

patho nomics

USERS GUIDE

Version 2.3

Abstract

To provide general and informative information to our users

Classification: Public

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GENERAL INFORMATION

Pathognomics Ltd is situated in units 11/12 within Halycon Court, Huntingdon and provides a bespoke routine diagnostic work to the private sector and to the NHS as to assist in their maintenance of work flow. We also provide research support to a variety of institutions.

We have a full team of consultant histopathologists covering all specialties and a team of HCPC registered biomedical scientists.

We are currently registering for ISO 15189 accreditation.

Pathognomics Ltd.
Unit 11
Halcyon Court
St Margaret's Way
Huntingdon
Cambridgeshire
PE29 6DG

OPENING HOURS

Monday to Friday 8:30 am to 5:30 pm

CONTACT INFORMATION

EMAILS:

Accounts: accounts@pathognomics.com

General: info@pathognomics.com

Research and clinical trial work: research@pathognomics.com

Report queries: support@pathognomics.com

Deliveries issues: operations@pathognomics.com

Coroner's queries: coroners@pathognomics.com

Laboratory manger: chris@pathognomics.com

PHONE NUMBER

This can be used for queries: 01480453437

STAFF MEMBERS

Head of Service: Dr Luis Beltran

Deputy Head of Service: Dr Dorota Markiewicz

Laboratory manager and operational director: Mr Christopher Evagora

Project Director: Mr Alec Hirst

SPECIALITIES

The department offers full histopathology service on all specialties, listed below;

- Dermatopathology
- Gastrointestinal
- Hepatobiliary
- Renal Biopsy
- Endocrine
- Male Genitourinary
- Gynae
- Neuropathology
- Lung Pathology
- Soft Tissue
- Lympho - reticular
- Breast
- Paediatric and Perinatal
- Head and Neck
- Muscle
- Cytology
 - Gynae and Non-gynae – currently we can only report on slides, we cannot process cytology specimens
 - Cytosponge preparation

The facility can also carry out sub-specialities which includes:

- Immunohistochemistry
- Immunofluorescence
- Sentinel Node - examined using the EORTC method
- Alopecia

Some additional testing may be carried out by referral ISO 15189 accredited laboratories (e.g. molecular studies, EM, or more specialised immunohistochemistry stains).

REQUEST FORMS

All specimens must be accompanied by a request form. Supplies of these are available by either contacting info@pathognomics.com or downloading a PDF version from the website.

If you do not have suppliers, then please use the Histopathology Request Form currently in use at your location

LABELLING THE FORM AND THE SPECIMEN

Both specimen container and request form must be completed as fully and as legibly as possible. Both should be labelled with:

- Patient's Full Name
- Patient's date of birth
- Patient's hospital number (if available)
- Name of Consultant
- Site of specimen.

In addition, the request form should contain:

- Patient's sex
- Previous biopsy numbers if known
- Full clinical details including history
- Site of biopsy
- Clinical diagnosis
- Previous surgery and relevant drug therapy
- Date of biopsy
- The name and signature of the requesting clinician.

REJECTION CRITERIA

It is the responsibility of the requester to ensure that samples are correctly labelled and request forms are completed to agreed standards. Before accepting a clinical specimen, laboratory staff must ensure that certain minimum criteria for sample identification are met. Below is a list of criteria we look for. To accept a specimen a minimum of three should be present. **One of which must be Patients full name or unique coded identifier**

<p>Sample</p>	<ul style="list-style-type: none"> • NHS or CHI number • Patients full name or unique coded identifier • Date of birth and/or hospital number ONLY if patients name given • Date and time • Nature of sample, including qualifying details, eg left, distal etc especially if more than one sample per request is submitted
<p>Request Form</p>	<ul style="list-style-type: none"> • NHS or CHI number • Patient's full name or unique coded identifier • Date of birth and/or hospital number ONLY if patients name given • Gender • Patient's location and destination for report • Patient's consultant, GP or name of requesting practitioner • Investigation(s) required • Clinical information including relevant medication (which is sometimes essential) • Date and time sample collected (which is sometimes essential) • Patient's address including postcode • Practitioner's contact number (bleep or extension)

If the minimum of three identification is not met the specimen is then returned to requesting client for re labeling.

Unlabeled specimens or request forms will not be accepted and will be returned for appropriate action. Discrepancies between specimen container and request form will be noted on the issued report.

TRANSPORTATION OF SPECIMENS

MEDIA FOR FIXATION

The specimen should be placed into an appropriate container of sufficient size to allow it to move freely without causing distortion. It should be completely covered by the fixative and securely sealed.

