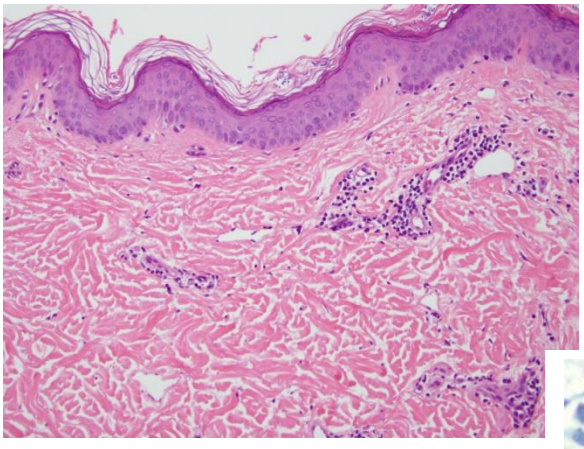
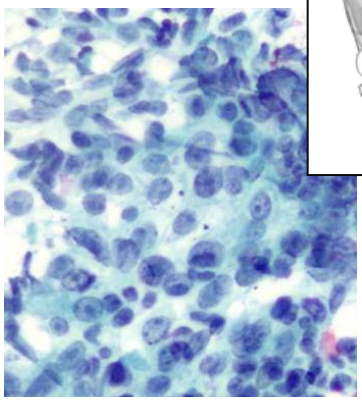
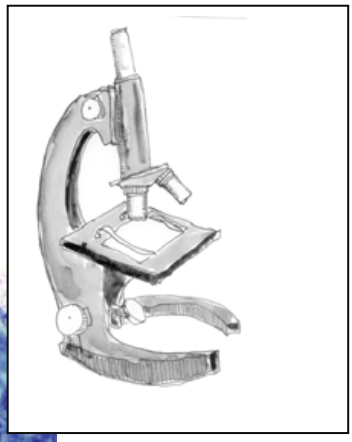
Cellular Pathology







SERVICE USER HANDBOOK

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0 INTRODUCTION

The Cellular Pathology Service is provided by the laboratories at the Great Western Hospital NHS Foundation Trust, Swindon, providing a formulary of tests reflecting the usual demands of a District General hospital service. Specialist and Reference test services are used where necessary.

Cellular Pathology operates Monday to Friday 08:00 to 17:15. There is currently no out of hour's service provision. Consultant or technical advice is available on-site on an open access basis during normal working hours. The service includes Histology, Non-Gynae Cytology and Andrology.

We provide an interpretative diagnostic service on a wide range of clinical samples, processing over 22,000 histology requests, 1800 Non-Gynae Cytology Requests and 650 Andrology samples per annum. The efficiency of the service we provide is reliant on the cooperation of our users with the necessary policies relating to safety, sample transport and sample identification.

In its pursuit of excellence and as part of its continuous quality improvement programme the Cellular Pathology service participates in all relevant internal and external quality assurance schemes. All laboratory work is carried out on up-to-date equipment in a modern laboratory which meets with all statutory requirements of a quality management system.

The repertoire of tests provided by Cellular Pathology supports the Trust in its diagnostic and screening programmes.

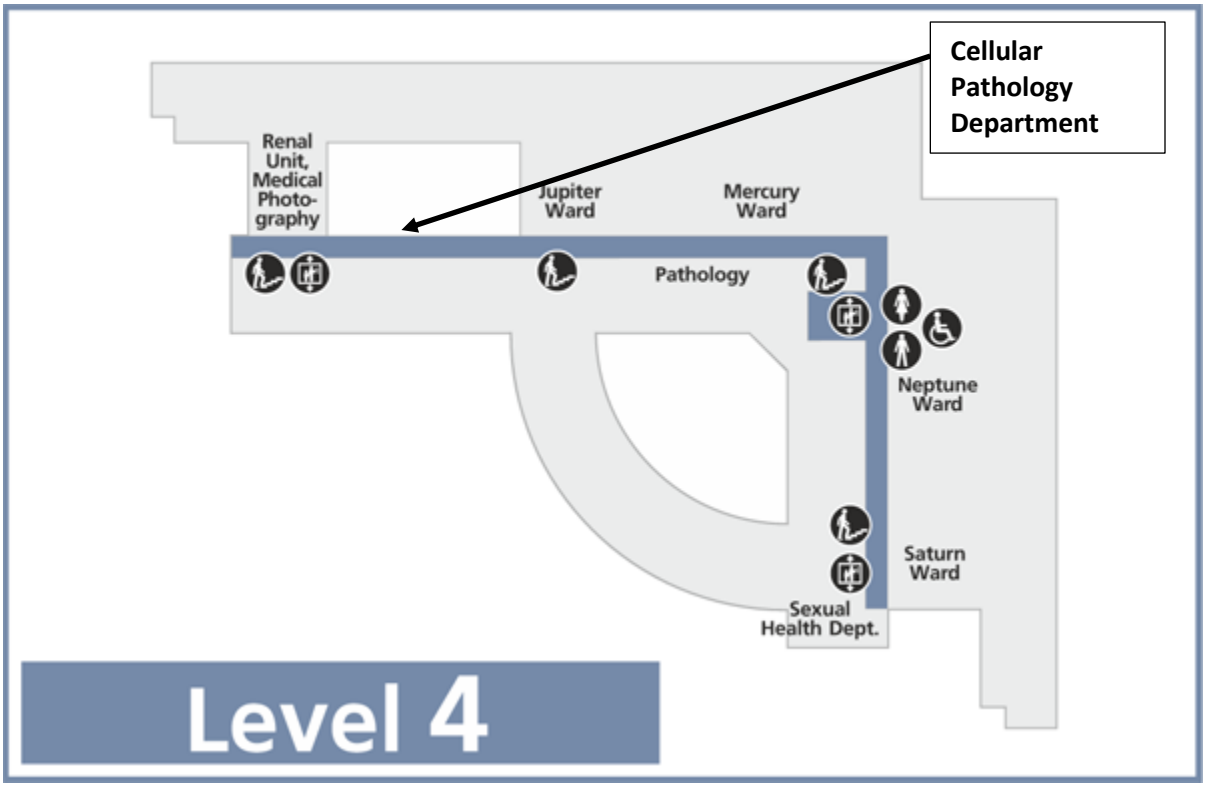
The laboratory is accredited by the Institute of Biomedical Science (IBMS) for Biomedical Scientist training and Biomedical Scientist Specialist training. We also support the University of Bristol in the provision of clinical undergraduate training and the development of junior doctors at Great Western Hospital.

The Pathology services are fully computerised with all laboratories using Clinisys Winpath laboratory information system. Pathology results are available electronically via the Trust network at ward level or via the GP electronics links. Hard copies (if required) are returned daily Monday-Friday.

We hope that this handbook contains all the information you require to use our service. However, please feel free to contact us to discuss any problems or issues you may have. Any comments or suggestions about the User Handbook should be addressed to the Laboratory Manager, by email to malcolm.goodwin1@nhs.net

1 LABORATORY LOCATION

The Cellular Pathology Department is part of the Division of Diagnostics and Outpatients, within the Great Western Hospitals NHS Foundation Trust. The department is sited on the fourth floor of the main hospital building (see diagram).



