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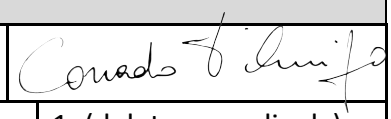
Authorised by:	Dr. C. D'Arrigo	**Authorised signature:**	
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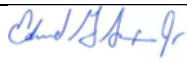
Document Review History

Version No	Review Date	Action Taken	Reviewed by	Signature
1.0	08/09/16	Updated clinical advice section, MU and Quality policy	G Sweet	
2.0	05/07/17	P7 Improved section concerning Specimen Advice to include optimal fixation for certain tests and time limits	G Sweet	
2.1	31/01/18	P10-12 Revision and improved sections concerning clinical advice, interpretation and referrals	G Sweet	
2.2	07/08/18	P3/4 Reference to UKAS schedule P12 Reference to PCR referral sites removed P13 Removal of reference to DPA	G Sweet	
2.3	12/03/19	Appendix 1 Reference to IBMS Sample and RF ID criteria guidance	G Sweet	
2.4	03/11/20	P8 – Specimen advice for molecular testing added, P11 referral laboratories reviewed and updated.	S. Diaz McLynn	
2.5	30/10/21	No change in content. Updated date with Quality Policy.	A Jurkiewicz	*Jurkiewicz*
2.5	31/01/22	P3 to include molecular service (PCR), IBMS link updated p14, p18 current molecular request form added (all from AUD101)	R de Havilland	
2.6	13/06/24	P1 – Corrected spelling error in "D'Arrigo". P15 – Updated the link to the current WHO Guidance on Regulations for the Transport of Infectious Substances.	E Saxon	
2.7	07/08/24	P18 – Added updated Molecular RF	E Saxon	
2.8	13/02/25	Update against ISO15189:2022	A Jurkiewicz	
3.0	15/04/26	New site for molecular testing added	A Jurkiewicz	

PCI LABORATORY HANDBOOK

Table of Contents

INTRODUCTION

Poundbury Cancer Institute is accredited to ISO15189 and seeks to provide a high quality comprehensive analytical, interpretive, advisory and consultancy service that is responsive to the needs of our patients and clients.

PCI is committed to maintaining a safe working environment, a highly skilled workforce and utilising up to date technology to deliver the right result on the right specimen from the right patient that is accurate, properly interpreted and delivered within a clinically appropriate timescale.

About us

Location:
Newborough House – main location
3 Queen Mother Square,
Poundbury,
Dorchester,
Dorset DT1 3BJ
Tel: +44 (0)1305 756485
The Old Cereal Factory – molecular service
Peverell Avenue East,
Poundbury,
Dorchester,
Dorset, DT1 3WE
Tel: 07485 386913

The laboratory provides a wide range of services including routine paraffin processing, special stains, immunocytochemistry, in situ hybridisation, molecular (PCR) and whole slide imaging for on site or remote diagnosis. Further details of individual tests may be found within the schedule supplied to UKAS for assessment under ISO15189 Medical Laboratories – Requirements for Quality and Competence.
https://www.ukas.com/wp-content/uploads/schedule_uploads/00007/9387-Medical-Single.pdf

The following sub-specialties of histology are covered by in-house pathologists

- Breast
- Urology
- Gynaecology
- Upper and Lower GI
- Respiratory
- Lymphoma
- Dermatology
- Head and neck
- Endocrine
- Soft tissue and bone

Consultant Histopathologists from PCI are able contribute to all relevant multi-disciplinary team meetings by video conferencing.

PCI Team

The service is led by the Laboratory Director, Dr Corrado D'Arrigo MBBS PhD FRCPath who is responsible for overall leadership, management commitment, risk management, quality and service review. The Director is supported by experienced consultant colleagues, qualified HCPC registered Biomedical scientists, laboratory scientists, medical laboratory assistants and administrative staff.

GOVERNANCE AND QUALITY

Poundbury Cancer Institute is committed to providing an analytical, interpretative and advisory service of the highest quality and shall be aware and take into consideration the needs and requirements of its users. Whilst the laboratory is ISO15189 accredited to the scope of work contained in the schedule (link above) there may be other tests and procedures provided by PCI which at any given time may not yet have been assessed by UKAS such as new antibodies/biomarkers. These will be subject to an extension to scope process. PCI may also elect not to include certain test within the accredited scope. Users can find information about current PCI repertoire on PCI website: www.poundburycancerinstitute.org – downloads.

