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1. Disclaimer

Disclaimer
This document is for use by Cyted and Pathognomics 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. **Pathognomics is a wholly owned subsidiary of Cyted Ltd. Pathognomics provide the laboratory environment and digital pathology infrastructure for Cyted. 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

Introduction

It is likely that at any given time there will be a number of specimens that present a risk of infection but are not identified either because at this stage a diagnosis has not yet been made or because the hazard is present in a latent state. There is therefore a need to ensure that all specimens are safely contained and transported.

It is recognised that a problem exists, in that, in many instances we have no control over the condition of the specimens received into the department.

Specimens are received via the post and courier. As the department does not supply the containers for most of our Users, we have little direct control over the type of container used or the packaging employed.

Our only recourse is to refuse to accept specimens that are unsatisfactorily presented and to return them once they have been safely re-packed. Obtaining an ideal situation can therefore only be achieved by the education of the people sending specimens to us. To this end, this procedure includes two types of statements. That which we have complete control over and is therefore adopted as the procedure for the department and that which all members of the department will encourage outsiders to adopt. Obviously, any specimens sent out from the department will conform to all aspects of the procedure.

For further information for external Users, in regards to state of specimens to be sent in, time frames, temperatures etc, please refer to LABSOP-34 Users Guide

Procedure and Safety

Procedure

1. All specimen containers must be sufficiently robust to withstand the stresses likely to be put on them and must not leak during normal use.
2. The person who sends the specimen must ensure that the container used is appropriate, is properly sealed and is not externally contaminated.
3. Specimen containers apart from buckets will be used once only.
4. Buckets and lids must be thoroughly cleaned and checked for damage before being re-used.
5. For patient safety, all labels on buckets and lids must be completely removed before the containers are re-used.
6. All labels used must be self-adhesive.

7. The container and request form must contain sufficient information to uniquely identify the patient, nature of the specimen and the name and location of the sender.
8. It is the responsibility of the person who requests the laboratory examination to ensure that both the form and container are correctly labelled to indicate any danger of infection.
9. Labels indicating a danger of infection must only be used for specimens that are suspected of containing a Hazard Group 3 pathogen see table below [1].

Route of Infection	Type of Disease	Organisms	Hazard Group
Contact: either direct via hands of employees, or indirect via equipment and other contaminated articles	Gastrointestinal disease	*E.Coli O157* *Salmonella typhi*	**3** **3**
Airborne: small particles that can reamina airborne and travel considerable distances	Respiratory tract infection	*Mycobacterium tuberculosis* *Mycobacterium bovis* *Avia flu* *Chlamydia psittaci*	**3** **3** **3** **3**
Blood-borne: either direct contact with blood or body fluids (or via skin-penetrating injury) or indirect via contaminated articles, eg, dressings	Immune system disease	HIV HTLV	**3** **3**

10. The labels should be positioned so that they are visible without removing the specimen or form from its transport bag.

11. Each request form relating to a specimen that presents a danger of infection must give sufficient clinical information to enable laboratory staff to know what special precautions to take.

12. All specimens must be placed in an individual transparent plastic transport bag as soon as they have been labelled.

13. The bag must be sealed by a means that enables it to be opened without the use of sharp pointed instruments.

14. Bags must not be sealed with pins, staples, metal clips etc.

15. The form must be placed in a separate pocket, integral to the bag and must not be pinned or stapled to it.

16. Large buckets must be enclosed in individual transparent plastic sacks tied at the neck. The form should be placed in a separate bag, which is then securely tied to the neck of the sack.

17. Any specimen container or bag, which shows signs of external contamination, should be refused until such time as it has been confirmed that there is no risk of infection.

18. Specimen transport bags should not be used more than once. If required, they are to be decontaminated before disposal.