Specimen Type	Fixation Medium
<i>Routine Histology</i>	10% Buffered Formal Saline
<i>Testicular Biopsies</i>	Bouins medium (Aids in the preservation of delicate architecture of the tissue)
<i>Direct immunofluorescence</i>	Michels Medium
Cytosponge	Bd Surepath preservative

CONTROL

PACKAGING

Specimens must be sent in accordance to the type of specimen being sent.

It is the senders' responsibility to ensure that specimens are safely packaged in accordance with the Post Office regulations for the transport of biological material. Please contact the laboratory if you require further classification.

Specimen type	Time Frame	Temperature
<p><i>Histological Specimen – Small biopsies and specimens</i></p>	<p>Small samples do not require incision to aid fixation therefore there is no real time frame.</p> <p><i>NOTE: Over fixation can lead to poorer immunohistochemistry results so next day is recommended</i></p>	<p>These can be delivered and stored at room temperature and therefore temperature does not need to be monitored.</p> <p><i>NOTE: cold temperatures will slow down the chemical reaction and the specimen will take longer to fix</i></p>
<p><i>Histological specimens – Large specimens</i></p>	<p>As these specimens need to be incised as to aid fixation, they must be delivered in 24 hours (next day) so the specimen can be treated appropriately.</p> <p><i>NOTE: any later than this can slow down fixation to the specimen and may cause damage to the tissue</i></p>	<p>These can be delivered and stored at room temperature and therefore temperature does not need to be monitored.</p> <p><i>NOTE: cold temperatures will slow down the chemical reaction and the specimen will take longer to fix</i></p>

<p><i>Histological specimens – Postmortem Tissue</i></p>	<p>As these come in small pieces they can be treated as small biopsies therefore no real time frame.</p> <p><i>NOTE: Over fixation can lead to poorer immunohistochemistry results so next day is recommended</i></p>	<p>These can be delivered and stored at room temperature and therefore temperature does not need to be monitored.</p> <p><i>NOTE: cold temperatures will slow down the chemical reaction and the specimen will take longer to fix</i></p>
<p><i>Immunofluorescence</i></p>	<p>Initially the Michels Medium and the specimen should be kept in the fridge at 4°C, up to shipment, and then the specimen must be sent within 48 hours</p>	<p>During transport it is fine for the specimen to remain at room temperature.</p> <p><i>NOTE: before and after transport the specimen must be kept at 4°C</i></p>
<p><i>Slides for Review / Reporting</i></p>	<p>No time frame is necessary as once cover-slipped slides are protected.</p>	<p>Can be shipped at room temperature therefore no monitoring required.</p>
<p>Cytosponge</p>	<p>Once the sponge is in the preservative the sample should be shipped as soon as possible (within 5 days at least)</p>	<p>Can be shipped at room temperature therefore no monitoring is required</p> <p><i>NOTE: after transport, the specimen must be kept at 4°C</i></p>

ON-CALL PROVISION

There is no 'on-call' service provided by the laboratory. All requests for work, which may involve staff working outside normal laboratory hours, should, in the first instance, be emailed to enquiries@pathognomcis.com and the laboratory will discuss with pathologist and staff to see if the request can be fulfilled and a response will be given.

URGENT REPORTING

If a case is urgent please indicate on the request form and the specimen will be dealt with accordingly.

CLINICAL ADVICE

Our consultant pathologists are happy to give clinical advice and interpretation.

In the first instance please contact the laboratory on 01480 1453 437 who will be able to direct you to the correct specialist or reporting consultant.

TURN AROUND TIMES

Specimen	Turn Around time
<i>Small Biopsy Specimens</i>	Provided that the specimen is received in the laboratory before 2pm, the majority will be reported the next working day and the report issued.
<i>Large and unfixed Specimens</i>	These specimens require additional fixation and the report will be delayed by at least 24 hours. The majority will be reported within 2 working days of receipt.
<i>Exceptions</i>	<p>Specimens requiring immunocytochemistry or special stains.</p> <p>Specimens where the pathologist feels a second opinion may be of benefit to the patient.</p> <p>Specimens where the tissue requires decalcification.</p> <p>High risk specimens.</p> <p>In instances where an extended delay is likely to occur, the Consultant Histopathologist reporting the case will inform the referring clinician.</p>
Cytosponge	Provided the samples are received before 2pm they will be processed that date and reported in 3 days (due to needing IHC).

HIGH RISK SPECIMENS

IDENTIFICATION

Specimens from confirmed or suspected infectious diseases **must** be identified with 'Danger of Infection' labels on the request form as well as specifying in the appropriate place on the form what the risk is and the specimen container.

