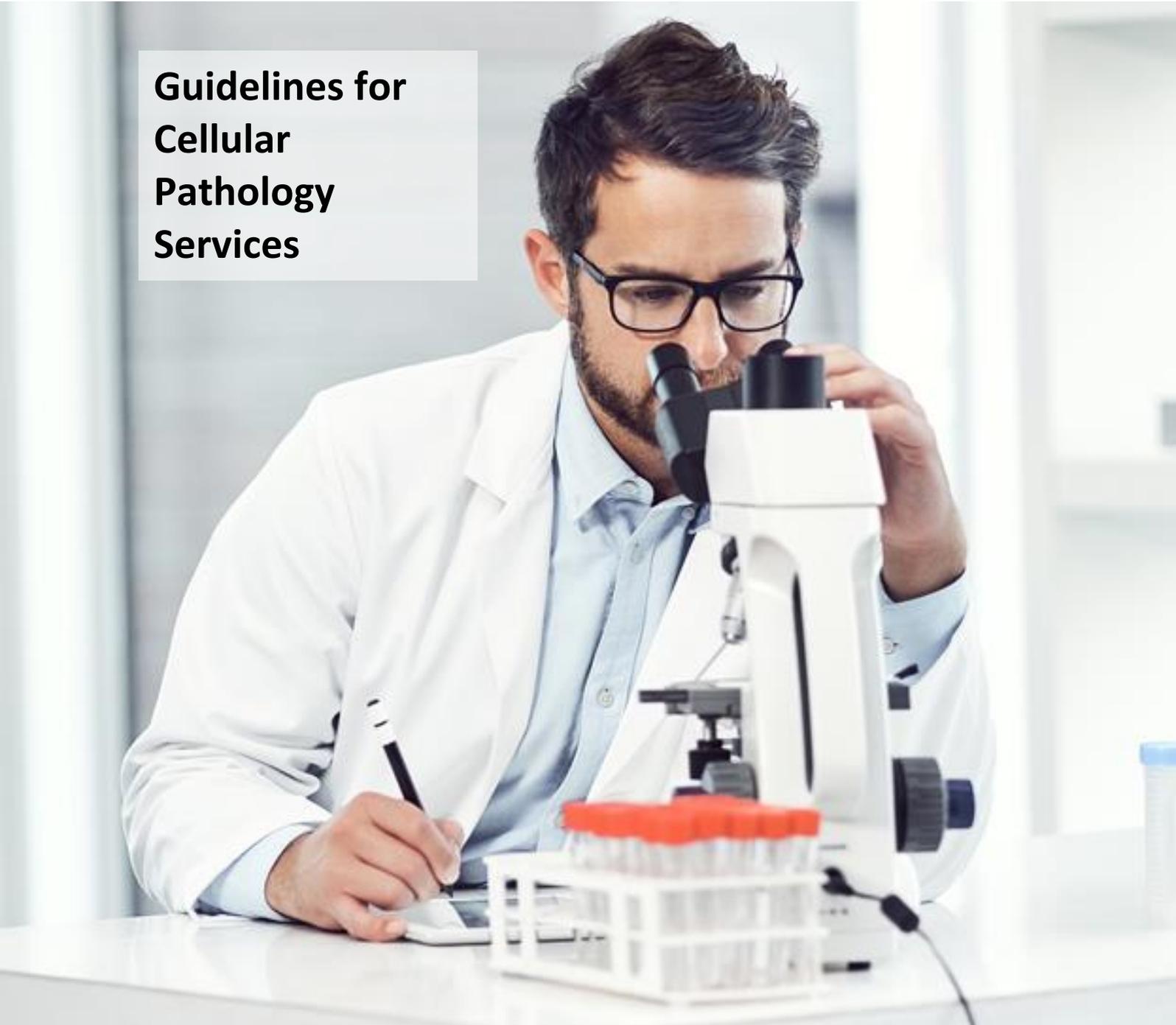


**Guidelines for
Cellular
Pathology
Services**



Submitting cases

For all cases please ensure samples are accompanied by the relevant test request form. These can be found on the Source BioScience 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 BioScience, 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 for samples whether sent as wet specimens or preprepared. A lack of clinical information, macroscopic descriptions or endoscopy reports (where applicable) can make examination and diagnosis of the sample difficult or impossible.

Please complete and return by email to reflab@sourcebioscience.com a list of cases submitted using the template provided (or similar) on page 7 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.

Precision Medicine

When submitting cases to Source BioScience 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.

Infectious Disease Testing

Test kits contain details of specimen requirements and shipping / handling conditions. Details can also be found on the Source BioScience website: <https://coviduk.sourcebioscience.com/>

Packaging

Samples transported in fixative - Wet specimens

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

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 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.

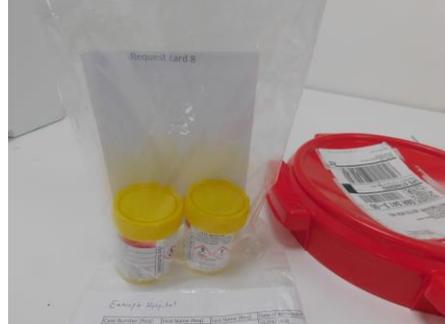
Please find below, information and suggestions that have been prepared following our experience of Wet specimen transportation. We hope that this will be informative and of use to you.

- 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 barrel. We will supply transportation barrels to service users for this purpose. In the event of a customer wishing to send a quantity of specimens that leads to the amount of formalin exceeding one litre, the specimens should be packaged into more than one barrel to accommodate the licence requirements.

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 of 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:
 - Conveyance labels x 2 (providing details of the chemical contained in the barrel and the UN grade of the transport medium)
 - Addressee



- Source BioScience 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 FFPE Blocks or slides – Pre-prepared

Boxes for transportation of Pre-prepared specimens will be provided by Source BioScience. 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 BioScience 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 in order 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 BioScience 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 provided free of charge.

Source BioScience 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 BioScience account manager or by emailing courier@sourcebioscience.com.

If a regular collection is required, Source BioScience 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 BioScience. 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 BioScience 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 in order 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 5.30pm Monday to Friday to answer any enquiries you might have about our SPA system.

Tests offered and Turn Around

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

The types of clinical services offered 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)
- FISH
- Infectious Disease testing (SARS-CoV-2 Virus)

(The majority of Source BioScience 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 BioScience provides the highest quality reporting and service standards with reports routinely turned around within 5 working days from receipt for Preprepared slides and 7 days from receipt from wet specimens.

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

Infectious Disease tests are routinely reported within 24 hours of receipt.

Customer Support

Source BioScience 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
 The Infectious Disease laboratory operates 24/7

Complaints Procedure

Source BioScience 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 guidance from ISO:15189:2012 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 15189:2012 guidelines.

Any improvements from this investigative process are raised as a CAPA. 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.

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

Protection of personal information

Source BioScience 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 are able to view such information

Name	Level	Comment
ISO27001	Mandatory	We are currently implementing ISO27001 and expecting to have the accreditation by the end of the year (2020).
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 hold ISO9001

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

Disposal of residual clinical tissue

Following the processing of samples received, Source BioScience 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 BioScience.

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 BioScience Customer Support on +44 (0)115 9739012

I, _____ hereby authorise Source BioScience 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.