19. All used bags and other material used for packaging must be placed into orange clinical waste sacks for disposal.

20. All specimens posted from the department must conform fully with the current post office regulations.

Post Office Regulations

Post Office Regulations for the Transport of Class 6.2 Products (Diagnostic Specimens, Infectious Substances and Biological Products)

1. Deleterious substances are normally prohibited from transmission by post. An exception is made for pathological specimens excluding those known or suspected to contain Hazard Group 4 pathogens. Pathological specimens may be sent for medical examination or analysis to a recognised medical laboratory or institution; or to a qualified medical practitioner; or to a registered dental practitioner; or to a veterinary surgeon.
2. **Only the FIRST CLASS LETTER POST or DATAPOST services may be used. The parcel post service may not be used for sending biological materials.**
3. **Only packaging approved by the Post Office may be used. See additional information below.**

   In all cases, the following must be strictly observed:

   1. Every pathological specimen must be packaged to meet Packing Instruction 602 in the International Civil Aviation Organisation's Technical Instructions and the International Air Transport Association's Dangerous Goods Regulations. For Dry Ice shipments Packing Instruction 904 must be followed.
   2. Specimens must be enclosed in a primary container. This may be glass, plastic or metal in construction. The closure may be screw cap, push-on or snap-on in their design type which must have been tested within the U.N. Certified Packaging and shown to be watertight and leak-proof in performance tests. Each primary receptacle must not exceed 50ml. unless packing instructions allow.
   3. Secondary packaging must be watertight and capable of withstanding 95kPa (0.95 bar, 13.8lbs/in ^{2}) in the range -40ºC to +55ºC temperatures. Secondary packaging must contain cushioning material, for the primary receptacles. Also it must contain sufficient absorbent material to absorb the entire contents. These units must not contain dry ice.
   4. Outer packaging must be subjected to water spray, temperature, puncture and drop testing. It must be capable of protecting the inner packagings. The box must be correctly marked to include the name and telephone number of a responsible person and have a Regulation Class 6.2 Hazard Label. These units must have the U.N. mark on the box.
   5. Overpacks with thermal control insulation must be used to transport specimens requiring packaging in ice packs or with dry ice. Dry ice or solid carbon dioxide is a Miscellaneous Class 9 Hazard. In addition to hazard labels, overpacks require "inner packagings conform to prescribed specifications" marking on the outer casing and the U.N. Dry Ice Number and its weights.

Royal Mail Statement on Biological Material

Biological Substances (Category B)	Diagnostic specimens including blood, urine, faeces and animal remains. Category B (UN3373) as classified in the latest edition of the Technical Instructions for Safe Transport of Dangerous Goods by Air published by the International Civil Aviation Organisation (ICAO). May only be sent by, or at the specific request of, a qualified medical practitioner, registered dental practitioner, veterinary surgeon, registered nurse or a recognised laboratory or institution. The total sample volume/mass in any parcel must not exceed 50ml/50g. All biological substances must be posted in packaging that complies with Packaging Instruction 650, such as our Safebox product. The sender's name and return address must be clearly visible on the outer packaging.

EXT-44 IATA Packing Guidance

WARNING

Any package containing biological material not conforming to these regulations, will be stopped and may be destroyed with all its wrappings and enclosures. Any person who sends by post a deleterious substance for medical examination or analysis without conforming to the above regulations, may be liable to prosecution resulting in a fine and imprisonment.

Transport of Specimens in Vehicles by Courier

General Histology Workstreams

Pathognomics Ltd has an account with an accredited medical courier 'City Sprint' and is used for anything sent within the UK or abroad. We also offer this service to some of our users.

Details for contacting City Sprint can be found in LABSOP-17 City Sprint Courier Service

All jobs booked by Pathognomics or packages sent via the post are logged via the material transport log found in this document.

All items waiting to be collected by a courier (booked either by Pathognomics or user) are placed in the main reception area. They are then stored in a folder and kept on a two-year rotation.

Note: A confirmation of receipt form (found in this document) needs to be sent with every sample sent by courier by us. Once returned it should be matched up with the relevant material log sheet and scanned and attached to the clinical details section of the case in the LIMs system.

Cytosponge™ Workstream

Cystosponge™ samples are transported from the client to Pathognomics via DX Courier or City Sprint.

DX Courier

A specific designated pick/drop off point is allocated at each site and an individual 'DX address' is generated by DX. The drop of point is checked daily at allocated times in the afternoon or evenings.

The clients are supplied with pre labeled transport box that has Pathognomic's DX address on them.

DX drops of at Pathognomics point between the hours of 5am-7am every day.

DX collections and bookings are managed by the Operations team (service@cyted.ai)

The DX user dispatch portal is located at https://webportal1.thedx.co.uk/cgi-bin/wcindex.pl

The user guide for the portal is located at http://deployment.thedx.co.uk/clientkithelp/index.htm

City Sprint

The logistics of the booking of couriers for Cytosponge sites is organised by the Operations department.

