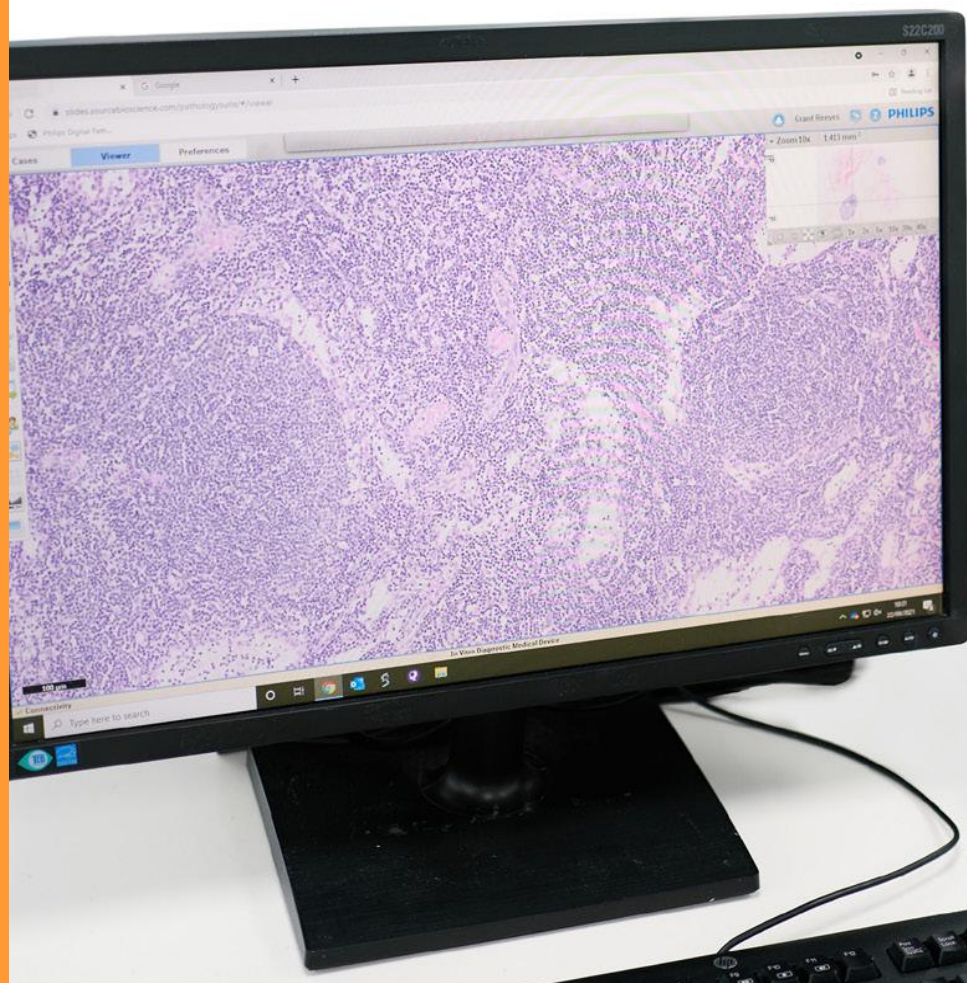


Guidelines for Cellular Pathology Services



Source LDPATH – Who We Are

The Source BioScience group operates across two main arms – **Source LDPATH** providing diagnostic histopathology and molecular diagnostic services to NHS and private healthcare users, and **Source Genomics** providing rapid and NGS sequencing services to industry and academia.

Source LDPATH provides industry leading histopathology services with a focus on digital pathology.

We offer an end-to-end clinical healthcare service from histopathology, including wet specimen dissection, block to slide and block to report services, through to Immunohistochemistry and molecular diagnostics services—bringing a unique clinical workflow for the delivery of precision therapeutics. Our digital pathology solutions utilise advanced slide scanning and high-resolution imaging to create digitised slides that enhance diagnostics.

We host a significant and growing network of Specialist Consultant Pathologists, all registered with the Royal College of Pathologists and General Medical Council, as well as meeting standards set by the College of American Pathologists, to ensure the highest quality reporting for patients.

Accreditation to ISO 15189 is held by Source BioScience Limited (00079136). This owns Source BioScience UK Limited and LDPATH Limited, allowing accreditation of Source LDPATH under a single UKAS number (9571).

Services that are accredited to ISO 15189 standards are listed on our UKAS Schedule of Accreditation. These are non-Hospital Pathology Services, Histopathology, Molecular Genetics and Molecular Diagnostics.

[9571 Medical Multiple](#)

Not all additional work requested by a Pathologist or Client can potentially be provided on one of our sites. As a result, work may be outsourced to an external supplier which has been approved through a supplier approval process. The functionality of the Laboratory Information Management System (LIMS) does not currently allow listing of where any outsource testing has occurred on reports. A list of tests which are within the scope of practice, subject to an extension to scope application or are outsourced can be found on our website.

For the purposes of this user information, the following locations apply.

Location	Address	The Services
Head Office, Nottingham – Orchard Place	1 Orchard Place, Nottingham Business Park, Nottingham, NG8 6PX, UK	Molecular Diagnostics Cellular pathology
The Courtyard Laboratory (TCL)	Units 3, 4 & 5, The Courtyard, Vinnetrov Business Park, Vinnetrov Road, Chichester, West Sussex, PO20 1QH	Cellular pathology

The User information is split between Orchard Place (Nottingham) and The Courtyard Laboratory (Chichester) and is indicated as such.

Source LDPATH – Orchard Place (Nottingham)

Submitting cases

For all cases, please ensure samples are accompanied by the relevant test request form. These can be found on the Source LDPATH website:

<https://www.sourcebioscience.com/histopathology/diagnostic-services>

Wet Specimens, Preprepared Blocks and Slides

When submitting wet specimens or preprepared blocks and slides cases to Source LDPATH, please adhere to the following minimum data requirements for the acceptance of any case into the laboratory.

