

CELLULAR PATHOLOGY DEPARTMENT

Procedure for the Transportation of Clinical Specimens

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YOU ARE INSTRUCTED TO READ THE FOLLOWING PROCEDURE BEFORE PROCEEDING. UNDER NO CIRCUMSTANCES ARE THESE INSTRUCTIONS TO BE AMENDED OR ALTERED IN ANY WAY WITHOUT THE PERMISSION OF EITHER THE AUTHOR OR THE AUTHORISER.

Review Interval:	Every 24 months
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Risk Assessment:

Provided that Departmental Safety Procedures, Protocols, Manufacturers' instructions, and good laboratory practice are followed throughout this procedure, the following risk assessment applies:-

Preparation	Low risk
Instrumental	Low risk
Chemical	Medium risk. Cytolyt- methanol based, buffered preservative solution. Refer to COSHH assessment for specific reagent hazard 10% Formalin. Solid carbon dioxide pellets (dry ice/ cardice). Refrigerated solidified gas exists at -78.5°C. Contact with product may cause severe cold burns or frostbite. Asphyxiant in high concentrations. Wear cold insulating gloves. Protect eyes, face and skin from contact with product. Refer to COSHH assessment for specific reagent hazard.
Sample	Formalin fixed and fresh frozen tissue samples, paraffin blocks and microscope slides. Low risk. Unfixed fluid samples and cytology samples sent in Cytolyt, Medium risk Infection risk. Samples from patients known to be high risk must only be accepted and processed as per Departmental policy.
Disposal	Low risk. See LP-CPY-DispRelMat

Risk Assessment Score:

2 x 1 = 2

Introduction:

Clause 5.4.5 in the standard ISO 15189:2012 concerns the transportation of samples and states:

The laboratory's instructions for post-collection activities shall include packaging of samples for transportation.

The laboratory shall have a documented procedure for monitoring the transportations of samples to ensure they are transported:

- a) Within a time frame appropriate to the nature of the requested examinations and the laboratory discipline concerned;*
- b) Within a temperature interval specified for sample collection and handling and with the designated preservatives to ensure the integrity of samples;*
- c) In a manner that ensures the integrity of the sample and the safety for the carrier, the general public and the receiving laboratory, in compliance with established requirements.*

This procedure gives an overview of how clinical material is transported to, from and within Cellular Pathology, Cardiff and Vale University Health Board, within a temperature interval specified for sample collection and handling and with the designated preservatives to ensure the integrity of samples. This information ensures the timely arrival of specimens at laboratory reception, in optimal condition, in a manner that does not pose a threat to the health and safety of anyone coming in contact with the sample and is in compliance with regulations.

The service has more detailed procedures for specific requirements for transportation in the user handbook.

Reference is made to procedures that are used in the parent organisation, but which do not form part of the controlled documents of the Directorate Quality Management System.

Clinical Relevance/Purpose:

Samples are referred to other specialist centers for review and specialist opinion as clinically appropriate. This provides an enhanced service to clinicians and patients.

Principle:

This procedure outlines the method of safely transporting specimens referencing the appropriate regulations covering transport of biological material and the appropriate packing regulations.

Responsibilities:

Responsibility for the safe collection and packaging of the clinical samples shall rest entirely upon the sender. Instructions are available for users of the service with advice for samples that require specific handling conditions or prompt delivery to and from the laboratory.

References:

- Medical laboratories - Requirements for quality and competence (ISO 15189:2012) 5.4.5 Sample transportation [EP-LAB-BS EN ISO 15189:2012]
- The transport of infectious substances from and to UK premises is subject to the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (2009 No. 1348). This reflects the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) Regulations governing the transport of dangerous goods by road [ED-CPY-DangerGoodsADR]
- Goods transported by rail are subject to the intergovernmental organisation dedicated to international rail transport [ED-CPY-DangerGoodRailRID]
- The International Civil Aviation Organisation (ICAO) issues the "Safe Transport of Dangerous Goods by Air [ED-CPY-DangerGoodsAir]
- UN Recommendations on the Transport of Dangerous Goods [ED-CPY-UNRegTranDangGood]
- Department of Health – Transport of Infectious Substances – Best Practice Guidelines for Microbiology Laboratories [EP-LAB-TransportInfect]
- The Advisory Committee on Dangerous Pathogens' (ACDP) [ED-CPY-ACDP]