Quality Policy

Form
Title: Quality Policy

Poundbury Cancer Institute
For Personalised Medicine

QUALITY POLICY

Poundbury Cancer Institute is committed to providing a service of the highest quality and shall be aware and take into consideration the needs and requirements of its users.

In order to ensure that the needs and requirements of users are met, Poundbury Cancer Institute will:

- Operate a quality management system to integrate the organisation, procedures, processes and resources.
- Set and maintain quality objectives and plans in order to implement this quality policy.
- Ensure that all personnel are familiar with this quality policy to ensure user satisfaction.
- Commit to the health, safety and welfare of its entire staff. Visitors to the department will be treated with respect and due consideration will be given to their safety while on site.
- Uphold professional values and is committed to good professional practice and conduct.
- Provide examinations that fulfil their intended use.
- Identify and mitigate actual and potential risk to patient care

Poundbury Cancer Institute will comply with standards set by ISO 15189, CQC, UKAS, and The Human Tissue Authority and is committed to:

- Making sure that all staff are familiar with the contents of the PCI Quality Manual and all policies and procedures relevant to their work
- Staff recruitment, training, development and retention at all levels to provide a full and effective service to its users
- The proper procurement and maintenance of such equipment and other resources as are needed for the provision of the service
- The treatment of patient's sample and remains with due care and respect
- The collection, transport and handling of all specimens in such a way as to ensure the correct performance of laboratory examinations
- The use of examination procedures that will ensure the highest achievable quality of all tests performed and are fit for their intended use
- Reporting results of examinations in ways which are timely, confidential, accurate and clinically useful
- The assessment of user satisfaction, in addition to internal audit and external quality assessment, in order to produce continual quality improvement.
- Comply with all relevant environmental legislation
- Conform to confidentiality in accordance with The Data Protection Act, Information Governance policies and Caldicott Guidelines.

Signed on behalf of Poundbury Cancer Institute

Conrado D'Arrigo

....**Date**.....2nd December 2025

Document No: PQM2
Author: Dr. C. D'Arrigo
Review Date: 02/12/2025

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Version No: 2.4
Issue date: 02/10/17
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Internal Quality and External Quality Assurance

Internal quality processes include:
Sample acceptance processes (SOP) for identity and integrity
Sample processing procedures
Audit of quality: equipment, procedures, staff competency and reporting
Equipment supplier maintenance service contracts
Key performance indicators
Internal methods quality control
Use of validated and verified methods/technologies with estimated uncertainty measurement if applicable
Use of industry standard equipment
Continuous quality improvement programme

External quality
PCI subscribes to relevant National external quality assurance schemes:
UKNEQAS Cellular Pathology Technique (CPT) UK
NEQAS Immunocytochemistry and In situ Hybridisation (ICC & ISH)
Molecular Genetics (EMQN)

Consultant staff are participants in all relevant Regional and subspecialist EQA schemes including:
Wessex General Histopathology
Uropathology EQA
Dermatopathology EQA
Gynae EQA
GI EQA
NHS Breast Screening Programme EQA
NHS Bowel Cancer Screening Programme

A schematic of workflow and tracking points is provided in Appendix 5.

OPENING HOURS

Core opening hours are 08.30 – 17.30 Monday – Friday.
In order to provide a flexible and comprehensive service there is an out of hours service through the evening until 20.00hrs including weekends, if required. Any urgent situation that requires longer opening hours shall be agreed upfront with PCI Operations Manager or Laboratory Director.

SUBMITTING SPECIMENS

Request forms and Specimen labelling
Specimens are accepted on the understanding that patients have consented to the specimen collection and subsequent laboratory procedures.

PCI operates a very strict zero tolerance approach to all requests. In order to fulfil the provision of safe and reliable tests, the laboratory is required to ensure the correct and accurate receipt of specimens and matching request forms. Specimens lacking the mandatory information will be referred to senior staff who will assess whether the sample can be processed or should be returned to the requesting clinic/ward/practice for amendment, therefore incurring in delays.

For this reason, it is essential when sending a specimen, that it is accompanied by a request form correctly and legibly completed by a clinician responsible for the care of the patient. All sections of the form should be completed.
Please provide all relevant clinical information since reports may be delayed if further inquiry has to be made by pathologists in cases with insufficient or illegible clinical information.
Please provide also information regarding danger of infection status if known or suspected. Specimens must be labelled in such a manner to provide an unequivocal link with the patients from whom they are collected.