TRANSPORTATION

City Sprint / Royal Mail Special Delivery

The specimen container should be securely closed and placed within a sealed plastic bag.

The request form should be placed in the bags pocket or in a separate plastic bag.

Do not use staples or other sharp objects to seal the bags or attach forms to the specimen container.

We can provide the packaging for small numbers of cases ie daily clinics that can be used to send samples via the Royal Mail we can also provide Specimen transport boxes when collecting samples via City Sprint



DX Courier

We also have a DX address if you are interested in sending via DX please email operations@pathonomics.com for further details.

REPORTING DELAYS

Since specimens from these cases will require thorough fixation to minimise the risk to staff, there will usually be a delay in reporting.

CONTROL OF SUBSTANCES HAZARDOUS TO HEALTH (COSHH) REGULATIONS

The fixative for histological specimens is 10% Buffered Formal Saline. This contains dilute formalin (formaldehyde) which is hazardous and



governed by COSHH regulations. All areas where this substance is used should have a hazard data sheet detailing the risks associated with its use and procedures for the correct handling of this substance. Copies are available by contacting the laboratory.

Surepath preservative contains dilute flammable liquid and is also governed by COSHH regulations. All areas where this substance is used should have a hazard data sheet detailing the risks associated with its use and procedures for the correct handling of this substance. Copies are available by contacting the laboratory.



CYTOLOGY

The department cannot process gynae or non gynae cytology samples but we can report on already prepared slides.

We are able to accept and process cytosponge samples. Please contact us if you require more information.

IMMUNOCYTOCHEMISTRY

Routine Immunocytochemistry staining is carried out by the Pathognomics Ltd, but any specialised Immunocytochemistry will be referred to another ~~CPA~~ ISO accredited department and then return to Pathognomics Ltd to be reported on.

ACCREDITATION

All of the above laboratories to which we send specialist work are ~~CPA~~ ISO accredited.

DATA PROTECTION

Pathognomics ensures the safe guarding and appropriate treatment of patient samples which includes handling and confidentiality. We are registered with the Care Quality Commission (CQC) and Information Commissions Office (ICO) and adhere to NHS Digital.

CQC: *Participant ID: 1-3839766903 Registered Manager and Individual: Mr Christopher Evagora*

ICO: *registration number: ZA224395*

NHS Digital: *Caldicott guardian: Mr Christopher Evagora, Information Governance Lead: Mr Alec Hirst*

In addition to being registered to the appropriate governing bodies in relation to data protection we also have the following documents embedded in our quality management system.

[\[Doc 43: Data protection act\]](#)

[\[Doc 44: Doc protection and data security policy\]](#)

[\[Doc 32: RCP retention and storage of pathological records and specimens\]](#)

[\[Doc 33: Document control\]](#)

[\[Doc 145: Safeguarding policy and procedures\]](#)

[\[Doc 77: MRC Ethics\]](#)

[\[Doc 78: HTA Act\]](#)

We encourage staff and users to bring to our attentions any governance issues they feel they need to which is covered in our code of conduct, staff

grievance and whistle blowing documents. The links below are to ICO if staff feel there is an issue with our data protection and the CQC if there are issues with our patient care.

<https://ico.org.uk/concerns/>

<http://www.cqc.org.uk/content/contact-us>

COMPLAINTS

All complaints either verbal or written, regarding any aspect of the service provided should be directed to the quality manager. This can be done either by;

- Email: chris@pathognmics.com
- Post: Pathognomics Ltd, Unit11 Halcyon court, St Margaret's way, Huntingdon, PE29 6DG
- Phone: 01480 453 437

All complaints will be logged using the error and non-conformity procedure.





The quality manager will assess the complaint and an acknowledgement of receipt of the complaint will be sent within 7 days of receipt.

All communication will be logged by the quality manager using the error form in the LIMs to document the investigation and outcome.

All communications from complaints will be kept for a minimum of 10 years.

At all times during the complaint's procedure, patient confidentiality will be maintained by both parties.

DOCUMENT HISTORY

Version	Author	Date	Authorised
1	Chris Evagora	28/11/2016	Chris Evagora 
1.1	Chris Evagora	11/04/2017	Chris Evagora 
1.2	Chris Evagora	12/12/2017	Chris Evagora 
2	Chris Evagora	17/04/2018	Chris Evagora 
2.1	Chris Evagora	05/01/2019	Alec Hirst
2.2	Chris Evagora	05/08/2019	Alec Hirst
2.3	Chris Evagora	19/04/2020	Alec Hirst

CONTROLLED DOCUMENT