All cases must detail:

- Patient name (or number, in cases of anonymised patients)
- Patient date of birth
- Referring location
- Referring laboratory number
- Specimen and clinical details

If this information is not present, or is illegible, it may delay or prevent the processing of the specimen. Please provide as much information as possible about samples whether they are sent as wet specimens or pre-prepared. A lack of clinical information, macroscopic descriptions or endoscopy reports (where applicable) can make examination and diagnosis of the sample difficult or impossible. Where relevant, copies of previous biopsy or resection reports along with radiological findings should be sent with the specimens.

Due to the irreplaceable nature of wet histology samples, if there is any compromise based on the acceptance criteria e.g., discrepancy in tube and ovaries seen versus request form, consideration, and evaluation of the risk to patient safety will be taken. This may result in the specimen being dissected and any caution of result interpretation consequently will be included in the diagnostic report issued. Communication will be always taken with referring departments (Histology Laboratories), and every effort will be taken to resolve issues before dissecting a sample.

Please complete and return by email to reflab@sourcebioscience.com a list of cases submitted using the template provided (or similar) on page 19 of this document. This information should be sent the same day as the specimen is collected. If a list of cases is not provided samples will not be rejected, however, it may slow down post-receipt activities, and it will not be possible to identify samples that have not been received. It is, therefore, highly encouraged to complete this process.

It is the assumption that samples being receipted by Source LDPATH that the referring laboratory has provided instructions which meet the ISO 15189:2022 7.2.4 Instructions for Collection Activities standard. Source LDPATH will also assume all consent activities have been completed by the referring laboratory as outlined in 7.2.4.3 Patient Consent of the ISO 15189:2022 standards. For Next Generation Sequencing (NGS) consent, this needs to be in line with Royal College of Pathologists Guidelines which outlines the Consent for analysis of DNA in Cellular Tissue, again, Source LDPATH on submission of a request for NGS testing will assume these requirements have been met.

Reference Laboratory Requests

When submitting cases to Source LDPATH for Diagnostic testing portfolio of tests (for example HER2 testing). All cases should be accompanied by a fully completed order form. These can be obtained from our website:

www.sourcebioscience.com

All diagnostic test requests should be sent via Royal Mail, courier, or Trust Transport to

Source BioScience
1 Orchard Place
Nottingham Business Park.
Nottingham
NG8 6PX.

Please ensure that any considerations have been given to the request, such as coated slides for increased adherence, slides cut as fresh as possible and any storage considerations which might be required. If you require any specific information in relation to the preexamination information for reference laboratory testing, then please contact the laboratory.

HER 2 ISH Testing

If referring samples for HER2 ISH testing in line with the test kit data sheet, samples should have been fixed with 10% Neutral Buffered Formalin for 6 to 72 hours and slides produced stained within the quickest time possible. Based on studies slides for HER2 ISH are stable if stored for 12 months if stored at 2-8 °C.

Due to the nature of receipting samples for testing, Source LDPATH cannot complete adequate suitability testing for each referring laboratory. Therefore, based on the data sheet information above, any referring laboratory should be aware of potential variation in diagnostic outputs based on fluctuations outside of the requirements. However, all ISH testing is completed under documented quality assurance and control procedures to assure the quality of examinations.

Next Generation Sequencing

As for HER2 ISH testing above, Source LDPATH cannot complete adequate suitability testing for each of the reference laboratories due to variances in pre analytical and processing methods. As a result, service users which send cases for Next Generation Sequencing on FFPE material need to be aware that these variances may influence the outputs of the examination methods, such as DNA extraction and tissue fixation time. We have provided the guidelines from our methodology below;

Standard formalin-fixation and paraffin-embedding procedures may cause significant fragmentation of nucleic acids. To limit the extent of nucleic acid fragmentation, be sure to:

- Fix tissue samples in 4%–10% formalin as quickly as possible after surgical removal.
- Use a fixation time of 14–24 h (longer fixation times lead to more severe DNA fragmentation, resulting in poor performance in downstream assays).
- Thoroughly dehydrate samples prior to embedding (residual formalin can inhibit proteinase K digestion).

All NGS testing is completed in line with documented quality assurance and control procedures which ensure the quality of examinations. If you require any further information, then please contact us.

Packaging

Samples transported in fixative - Wet specimens

Barrels for transportation of wet specimens will be provided by Source LDPATH. Please contact courier@sourcebioscience.com with your requirement.

It is important that specimens are adequately fixed before being dispatched to Source LDPATH. For large resection specimens, such as GI and gynae specimens the preference would be to receive specimens pre-incised to aid fixation.

Should you wish to send HIGH RISK (e.g. HIV positive) wet specimens please contact courier@sourcebioscience.com first.

Poor fixation or inappropriate containers may result in deterioration or distortion of the sample.

BY LAW, THE SENDER OF A PACKAGE IS LEGALLY RESPONSIBLE FOR ITS APPROPRIATE PACKAGING.

The correct packing of the specimens in the barrels is essential to prevent spillages. Under the Control of Substances Hazardous to Health (COSHH) regulations (<http://www.hse.gov.uk/coshh>), formaldehyde is classed as a toxic substance and as such must be treated with care.

The Carriage of Dangerous Goods and Use of Transportable Pressure Regulations came into force in May 2004. Under its requirements, diagnostic and infectious samples are identified by the United Nations substance identification number UN3373 as diagnostic specimens and are subject to IATA Packing Instruction P650.

Please find below, information and suggestions that have been prepared following our experience of Wet specimen transportation. We hope that this will be informative and of use to you.