Related Documents:

- Laboratory Medicine Quality Manual [QM-LAB-QualMan]
- Laboratory Medicine Health & Safety Manual [MP-LAB-SafePol]
- Cellular Pathology user handbook on the Cardiff and Vale clinical portal contain details of transportation requirements for users [PD-CPY-UserHbk]
- Transport of Infectious Material [EP-LAB-TransportInfect]
- Procedure for the Overland Transportation of Tissue Potentially Contaminated with Creutzfeldt-Jakob Disease [LI-CPY-CJDTran]
- Procedure for Sending Muscle Biopsy Specimens to Cellular Pathology UHW [LP-CPY-NrMusInfo]
- Procedure for Transport and Storage of Pathology Specimens [PD-LAB-Tran&Store]
- Transportation of Frozen Specimens [LI-CPY-TranFz]
- Procedure for the control of records [LP-CPY-ContRec]
- Post Mortem Specimen tracking and recording system [LP-CPY-PMSpecTrack]
- Tissue From Deceased Worksheet 3 [LF-CPY-PMWkSt3]
- Referral of Brain Specimens to UHW [LI-CPY-BrainRef]
- Relevant Material Chain of Custody Form [LF-CPY-ChainCust]
- Relevant Material Chain of Custody external referralForm [LF-CPY-ChainCustExt]
- Tracking Tissue for Transportation to External Sites using Confirmation of Receipt Form [LI-CPY-TissTrack]

Specimen Requirements:

- Formalin fixed tissue
- Paraffin wax blocks
- Microscope slides
- Frozen tissue samples
- Fresh tissue in cell culture media
- Unfixed fluid sample
- Cytology samples in cytolyt

Equipment: N/A

Consumables:

- UN3373 compliant approved ridged postal containers with outer cardboard box.
- Slide carriage containers
- Padded postal envelopes

For frozen tissue:

- Thermal control transport box
- Solid carbon dioxide pellets

Calibration: N/A

Internal Quality Control:

For Neuropathology and Post Mortem cases:

A second person checks the sample identifiers and that the packing is in accordance with UN3373 and LP. For neuro-surgical biopsies, this is recorded in the neuropathology referral spreadsheet (S Drive). Referral of Post Mortem material is recorded on LF-CPY-PMWkSt3 with the location amended in the set tissue archive spreadsheet (LP-CPY-PMSpecTrack) and a chain of custody form must accompany the material.

Limitations of Procedure:

- This procedure applies to the packing and sending of fixed and frozen tissue samples, blocks and slides only.
- The transportation of cadavers to and from the Mortuaries is outside the scope of this document.
- This procedure does not apply to specimens from patients with suspected CJD (see LI-CPY-CJDTran)
- This procedure excludes detailed instructions for the transport of frozen biopsies (see LI-CPY-TranFz)

Procedure:

Bio hazardous agents are classified for transportation by UN Number:

Category B, UN 3373 - Biological substance transported for diagnostic or investigative purposes. This includes blocks, slides fixed, fresh and frozen samples.

<http://www.hse.gov.uk/biosafety/biologagents.pdf>)

A Summary of Packing Instruction 650 (PI650) applied to UN3373 Biological substance Category B.

Requirements

- The packaging shall be of good quality, strong enough to withstand the shocks and loadings normally encountered during carriage transfer between vehicles or containers or mechanical handling.
- The packaging shall be constructed and closed to prevent any loss of contents that might be caused under normal conditions of carriage by vibration or by change in temperature, humidity or pressure.