The postal address is as follows:

Cellular Pathology Department
Great Western Hospitals NHS Foundation Trust
The Great Western Hospital
Marlborough Road
Swindon
Wiltshire
SN3 6BB

2 PATHOLOGY QUALITY POLICY

Refer to the Quality Policy (DCN PAT-P-012) The Pathology Department provides Microbiology, Cellular Pathology, Blood Sciences (incorporating Haematology, Biochemistry, Blood Transfusion and Point of Care Testing) and Mortuary and Bereavement services to the Great Western Hospitals NHS Foundation Trust, Swindon Clinical Commissioning Group (CCG), Wiltshire CCG and other users where such arrangements have been made.

The management of the Pathology Department is committed to delivering a service that is compliant with the requirements for Medical Laboratories set by the International Standard Organisation (ISO 15189:2012), Health and Safety Executive (HSE), Public Health England (PHE), Medicines and Healthcare Products Regulatory Agency (MHRA), and Human Tissue Authority (HTA).

The Pathology management team is fully committed to the on-going improvement of laboratory services through the continual assessment of the Pathology Quality Management System and the establishment by means of regular meetings, internal and external audits and annual review of quality objectives during the Pathology Annual Management Review.

The management of the Pathology Department is committed to good professional practice and the provision of examinations that are fit for intended use to ensure the delivery of a high-quality service that meets the requirements of its users. This commitment is reflected in the core values of the Quality Management System.

3 OPENING HOURS, CLINICAL ADVICE AND RESULTS

3.1 Laboratory Opening Hours

The laboratory is open:

Monday to Friday:	08:00 – 17:15
Saturday:	Closed
Sunday:	Closed
Bank Holidays:	Closed

Andrology Service (Post-Vasectomy and Fertility Analysis) specimens must be booked in prior to submitting to the laboratory. The service is Biomedical Scientist led and is available on Tuesday, Wednesday and Thursday 08:30 to 11:30, with appointments allocated from 08:40 to 10:40 for specimen drop-off.

3.2 Clinical advice

Consultant advice is available on-site on an open access basis during normal working hours. For clinical advice on the interpretation of results, please contact the relevant Consultant Pathologist. Clinical advice on Andrology samples can be provided by the Fertility clinical lead.

Laboratory and office staff are not authorised to provide advice on the interpretation of results.

For advice on technical aspects of histology testing, contact the Laboratory manager or Biomedical Scientists in the laboratory.

Please see contact information in section 5.

3.3 Urgent samples

Urgent samples can be requested on the request form by indicating so. If a result is required more urgently than our urgent turnaround time of 7 days, the department MUST be notified prior to sending the sample so that the request can be prioritized. The case may need to be passed to a Consultant Pathologist.

Please ensure that the requesting doctor contact details are provided on the request form to enable contact for any further information.

3.4 Testing out of hours

The department does not provide an out of hour's service. All specimens must be delivered to Pathology Reception. Any histology specimens delivered to Pathology reception out-of-hours must be in formalin otherwise diagnostic interpretation may be affected.

3.5 Additional tests

All tests should be requested at the time of submitting the sample to the laboratory. However, amendments to requests, or the need for additional tests, can still be discussed with the laboratory after processing has started. Further advice can be obtained from the laboratory on 01793 604278.

3.6 Results

Pathology results are available electronically immediately after authorisation via Medway PAS at ward level or via the GP electronic links. Hard copies of reports are produced and returned daily Monday – Friday.

All laboratory results are returned to the requesting clinician who has ultimate responsibility for ensuring that all results are actioned and communicated to the patient as appropriate.

Results are not available until they have been authorised. In exceptional circumstances, preliminary results may be available direct from the relevant pathologist. However, please bear in mind that this is to the discretion of the pathologist.

3.7 Telephoned results

We discourage results by telephone unless absolutely necessary. Please note that we need to establish the caller's identity before giving authorised results over the telephone. We are unable to give results directly to patients or their relatives.

Authorised results are available on the Medway system, ICE, and the Winpath Ward Enquiry system. Results may also be obtained by telephoning extension 4999, 5000 or 5001 (direct dial 01793 604999 / 605000 / 605001).

Results are not available until they have been authorised. In exceptional circumstances, preliminary results may be available direct from the Consultant Pathologists. Please bear in mind however, that this may delay the testing of other samples.

3.8 Turnaround times

The laboratory continually monitors its turnaround times to ensure that it complies with its responsibilities within the patient pathway. The laboratory measures its turnaround times as the time from collection until the point at which the result is authorised.

Sample	**Turnaround time**
Urgent Histology Samples	80% within 7 days 90% within 10 days
Routine Histology Samples	100% in 6 weeks
Diagnostic Cytology Samples	80% within 7 days 90% within 10 days
Andrology Samples	100% within 3 days

Interrogation of the electronic systems allows for full audit of the reception, testing and reporting process, including time of report viewing and report printing.

The Turnaround Times may be breached if additional supplementary testing is required or if a case is complex. Capacity may also affect the department's ability to meet service user requirements. The turnaround times are monitored in accordance with Royal College of Pathologist's guidelines in addition to the above specification. We encourage any issues to be directed to the Laboratory Manager.

4 CONTACT DETAILS

Name	External Number	Internal Number
Cellular Pathology Office Preferred contact for non-technical enquiries	01793 605000 01793 605001 01793 604999	4999/5000/5001
Dr. Sanjiv Manek Clinical Lead Consultant Pathologist	01865 220520	-
Dr. Lawrence John Consultant Pathologist, Clinical Lead Mortuary	Via Office	4282
Dr. Darko Lazic Consultant Pathologist	Via Office	4280
Dr. Kim Billingham Consultant Pathologist	Via Office	4283
Dr. Harry Haynes Consultant Pathologist	Via Office	4279
Dr. Kevin Jones Andrology Clinical Lead	01793 604947	4947
Malcolm Goodwin Interim Cellular Pathology Laboratory Manager	01793 604277	4277
Louise Hacker Deputy Laboratory Manager Advanced Biomedical Scientist (Histopathology Lead)	01793 604278	4278
Matthew Long Advanced Biomedical Scientist (Dissection Lead) Training Officer	01793 604278	4278
Vinitha Thomas Advanced Biomedical Scientist (Non-Gynae Cytology and Andrology Lead)	01793 603108	3108
Amy Humphries Advanced Biomedical Scientist (Immunohistochemistry Lead)	01793 604278	4278
Nyree McCool Advanced Biomedical Scientist (Digital Pathology Lead)	01793 604278	4278
Laboratory	01793 604278	4278
Hospital switchboard	01793 604020	0

5 SAMPLE COLLECTION

5.1 Preparation of patient

Adequate privacy during reception and sampling should be available and appropriate to the type of information being requested and primary sample being collected.

Information for patients regarding tests performed, including instruction for preparation of the patient and instructions for patient-collected samples, can be accessed at the Lab Tests Online UK website.

For details of the Laboratory Policy on protection of personal information, patient consent, medico-legal samples and the Human Tissue Act refer to Patient Consent Disclosure.

5.2 Optimum time of and conditions for collection

The clinician's sampling tissue and fluids are responsible for the timing of collections (Refer to Selection of appropriate container). The specimen must be clearly labelled. Once collected, place the specimen into a plastic specimen bag and seal the bag. Wash your hands and dispose of clinical waste into a yellow clinical waste collection bag. Sharps must be disposed of safely.