Failure to follow this procedure will result in delayed testing and ultimately delayed receipt of the final report and results. The User guide in Appendix 1 summarises the PCI Sample acceptance requirements for both the request form and specimen/s.

Request forms and specimen bags can be requested from PCI via the contact number as above or email pci.lab@nhs.net. For significant volumes of work PCI will provide a bespoke request form in consultation with a client.

SPECIMEN ADVICE

Specimens for routine Histology should be submitted to the laboratory in 10% buffered formalin (3.7 – 4% w/v Formaldehyde). Containers and prefilled with formalin are available from PCI by contacting the number above. Please ensure that the lids of specimen containers are properly secured to avoid leakage of formalin.
Specimens should be labelled with all demographic details and specimen details on the side of the container **NOT** the lid and contained within a sealed leak proof specimen bag. Containers must be place within a sealed, leak proof specimen bag and request forms must be placed in a different compartment separate from the container. If specimen is shipped to PCI, please ensure that it is transported according to UN3373 requirements (see Appendix 2).

Histology specimens should be excised and handled with care. If small specimens such as endoscopic biopsies, punch biopsies, small skin biopsies etc are crushed or allowed to dry out accurate histological diagnosis may be impossible. This may also lead to a degree of uncertainty of measurement within the result being provided.
'Fixation' of specimens in formalin is the crucial first step in the histology process and should not be delayed unnecessarily. Certain immunohistochemical and molecular testing regimes require fixation within certain time limits for optimum results. For example, HER2 for breast cancer requires fixation optimally between 6-72 hours. Please discuss with the laboratory if there is any doubt concerning fixation or delays to transport which might impact upon the requested investigations. Considerable artefacts will occur also if the sample is allowed to dry before fixation therefore it is important to immerse the samples in formalin as soon as possible. This is especially important with very small samples, where dehydration can be very rapid.

PCI advises that a check of details on cards and specimens be made before specimens are bagged for dispatch to the laboratory. Any unacceptable transcription errors (as noted under zero tolerance above) may result in the specimen being returned to the source. This will cause longer turnaround times and delays in diagnosis which may cause breach of targets.
For molecular testing, a FFPE block (preferred), a minimum of 5 unstained and unbaked coated slides or both should be provided, accompanied by a correctly filled request form and case report. Additional slides that are relevant for the case could also be provided (ie. Original H&E, IHC).

HIGH RISK SPECIMENS

Specimens from individuals known, or suspected to have Blood Borne Viruses (BBV) eg. Hepatitis or HIV, as well as TB and transmittable prion disease should have the a 'Danger of Infection' label attached to each specimen and on the accompanying request form.
Clinical details on the request form should be adequate to convey information of the suspected hazard to the staff who handle the specimens. To maintain patient confidentiality during transit to the laboratory, it is recommended to seal the specimen and request form in a suitable envelope.
Specimens presenting a risk of infection for the laboratory include:

- unfixed or partly fixed tissues and organs
- any body fluid

Specimens containing open source radiation (for instance sentinel lymph nodes) should be labelled as radio-active specimen and be accompanied by information of the amount of radioactivity included in the sample, the type of radioisotope and the date of administration of the radioactivity.

TRANSPORT OF SPECIMENS TO THE LABORATORY

PCI is able to provide dedicated courier services for specimen transport by arrangement or alternatively PCI will accept specimens form users who may wish to provide their own courier or send by post. PCI can provide advice for users for safe transport of specimens.

Strict regulations for transporting specimens by road or post apply in the UK.
All specimens transported to the Laboratory via Taxi, Private Courier, or Post must be packaged in compliance with UN packing instruction P650. The outside of the package must be clearly labelled 'UN 3373'. See appendix 2.
All couriers' vehicles contracted to PCI carry pathological samples are equipped with compliant specimen transport cases.

HEALTH AND SAFETY ADVICE FOR HANDLING FORMALDEHYDE

Histological fixative is a 4% solution of formaldehyde in water (otherwise known as 10% buffered formalin). Formaldehyde at this concentration is classified under COSHH regulations as harmful. It is sensible to avoid all contact with skin and inhaling fumes. Repeated exposure to formaldehyde can lead to sensitisation. The following safety information is printed on the label of all histology specimens:

- **Possible risk of irreversible effects.**
- **May cause sensitisation by skin contact.**
- **In case of contact with eyes rinse immediately with water and seek medical advice.**
- **Use only in well ventilated areas.**
- **Wear suitable protective clothing and gloves.**
- **In case of accident or if you feel unwell seek medical advice immediately.**

Spillage advice

In the event of a small spillage (up to 100ml) ventilate the area, put on gloves and apron and dilute the spill with water and mop up the fluid with tissue paper. Put the tissue into a polythene bag and seal it and then double bag. This can be disposed of into normal waste. Keep the area ventilated until the spillage site is dry.

