate blocking and cutting of the specimen can be undertaken.

#### 4.2 Surgical specimens

<u>On the RBH site</u>, specimens taken between 9.00am and 5.00pm may be sent fresh as soon after resection as possible, without fixative unless there is a **biohazard** associated with the patient, in which case the specimens **must** be put into fixative, double bagged and labelled in accordance with safety policies. However, **we do not provide this service after 5.00pm and any routine specimens taken after that time must be put into fixative and sent to the laboratory the following day.** 

<u>On the HH site</u>, all specimens **except those for frozen section** should be placed in fixative as soon as possible after resection.

**NOTE**: Donor organ tissue (including trimmed pieces of lung, organs rejected for transplantation, and EVLP tissue (whole lungs and wedge biopsies)) **Donor organ tissue will not be processed without donor consent.** A copy of the donor consent form (either the original consent form or printout from the EOS database) must be received with this tissue, or it will be disposed of as clinical waste without histological examination.

#### 4.3 Endomyocardial biopsies

When possible, notification of biopsy should be given in advance. If special fixation for EM studies or snap freezing is required, the specimen should be sent without fixative so a Histopathology member of staff can fix / freeze it accordingly. Otherwise, biopsies that only require Histological studies should be placed into formalin and sent to the laboratory as soon as possible with a completed request form.

#### 4.4 Transplant biopsies

Nearly all transplant biopsies will be taken on the HH site. Non-urgent samples should be sent to the laboratory in formalin as soon as possible. If they arrive before 5pm at RBH, they will be processed overnight and reported the next working day. When appropriate, CD68 and/or C4d staining will follow in 24-48 hours.

**Friday transplant biopsies:** These must be transported to the laboratory as urgent specimens. A specific procedure has been established whereby the theatre porter collects any urgent biopsies from theatres at 10:30am. Biopsies reaching the laboratory before 12:00 noon will be processed for reporting that same day.

Specimens arriving after that time will be processed either overnight or over the weekend and reported the next working day, unless arrangements are made with the reporting pathologist.



If a case requires reporting or processing out of hours, the clinician must contact the pathologist on-call.

#### 4.5 Non-thoracic Specimens

Occasionally there is a need for biopsies/resections from extra-thoracic sites. These can usually be place into formalin-filled pots but if doubt then the <u>case must be</u> <u>discussed with the consultant on-call and the laboratory 24 hours prior to biopsy, if not</u> <u>dictated by the clinical situation</u>. For example, skin biopsies may require immunofluorescence that requires some of the tissue being submitted unfixed.

Paediatric skin and muscle biopsies may rarely be requested and these need to be transported to specialist centres for analysis (usually Queen Square), again with specific requirements for freezing and fixation. The Surgical team will arrange transport but must inform the laboratory of required tests and external provider(s) at least 48 hours before sampling. Mandatory forms for submission to the laboratory regarding the above are available in the laboratory (ext 82101). Of note, it is ideal that sampling is not arranged late in the day or on Fridays as specimens are often needed fresh for specific tests and provider laboratories may not be open out of hours.

#### 4.6 Amputation specimens

These should be sent to the mortuary for incineration unless they are required for histological examination. They should be sent in a sealed container (if needed supplied by laboratory or Mortuary-RBH) stored in a body fridge with appropriate labelling and completed request form clearly marked for disposal only. Also, all patient details need to be entered into the Mortuary Register. Unless we are otherwise instructed by the patient/family (e.g. to be retained for burial with the patient) arrangements will be made to dispose of the limb as soon as is practicable thereafter. If long-term retention is required, the Histology Department should be informed as soon as possible, as alternative storage arrangements will have to be made, possibly at the patient's expense.

# 5. Cytopathology

#### 5.1 Specimen Types

We provide a non-gynae cytology service. The samples we accept are listed below:

- Sputum
- Pleural
- Pericardial fluids
- Bronchioloalveolar lavage (BAL)
- Bronchial washings and brushings
- Fine needle aspirates, including transbronchial (EBUS-TBNA)
- Synovial fluids
- Urine
- Faecal fat microscopy



#### 5.2 Range of Investigations

Eosinophil counts, malignant cell identification, BAL cell differential counts, immunohistochemistry via preparation of cell blocks when appropriate, special histology stains for fungi when appropriate, fat-laden macrophages.

N.B.

- The Cytology department provides white cell differential cell counts on BAL specimens ONLY.
- We <u>do not</u> routinely undertake ZN staining for mycobacteria (TB) or Pneumocystis or other infective agents apart from visualising fungi. These tests are undertaken by the microbiology department and separate samples should be sent to that department with an accompanying microbiology form

### 6. Use of Cytology Service

#### 6.1 Same day cytology results

Please follow the same protocol for biopsies (2 and 3.3)

#### 6.2 Sputum specimens

Specimens should be taken in the early morning before contamination with food or toothpaste has occurred. The patient should be instructed to avoid spitting saliva or hawking nasal secretions into the container. The products of a <u>deep cough</u> are the only useful specimens. If you require both cytology and microbiology please send sputum in **2** specimen pots with two separate request forms.

#### 6.3 Pleural/Serous fluids

When pleural/serous fluids are drawn off they <u>MUST</u> be placed directly into the polypropylene Falcon tubes (blue lid). Failure to do so will allow the formation of a fibrin clot which may compromise and delay diagnosis.