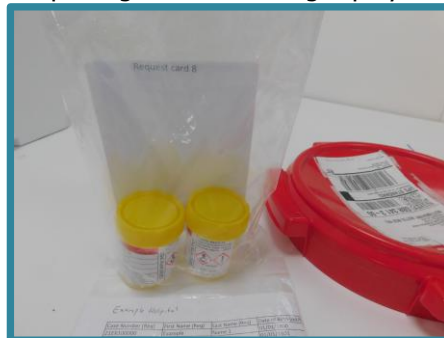
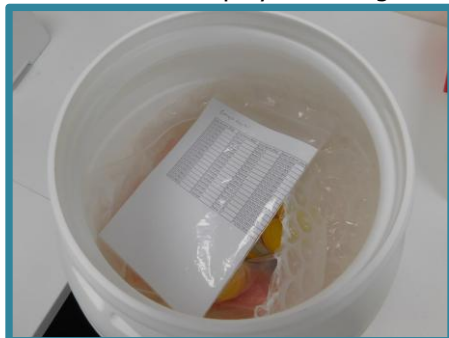
The couriers whose services we utilise for transportation of specimens are licensed to carry a maximum of one litre of formalin per container, i.e. one litre of formalin per specimen pot. An accumulation of formalin in smaller pots (such as 50ml containers) is acceptable to be transported in the barrels. We will supply the transportation barrels to service users for this purpose.

Some Trusts have found it preferable to drain off some formalin prior to transportation, particularly in larger specimens. Please ensure that the specimen is completely fixed and there is sufficient formalin (perhaps using formalin-saturated absorbance material) in the specimen pot to maintain a moist environment.

Statutory requirements dictate that specimens in formalin should be packaged to meet the following minimum transportation requirements:

- a) The specimen should be in a primary container with a secure screw-top lid. If the lid is not a screw top, please seal it with tape to reduce the risk of the lid detaching.
- b) The specimen pot should be placed in an airtight polythene bag relative to the size of the specimen pot

- c) The 'bagged pot' should then be placed in a second airtight polythene bag – we suggest that all the specimens in their individual polythene bags should be packaged into one larger polythene bag



- Transportation barrels are supplied with the following external labelling, which have been implemented following consultation with our couriers and in observance of the current transportation laws:
 - a) Conveyance labels x 2 (providing details of the chemical contained in the barrel and the UN grade of the transport medium)
 - b) Addressee



Source LDPATH will supply transportation barrels, absorbent pads (which will absorb up to two litres of fluid in the event of a leakage), bubble wrap and cable ties, which should be used to secure the barrel lid during transportation.

Any excess space in the barrel should be packed with "filler", for example, bubble wrap.



Samples transported as Formalin Fixed Paraffin Embedded (FFPE) Blocks or slides – pre-prepared

Boxes for transportation of pre-prepared specimens will be provided by Source LDPATH. Please contact courier@sourcebioscience.com with your requirement.

The correct packaging of slides and FFPE blocks is essential to minimise the risk of breakages and potential loss during transportation. Each Source LDPATH transport box can hold approximately 30 trays of slides, and each tray can hold a maximum of 9 slides. Please try to place multiple slides per slide tray to help minimise the slides mobility in transit. Please ensure slides and FFPE blocks are clearly labelled and packaged in a logical order (i.e. in cases of ascending numerical identifiers, and in block sub number order).

Below are instructions on how to correctly package your slides into our transportation boxes to minimise the chances of any breakages in transit.

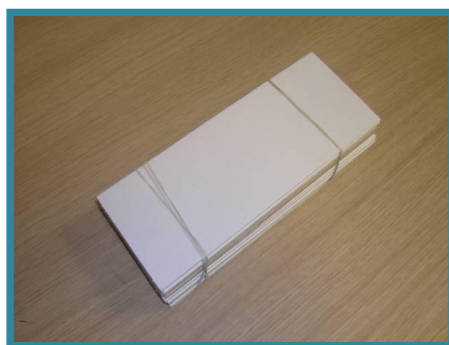
Step 1. Please ensure the slides are quality checked for artefacts, well mounted and as clean as possible to aid examination. Also ensure the slides are appropriately and clearly labelled with the sample identifiers and block numbers. Load Slides into slide tray as pictured below.



Step 2. Once all slides have been placed into slide trays, please place an empty slide tray on top of the stack, face down, as pictured below, as well as an empty slide tray underneath the stack.



Step 3. Place an elastic band over each end of the stack to secure them in place, as pictured below.



Step 4. Securely wrap the stack of slide trays in bubble wrap, ensuring that each end of the stack is also taped.



Step 5. Insert the wrapped stack into the transport box. You will notice that there is a drawstring within the box. Please ensure that the stack is securely restrained between the drawstring cords.

Step 6. Insert the request cards to accompany the slides into the space provided and secure the transport box ready for shipping.

Step 7. Contact the Source LDPATH courier department to arrange a courier collection via email courier@sourcebioscience.com or via phone on +44 (0)115 973 9012.

Should you have any queries relating to any part of the packaging or courier collection process, please do not hesitate to contact customer support on +44 (0)115 973 9012.

Courier collections

Courier collection of Cellular Pathology specimens is organised through the client onboarding process.

Source LDPATH can organise daily, regular (e.g. Monday and Wednesday each week) or ad-hoc collections as required. Please advise us of your preferred collection arrangements and times through discussion with your Source LDPATH account manager or by emailing courier@sourcebioscience.com.

If a regular collection is required, Source LDPATH will forward a batch of airway bills or arrange for the courier to bring them when they arrive to collect the package. One airway bill should be adhered to each package sent to Source LDPATH. If ad-hoc or additional collections are preferred, we need to be in receipt of your instruction to arrange same-day collection before 11am on the day of collection; otherwise, same-day collection cannot be guaranteed and may take place the next working day.