In the event of a large spillage of formalin (over 100ml), warn others to keep away from the area. Contact your local COSHH advisor or spillage response team for immediate remedial action or telephone PCI 01305 756485. Ventilate the area well; wear a respirator if necessary along with other protective clothing. Use spillage absorption granules or pads to soak up the spillage (special formalin neutralising granules or pads are available). Collect up the granules/pads and double bag them and wash the area well with water and then mop this up. Keep the area well-ventilated until the spill area is dry. Used spillage granules should be incinerated with clinical waste.

Further advice and information in Appendix 3.

ROUTINE SPECIMENS

Wet - Specimens for routine histology should be sent totally immersed in 10% buffered formalin (4% Formaldehyde). Please note the warning on the label. Ideally the formalin should be 10 times the volume of the tissue and as a minimum 3 times the volume. Please use the correct sized container. Please see 'Specimen Advice' section above.

Slides/Blocks - Un/stained slides and paraffin tissue blocks must be sent securely in such a way that there is no threat to the specimen integrity/breakage in transit. PCI can advise if required.

URGENT SPECIMENS

If a report is required urgently, please state clearly on the request form when it is required for, where it is to be sent and also a contact name and phone or bleep number. Patients being treated under cancer wait pathways should be clearly indicated on the request card.

If you wish to speak to someone about your requirements, please telephone PCI on 01305 756485 and ask to speak with a Heady/Deputy Head of Laboratory or Consultant Histopathologist. It is, under special circumstances, possible to provide a report on the same day as a biopsy is taken but this can only be done by prior arrangement. Small biopsies received before 17.00 will be processed overnight and reported as per SLA.

SPECIMENS SENT 'DRY'

Please note that we would advise that Histology specimens are always fixed due to the transport times of these samples. If you are in any doubt please contact PCI on 01305 756485.
If dry specimens are not transported to the laboratory immediately, within a short timeframe and handled correctly on arrival it can result in compromised quality of the subsequent histological examination and report. This may also lead to a degree of uncertainty of measurement within the result being provided. Small biopsies, endoscopic specimens will dry out within minutes, especially if left on absorbent paper and compromise the result.

If a specimen is to be sent to the laboratory 'dry', i.e. not in formalin, it is very important to inform PCI beforehand by telephone so that appropriate transport and handling arrangements can be discussed and made. Always use a standard formalin label as the specimen will be placed in formalin when received in the department.

CLINICAL ADVICE AND REPORTS

Clinical advice and Interpretation

PCI provides the following services:

- Interpretation of slides for primary diagnosis

- Interpretation of slides for second opinion
- MDT (multidisciplinary team meeting) participation, including review of cases

Consultant Histopathologists are available to provide clinical advice on diagnostic reports on an open access basis during PCI normal working hours.

Report Availability

All Histopathology reports, once authorised are available remotely via secure login to the web based laboratory information management system (LIMS) or can be directly sent via secure e-mail address to the requestor (subject to agreement). Hard copies of all reports are available by request. This site also includes a link to register as a user.

Click on the Interactive login tab and your details – ID and password. Once logged in:

- There is an option to search by a number of parameters including case reference, name (first,last), date range.
- When a list of results for the correct patient is retrieved, click the pdf file to the right of the patient listing to open the specific specimen result details.
- If required print or save the file locally
- Click the X to close the pdf file to exit
- If a case is not reported the system will provide an indication of the status of the request such as ALW (Additional Laboratory Work)
- ***Please attempt to find your results on the browser.*** If you cannot find the ones you want, contact PCI where the staff should be able to help you.

For PCI users not requiring an on site diagnostic service but a routine Histology processing service through to whole slide imaging, the scanned images will be available for reporting via the LIMS in a manner similar to above.

REFERRAL OF CASES TO OTHER PRACTITIONERS FOR SECOND OPINIONS

When cases require second opinions for interpretation, they are referred to practitioners (either histopathologists or clinical scientists) with relevant expertise. For these referrals, the principles described in the Royal College of Pathologists guidance (Guidance on inter-departmental dispatch of histopathology material for referral and clinical trials – G137) will be followed.

MEASUREMENT UNCERTAINTY

The opinion described in a Histopathology report must be interpreted within the clinical findings and a judgement made. If any Histopathology report contradicts clinical findings, please discuss the case with the Consultant Histopathologist.