5.3 Health and safety issues pertaining to sample collection

Every clinical specimen sent for histology or cytology examination should be treated as potentially infectious. Standard precautions must be observed at all times.

With patients known to be infected, or if there is a strong suspicion that they may be infected with a high-risk organism (e.g., tuberculosis), then procedures likely to produce aerosols must be conducted whilst wearing face masks, goggles or full facial visors as appropriate. Such investigations include cough inducing procedures and lancing of an abscess.

Used sharps must be disposed of according to Trust policy (see Safe Handling and Disposal of Sharps Policy & Guidelines). This is the responsibility of the individual(s) who generates them.

It is the responsibility of the person collecting the specimen to ensure that it is properly labelled and safe for transportation (see Transportation of Samples).

Refer to appropriate Trust policies for further information:

- Hand Hygiene and Skin Care Policy (including scrubbing gowning and gloving)
- Standard Infection Control Precautions Policy
- Safe Handling and Disposal of Sharps Policy & Guidelines
- Transportation of Samples

5.4 Sampling Checklist

The 'PROCESS' acronym is useful to ensure all specimen collection and transport of Cellular pathology Samples are optimally handled:

Positively identify the patient

Remember to add the label to the specimen

Observe Trust policy when taking the sample

Confirm (if appropriate) the details with the patient

Ensure the pot and request form details are correct and match

Seal/package the specimen correctly

Send to the laboratory promptly – Do not batch – dispatch.

6 SAMPLE CONTAINERS

6.1 Supply of specimen containers

The following Cellular Pathology consumables can be obtained from the following locations:

Consumable	Description	Issue from
	Green form (histology and non-gynae cytology requests) For locations that do not have access to ICE only	Materials Management Team
	Blue Forms Histology only	Materials Management Team
	Pre-filled 10% Formalin Biopsy Pots (60ml) Suitable for biopsies and small resections	Materials Management Team
	Specimen containers – Small/Medium/Large Addition of Neutral Buffered Formalin required. Suitable for tissue resections.	Materials Management Team
	Universal containers (sterile and empty) Suitable for CSF,	Materials Management Team
	Urine Specimen Container Kits are made up by the laboratory	Materials Management Team/Non-Gynae Cytology Laboratory
	Sputum/Sample container	Materials Management Team

Andrology kits and FNA needle washings and fixatives are provided by the department. Please contact the laboratory.

6.2 Selection of appropriate container

Please see Repertoire Index for the selection of appropriate container for test.

Sample containers must be CE marked. Specimen containers must be leak proof and be sufficiently robust to withstand stresses during transit. Only containers approved by the Cellular Pathology Department may be used to ensure sample integrity during transit to the Laboratory. Samples that are sent in non-approved containers may not be processed by the Laboratory. It is the responsibility of the person sending the sample to the Laboratory to ensure that the container used for transportation is appropriate.

The container must be adequately closed to avoid leakage. Samples that have leaked in transit may not be processed by the Laboratory.

For testing which requires fresh tissue, the specimen can be sent in a white specimen bucket or universal container. This must be sent to the Histology department on the day during opening hours. If this is not possible, the sample must be refrigerated until the next day.

6.3 Labeling of sample containers

Clinical governance requires the sample container to be labelled with sufficient information to provide an unequivocal link with the request form and the patient from whom they are collected.

Pre-printed addressograph labels are acceptable on sample containers for Cellular Pathology investigations.

Minimum Data Set for Identification:

- Patient's surname
- Patient's forename (initial is acceptable)
- Date of birth and /or district number / NHS number

Failure to comply with correct guidance may result in the sample being rejected by the Cellular Pathology department (refer to Sample Acceptance Criteria).

Multiple samples taken from a patient MUST be labelled on the sample container with the number and state the site of tissue for example 1=oesophageal, 2= gastric etc. The request form should be labelled accordingly to allow clear specimen location to be identified.

7 REQUEST FORMS

All samples must be accompanied by a properly completed request form. Failure to comply with correct guidance may result in the sample being rejected by Cellular Pathology (refer to Sample Acceptance Criteria).

7.1 Electronic requesting (ICE)


ICE Classic.url

Please use electronic requesting (ICE) order-comms where available using ICE Classic
Please ensure that you order the correct test and select the correct sample type as failure to do so may lead to incorrect testing.

The information required is the same as that required on a handwritten request form and should include clinical details and symptoms, as well as tissue type and location as required. Print the form to accompany the sample. Ensure the form matches the sample being sent.

In the event of IT downtime follow the ward contingency plans.

Where ICE requesting is not available handwritten request forms must be used.

7.2 Handwritten request forms

Minimum Data Set for Identification:

- NHS/Hospital number
- Patient surname and forename (in full, not initials)
- Date of birth (DOB)
- Patient address if hospital number/NHS number not supplied

In addition to the minimum data set for patient identification please ensure all other relevant fields are completed:

- Ward/ Practice, Consultant/GP
- Patient address
- Patient gender
- Date and time of collection
- Specimen type
- Investigation(s) required
- Name of requesting clinician and bleep/contact number
- Relevant clinical details
- Copy reports, if required
- Patient category (PP/AQP/NHS)

It is essential to use a ballpoint pen when completing request forms. Use of felt tip and fountain pens can lead to delay in processing samples, or requests being missed altogether, as carbon copies are often incomplete. When addressograph labels are used, please ensure that a label is fixed to EACH part of the request form.

7.3 Anonymous/uniquely identified samples

In rare circumstances patient identification details are intentionally hidden or substituted with particular ID numbers (for example, Sexual Health, donor samples, samples from unconscious or incoherent patients). This is more likely to affect other pathology disciplines, but in such instances, a properly coded identifier must be used in place of the patient last name and first name.

Unidentified Patients

Samples from unconscious or incoherent patients should be labelled with "UNKNOWN MALE OR FEMALE" and the emergency unit number.

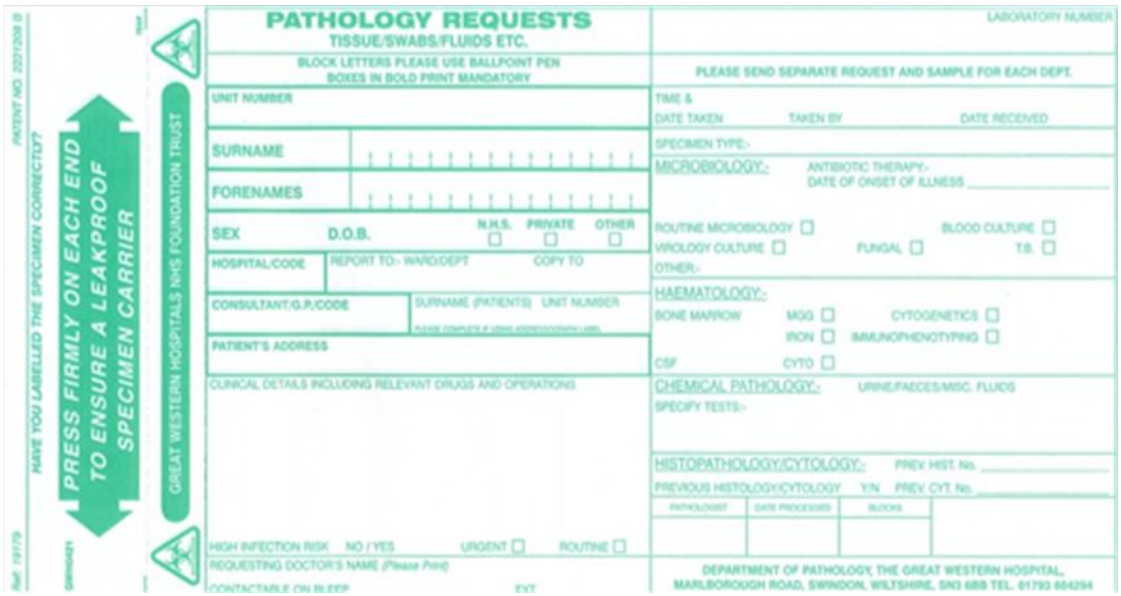
All request forms must be signed.