Report provision

Source LDPATH offers a fast and secure method of receiving reports for both histopathology specimens and diagnostic tests.

Our Secure Portal Access (SPA) system requires a user name, password and a random number generating key fob to log in to an account, ensuring that reports are securely stored and can only be accessed by those set up on the system.

Upon Consultant authorisation reports are uploaded immediately onto the SPA, automatically triggering email notification to inform the user that a new report is available to download. As reports are downloaded from the SPA system they are removed from the main screen, however, they will be stored as "read" items, ensuring that at any time you can search for and view old reports within the system.

The SPA can be accessed via the following link <https://secure.sourcebioscience.com>. Access for users should be arranged through your Account Manager or by contacting reflab@sourcebioscience.com.

A hospital site or Trust can have more than one account set up to allow for different groups or individuals downloading reports, for example if you wish to send any Duty of Care work in addition to routine pre-prepared work, retaining the two sets of work separately allowing for only named persons having access to Duty of Care reports.

Our team are available between 8:30am and 5.00pm Monday to Friday to answer any enquiries you might have about our SPA system.

Tests offered and Turn Around

Source LDPATH offers a wide range of services within its laboratories. Full service offerings can be requested via the customer support team, from your Account Manager or by visiting <https://www.sourcebioscience.com/histopathology/diagnostic-tests>.

The types of clinical services offered at Orchard Place include:

- Nucleic acid isolation and purification
- Targeted gene mutation analysis (e.g. KRAS testing)
- Routine histopathology activities (e.g. specimen dissection, processing, section cutting, staining and reporting by specialist histopathologists)
- Histopathological special stains
- Immunohistochemistry (routine markers and semi quantitative IHC such as ER/PR/HER2)
- ISH

(The majority of Source LDPATH diagnostic tests are performed in our accredited laboratories. However more esoteric or low throughput tests may still be requested and referred to carefully selected third party specialist partner laboratories).

Source LDPATH provides the highest quality reporting and service standards with reports routinely turned around within 7 working days from receipt for Preprepared slides and 10 days from receipt from wet specimens.

Cases submitted as part of the routine reference laboratory portfolio of tests (e.g.: Her2 IHC) are returned within 5 working days from receipt, with reflex tests (e.g.: HER2 ISH) turned around in an additional 2 days.

For NGS requests submitted, the results are returned on average within 10-14 calendar days.

Customer Support

Source LDPATH has a dedicated team of scientific and laboratory professionals available to offer technical and diagnostic advice and any queries regarding logistics and delivery of results.

In addition, there is a 24-hour Service Support answering service **0115 9739012** and an email support function via reflab@sourcebioscience.com.

Feedback on the performance of our service is encouraged and should be directed via the contact methods below. Through this process we actively seek feedback on our services which is then collated, discussed and any appropriate actions agreed and determined.

For further information, clarifications or advice on how to order or interpret examination results please contact our Customer Support team.

e: reflab@sourcebioscience.com

t: **+44 (0)115 973 9012**

Laboratory Location:

Source BioScience
1 Orchard Place
Nottingham
NG8 6PX

Laboratory Opening Hours

The Diagnostic laboratory operates between the hours of 8.30am and 5.30pm

Source LDPATH – The Courtyard Laboratory (Chichester)

Submitting cases

Private clients/clinics

For all cases, please ensure samples are accompanied by the relevant test request form. This will be provided to you by our Operations Team when the client is set up on the system. The minimum data requirements are as follows:

All cases must detail:

All cases must detail:

- Patient name (or number, in cases of anonymised patients)
- Patient date of birth
- Referring location
- Referring laboratory number
- Specimen and clinical details

If this information is not present, or is illegible, it may delay or prevent the processing of the specimen. Please provide as much information as possible about samples whether they are sent as wet specimens or pre-prepared. A lack of clinical information, macroscopic descriptions or endoscopy reports (where applicable) can make examination and diagnosis of the sample difficult or impossible. Where relevant, copies of previous biopsy or resection report along with radiological findings should be sent with the specimens.

Due to the irreplaceable nature of wet histology samples, if there is any compromise based on the acceptance criteria e.g., discrepancy in tube and ovaries seen versus request form, consideration, and evaluation of the risk to patient safety will be taken. This may result in the specimen being dissected and any caution of result interpretation consequently will be included in the diagnostic report issued. Communication will be always taken with referring departments (Histology Laboratories), and every effort will be taken to resolve issues before dissecting a sample.

Please complete and return the manifesto with a list of cases submitted using the template provided on this document. This is imperative so the team knows that all cases are present and will be processed as soon as possible. This manifesto needs to be sent together with the specimens. If a list of cases is not provided samples will not be rejected, however, it may slow down post-receipt activities, and it will not be possible to identify samples that have not been received. It is, therefore, highly encouraged to complete this process.

It is the assumption that samples being receipted by Source LDPATH that the referring laboratory has provided instructions which meet the ISO 15189:2022 7.2.4 Instructions for Collection Activities standard. Source LDPATH will also assume all consent activities have been completed by the referring laboratory as outlined in 7.2.4.3 Patient Consent of the ISO 15189:2022 standards.

For collections within London and Greater London:

For the samples to be processed on the same day we need to receive them before 3PM. Samples received after 3PM would likely be processed on the following working day.

To inform us about specimen collection please:

Email us: courier@ldpath.com (preferred option for traceability).

Call us: 0207 336 0921 - select option "1"



For collections outside of Greater London:

We use special Overnight Medical UPS service. All samples sent overnight need to be packaged inside special UN3373 carton boxes – sent by Source LDPATH.