Components

- **Primary Leak-proof Receptacle i.e. sample container**
Multiple primary receptacles within a single secondary package must be individually wrapped to prevent contact between them.
Primary receptacles or secondary packaging shall be capable of withstanding, without leakage, an internal pressure of 95kPa (0.95 bar).
- **Absorbent Material (e.g. tissue paper or cotton wool)**
Sufficient to absorb the entire contents of the primary receptacle(s) without compromising the integrity of cushioning material or outer packaging.
- **Secondary Packaging**
The nature of secondary packaging is not specified however, to meet the requirements; it should be leak proof to protect the outer packaging should a primary vessel be caused to leak.
- **Cushioning Material**
Unspecified cushioning material to secure the secondary packaging within the outer packaging.
- **Outer Packaging**
The nature of the outer packaging is not specified; however the external dimensions of the outer packaging should be shall at least 100mm in two dimension. For transport the outer packaging should be marked externally with the symbol shown in Fig. 1 below. This symbol must have a contrasting background colour, be clearly visible and legible. The width of the line shall at least 2mm and the numbers & letters at least 6mm in height.

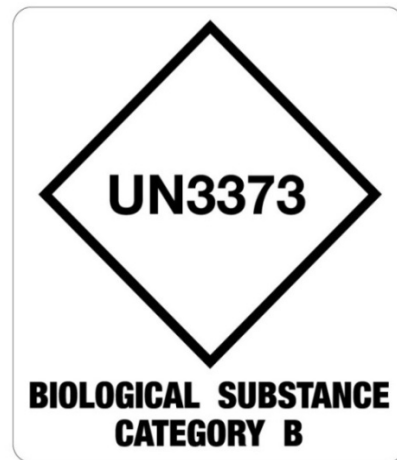


Figure 1
Hazard Label

It should also be labelled 'diagnostic sample'.

Transport of blocks and slides

The Instruction for Tracking Tissue for Transportation to External Sites using Confirmation of Receipt Form [LI-CPY-TissTrack] must be followed to ensure tissue is tracked so that all relevant staff has access to its whereabouts.

The outer packaging should be labelled as described, however the following changes are appropriate for the packaging:

- **Blocks**
These should be placed inside two layers of packaging with sufficient cushioning to provide safe transport (within a well secured plastic bag inside a padded mailing bag is appropriate)
- **Slides**
Use appropriate commercially available slide transport containers inside outer packaging with sufficient cushioning (again a padded mailing bag would be appropriate)

Completed Package - Drop Test Requirement

The completed package shall be capable of successfully passing a drop test of not less than 1.2m.

A. POSTAL SPECIMENS

All surgical material is to be sent by recorded delivery via the Post Room.
All post mortem material must be transported via courier (see section E).

B. SPECIMENS TRANSPORTED BY WELSH AMBULANCE SERVICE

References:

- Transport of Infectious Material [EP-LAB-TransportInfect].

All transport boxes used to transport specimens by road must have a UN3373 Biological substance category B diamond on them. They should also have hazard labels and contact telephone numbers in case of spillage.

Specimens are fixed prior to transportation thus the biological (infection) hazard is eliminated but a chemical hazard is introduced as formalin is toxic by inhalation and ingestion and is a contact irritant. Occupational Exposure limits MEL 2ppm.

All drivers should receive training and education to make them aware of the potential hazards to which they may be exposed and a contact number for further information.

Small histology specimens are sent in leak proof plastic containers containing buffered formalin or cell culture media as appropriate. Cytology samples are transported unfixed in universal containers. All containers are fully labelled and placed in an individual plastic transport bag. The bag must be sealed by means of an integral sealing strip. The Request form must be placed in a separate pocket but attached to the specimen. These should then be placed in a transport box along with enough absorbent material to soak up the fluid contained in the specimens in the result of a spillage.

If a specimen is found to be leaking or broken a senior member of staff should be asked to deal with it and the leakage reported to the designated safety officer. Incidents should be reported as on the UHB incident reporting form and entered on to the CAPA module of Q-Pulse which is reviewed to ensure there are no trends.