7.4 Cellular Pathology request forms

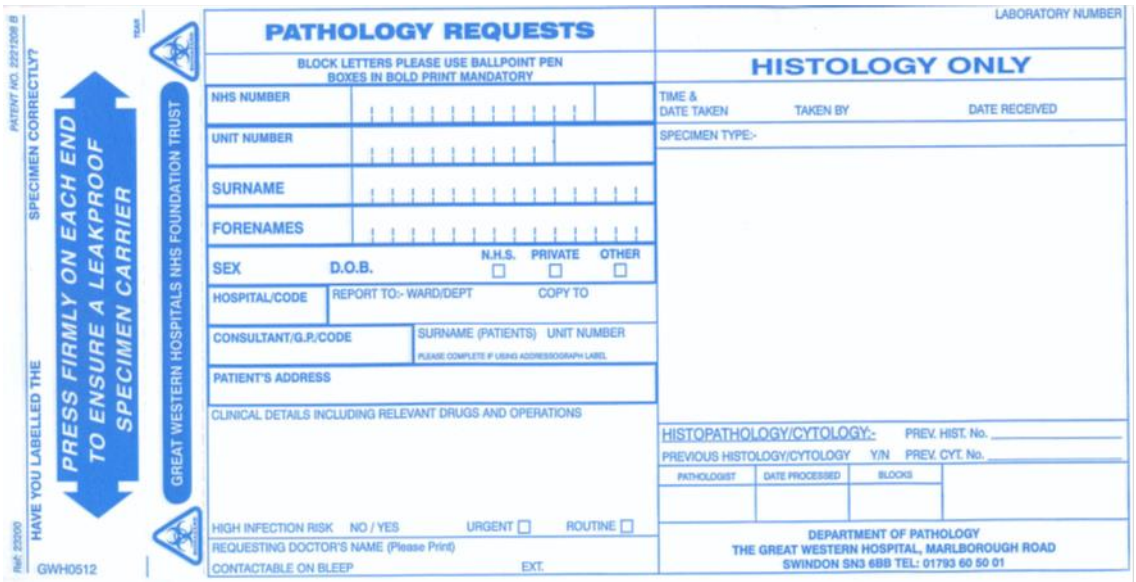
When requesting a Cellular Pathology investigation, please do not mix with samples intended for another department. Each pathology test should have a separate request form. When completing any of the cellular pathology requests forms patient should be aware that financial information may be collected from request form - information for billing purposes, financial audit, resource management and utilization reviews.

The following request forms are used by the department, each are accepted for requests:

GREEN FORM: Histology/Cytology/Andrology Requests



BLUE FORM – HISTOLOGY ONLY Request Form



8 TRANSPORTATION OF SAMPLES

Please refer to the Trust Specimen Transportation Policy for the correct procedures for submitting samples to the laboratory.

8.1 Transportation of routine samples to the laboratory

All sample containers for transport to the Laboratory must be sealed in a plastic bag attached to the request form.

For larger samples requiring larger specimen pots, the form must be placed in the plastic bag and attached securely to the specimen pot.

For transportation of samples to the laboratory from external sites or by post, and use of the pneumatic chute system, please refer to the Trust Specimen Transportation Policy.

In cases of difficulty or further clarification, the laboratory enquiry telephone number is 01793 604798.

8.2 Transportation of urgent samples

Urgent samples must be sent to the laboratory immediately and arrangements made with the portering service.

To discuss an urgent sample with the Laboratory: telephone 01793 604278. Requests may be directed to the Laboratory manager or Consultant Pathologist.

9 HIGH RISK SAMPLES

All samples should be regarded as potentially infectious.

Certain samples from patients who are known or suspected to have the following diseases/conditions constitute a potential higher risk of infection to persons handling the samples:

Requests for reports on specimens from patients known to have or suspected of having Transmissible Spongiform Encephalopathy (TSE), Tuberculosis (TB), Human Immunodeficiency Virus (HIV), hepatitis infection, Viral Haemorrhagic Fever (VHF), Covid-19 or any other category 3 or 4 pathogen must be clearly labelled as such and sent fixed and double bagged, marked with a biohazard label on both the request form and specimen container.

It is preferred that histology samples of this nature are fixed in formalin prior to receipt into the department to allow adequate fixation and lower the sample risk.

For non-gynae cytology/Andrology samples/fresh tissue if necessary (e.g., Lymph nodes), to minimise the risks ensure that such samples are packaged as follows:

- Attach a "Danger of Infection" label to the sample container and request form for all qualifying samples (available from Phlebotomy Department, GWH)
- Specify the nature of the risk on the request form
- Use unambiguous and commonly recognised terminology
- Place the sample in a sealable plastic bag and close the seal

This is a necessary procedure to safeguard both laboratory staff and other downstream workers. The labels must be used in accordance with the Trust Specimen Transportation Policy.

Samples thought to constitute a risk to laboratory staff because of inadequate packaging or warning may be rejected.

These lists are not exhaustive and rarely other biological agents that can cause severe human disease, and present a serious hazard to employees, may be present in samples. If there is any suspicion of a high risk atypical organism advice on sample collection and transport should be sought from the Consultant Pathologist.

10 SAMPLE ACCEPTANCE CRITERIA

Sample acceptance criteria ensure adequate identification for Cellular Pathology samples and request forms in order for them to be accepted by the laboratory for analysis.

The laboratory will make every effort to ensure requests are processed in a safe and timely manner, but it is essential that request forms and samples are labelled appropriately and legibly in compliance with this policy. It is also important to clearly identify the investigations required with relevant supporting information. Inadequate or inaccurate labelling results in delays before results are available and hence affect patient care. If you have any doubts regarding this policy, please ring the relevant department for further information.

The requesting clinician is responsible for the correct completion of the request form and the correct labelling of the sample.

It is the requester's responsibility to ensure that all details are correct, clearly written and that the sample details match those on the form and patient wrist band (if applicable).

Any labelling discrepancy will be included on the pathology report.

Samples will **not** be accepted for analysis if:

- There is no unique identification of the patient i.e. they do not meet the minimum data set for identification
- There is an incorrect sample type or tube
- Incorrect transportation conditions
- Sample is received in a hazardous condition e.g. leaking or sharps attached

- Sample or request form is unlabelled or incorrectly labelled with less than the minimum data sets for patient identification
- Mismatch of details between the form and sample(s)
- The information provided is illegible. Clinical detail is important and should be included and interpretable on the request.