To book collection please e-mail courier@ldpath.com and our Courier Officer will send you the UPS Tracking Label that you would need to print and securely stick onto the UN3373 box with the samples. It best to pre-book collection with us the day before the planned procedure or let us know about the required collection before 12AM – this way we can ensure that samples are collected on the same day.

Packaging

Samples transported in fixative - Wet specimens

For same day collections, the company provides branded specimen and branded transportation bags, if this is agreed beforehand, if any consumables are required, please contact operations@sourceldpath.com. It is important that specimens are adequately fixed. For large resection specimens it is suggested that specimens be incised to aid fixation prior to despatch. Should you wish to send HIGH RISK (e.g. HIV positive) wet specimens please contact operations@sourceldpath.com first. Also, if there are any queries if the laboratory can handle any type of samples, please contact **0207 336 0921 - select option "1"** or email. Poor fixation or inappropriate containers may result in deterioration or distortion of the sample.

BY LAW, THE SENDER OF A PACKAGE IS LEGALLY RESPONSIBLE FOR ITS APPROPRIATE PACKAGING.

The correct packing of the specimens is crucial to avoid spillages of formalin. Under the Control of Substances Hazardous to Health (COSHH) regulations (<http://www.hse.gov.uk/coshh>), formaldehyde is classed as a toxic substance and as such must be treated with care.

The Carriage of Dangerous Goods and Use of Transportable Pressure Regulations came into force in May 2004. Under its requirements, diagnostic and infectious samples are identified by the United Nations substance identification number UN3373 as diagnostic specimens and are subject to IATA Packing Instruction P650.

The couriers whose services we utilise for transportation of specimens are licensed to carry a maximum of one litre of formalin per container, i.e. one litre of formalin per specimen pot. An accumulation of formalin in smaller pots (such as 50ml containers) is acceptable to be transported in the barrels. We will supply the transportation barrels to service users for this purpose.

Statutory requirements dictate that specimens in formalin should be packaged to meet the following minimum transportation requirements:

- a. Place the specimen inside the labelled histology pot, check the pot lid is closed tight. Please seal it with tape to reduce the risk of the lid detaching.
- b. If multiple specimens are taken, each specimen must be placed into individual labelled pot.
- c. Place the pot(s) into the singular specimen bag.
- d. Ensure the request form is fully completed, and check that clinician full name, hospital name and billing details are present on form.
- e. Fold the request form in half, so that written information is facing inwards.
- f. Place the request form inside the side pocket of the specimen bag with pot(s).
- g. Print Cases Manifesto listing all cases that are being sent in the delivery, enclose it with the cases and keep copy for your records, as seen on page 19.

For same day deliveries via direct courier:

- a. Place specimen bags and manifesto inside the Large Transportation bag, seal the bag.
- b. Apply destination address sticker on the transportation bag.
- c. When courier arrives, check destination address matches to the one on their docket – pass the bag to the courier.

If cases are transported via UPS Overnight Medical Courier:

- a. Place the specimen bags and manifesto inside UN3373 box, apply security seal provided.
- b. Print UPS label e-mailed to you by Source LDPATH Courier officer.
- c. Place UPS label inside the sticky pouch, apply pouch on top of the UN3373 box.
- d. When courier arrives, ensure the courier scans the tracking label on the box – pass the box to the courier.

Samples transported as FFPE Blocks or slides – Pre-prepared

Boxes for transportation of Pre-prepared specimens will be provided by Source LDPATH. Please contact nhs@sourceldpath.com with your requirement. The transport boxes include a spare bag and prepaid return label.

- a. When packaging the slide we add extra slide trays, secure with elastic bands and protect with bubble wrap.
- b. The boxes clasps but we always secure the box with more elastic bands for extra precaution.
- c. Examples are showed below.
- d. Use the manifesto that is provided to have a record of number of slides/blocks sent as seen on page 19.

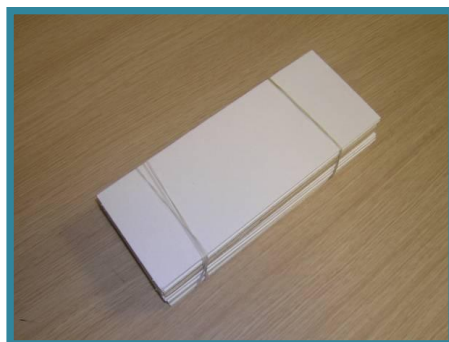
Step 1. Please ensure the slides are quality checked for artefacts, well mounted and as clean as possible to aid examination. Also ensure the slides are appropriately and clearly labelled with the sample identifiers and block numbers. Load Slides into slide tray as pictured below.



Step 2. Once all slides have been placed into slide trays, please place an empty slide tray on top of the stack, face down, as pictured below, as well as an empty slide tray underneath the stack



Step 3. Place an elastic band over each end of the stack to secure them in place, as pictured below.



Step 4. Securely wrap the stack of slide trays in bubble wrap, ensuring that each end of the stack is also taped.



Step 5. Insert the wrapped stack into the transport box. You will notice that there is a drawstring within the box. Please ensure that the stack is securely restrained between the drawstring cords.

Step 6. Insert the request cards to accompany the slides into the space provided and secure the transport box ready for shipping.

Step 7. Contact the Source LDPATH courier department – courier@ldpath.com or **02073360921**.

Courier collections

Courier collection of Cellular Pathology specimens is organised through the client onboarding process

Source LDPATH can organise daily, regular (e.g. Monday and Wednesday each week) or ad-hoc collections as required. Please advise us of your preferred collection arrangements and times through discussion with your Source LDPATH account manager or by emailing courier@ldpath.com

Tests offered and Turn Around Times

Private

We prioritise fast turnaround times, delivering results within an unrivalled 24 – 72 hours whilst maintaining premium accuracy. High-risk cases will benefit from our priority service with an aim to deliver results within 24 hours. Depending on the complexity of the cases and if require additional tests.