In clinical laboratory testing there are potential ‘uncertainties’ that can affect results (for example; poor specimen collection or transport, patient related factors such as biological variation and the presence of drugs, or other interfering factors).
In addition, the analytical process itself is subject to some degree of inherent variability and this is often referred to as the “reproducibility” or “imprecision” of the methods employed. Laboratories regularly monitor this by the use of internal quality control samples within each batch of analysis and by comparing the results of external quality assurance schemes designed to ensure that results are comparable with other laboratories using similar methods.

Despite these control measures it must be recognised that variation can occur. Macroscopic and microscopic measurements are an approximation and should be viewed within clinical context. The routine processes of fixation, processing, orientation and subsequent staining can have an effect on the size and shape of tissues which can invalidate stated measurements. The relevance of a particular result or a change in value must be considered in light of both the reproducibility of the method and the biological variation within the patient tissue. If in doubt concerning the significance of a result a member of the laboratory or relevant clinical staff should be contacted to help guide interpretation.

Providing relevant clinical details at the time that the request is made can also clarify the significance of a particular result or a change in results

REFERRAL OF SPECIMENS TO OTHER LABORATORIES/SERVICES

When PCI is not able to provide an element of service within its assessed repertoire or there is a requirement for a second consultant opinion it will be necessary to refer certain investigations and to an approved relevant provider. PCI will ascertain whether referral laboratories/services are accredited and current to National or International applicable standards. Examples include but are not limited to:

ISO 15189 (Medical laboratories -- Requirements for quality and competence),
ISO 17043 (Conformity assessment -- General requirements for proficiency testing),
or any other relevant recognised standard.

At present the Referral centres used are as follows:

Immunocytochemistry and in situ hybridisation investigations: HSL-AD London, Royal Marsden, Dorset County Hospital NHS FT.
Immunofluorescence: St John's Institute of Dermatology, St Thomas' Hospital, London (Synnovis Analytics LLP).
Molecular testing: Royal Marsden, Manchester University NHS FT, University Hospital Birmingham
Special Stains: Synnovis LLP, Cellular Pathology, London.

This list is not exhaustive (***list available under PGM25I9***). If there is a technique not listed here but is required for diagnosis, the referral labs will be contacted in order to facilitate the use of their testing repertoire.

HISTOLOGY TURNAROUND TIMES (HOURS) – not concordant with PCI website

Average turnaround times (from receipt of wet specimen to a report) are listed below. Inevitably some cases, particularly complex cases, cases requiring prolonged decalcification or cases requiring tertiary referral will take longer:

Request type	TAT (days)
Urgent cases	By arrangement
Routine biopsies (core bx, endoscopic bx etc)	3-5
Cancer resection specimens	7-10
Routine diagnostic Histology	3-7
Molecular (BRAF/NRAS, EGFR, KRAS, PIK3CA)	2-3
IHC (incl. PD-L1, Her-2, MMR)	1-2

Further Information

For clinical information on a specific case or report callers should speak to a Consultant Histopathologist. Please phone 01305 756485 and you will be put you through to the correct Consultant Histopathologist. For scientific/technical inquires callers should contact a Biomedical Scientist or the Head of Laboratory at PCI on the above number or email pci.lab@nhs.net.

STORAGE OF SAMPLES AND RECORDS

PCI retains samples and records according to the most recent guidance from the RCPath/IBMS – The retention and storage of pathological records and specimens.

- Histology wet samples are kept for 4 weeks after the final report has been authorised.
- Histology blocks and slides are stored for 30 years.
- Histology digital images are stored for 8 years (were possible).

COMPLAINTS PROCEDURE

Complaints may be lodged by various means in writing, electronically through e-mail, by telephone, web application, and in person.

On receipt of a complaint PCI will enact the provisions of its procedure (***PGM6***). PCI will aim to meet the following deadlines:

- Written complaints shall be acknowledged in writing within 2 working days by the Laboratory Director or Quality manager from date of receipt.
- Complaints shall be finalised within 2 weeks (14 days) of receiving the complaint.

When the *complaint* takes longer than 2 weeks to resolve/clear an interim report with a corrective action plan indicating when the final report is expected to be completed. This report shall be sent by PCI management to the complainant.