Inadequately or inaccurately labelled samples or forms will not be accepted unless they are considered to be unrepeatable or reproducible. An assessment of acceptance will be made by the Consultant Pathologist and/or Laboratory Manager or Advanced Biomedical Scientist on an individual basis. The risk to the patient of rejection of the sample will be weighed against the risk of acceptance of a wrongly labelled sample. Cellular Pathology will accept no responsibility for samples analysed which initially failed to meet the acceptance criteria and will issue a disclaimer on such reports.

Where no analysis is performed, an appropriate comment will be included on the pathology report. The event may be reported as an incident on the Trust incident report system.

11 REPERTOIRE OF TESTS

This section covers the tests that the Cellular Pathology department offers according to the service repertoire agreed with our users.

With each test we provide the following information where appropriate:

- Name of test
- Examinations offered
  - Which sample containers are required
  - What specimen type is required
  - What sample volume is required
  - Which request form should be used
- Sample instructions
  - Collection of the specimen
  - Specimen transportation requirements
  - Specimen storage requirements
  - Special requirements for performing this examination
- Laboratory information
  - What test will be performed
  - Measurement units of examination performed
  - Biological reference intervals of examination performed
  - Turnaround time of examination performed
  - When the test is available
- Clinical information - Factors known to significantly affect the results

11.1 Referred Tests

Following routine histology/cytology assessment, the laboratory provides a range of specialist testing which is undertaken at reference centres. This encompasses molecular testing, immunohistochemistry testing and flow cytometry. Downstream testing is usually requested following initial reporting and follow up discussed at Multi-disciplinary team meetings (MDTs). Please contact the laboratory on Telephone 01793 604278 for details of the tests offered, name and location of the testing laboratory and information regarding any special sample requirements.

The parameters analysed in referred tests and any reference ranges for these parameters will be displayed on the report when it is returned to the requestor.

11.2 Unaccredited Tests

The GWH Cellular Pathology laboratory is very keen to ensure it is completely clear to users which of its tests are UKAS ISO 15189 accredited and to positively demarcate these from those assessments that are not accredited.

The ongoing arrangements to seek referral laboratories that have the send-away test UKAS ISO 15189 (or equivalent) accredited still apply. The list of referral laboratories and the tests that the GWH sends to them can be inspected in Section 12.

At current time the following tests are unaccredited:

- Immunohistochemistry
- Andrology

The laboratory would ask if the UKAS Accredited status of any test whatsoever is not totally clear or might seem the least equivocal please contact us without delay

Cellular Pathology Manager (Interim) Malcolm Goodwin malcolm.goodwin1@nhs.net

Deputy Cellular Pathology Manager Louise Hacker l.hacker@nhs.net

Histology – Biopsies/Small resections (fixed)

Biopsies of tissue from all sites placed in 10% neutral buffered formalin.

Examinations offered			
Collection container	**Specimen**	**Sample volume**	**Request form**
	Tissue	Not standard (see below)	Blue/Green
Sample instructions			
Collection	GP Surgery/Theatre surgical procedures including punch biopsy, curettage, incisional, excisional and resection tissue. Samples should be placed in fixative immediately, and not allowed to dry out. Samples should be free floating, alternatively place in larger containers.		
Specimen transport	Specimens should be sent to the laboratory in a timely manner. Pre-filled formalin pots assure sample integrity, laboratory receipt during normal working hours.		
Storage requirements	Outside of normal working hours samples should be placed in 10% neutral buffered formalin at room temperature.		
Special requirements	Clinical details and biopsy site are required for processing Container lids must be correctly fitted to avoid spillage. Include any information of potential infection.		
Laboratory information			
Tests	Histology – Specimen preparation of Formalin-Fixed Paraffin embedded Block (FFPE) and subsequent slide production.		
Measurement units	mm or g		
Biological reference units	N/A		
Turnaround time	7 days (urgent samples) up to 6 weeks (routine samples)		
Availability	Routine hours.		
Clinical information			
Factors known to significantly affect the results	Inadequate fixation. The standard ratio of fixative to tissue volume is 10:1. Lower volumes can be used if frequent changes of the fixative are carried out to prevent exhaustion. Users must ensure samples are sent in formalin. Samples are required to have optimal fixation time prior to processing through the laboratory. Temperature can affect tissue fixation rates.		

Histology – Large samples/resections (fixed)

For larger tissue that do not fit pre-filled biopsy specimen containers. The specimen container should be appropriate for the tissue volume.

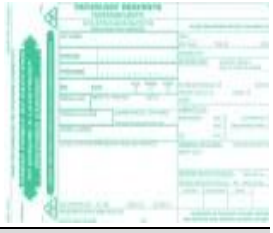
Examinations offered			
Collection container	**Specimen**	**Sample volume**	**Request form**
	Tissue	Not standard (see below)	Blue/Green
Sample instructions			
Collection	Samples sent from theatre. Sample container should be appropriate to tissue size to allow adequate fixation. 10% neutral buffered formalin must be added to the specimen container, samples must not be left fresh to dry out. Samples should be free floating, alternatively place in larger containers.		
Specimen transport	Specimens should be sent to the laboratory in a timely manner. Laboratory receipt required during normal working hours.		
Storage requirements	Outside of normal working hours samples should always be placed in 10% neutral buffered formalin at room temperature.		
Special requirements	Clinical details and sample anatomical site are required for processing Container lids must be correctly fitted to avoid spillage. Include any information of potential infection.		
Laboratory information			
Tests	Histology – Specimen preparation of Formalin-Fixed Paraffin embedded Block (FFPE) and subsequent slide production for pathological assessment.		
Measurement units	mm or g		
Biological reference units	N/A		
Turnaround time	7 days (urgent samples) up to 6 weeks (routine samples)		
Availability	Routine hours.		
Clinical information			
Factors known to significantly affect the results	Inadequate fixation. The standard ratio of fixative to tissue volume is 10:1. Lower volumes can be used if frequent changes of the fixative are carried out to prevent exhaustion. Users must ensure samples are sent in formalin. Samples are required to have optimal fixation time prior to processing through the laboratory. Temperature can affect tissue fixation rates.		

Histology – Fresh Tissue

The department does not undertake much fresh tissue sampling. No frozen tissue service is available. Occasionally fresh tissue may be submitted

Examinations offered			
Collection container	**Specimen**	**Sample volume**	**Request form**
	Fresh Tissue	To fit sterile container	Blue/Green
Sample instructions			
Collection	Theatre surgical procedures, often lymph nodes or BCC skin specimens. Sterile containers should be used. The specimen must be placed in a clean, dry container and sealed with a well -fitting lid. Extreme care must be taken to avoid contamination of the outside surfaces of the container.		
Specimen transport	Specimens should be sent to the laboratory immediately. The laboratory should be pre-notified on all fresh samples as laboratory receipt MUST be during normal working hours.		
Storage requirements	Samples must be sent direct to the lab. In unforeseen circumstances refrigerate (2-4°C) and contact the lab at the earliest opportunity.		
Special requirements	Clinical details and biopsy site are required for processing Fresh sample containers must be placed in a clear specimen bag and the request form kept separate from the sample container. Include any information of potential infection.		
Laboratory information			
Tests	Touch preparations for cytological assessment. Histology – Specimen preparation of Formalin-Fixed Paraffin embedded Block (FFPE) and subsequent slide production for pathological assessment.		
Measurement units	mm		
Biological reference units	N/A		
Turnaround time	7 days (urgent samples) up to 6 weeks (routine samples following FFPE)		
Availability	Within laboratory routine hours. The laboratory should be contacted prior to collection and at time of sending the specimen.		
Clinical information			
Factors known to significantly affect the results	Drying out of samples if laboratory receipt is delayed. Please inform the laboratory of any suspected biohazards. Label the forms and specimen containers accordingly. Samples must be discussed with the laboratory.		