NHS

Source LDPATH provides the highest quality reporting and service standards with reports routinely turned around within 7 working days from receipt for Preprepared slides and 10 days from receipt from wet specimens

The types of clinical services offered at The Courtyard Laboratory include:

- Routine histopathology activities (e.g. specimen dissection, processing, section cutting, staining and reporting by specialist histopathologists)
- Histopathological special stains
- Immunohistochemistry (routine markers and semi quantitative IHC such as ER/PR)

(The majority of Source LDPATH diagnostic tests are performed in our accredited laboratories. However more esoteric or low throughput tests may still be requested and referred to carefully selected third party specialist partner laboratories).

Customer Support

Source LDPATH has a dedicated team of scientific and laboratory professionals available to offer technical and diagnostic advice and any queries regarding logistics and delivery of results.

For private team please contact: operations@sourceldpath.com or **0207 336 0921 - select option "3"**

For NHS Team please contact: nhs@sourceldpath.com or **0207 336 0921 - select option "2"**

Laboratory Location:

Source LDPATH
3-4 The Courtyard Vinnetrow Business Park
Vinnetrow Road
Chichester
PO20 1QH

Laboratory Opening Hours:

The Diagnostic laboratory operates between the hours of 8.30am and 5.30pm.

Complaints Procedure and Governance Arrangements

Source LDPATH has a strict and robust quality management system which includes the handling of incidents, serious incidents and complaints. This process is overseen by our Quality Assurance team who operate independently from both operational and commercial teams to ensure the process remains unbiased. All incidents, serious incidents and complaints are managed and investigated through our electronic quality management system Q-Pulse in accordance with our incident SOP and in line with relevant standards and guidance from ISO:15189, ISO:9001 and RCPATH.

Should the concern raised be of a clinical nature this would be subject to our full non-conformance procedure in line with ISO 15189 standards. On occasion we may conduct an investigative audit for result discrepancies, due to the nature of the process, these can take some time, which clients will be provided with regular updates.

Any improvements from investigative processes are raised as a CAPAs. This then has an effectiveness check to ensure that the actions implemented have resulted in the desired improvements. All incidents and CAPAs are subjected to a management and QA review prior to being closed. Upon completion of an incident a summary of the investigation, root cause and any corrective actions can be provided to the customer to facilitate the closing of their own non-conformance.

Source LDPATH will contribute to all investigations associated with complaints and incidents raised by clients, their local governance teams or patients. It is the expectation of Source LDPATH that the ownership and responsibility will sit with the clients who own the original referral. Any variations on this will be specified within the contract entered by each individual client and Source LDPATH.

Where any incident or non-conformity is deemed of a severity where the reputational damage, patient safety or confidence of an external interested party, Source LDPATH will inform the relevant accreditation body or regulator. This is managed through a designated policy and set criteria and if on the unlikely event that an occurrence of this nature emerges then respective clients will be informed, though this maybe after the initial regulator or accreditation body notification.

All accredited activities can be found on the website, and it would be the expectation of the client to inform Source LDPATH of any activity or loss of accreditation which might have an adverse outcome on results or reputational damage, such as processing issues on blocks being sent for report. Source LDPATH will contact clients with any issues, incidents or concerns with the accreditation of the services of which they provide.

To raise an incident, serious incident or complaint please email the full detail of the event to:
Customercare@sourcebioscience.com / operations@sourceldpath.com

Protection of personal information

Source LDPATH takes the protection of patient and customer personal information seriously and has implemented systems to ensure the safety of this information in both electronic and physical form.

All data is stored in a secure building. Card access control points are placed on all doors and intruder alarms are activated when the building is not occupied with the server and archive rooms having both electronic and physical locks. The electronic door access system is operated with the principle of 'least privilege' ensuring only users who require access to personal information to support the delivery of the service can view such information

Name	Level	Comment
Cyber Essentials Plus	Mandatory	We currently hold and have maintained CE+ for 3 years
Data security and protection toolkit	Mandatory	We renew this yearly
Processing of Data	Mandatory	All data will be processed in the EU, and no data will be transferred outside of the EEA
Data Protection Registration	Mandatory	We are registered with the ICO – Ref No. ZA743375
ISO9001	Desirable	We are certified to ISO 9001

Questions relating to Data Protection can be addressed to the Data Protection Officer at data.protection@sourcebioscience.com.

Example Manifesto for Private Clients – The Courtyard Laboratory

Hospital:				Receiving Lab: SourceLDPATH				
To be filled out by Hospital Staff							To be filled out by Courier	
Sample Date	Surname	Forename	DoB	Consultant	Specimen type	No of pots	Dispatch Date/Time	Courier Name / Signature

Example Manifesto – Orchard Place

Date

CASES SUBMITTED TO SOURCE LDPATH

FROM:.....

Case Number (Required)	Patient Name	Date of Birth	Specimen type (Required)	No of Pots	No of Blocks	No of slides	Received (SBS use only)