#### 6.4 Fine Needle Aspirates, including TBNAs

<u>RBH site:</u> The FNA syringe should be washed out into normal saline (~5-10ml) and sent <u>immediately</u> to the laboratory.

<u>HH site:</u> In order to ensure appropriate fixation prior to transportation, samples should additionally be mixed with fixative (Cytorich Red) prior to submission to the laboratory. Details on ordering can be found on the Trust Eproc ordering system.

We will concentrate cells and make the necessary cell blocks for reporting and molecular tests when appropriate. There is no need to make any direct smears as these waste samples.



#### 6.5 Bronchial lavage for differential counts

Specimens **<u>MUST</u>** be placed directly in a Falcon Polypropylene tube (Blue Top) and clearly labelled "Differential Count", otherwise the sample will be reported as a standard cytology specimen. Please note there is a calculated variation of percentage in BAL counts.

Macrophages - 4-10% Lymphocytes - 4-10% Neutrophils - up to 6% Eosinophils - up to 5% Mast Cells - up to 3%

This variation is assessed on a 6 monthly basis and the user guide and BAL count reports updated accordingly.

# 6.6 Bronchial washings and trap specimens and Bronchio alveolar lavage (not for differential count)

Specimens should be put into a universal pot and submitted to the laboratory.

#### 6.7 Bronchial brushings

It is preferred that brushings are transferred to saline and the same process for aspirates is followed (6.4), especially in cases of suspected malignancy as this allows material to be used more flexibly and efficiently for immunohistochemistry and molecular testing.

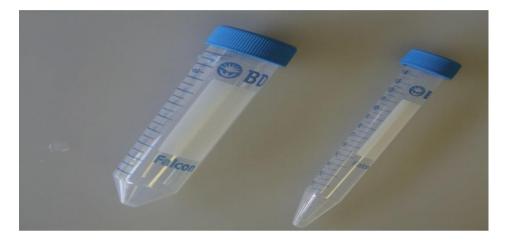
#### 6.8 Specimen Collection for Cytology

FAILURE TO USE THE APPROPRIATE CONTAINER WILL LEAD TO A DELAYED OR COMPROMISED DIAGNOSIS AND MAY RESULT IN THE SPECIMEN BEING DISCARDED. **A RADAR REPORT WILL BE RAISED** IF THE INAPPROPRIATE CONTAINER IS USED AND IF THE SPECIMENS ARE NOT RECEIVED IN TIMELY FASHION.

Collection Bottle
Polystyrene or polypropylene tube
Polystyrene or polypropylene tube
Falcon Polypropylene tube (BLUE
top)
Polystyrene tube
Universal container.
Cut the end of the brush into saline.
Universal container. Wash needle
into saline
Polystyrene Universal or Sputum pot.



CSF	Falcon Polypropylene tube (BLUE
	top)
Sputum	Polystyrene Sputum pot.
IF YOU ARE UNCERTAIN OF THE CORRECT CONTAINER, PLEASE CALL Ext 2101 FOR ADVICE.	



### FALCON TUBES FOR CYTOLOGY

# 7. Turnaround Times

The department aims to meet the Royal College of Pathologists turnaround time guidelines which are in calendar days from the sample taken date. Bank holidays and particularly busy periods may result in slight delays

Specimen type	TAT	Exceptions
Diagnostic cytology	90% in 10 days	
Urgent cytology	Within 24 hours	
Urgent biopsies,	Within 24 hours	Large complex chest wall
including transplant		resections, explant lungs
Non-transplant	80% in 7 days	and hearts, VADs,
Biopsies		specimens requiring
Routine transplant	24-48 hours	decalcification (e.g. heart
biopsies		valves), PMs.
Whole workload	90% in 10 days	
Whole workload	100% in 20 days	Harefield PMs, whose TAT
		relates to Governance day
		discussions.
Frozen section (verbal	10-30 minutes from	(multiple specimens,
report)	receipt	complex cases or remote
		digital reporting can
		increase this TAT).



# 8. Complaint Procedure

We realise that there may be times when we do not always get things right. On these occasions we welcome your feedback as this helps us to improve the services we provide. If you have any problems with any aspect of the Histopathology/Cytopathology Services, please tell us by contacting a member of Pathology staff (refer to contacts list in section 1).

If you feel that you have made every effort to try and resolve your concerns directly with the staff but this has not been resolved successfully you may decide to make a formal complaint. If this is what you decide to do then it is important to do this as soon as possible. An incident can also be reported through the RADAR online incident reporting system.

You can make a formal complaint by letter, telephone or by email to the Head of the Department, Consultant Pathologist, Service Manager or any other senior members of staff.

## 9. Laboratory's Policy on Protection of Personal Information

All staff have a professional and legal responsibility to respect the confidentiality of personal data, which may relate to patients, staff or others and to protect such data from unauthorized disclosure or processing. Information gathered by laboratory staff as part of their duties is handled confidentially, and with regard to principles stated in the Data Protection Act and Freedom of Information Act. All staff are responsible in their area for maintaining confidentiality and this forms part of the standard terms and conditions of employment.

Information collected by laboratories is only for legitimate reasons such as correct identification of patients and specimens, information relevant to the safety of other patients and staff, clinical information relevant to the interpretation of results, billing purposes, etc. as appropriate. Should there be any reason for extra information patients are made aware of the information collected and the purpose for which it is collected.