Operations liaise with the sites to ensure that the clinics dates are updated every week and the appropriate couriers is booked and managed.

Refer to LABSOP-17 City Sprint Courier Service to see how to book a courier and all information relating to City Sprint.

Risk Assessment

Outcome

Name of Assessor	**Mr Alex Bowman (Laboratory Manager)**
Checked by	Mr Alec Hirst (Laboratory Director)
Groups at Risk	All personnel but specifically those directly involved in the collection and transport of specimens. This includes couriers, postal workers and patients.
Overall Risk Rating	Acceptable

Patient Preparation

Hazards Identified

1. Infection from unfixed or inadequately fixed material.
2. Formal saline solution. Harmful if ingested or if exposure to the vapour is prolonged. Irritating to skin and eyes. Has been found to cause cancer in laboratory animals.
3. Formaldehyde solution. Toxic by ingestion and inhalation. Prolonged exposure to vapour can cause conjunctivitis, laryngitis, bronchitis or bronchial pneumonia. Causes burns to eyes and skin, with cracking and ulceration, particularly around fingernails. Has been found to cause cancer in laboratory animals. Flammable liquid which reacts with hydrochloric acid to produce a carcinogenic compound. Can react vigorously with oxidising agents.
4. Injury to patients through incorrect identification.

Risks

Infection

The Advisory Committee on Dangerous Pathogens has confirmed that the Human immunodeficiency viruses currently known as HIV1 and HIV2, Mycobacterium tuberculosis and Hepatitis B virus should remain in Hazard Group 3. These are the three most likely Category III pathogens to be encountered in Histopathology. In cases where the handling of such material is vital to the welfare of the patient, the procedure will be carried out by the Senior Chief Technician or such persons as he deems to be adequately trained. When dealing with inadequately fixed tissue there is also the possibility that other infectious organisms not classified as above may be present. Therefore it is essential that all staff carrying out the procedure are adequately trained and are aware of the Safety Rules, particularly the section on the prevention of infection, and that they follow the procedure laid down in the

Standard Operating Procedure. If the guidelines contained in the Standard Operating Procedure and Local Rules for Safety at Work are followed, the risk of infection is reduced to a minimum.

Existing Control Methods Include:

1. Only specimen containers specifically designed for the purpose are used.
2. Specimen containers apart from buckets are used once only.
3. Buckets and lids are thoroughly cleaned and inspected before re-using.
4. All labels used are self-adhesive.
5. Danger of Infection labels are used where appropriate.
6. All specimen containers are placed in transparent plastic bags before transporting.
7. Documentation is placed in a separate compartment of the plastic bag.
8. All waste is disposed of into appropriate clinical waste sacks.
9. Specimen containers are transported in boxes.
10. Specimen containers and bags, which show signs of external contamination, are not dealt with until it is confirmed that they are free of infection.
11. Full postal regulations are employed when sending specimens.

Chemical

Formal saline presents a small risk during this procedure as normally the container and bag will protect the operator. However, this risk is increased when containers are broken in transit. The Procedure and Risk Assessment for the Reception of Specimens outlines the method of dealing with such incidents. The risk of excessive inhalation is minimal due to the small volumes employed and the short exposure time.

The guidelines contained in the Standard Operating Procedures and Local Rules for Safety at Work have been formulated to reduce these risks to a minimum compatible with undertaking the task.

Existing Control Measures Include:

1. Those as listed under existing control measures for infection.
2. Spillage control kits and eye wash bottles are available
3. Preparation of Formal saline stock solution is carried out in a fume cupboard.

Injury to Patients

The risk of causing harm to a patient during this procedure is minimal. However, failure to completely remove patient identification labels from re-usable containers could lead to confusion when the container is re-used. A further possibility of causing harm arises when sending specimens from the department. Care must be taken to ensure that the documentation and specimen match.

Existing Control Measures Include:

1. All re-usable containers are checked to ensure that the labels have been removed whilst they are being cleaned.
2. Forms and specimens are double checked before dispatch.

Document References

EXT-43 HSE - Biological agents

EXT-44 IATA Packing Guidance

LABSOP-17 City Sprint Courier Service