Pre-advice Portal User guide – Orchard Place Customers Only

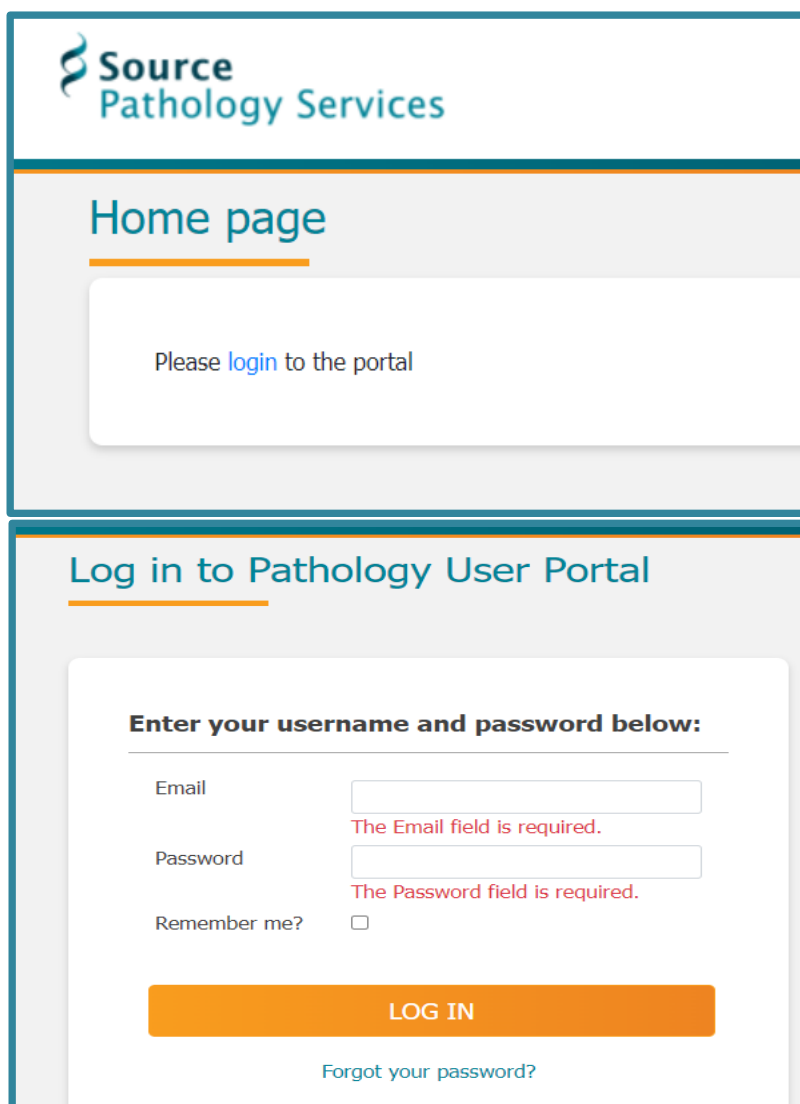
The purpose of the pre-advice portal is to allow our clients to upload the cases they are sending to us ahead of us receiving the cases at Source LDPATH. This feeds into our LIMS system and eliminates the need to manually book in cases once received, allowing a quicker turnaround of specimens getting processed. The pre-advice portal is a useful tool for our clients too, as the portal allows the client to see live what status the case is at within the process, for example, Received, Cut up, with Pathologist or Awaiting Additional. This can reduce the need to contact the customer service team to query the status of cases.

Once all users are set up to use the portal, Usernames and Passwords will be sent.

To Use.

Visit: <https://portal.sourcebioscience.com/>

Step 1. Log in



The image shows two screenshots of the Source Pathology Services portal. The top screenshot is the 'Home page' which displays the 'Source Pathology Services' logo and a message: 'Please login to the portal'. The bottom screenshot is the 'Log in to Pathology User Portal' page. It features a login form with the heading 'Enter your username and password below:'. The form includes fields for 'Email' and 'Password', a 'Remember me?' checkbox, and a 'LOG IN' button. Red error messages are visible: 'The Email field is required.' and 'The Password field is required.'. A link for 'Forgot your password?' is located below the login button.

Step 2. Home page, this shows you a list of the cases that have been uploaded to the pre-advice portal, this gives you the details of the cases and at what status is at in our process.

Home page

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	Histology Number	Case Number	Status	Specimen	Slides	Forename	Surname	Date Of Birth	Created Date	
✕			Please select...	Please select...						Q
	TestAPI070422	22-L-029423	Entered	SKIN	2	Test	API	07/Apr/2022	07/Apr/2022 14:10	VIEW

Step 3. Upload individual cases, this can be used to upload one case at a time. Add the case details as requested and save. This will populate our LIMs system the case.

Source Pathology Services

Welcome Sara Baker, Source BioScience

Upload Individual Bulk Upload Request Form Upload Sign out

Upload Individual

REQUEST FORM UPLOAD

Histology Number

First Name

Last Name

Date of Birth

Gender

Specimen Category

Pots

Blocks

Slides

Please note we are currently only able to take pots, blocks OR slides per case on the preadvise portal.

Reset Save

Step 4. Bulk upload. To upload multiple cases in one go, Select Bulk upload.

Source Pathology Services

Welcome Sara Baker, Source BioScience

Upload Individual Bulk Upload Request Form Upload Sign out

Bulk Upload

Download Template REQUEST FORM UPLOAD

Choose file

Browse Upload

Spreadsheet Password

If your spreadsheet is password protected, please enter the password above

Click download template to open an Excel Spreadsheet.

[REQUEST FORM UPLOAD](#)

If your spreadsheet is password protected, please enter the password above

[illegible]

REQUEST FORM UPLOAD

If your spreadsheet is password protected, please enter the password above

CUST-DOC-14 Version 8.0



Disposal of residual clinical tissue

Following the processing of samples received, Source LDPATH will dispose of residual tissue samples. This will take place at least 4 weeks after the reporting date. Waste will be disposed of in accordance with our SOP's and local clinical waste policy.

Please note: unless you state otherwise, all residual tissue samples and pots will be disposed of by Source LDPATH.

Any samples known to be 'Products of Conception' will be identified and excluded from this process. These will be returned to the originating laboratory for sensitive disposal.

