

## CELLULAR PATHOLOGY DEPARTMENT

### INSTRUCTION FOR REFFERAL OF MUSCLE OR NERVE BIOPSY SPECIMENS TO CELLULAR PATHOLOGY DEPARTMENT UHW

**THIS IS A CONTROLLED DOCUMENT AND MUST NOT BE PHOTOCOPIED OR  
DISTRIBUTED WITHOUT AUTHORISATION**

**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

#### **Risk Assessment:**

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

<b>Preparation</b>	Low risk
<b>Instrumental</b>	N/A
<b>Chemical</b>	No risk.
<b>Sample</b>	Fresh muscle or nerve tissue samples. Samples from patients known to be high risk must only be accepted and processed as per departmental policy.
<b>Disposal</b>	Not applicable to this procedure

#### **Risk Assessment Score:**

$$3 \times 1 = 3$$

See QF-CPY-RAMusCollectPrep

#### **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 diagnostic muscle and nerve biopsies should be transported to the Cellular Pathology Department, Cardiff and Vale University Health Board. This information ensures the timely arrival of specimens at the Cellular Pathology 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 in compliance with regulations.

All communication regarding these samples must be made directly with the Neuropathology Laboratory (02920 45983)

### **Clinical Relevance/Purpose:**

Fresh muscle and nerve biopsy samples are referred to the Cellular Pathology department for specialist diagnosis.

### **Principle:**

This procedure outlines the method of safely transporting muscle biopsy specimens. It references the appropriate regulations covering transport of biological material and the appropriate packing regulations.

### **Responsibilities:**

Responsibility for the safe collection, correct packaging and prompt delivery of the clinical samples shall rest entirely upon the sender.

### **References:**

- EP-LAB-BS EN ISO 15189:2012 – Medical laboratories - Requirements for quality and competence 5.4.5 - Sample transportation
- EI-LAB-GuideNoteTransSpec Packing Instruction 650 (PI650) applied to UN3373 Biological substance Category B.

[Packaging and transport requirements for patient samples – UN3373 - GOV.UK \(www.gov.uk\)](http://www.gov.uk)

### **Related Documents:**

Cellular Pathology user handbook on the Cardiff and Vale clinical portal contain details of transportation requirements for users [PD-CPY-UserHbk]

QF-CPY-RAMusCollectPrep – Muscle biopsy collection and preparation

LP-CPY-ContRec - Procedure for the control of records

LP-CPY-NrMusBx – procedure for reception and handling of muscle biopsies

## LP-CPY-NerveBx - Procedure for Nerve Biopsies

### **Specimen Requirements:**

#### 1. Fresh muscle tissue

Site of biopsy to be determined by clinician and surgeon and dependent on patient's symptoms and previous investigations:

Adult muscle biopsy: Fresh muscle tissue measuring approximately 15x10x5mm.

Paediatric muscle biopsy: Fresh muscle tissue, minimum recommended size 10x5x5mm however this is dependent on age and determined by surgeon on a case by case basis.

As the quality of histopathology is highly dependent upon the handling of the tissue after removal from the patient, the treatment should be as follows:

A piece of muscle should be removed from the chosen site of biopsy. In severe cases of muscle disease this should not be the worst affected muscle but the nearest muscle to it.

The biopsy should be laid longitudinally on a piece of glossy card. The card, bearing the tissue should be inserted into a dry, specimen container.

Please do not use paper or gauze, if no glossy i.e. non-absorbent card is available, place the tissue directly into the specimen container.

Please do not wrap, suture or pin the specimen. Please do not add saline or any other fluid to the sample container.

Under no circumstances should ice be allowed to come into contact with the muscle biopsy, either directly or indirectly.

#### 2. Nerve biopsy:

Fresh nerve biopsy (usually sural nerve) measuring 40 mm in length. The biopsy should be laid longitudinally on a piece of glossy card. The card, bearing the tissue should be inserted into a dry, specimen container. Please do not use paper, if no glossy i.e. non-absorbent card is available, place the tissue directly into the specimen container. Do not fold, wrap or attach the nerve to the card.

Under no circumstances should ice be allowed to come into contact with the nerve biopsy, either directly or indirectly.

### **Consumables:**

Dry Histopathology specimen container / Universal container

UN3373 compliant approved ridged postal containers with outer cardboard box.

**Calibration:**

N/A

**Limitations of Procedure:**

This procedure only covers the referral of fresh muscle and nerve biopsies to UHW

**Procedure:**

Muscle and nerve biopsies require special handling. At least 24 hours' notice of intention to carry out such biopsies is required. Please ring the Neuropathology section ex 45983.

Biopsies should not be sent without prior notification.

Biopsies must arrive at UHW between 9:00am and 3:00pm on the same day they were taken.

Telephone notification should be recorded by UHW lab staff on a telephone log form [LF-CPY-SensTelLog] and be recorded in the neuropathology laboratory diary for the day the sample is due to be received.

A UHW Muscle and Nerve biopsy request form (available in the Cardiff and Vale UHB intranet Cellular Pathology website) should be completed with as much clinical information as possible, including the results of any relevant previous investigations e.g. electromyography, CK levels, family history, etc. The date and time of biopsy and the address for the report must also be recorded on the request form.

Please ensure the Clinicians name and department is recorded on the form and not just the surgeon.

A signed consent form permitting storage for future investigations or research (Pg. 2 of the request form) should be sent either with the specimen or in advance to the Neuropathology secretary.

Please note, biopsies will not be reported unless full clinical information is supplied either in advance of the biopsy or attached to the request form.

**1 Packaging**

Bio hazardous agents are classified for transportation by UN Number: UN3373 category B - Biological substance transported for diagnostic or investigative purposes and Packing Instruction 650 (PI650) applies:

**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 dimensions. 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.

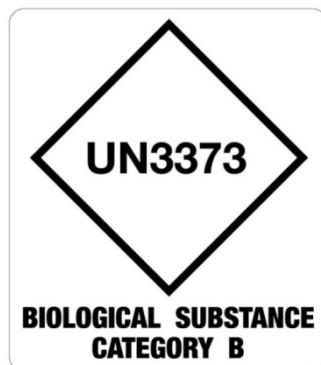


Figure 1  
Hazard Label

## Completed Package - Drop Test Requirement

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

## 2. Transport

The biopsy and request form should be sent immediately to Cellular Pathology reception, UHW, ideally being received within 1 hour of the biopsy being taken. Transport should be arranged by the referring hospital. However, hospital transport is not considered appropriate due to the delay this mode of delivery incurs.

The package should be labelled:

**“URGENT – PLEASE PHONE NEUROPATHOLOGY  
ON EXTENSION 45983 ON ARRIVAL”.**

A referral letter containing all relevant clinical information, relevant family history and EMG study results together with the signed consent form permitting storage for future investigations or research should be sent either with the specimen or in advance to the Neuropathology secretary.

The Neuropathology Section at UHW should be notified by telephone (02920 745983) of the departure and approximate time of arrival of the biopsy. **The biopsy must arrive between 9:00am and 3:00pm on the same day it was taken.**

In cases where a diagnosis of mitochondrial myopathy is suspected consideration should be given to referring the patient to UHW for biopsy as the sample required for mitochondrial DNA/RNA analysis must be snap frozen as quickly as possible after removal from the patient. A delay of an hour may compromise the results of this analysis.

### **Results:**

Specimens received in optimum condition for diagnosis

### **Record Keeping and Archiving:**

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