Cytology - Respiratory samples

Examinations offered			
Collection container	**Specimen**	**Sample volume**	**Request form**
	Bronchial aspirate Transthoracic aspirate Bronchoalveolar lavage Transtracheal aspirate Bronchial brushings* Bronchial washings Sputum EBUS**	Minimum volume 1ml Maximum volume 25ml	Green 

Sample instructions	
Collection	All specimens should be fresh for optimal assessment. Sputum: Best results are achieved with freshly obtained sputa following chest physiotherapy, with an early morning sputum before the patient has eaten Contamination with large amounts of saliva or food leads to inadequate specimens. *Bronchial brushings follow FNA procedure.
Specimen transport	Specimens should be sent to the laboratory without delay during normal working hours.
Storage requirements	Outside of normal working hours samples should be refrigerated (2-4°C) Delays of over 48 hours are undesirable.
Special requirements	Include relevant clinical details. Ensure sample containers are sealed. Include any information of potential infection. **EBUS samples must be sent direct to the laboratory for urgent handling.

Laboratory information	
Tests	Cytological assessment to exclude or confirm presence of malignant cells.
Measurement units	ml
Biological reference units	N/A
Turnaround time	7 days
Availability	Routine hours.

Clinical information	
Factors known to significantly affect the results	All samples are suitable for overnight refrigeration. Some specimens may require refrigeration over the weekend. Delays in transportation may affect cell analysis. Any specimen handling delay may allow overgrowth of bacteria. Cytology assessment is primarily for cytological assessment of the presence of cancer cells. Consider other pathology discipline tests such as microbiology for the investigation of pathogens etc.

Cytology - Urine Specimens

Examinations offered			
Collection container	**Specimen**	**Sample volume**	**Request form**
	Urine	200 ml maximum	Green 

Sample instructions	
Collection	An adequate urine sample is the second voided of the day, preferably mid-morning or random. Urine can be collected from catheters as well as washings from the bladder or upper urinary tract. The request form must state the method of collection. Urine kits (large 400ml container with yellow lid with patient instructions) can be obtained from the Cellular Pathology department.
Specimen transport	Specimens should be sent to the laboratory without delay during normal working hours.
Storage requirements	Outside of normal working hours samples should be refrigerated (2-4°C). Delays of over 48 hours are undesirable.
Special requirements	Ensure sample container lids are secured and ideally kept upright for transportation. Include relevant clinical details. Include any information of potential infection.
Laboratory information	
Tests	Cytological assessment to exclude or confirm presence of malignant cells.
Measurement units	ml
Biological reference units	N/A
Turnaround time	7 days
Availability	Routine hours.
Clinical information	
Factors known to significantly affect the results	All samples are suitable for overnight refrigeration. Some specimens may require refrigeration over the weekend. Delays in transportation may affect cell analysis. Any specimen handling delay may allow overgrowth of bacteria. Cytology assessment is primarily for cytological assessment of the presence of cancer cells. Consider other pathology discipline tests such as microbiology for the investigation of pathogens etc.

Cytology – Serous Fluid

Examinations offered			
Collection container	**Specimen**	**Sample volume**	**Request form**
 	Peritoneal washings Pleural fluid Peritoneal fluid Ascetic fluid Pericardial fluid	Minimum volume 1ml Maximum volume 25ml	Green 

Sample instructions	
Collection	All specimens should be fresh for optimal assessment.
Specimen transport	Specimens should be sent to the laboratory without delay during normal working hours.
Storage requirements	Outside of normal working hours samples should be refrigerated (2-4°C). Delays of over 48 hours are undesirable.
Special requirements	Ensure containers are correctly sealed. Include relevant clinical details. Include any information of potential infection.
Laboratory information	
Tests	Cytological assessment to exclude or confirm presence of malignant cells
Measurement units	ml
Biological reference units	N/A
Turnaround time	7 days
Availability	Routine hours.
Clinical information	
Factors known to significantly affect the results	All samples are suitable for overnight refrigeration. Some specimens may require refrigeration over the weekend. Delays in transportation may affect cell analysis. Any specimen handling delay may allow overgrowth of bacteria. Cytology assessment is primarily for cytological assessment of the presence of cancer cells. Consider other pathology discipline tests such as microbiology for the investigation of pathogens etc.

Cytology – Synovial Fluid

Examinations offered			
Collection container	**Specimen**	**Sample volume**	**Request form**
	Synovial Fluid	Minimum volume 5ml	Green 

Sample instructions	
Collection	All specimens should be fresh for optimal assessment.
Specimen transport	Specimens should be sent to the laboratory without delay during normal working hours.
Storage requirements	Outside of normal working hours samples should be refrigerated (2-4°C). Delays of over 48 hours are undesirable.
Special requirements	Ensure containers are correctly sealed. Include relevant clinical details. Include any information of potential infection.
Laboratory information	
Tests	Cytological assessment to exclude or confirm presence of malignant cells
Measurement units	ml
Biological reference units	N/A
Turnaround time	7 days
Availability	Routine hours.
Clinical information	
Factors known to significantly affect the results	All samples are suitable for overnight refrigeration. Some specimens may require refrigeration over the weekend. Delays in transportation may affect cell analysis. Any specimen handling delay may allow overgrowth of bacteria. Cytology assessment is primarily for cytological assessment of the presence of cancer cells. Consider other pathology discipline tests such as microbiology for the investigation of pathogens etc. Crystal analysis may be undertaken by Microbiology or Cytology when available. Please discuss with the laboratory as required.

Cytology – Cyst Fluid

Examinations offered			
Collection container	**Specimen**	**Sample volume**	**Request form**
 	Breast Ovarian Thyroid	Minimum volume 1ml Maximum volume 25ml	Green 

Sample instructions	
Collection	All specimens should be fresh for optimal assessment.
Specimen transport	Specimens should be sent to the laboratory without delay during normal working hours.
Storage requirements	Outside of normal working hours samples should be refrigerated (2-4°C). Delays of over 48 hours are undesirable.
Special requirements	Include relevant clinical details. Ensure sample containers are sealed. Include any information of potential infection.
Laboratory information	
Tests	Cytological assessment to exclude or confirm presence of malignant cells.
Measurement units	N/A
Biological reference units	N/A
Turnaround time	7 days
Availability	Routine hours.
Clinical information	
Factors known to significantly affect the results	All samples are suitable for overnight refrigeration. Some specimens may require refrigeration over the weekend. Delays in transportation may affect cell analysis. Any specimen handling delay may allow overgrowth of bacteria. Cytology assessment is primarily for cytological assessment of the presence of cancer cells. Consider other pathology discipline tests such as microbiology for the investigation of pathogens etc.

