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Author:	Claire McGowan
Owner:	Claire McGowan
Approver(s):	Claire McGowan <i>approved at 2021-07-20 15:19 (UTC +0100)</i> Christopher Evagora <i>approved at 2021-07-20 15:22 (UTC +0100)</i> Alex Bowman <i>approved at 2021-07-20 15:53 (UTC +0100)</i>
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1. Disclaimer

Disclaimer

This document is for use by Cytel and Pathgnomics personnel and is written to meet the requirements for ISO 15189:2012 Medical laboratories — Requirements for quality and competence, Care Quality Commission and Human Tissues Authority.

Pathgnomics is a wholly owned subsidiary of Cytel Ltd. Pathgnomics provide the laboratory environment and digital pathology infrastructure for Cytel. The information contained in these documents is confidential, privileged and only for the information of the intended recipient and will be controlled via Qualio

2. Procedure

General Information

Pathgnomics Ltd is situated in units 11 and 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 workflow. 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.

Pathgnomics is accredited to ISO 15189:2012 Medical laboratories, UKAS No. 9923 for full schedule see link below

https://www.ukas.com/wp-content/uploads/schedule_uploads/00007/9923-Medical-Single.pdf

Pathgnomics Ltd.

Unit 11

Halcyon Court

St Margaret's Way

Huntingdon

Cambridgeshire

PE29 6DG

Since October 2020, Pathgnomics is a wholly owned subsidiary of Cytel Ltd. Pathgnomics provide the laboratory environment and digital pathology infrastructure for Cytel.

Opening Hours

Monday to Friday 8:00 am to 5:00 pm

Contact Information

Emails:

Accounts: accounts@pathgnomics.com

General: info@pathgnomics.com

Research and clinical trial work: operations@pathgnomics.com

Report queries: operations@pathognomics.com

Logistics queries: operations@pathognomics.com

Coroner's queries: coroners@pathognomics.com

Laboratory manger: alex@pathognomics.com

Phone Number:

01480 453437

Staff Members

Head of Service: Dr Luis Beltran

Deputy Head of Service: Dr Alexia Tsigka

Laboratory Director: Mr Alec Hirst

Laboratory Manager: Mr Alex Bowman

Specialities

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

- Dermatopathology
- Gastrointestinal
- Hepatobiliary
- Renal Biopsy
- Endocrine
- Male Genitourinary
- Gynae
- Neuropathology
- Respiratory
- Soft Tissue
- Lymphoreticular
- 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, electron microscopy, 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 Pathognomics website.

If for whatever reason you cannot use our request forms and need to send a specimen, 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

Sample	<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
Request Form	<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 • 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 identifications are not met the specimen is then returned to the requesting client for re-labelling.

Unlabelled 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
Routine Histology	10% Neutral Buffered Formalin
Testicular Biopsies	Bouin's medium (Aids in the preservation of delicate architecture of the tissue)
Direct immunofluorescence	Michel's Medium

Cytosponge	BD SurePath preservative
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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	Timeframe	Temperature
Histological Specimen Small biopsies and specimens	Small samples do not require incision to aid fixation therefore there is no real time frame. NOTE: Over-fixation can lead to poorer immunohistochemistry results so next day is recommended	These can be delivered and stored at room temperature and therefore temperature does not need to be monitored. NOTE: cold temperatures will slow down the chemical reaction and the specimen will take longer to fix
Histological specimens Large specimens	As these specimens need to be incised to aid fixation, they must be delivered in 24 hours (next day) so the specimen can be treated appropriately. NOTE: any later than this can slow down fixation to the specimen and may cause damage to the tissue	These can be delivered and stored at room temperature and therefore temperature does not need to be monitored. NOTE: cold temperatures will slow down the chemical reaction and the specimen will take longer to fix
Histological specimens Postmortem Tissue	As these come in small pieces they can be treated as small biopsies therefore no strict timeframe. NOTE: Over fixation can lead to poorer immunohistochemistry results so next day is recommended	These can be delivered and stored at room temperature and therefore temperature does not need to be monitored. NOTE: cold temperatures will slow down the chemical reaction and the specimen will take longer to fix
Immunofluorescence	The Michel's Medium and the specimen should be kept in the fridge at 4°C, up to shipment. The specimen must be sent within 48 hours.	During transport it is acceptable for the specimen to remain at room temperature. Transit time kept to a reasonable minimum where possible. NOTE: before and after transport the specimen must be kept at 4°C
Slides for Review / Reporting	No timeframe is necessary as once cover-slipped, slides are protected.	Can be shipped at room temperature therefore no monitoring required.

Cytosponge	One the sponge is in the preservative the sample should be shipped as soon as possible (within 5 days at most)	Can be shipped at room temperature therefore no monitoring is required NOTE: after transport, the specimen must be kept at 4°C
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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 operations@pathognomics.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 453 437 who will be able to direct you to the correct specialist or reporting consultant.

Turn Around Times

Backlog Work

Specimen Type	Turn Around Time
Cases requiring no additional work	We aim to turn around 95 % of cases within 1 week
Cases requiring additional work	As we have to request these from the originating hospitals there is a slight additional delay and we aim to report 95% within two weeks.

Internal Wet Work Processing

Specimen Type	Turn Around Time
Small Biopsy Specimens	Provided that the specimen is received in the laboratory before 2pm, the majority will be reported in the next 48 hours with an aim of 95% within a week.
Large and unfixed Specimens	These specimens require additional fixation and the report will be delayed by at least 24 hours. The majority will be reported in one week (95%

Exceptions	<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>
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Cyted Workflow

Specimens for this workflow all specimen will be reported with 14 working days.

Coroners Work

We do not provide a report for these but we aim to have either the slides or digital images provided to the pathologist within 1 week for reporting.

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 and pot what the risk is.

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@pathgnomics.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 and Hazardous to Health (COSHH) Regulations

The fixative for histological specimens is 10% Neutral Buffered Formalin. 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 via phone or operations@pathgnomics.com.



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 via phone or operations@pathgnomics.com.



Cytology

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

We can accept and process cytosponge samples. Please contact us if you require more information.

Immunohistochemistry

Routine Immunohistochemistry staining is carried out by the Pathognomics Ltd, but any specialised Immunohistochemistry will be referred to another ISO 15189: 2012 accredited department and then return to Pathognomics Ltd to be reported.

Accreditation

All of the above laboratories to which we send specialist work are ISO 15189:2012 accredited.

Data Protection

Pathognomics ensures the safeguarding and appropriate treatment of patient samples which includes data 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 Alex Hirst

ICO: Registration number: ZA224395

NHS Digital: Caldicott Guardian: Mr Alex Bowman.

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.

[EXT-42 Data Protection Act 2018](#)

[DSPOL-5 Data Protection and Data Security Policy](#)

[EXT-38 RCP - The retention and storage of pathological records and specimens](#)

[LABSOP-82 Document Control & Management of Records & Patient Samples Document](#)

[LABSOP-27 Safe Guarding Policy and Procedures](#)

[EXT-47 MRC ethics series](#)

[EXT-48 Human Tissue Act 2004](#)

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: operations@pathognomics.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.