PROTECTION OF PERSONAL INFORMATION

PCI needs to collect and use certain types of information about the Individuals or Service Users who come into contact with ***PCI*** in order to carry out diagnostic work. This personal information will be collected and dealt with appropriately whether is collected on paper, stored in a computer database, or recorded on other material and there are safeguards to ensure this under the General Data Protection Regulation. The full procedure is contained within PCI's Data Protection policy (***PIT3***).

Poundbury Cancer Centre Ltd is registered with the Information Commissioner (ICO Ref ZA155750) and is the Data Controller under the Data Protection Act, which means that it determines what purposes personal information held, will be used for. It is also responsible for notifying the Information Commissioner of the data it holds or is likely to hold, and the general purposes that this data will be used for.

DOCUMENT LIBRARY

Information from the following documents have been used to inform this handbook.

Reference	Title
PQM1	PCI Quality Manual
PHS1	Health and Safety policy
PGM1	Sample Acceptance policy
PGM32 F32 PGM32 F66	Request Forms

Appendix 1 – Sample acceptance policy – user guide

The PCI Sample acceptance policy sets out the requirements for adequate and safe identification of Histopathology specimens to enable processing and analysis. The mandatory elements must be included on BOTH specimen and request form. Other essential information is also required and stated below.

Mandatory Labelling Requirement	Action by Laboratory if requirement not met
Specimens AND Request forms MUST be labelled with 3 unique identifiers from: • Unique identification number • Patient's full name • Date of birth (not age and ONLY if patient's name given) If a unique identification number has not been provided as part of the minimum data then the current residential patient address must be provided on the request form.	No analysis will be performed. The event will be referred to a senior member of staff and may be reported as an incident. Where the specimen is unrepeatable/ unreproducible as with Histology specimens, the risk to the patient of rejection of the specimen will be assessed against the risk of acceptance of a wrongly labelled specimen. There will be a discussion with the client and/or responsible clinician. PCI will accept no responsibility for specimens analysed which initially failed to meet the acceptance criteria and will issue a disclaimer on such electronic records and/or reports.
The request form data MUST match the above information on the specimen or be labelled with another suitable unique identifier.	
Multiple specimens taken at different times on a patient MUST be labelled on the specimen container with the time (24 hr clock) when the specimen is taken. The request form should be labelled accordingly.	
Request forms SHALL also contain: • Patient's location/destination for the report (or a location code) • **All relevant clinical information** • Name of Consultant or GP • Name of the requester and contact number • Biological Sex • Date and time of specimen procedure • Anatomical site and type of specimen • Investigation required • Patient address	A lack of patient or specimen information may result in the laboratory not conducting the analysis / examination or a delayed report. It may not be possible to issue a report or to interpret results. Appropriate comments will be made on the report where this can be issued.
Correction fluid MUST not be used to alter Patient details. Other alterations require a legible signature of a responsible clinician or delegate.	

Ref: Patient Sample and Request Form Identification Criteria – Institute of Biomedical Science Version 5 2024
https://www.ibms.org/resource/ibms-patient-sample-guidance.html

Appendix 2 Packaging of pathological samples for transport by road or post

Packaging of pathological samples for transport by road or post
Further information is available from WHO Guidance on Regulations for the Transport of Infectious Substances: 9789240089525-eng.pdf (who.int)

Category A and Category B Classification For transport reasons, pathogens are assigned to either Category A or Category B.

Category A: an infectious substance which is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals. E.g. cultures of *B*. *Anthracis*, *S. dysenteriae*, or specimens from patients suspected to be suffering from viral haemorrhagic fever.
Infectious substances meeting Category A criteria which cause disease in humans or both humans and animals are assigned the United Nations number UN2814.Those which cause disease in animals only are assigned to UN2900.
Specimens or cultures classed as Category A should be packed according to Packing Instructions P620. Please see WHO Transport of Infectious Substances as above.

It is recommended that packaging once used, should be discarded and never re- used
Specimens or cultures which fall into this category must be transported in Category A packaging, by specialist courier, following the procedures described in MC.SOP.054 Urgent Referral by Courier.

Category B: an infectious substance which does not meet the criteria for inclusion in Category A. Infectious substances in Category B are assigned to UN3373 and must be transported in compliant packaging. These packages may be transported by road, by Royal Mail and by dedicated courier services. Specimens or cultures classed as Category B should be packed according to Packing Instructions P650. This type of packaging may be recycled & used again, provided it is not contaminated or damaged.

Appendix 3 Information for Users – Formalin/Formaldehyde

FORMALDEHYDE/FORMALIN (NEUTRAL BUFFERED OR FORMAL SALINE)

USE: 10% Formalin is supplied by PCI for the preservation (fixation) of tissue specimens for Histological investigation.