Cytology – CSF

Examinations offered			
Collection container	**Specimen**	**Sample volume**	**Request form**
	CSF	2 ml or less	Green 

Sample instructions	
Collection	All specimens should be fresh for optimal assessment. CSF samples are liable to degenerate rapidly and as such must be prepared immediately.
Specimen transport	Specimens should be sent to the laboratory without delay as they degenerate rapidly - during normal working hours.
Storage requirements	Outside of normal working hours samples should be refrigerated (2-4°C). Delays of over 48 hours are undesirable.
Special requirements	Include relevant clinical details. Ensure sample containers are sealed. Include any information of potential infection.
Laboratory information	
Tests	Cytological assessment to exclude or confirm presence of malignant cells.
Measurement units	N/A
Biological reference units	N/A
Turnaround time	7 days (usually results are confirmed sooner)
Availability	Routine hours.
Clinical information	
Factors known to significantly affect the results	Delays in transportation may affect cell analysis. If absolutely necessary samples will be analysed following refrigeration overnight but quality may be compromised. Any specimen handling delay may allow overgrowth of bacteria. Cytology assessment is primarily for cytological assessment of the presence of cancer cells. Consider other pathology discipline tests such as microbiology for the investigation of pathogens etc.

Cytology – Fine Needle Aspirates (FNA)

Examinations offered			
Collection container	**Specimen**	**Sample volume**	**Request form**
 Containers are provided by the laboratory.	Breast Lymph Node Lung Bronchial Brushings Other sites	Needle washings 2 x Air Dried slides 2 x Fixed Slides	Green 

Sample instructions	
Collection	All specimens should be fresh for optimal assessment. Follow FNA procedure.
Specimen transport	Specimens should be sent to the laboratory without delay as they degenerate rapidly - during normal working hours.
Storage requirements	Outside of normal working hours samples should be refrigerated (2-4°C). Delays of over 48 hours are undesirable.
Special requirements	Users are trained in the FNA procedure further details are available on the website and from the department. Needle washings and fixative available from the laboratory.
Laboratory information	
Tests	Cytological assessment to exclude or confirm presence of malignant cells.
Measurement units	N/A
Biological reference units	N/A
Turnaround time	7 days (usually results are confirmed sooner)
Availability	Routine hours.
Clinical information	
Factors known to significantly affect the results	Delays in transportation may affect cell analysis. If absolutely necessary samples will be analysed following refrigeration next day but quality may be compromised. Any specimen handling delay may allow overgrowth of bacteria. Cytology assessment is primarily for cytological assessment of the presence of cancer cells. Consider other pathology discipline tests such as microbiology for the investigation of pathogens etc.

Andrology Samples – Post Vasectomy

Examinations offered			
Collection container	**Specimen**	**Sample volume**	**Request form**
	Semen	Complete ejaculate	Green 

Sample instructions	
Collection	GP Surgery/Clinic provides the kits which contain a patient information leaflet and toxicity tested specimen pots. The department does not provide a facility for specimen production on-site.
Specimen transport	Specimens should be submitted to pathology reception within 1 hour of production.
Storage requirements	Samples should be kept as near to body temperature as possible in transit such as inside pocket.
Special requirements	Appointments for sample submission **must** be pre-arranged with the laboratory as per the patient information leaflets.
Laboratory information	
Tests	Samples are analysed for the presence or absence of sperm following Vasectomy.
Measurement units	Number of sperm/percentage
Biological reference units	Contact laboratory for further information
Turnaround time	3 days
Availability	The service is provided Tuesday, Wednesday and Thursday 08:30 to 11:30 with appointment times from 08:40 to 11:40 only. These times might change due to limited laboratory staffing capacity. Failure to follow procedure will result in rejection of samples for analysis.
Clinical information	
Factors known to significantly affect the results	Delayed sample submission, failure to follow patient instructions. . Clinicians should complete the histology request form and indicate date of vasectomy for submission with the patient instruction leaflet.

Andrology Samples – Fertility Analysis

Examinations offered			
Collection container	**Specimen**	**Sample volume**	**Request form**
	Semen	Complete ejaculate	Green 

Sample instructions	
Collection	GP Surgery/Clinic provides the kits which contain a patient information leaflet and toxicity tested specimen pots. The department does not provide a facility for specimen production on-site.
Specimen transport	Specimens should be submitted to pathology reception within 1 hour of production.
Storage requirements	Samples should be kept as near to body temperature as possible in transit such as inside pocket.
Special requirements	Appointments for sample submission **must** be pre-arranged with the laboratory as per the patient information leaflets.
Laboratory information	
Tests	Samples are analysed for parameters of concentration, number morphology and motility for the requesting clinician to interpret.
Measurement units	Number of sperm/percentage
Biological reference units	**SEMINAL PARAMETER** / **COMMENTS** **Ejaculate volume** – The volume of the ejaculate measured in millilitres (ml) **Sperm concentration** – Millions sperm per ml of ejaculate (millions/ml) **Sperm morphology** – Percentage of sperm with 'normal' morphology (%) **Sperm motility** – The motility of at least 200 sperm is assessed (at 37°C) and expressed as the percentage showing progressive, non-progressive or immotile. **Total sperm number** – Millions per Ejaculate **Semen PH** – PH of the semen sample ≥7.2
Turnaround time	3 days
Availability	The service is provided Tuesday, Wednesday and Thursday 08:30 to 11:30 with appointment times from 08:40 to 10:40 only. These times might change due to limited laboratory staffing capacity.
Clinical information	
Factors known to significantly affect the results	Delayed sample submission, failure to follow patient instructions. Clinicians should complete the histology request form.

12 REFERENCE LABORATORIES

As part of the testing process, it may be necessary to refer some, or all, of the sample to an external reference laboratory which has the necessary expertise. In some cases, there will be only one specialist laboratory in the whole country which performs a particular test, meaning using referral laboratories is essential.

There is a detailed policy in place to govern how we choose these referral laboratories. They are selected for their expertise and their quality standards and are regularly checked for their accreditation status.

The name of the reference laboratory used will be indicated on the Cellular Pathology report.

All tissue is processed and slides produced in-house, however some cases are sent for external primary diagnostic reporting to link with the network MDTs. Urology specimens are sent to North Bristol NHS Trust Southmead Hospital and Poundbury Cancer Institute for primary reporting. Gynaecological specimens, testes and thyroid are sent to Oxford University Hospitals NHS Foundation Trust John Radcliffe Hospital. Occasionally non screening programme breast specimens are sent to Poundbury Cancer Institute to cover consultant Histopathologists leave.