Should you require all residual tissue to be returned please complete this form and email a signed copy to reflab@sourcebioscience.com

If you have any questions or wish to discuss, please contact Source LDPATH Customer Support on **+44 (0)115 9739012**

I,
hereby authorise Source LDPATH to dispose of any residual tissue
samples received from.....
(NAME OF HOSPITAL)

Signed	Position	Date

THIS FORM SHOULD BE SIGNED AND RETURNED TO reflab@sourcebioscience.com.

For Patho Box Clients (reference to in house document COU-DOC-12)

Box Packaging Instructions for Sending Specimens

Purpose

These instructions outline the correct procedure for packaging and sending specimens to Source BioScience. Following these steps helps ensure sample integrity, compliance with UN3373 packaging regulations, and safe transport.

1. Contact Before Shipping

Before sending your specimens, please notify us that a sample shipment is on its way.

Phone: 0115 973 9012

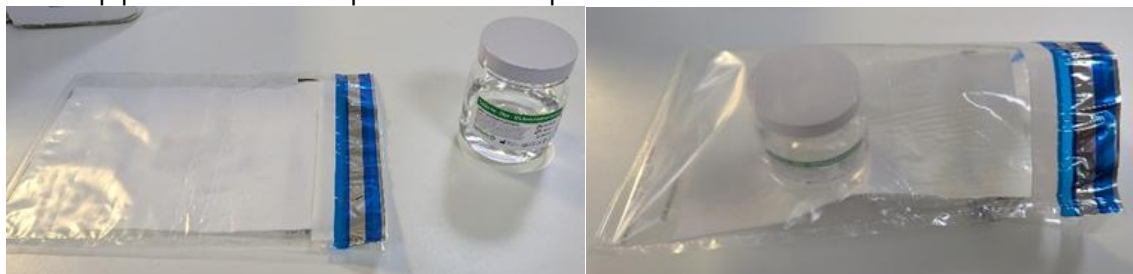
Email: courier@sourcebioscience.com

Providing advance notice allows us to prepare for receipt and avoid delays.

2. Prepare the Specimen

Place the formalin pot containing the specimen into a Patho Seal bag or an equivalent leak-proof container. Ensure that the absorbent material included is sufficient to contain the volume of any liquids present in the event of leakage during transit.

This step provides additional protection from spills and contamination.



Seal the bag by:

Removing the shiny grey strip.

Squeezing the air out.

Firmly pressing the two sides together to ensure a tight seal.



Insert all documentation (e.g., patient details, test request forms) into the pouch attached to the Patho Seal bag.



Ensure that paperwork is dry and legible.

3. Pack the Patho Seal Bag into the Patho Shield Box

Place the sealed Patho Seal bag inside the Patho Shield box.



Left-hand side: for larger specimen pots.

Right-hand side: for smaller pots.

The arrangement examples on the box illustrates these placements.

You may include multiple specimens within one box, as space allows.

Fill any remaining void space with packaging material (e.g., bubble wrap or paper) to prevent movement during transit.



Close the box securely and apply the security seal.



4. Place the Box in the UN3373 Outer Bag

Insert the sealed Patho Shield box into the UN3373-labelled transport bag.



Remove the blue adhesive strip and seal the bag tightly, ensuring it sticks firmly to itself.

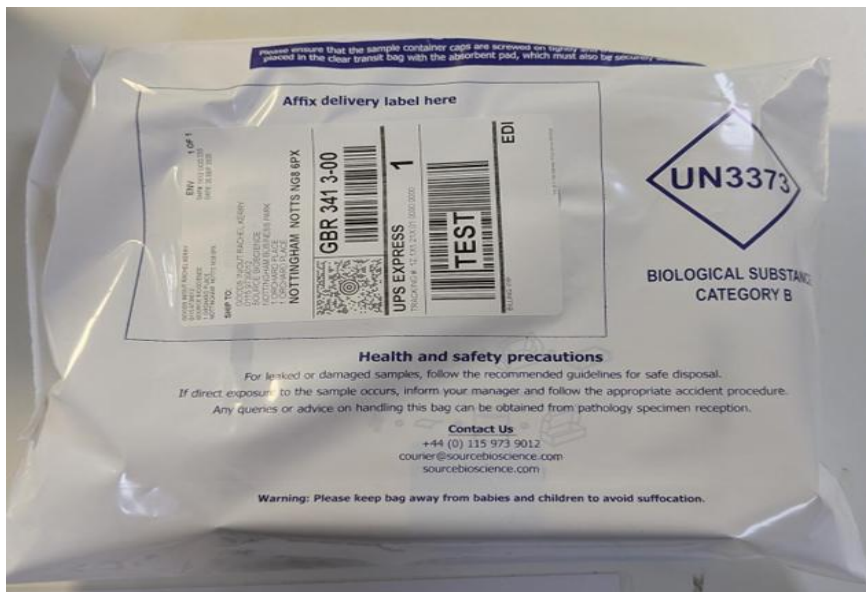


5. Attach the Shipping Label

Affix the shipping label securely to the outer packaging.

The label may correspond to UPS or another authorized courier. Ensure that the selected carrier is approved to transport materials classified as UN3373 "Biological Substance, Category B."

Ensure the label is clearly visible and fully adhered to the bag.



6. Check the shipping address

Please ensure that the address on the shipping label is correct to avoid delays or possible lost packages, if you are sending your own specimens the address is:

The Courtyard Laboratory,
Unit 3-4,
Vinnetrow Business Park,
Vinnetrow Road,
Chichester,
PO20 1QH

If you have any doubts or questions, please contact us at the details above.

7. Compliance Reminder

Please ensure that UN3373 packaging instructions are followed at all times. Further guidance can be found [here](#)

The packaging system (primary, secondary, and outer) must meet UN3373 “Biological Substance, Category B” packing instruction P650 requirements.

Only approved packaging materials should be used.

For any questions regarding compliance, contact us at the details above.

Thank you for ensuring safe and compliant specimen shipping!