COMPOSITION: 10% Formalin consists of:-

Formalin solution	10% (3.7-4% w/v Formaldehyde)
Methanol	(1-10%)
Buffer salts or Sodium Chloride	0.9% in water

Formaldehyde is a colourless, pungent, heavier than air, irritating gas.
Formaldehyde solution (Formalin) is a saturated solution of Formaldehyde gas in water (37 – 40% w/v)

HAZARDS: 10% Formaldehyde has limited evidence of a carcinogenic effect. Harmful by inhalation, ingestion and skin contact, irritating to respiratory system. May cause skin sensitisation.

PRECAUTIONS:

Use: In well ventilated areas, preferably over a sink. Wear disposable gloves (to standard EN374) if there is a possibility of skin contact. Wear eye protection if there is a possibility of splashing.

Store: At room temperature, in well sealed containers.

Spillage: Small spillages (up to 100ml) not contained within a sink area should be mopped up with a suitable absorbing material such as the supplied neutralising Formalizer pads and then placed into a sealed clinical waste bag or the waste bag provided. (if the spill is a leaking pot already contained within a sealed specimen bag place in another bag and transport to PCI). Small spillages contained within a sink area should be flushed away with a large volume of water.

Large spillages should be contained using suitable spillage granules (following the guidelines supplied with the granules), when the granules have absorbed and neutralised the formalin spill they should be disposed of in a clinical waste bag.

If the spill is in an enclosed area such as a transport vehicle, open all windows and ventilate the area before attending to the spillage.

PPE - GLOVES AND EYE PROTECTION MUST ALWAYS BE WORN WHEN DEALING WITH FORMALIN SPILLAGES

Products codes for a suitable formalin spillage granule kit or Formalizer pads may be obtained from the following:

Suppliers	Formalin Granules	Formalin Pads
CellPath	XSA-4000-00A	XSA-0300-0010

See below for First aid measures

FIRST AID MEASURES:

EXPOSURE ROUTE	**SYMPTOM**	**TREATMENT**
Inhalation	Coughing, wheezing, shortness of breath,	Remove from exposure, apply mouth to mouth or mechanical ventilation if necessary. In severe cases, or if recovery is not rapid or complete seek medical attention.
Skin contact	Irritation, reddening.	Drench the skin with plenty of water. Remove contaminated clothing and wash before reuse. If large area of skin is damaged or if irritation persists seek medical attention.
Eye contact	Blistering, reddening, watering.	Irrigate thoroughly with water with the eyelid held wide open. Obtain medical attention.
Ingestion	Stomach upset, nausea, vomiting.	Wash out mouth with water. DO NOT induce vomiting. If patient is conscious give water to drink. Seek medical attention.

For further information contact: PCI 01305 756485

Appendix 4 Request Form

HISTOPATHOLOGY REQUEST FORM

laboratory use only

Surname (block letters)		Forename	source: _____ location: _____	date sample taken
sex	date of birth	registration, NHS or hospital number	Clinician: _____ (block letters)	time sample taken
Patient address (or affix patients label here)			priority: ☐routine ☐urgent signature: _____	previous biopsy

Specimen 1 site:
site of marker suture:
☐excision ☐incision ☐punch ☐wedge ☐curettage ☐shave ☐IF ☐other

Specimen 2 site:
site of marker suture:
☐excision ☐incision ☐punch ☐wedge ☐curettage ☐shave ☐IF ☐other

Specimen 3 site:
site of marker suture:
☐excision ☐incision ☐punch ☐wedge ☐curettage ☐shave ☐IF ☐other

Specimen 4 site:
site of marker suture:
☐excision ☐incision ☐punch ☐wedge ☐curettage ☐shave ☐IF ☐other

Specimen 5 site:
site of marker suture:
☐excision ☐incision ☐punch ☐wedge ☐curettage ☐shave ☐IF ☐other

Specimen 6 site:
site of marker suture:
☐excision ☐incision ☐punch ☐wedge ☐curettage ☐shave ☐IF ☐other

clinical details

Pci
Diagnostic & Molecular
HISTOPATHOLOGY

Referring laboratory

Referring Lab specimen number ☐ *NHS* ☐ Private

Date of request

Lab contact name and telephone number

Patient's details

Name

Surname

Date of birth

Hospital or NHS number

Pci MOLECULAR Pathology Request form

Requesting Oncologist (if applicable) **telephone number:**

Email test results? ☐ no ☐ yes **email:**

SLA number: **(If no SLA number, please fill in details below)**

Invoice to:

Address:

Billing contact name: **email:** **telephone:**

Return address for blocks/slides:

Tests requested									
Lung	☐ EGF-R pcr	☐ ALK	☐ ROS1	☐ NTRK		☐ KRAS^{G12C}	☐ HER2 amp	☐ HER2^{Exon20ins}	☐ PD-L1 (TPS)
	☐ MET^{Ex14skip}	☐ MET fusion	☐ RET fusion	☐ PIK3CA pcr		☐ BRAF^{V600E}		☐ PD-L1 (atezo, (SP142, TC/IC)	
CRC	☐ KRAS pcr	☐ NRAS pcr	☐ BRAF pcr	☐ BRAF^{V600E}	☐ MMR (IHC)	☐ PIK3CA pcr	☐ Her2 (IHC)	☐ HER2 (IHC+/-	☐ PD-L1 (CPS)
Upper GI	☐ BRAF^{V600E}	☐ Her2 (ICH)	☐ HER2 (DDISH)	☐ HER2 (IHC+/-ISH)		☐ Claudin18.2	☐ Her2 (IHC+/-ISH) +/- PD-L1		☐ PD-L1 (pembro)
	☐ EBER	☐ p53	☐ E-cad	☐ β-cat	☐ MMR (IHC)	☐ GC mol. classification			☐ PD-L1 (nivo)
Melanoma	☐ NRAS pcr	☐ cKIT pcr	☐BRAF pcr	☐ BRAF^{V600E}		☐ PRAME	☐ BAP-1	☐ myPATH	☐ PD-L1 (28.8)
	☐ NTRK	☐ ROS1	☐ ALK	☐ Spitz panel		☐ TERT			
Prostate	☐ PIN4 (CK5/p63/K167/racemase)			☐ ERG/PTEN	☐ MMR (IHC)	☐ Prolaris	☐ tumour-BRCA1/2		
Gynae	☐ p16/Ki-67		☐ HER2						☐ PD-L1 (CPS)
	☐ tumour-BRCA1/2	☐ germ line-BRCA1/2		☐ POL-E pcr	☐ MMR (IHC)	☐ p53	☐ EC mol. classification		
Head & Neck	☐ p16/Ki-67				☐ MMR (IHC)			☐ PD-L1 (nivo)	☐ PD-L1 (pembro)
Bladder			☐ MMR		☐ PD-L1 (nivo)	☐ PD-L1 (atezo +/- pembro)		☐ PD-L1 (pembro)	☐ PD-L1 (atezo)
Breast	☐ AR ☐ ER ☐ PR	☐ Her2 (IHC)	☐ Her2-Low	☐ HER2 (DDISH)		☐ Her2 IHC +/- DDISH		☐ PD-L1 (atezo +/- pembro)	☐ PD-L1 (atezo)
	☐ tumour-BRCA1/2	☐ germ line-BRCA1/2		☐ PIK3CA pcr		☐ Oncotype	☐ Endopredict	☐ IHC4	☐ PD-L1 (pembro)
Other	(specify test)								

Important:

- Please attach <u>non anonymised</u> histopathology report to enable identification since we need to link the patient to the tissue received.
- Reporting molecular tests requires clinical information; please provide relevant previous histopathology reports and/or a clinical summary.
- For pcr work, please send paraffin blocks.
- For on slide tests, paraffin blocks preferred; alternatively <u>unbaked</u> sections on good quality coated slides with sufficient blank space all around.

Post to: Poundbury Cancer Institute, Newborough House, 3 Queen Mother Square, Poundbury, Dorchester, Dorset, UK, DT1 3BJ

Enquiries: +44 (0)1305-756485 **Email:** lab@histo.org

For PCI Lab use only

Date received:

H&E
Cut by:
Date:

Evaluated by:
Date:

Size of tissue (estimate mm²):
Tumour cell % :

Is there sufficient material to perform DNA extraction? ☐Yes ☐No

How many curls/slides should be used:

Is micro dissection needed? ☐Yes ☐No

Curl(s)
Cut by:
Date:

Slide(s)
Cut by:
Date:

Macro dissection
by:
Date:

DNA

Extraction by: Date:

DNA concentration (ng/µl):

qPCR

Test performed by: Date:

PGM32F98 August 2024

the difference we make ... is identifying our differences

Appendix 5 Workflow and Tracking

POUNDBURY CANCER INSTITUTE
For Personalised Medicine