Large specimens, e.g. breast, should be thoroughly fixed, drained and then sealed in a clear plastic bag of suitable proportions. It should be surrounded by absorbent materials and placed in a sealed clean plastic container comprehensively labelled. The request form or documentation should not be placed in the bag with the specimen, but should be placed in a plastic envelope which should be included in the transport container.

Everything placed in the box at UHW for transfer must be logged on the District Transport Log.

Emergency requests contact:

HCS Controller – 07764 835755

HCS Manager – 07730 015761

C. LABORATORY SPECIMENS TRANSPORTED BY PORTERS

Ref. PD-LAB-Tran&Store

The specimen in its primary container must be placed in a transport specimen bag attached to the request form (secondary container) and sealed by means of the integral sealing strip. If more than one primary specimen container is placed into a secondary bag then there should be sufficient cushioning to prevent contact and breakage and sufficient absorbent material to absorb the total volume of any possible liquid spillage. It is the responsibility of the requester to ensure the samples/forms are correctly labelled and packaged.

The porter must transfer the specimen bags into a specimen carrier container (the outer container) that is suitable for the purpose, prior to being removed from the ward/department.

For the majority of samples this should be a lockable carrier such as a toolbox lined with suitable absorbent material. The specimen carrier should be made of a smooth impervious material with entire sides that can be easily disinfected and must be able to retain any fluid in the case of a spill.

For large specimens the containers must be enclosed in a large sealable specimen bag.

The container should have a secure lid for transport purposes and the outer carrier should be marked with a biohazard sign. There should also be a notice with contact instructions in the event of it becoming lost.

Fresh tissue samples and cytology samples must be sent to the laboratory in a timely manner and should be stored in a fridge between 2-6 °C for up to 48 hours without altering the sample integrity if access to the laboratory is unavailable.

All personnel involved in the transportation of specimens should be made aware of the potential hazards to which they may be exposed and provided with the necessary control measures to minimize the risks to an acceptable level.

- Education and training
- Policies and procedures
- Advice and contact numbers in the event of a spillage
- Immunisations
- PPE if required

Decontamination Procedure

Wash transport boxes weekly using a general purpose detergent solution and hot water. If the transport box is contaminated e.g. as a result of a broken specimen or specimen spillage the box will be disinfected.

If transporting samples between buildings then a UN3373 Transport box with appropriate signage should be used.

D. TRANSPORT OF FROZEN TISSUE

For packing and sending instructions refer to LI-CPY-TranFz.

E. POST MORTEM SPECIMENS

(see also LP-CPY-PMSpecTrack)

i. Frozen Brain Referral

Relatives of the deceased sometimes request brain donation to a number of brain banks. In these cases the Neuropathologist may freeze either the whole, half or samples from the brain at the request of the relevant brain banks according to their LPs. These frozen

specimens are then sent to the brain banks following their instructions. The brain banks provide dry ice in a polystyrene box and plastic bags in which to place the frozen brain specimens, they also arrange courier transport.

The referral is recorded in the wet tissue archive and on a 'Tissue from the deceased' Worksheet 3 (LF-CPY-PMWkSt3). A Relevant Material Chain of Custody external referralForm [LF-CPY-ChainCustExt] must accompany the samples.

The retained frozen tissue records are updated.

ii. **Brain Referral to UHW**

See [LI-CPY-BrainRef] "Referral of Brain Specimens to UHW"

F. TRANSPORT OF TISSUE POTENTIALLY CONTAMINATED WITH CJD

Ref. LI-CPY-CJDTran "Procedure for the Overland Transportation of Tissue Potentially Contaminated with Creutzfeldt-Jakob Disease"

G. INCIDENTS RELATED TO SPECIMEN TRANSPORT

Any incident that occurs whilst transporting specimens to the hospital/laboratory that may affect the quality of the specimen or the safety of personnel must be reported on e-Datix.

Results: N/A

Reporting Reference Limits: N/A

Interpretation: N/A

Alert Values: N/A

Performance Criteria: N/A

Record Keeping and Archiving:

Please refer to the departmental records procedures:
[LP-CPY-ContRec] – Procedure for the Control of Records

Any Other Information: N/A