The reference laboratories currently used are:

Laboratory	Address	CPA/UKAS accreditation	Examinations offered
Royal University Hospitals NHS Trust Bath	Cellular Pathology Royal United Hospital Coombe Park Bath BA1 3NG	Accredited to ISO 15189:2012 - 9402	Second/Expert opinion MDT review - Cytology link for screening and colposcopy biopsies.
Birmingham University Medical School	University of Birmingham Medical School Department of Clinical Immunology Vincent Drive Birmingham B15 2TT	Accredited to ISO 15189:2012 - 9556	Flow Cytometry
North Bristol NHS Trust	Cellular Pathology Southmead Hospital Westbury on-Tyne Bristol Avon BS10 5NB	Accredited to ISO 15189:2012 - 8067	Primary reporting of Urology cases Second/Expert Opinion MDT review Immunohistochemistry test referrals
Royal Brompton & Harefield NHS	Department of Histopathology	Accredited to ISO 15189:2012 - 8818	Second/Expert Opinion

Laboratory	Address	CPA/UKAS accreditation	Examinations offered
Foundation Trust	Royal Brompton Hospital Sydney Street London SW3 6NP		
Cheltenham General Hospital Gloucestershire NHS Foundation Trust	Histopathology Cheltenham General Hospital Sandford Road Cheltenham Gloucestershire GL53 7AN	Accredited to ISO 15189:2012 - 9577	Second/Expert Opinion
Genomic Health	Genomic Health Inc 301 Penobscot Drive Redwood City California 94063 USA	CLIA Certificate No. 05D1018272	Oncotype-DX Breast Cancer Assay
Royal Marsden NHS Foundation Trust	Department of Histopathology Royal Marsden Hospital Fulham Road London SW3 6JJ	Accredited to ISO 15189:2012 - 9929	Second/Expert Opinion
National Amyloidosis Centre	Centre for Amyloidosis University College London Rowland Hill Street London NW3 2PF	Accredited to ISO 15189:2012 - 8040	National Referral Centre for Amyloidosis
Oxford University Hospitals NHS Foundation Trust	Cellular Pathology John Radcliffe Hospital Headley Way Headington Oxford OX3 9DU	Accredited to ISO 15189:2012 - 8415	Second/Expert Opinion Primary Diagnostic Reporting of gynaecological, thyroid and testes cases. Technical work MDT Review
Oxford University Hospitals NHS Foundation Trust	Histopathology Nuffield Orthopaedic Centre Windmill Road Headington Oxford OX3 7HE	Accredited to ISO 15189:2012 - 8683	Second/Expert Opinion MDT Review
Oxford University Hospitals NHS Foundation Trust	Medical Genetics Laboratory Churchill Hospital Old Road Headington	Accredited to ISO 15189:2012 - 8694	Cytogenetic testing Molecular Testing

Laboratory	Address	CPA/UKAS accreditation	Examinations offered
	Oxford OX3 7LE		
Source Bioscience UK Ltd	Pathology Services Source Bioscience UK Ltd 1 Orchard Place Business Park Nottingham NG8 6PX	Accredited to ISO 15189:2012 - 9571	Molecular Testing
UCL Hospital NHS Foundation Trust	Cellular Pathology University College London Hospital University Street London WC1W 6JJ	Accredited to ISO 15189:2012 - 8045	Second/Expert Opinion Immunohistochemistry test referrals
Synnovis Analytics LLP	Dermatopathology laboratory St John's Institute of Dermatology South Wing, Staircase C St Thomas' Hospital Westminster Bridge Road London SE1 7EH	Accredited to ISO 15189:2012 - 8126	Second/Expert Opinion Test referrals
Synnovis Analytics LLP	Head and Neck/Oral Pathology Laboratory Floor 4 Tower Wing Guy's Hospital, London SE1 9RT.	Accredited to ISO 15189:2012 - 8611	Second/Expert Opinion
Synnovis Analytics LLP	Genetics Laboratories 5th Floor, Tower Wing, Guy's Hospital Great Maze Pond London SE1 9RT	Accredited to ISO 15189:2012 - 8688	Molecular Testing
Poundbury Cancer Institute	Newborough House, 3 Queen Mother Square, Poundbury, Dorchester, Dorset, DT1 3BJ	Accredited to ISO 15189:2012 - 9387	Primary External Reporting of non-screening programme breast cases MDT cover Molecular Testing

13 PATIENT CONSENT DISCLOSURE

12.1 Laboratory Policy on protection of personal information

The Cellular Pathology Department regards the lawful and correct treatment of patients' personal information as vital to successful operations and to maintaining the confidence of users of the service. Request form information may additionally be used for billing purposes, financial audit, resource management and utilisation reviews.

Our policy is that we will treat personal information lawfully and correctly in adherence to the principles of data protection described in the Data Protection Act 1998.

As part of the Great Western Hospital NHS Foundation Trust we also work to its governance and data protection policies which incorporate the Data Protection Act, the Department of Health Confidentiality NHS Code of Practice, and Department of Health Security Management NHS Code of Practise, as listed below:

- Information Governance Strategy and Policy
- Information Protection and Security Policy
- Information Asset Register Procedure
- Data Protection Policy
- Data Transfer Policy
- Data Quality Policy
- Code of Conduct for Employees in Respect of Confidentiality Policy
- Freedom of Information Requests Procedure
- Consent for Medical Treatment for All Patients at the Great Western Hospital Policy

All the above Trust policy documentation is available upon request to the Laboratory Manager on 01793 604277.

12.2 Patient consent

Consent to a specimen being taken and analysed is implied by the patient presenting to the point of specimen collection. The responsibility for obtaining informed consent for the tests(s) resides with the individual ordering the test. Informed consent should cover all the tests being done, implications of their results and disclosure of clinical and personal details to personnel (in the requesting organisation and any other healthcare organisations involved in providing the test). Special procedures, including more invasive procedures, or those with an increased risk of complications to the procedure, will need a more detailed explanation and, in some cases, written consent.

Patients in a hospital bed should normally be given the opportunity to refuse.

For most routine laboratory procedures the laboratory assumes that patient consent has been obtained for the investigations requested, as the patient has presented themselves and willingly submitted to the usual collecting procedure.

In emergency situations consent may not be possible. Under these circumstances the laboratory will carry out the necessary investigations provided they are in the patient's best interest.

12.3 Medico-legal samples

Any specimens submitted for medico – legal purposes should have documentation accompanying these specimens to provide an unbroken chain of evidence.

12.4 The Human Tissue Act

Great Western Hospitals NHS Foundation Trust is licensed by the Human Tissue Act (HTA) to undertake examinations of post mortem samples submitted by clinical consultants and pathologists. Under the license, the samples may be retained until the examination has been completed and in line with the sample retention policies.

It is the obligation of the requesting clinician or pathologist to ensure that examination of samples they submit have been requested by the coroner where applicable or appropriate consent has been obtained from the deceased person or their relatives.

Only the specific examinations requested by the sending clinician or pathologist may be performed. It must be assumed that the coroner has not asked for any other examinations to be performed and consent has not been obtained for any other work and so this would be outside the scope of the licence.

All relevant material is stored securely and under conditions which maintain the integrity of the sample if possible and confidentiality is maintained in compliance with Caldicott principles, as are all samples received. Following processing, relevant material is only retained for the period specified by the retention policy.

13 FEEDBACK ON OUR CELLULAR PATHOLOGY SERVICE AND COMPLAINTS PROCEDURE

Any complaints should be directed to the Laboratory Manager or Consultant Lead.

Any suggestions from users on how this user guide could be improved would be welcome for inclusion in future editions. Please forward suggestions to the Laboratory manager.

We welcome any suggestions for service improvements.