TRANSPORT OF SAMPLES

NUTRITION CENTRES

TRANSPORT OF SAMPLES NUTRITION CENTRES

1. Scope

This procedure is to be followed by the ECRIN Nutrition Centres when transporting samples (blood samples, tissue biopsies, etc).

This procedure describes the Best practices for transporting samples applicable to packaging, transport and reception of these products.

The products must be transported under conditions permitting:

- To ensure their preservation and integrity;
- Routing within previously defined timelines;
- Respect the rules of hygiene and safety vis-à-vis the people and the environment.

2. Responsibilities

It is the responsibility of the Management team in the Nutrition Centres to ensure that this procedure is adapted and followed.

The responsibility for the establishment of dispatch runs until the receipt of the product by the recipient.

When the routing operations are the responsibility of the receiving facility or a service, this or that provider is responsible until reception of the products.

3. References

- WHO /CDS/EPR/2007. Guidance on regulations for the transport of infectious substances 2007.
- ADR: European Agreement concerning the international carriage of Dangerous goods by Road, entered into force on 29/01/1968, regularly amended and updated for entry into force on 1 January 2013, a revised consolidated version has been published as document ECE/TRANS/225, Vol. I and II ("ADR 2013").

- European regulation on blood and blood components: mother Directive 2002/98/EC of 27 January 2003 and daughter directives 2004/33/EC, 2005/61/EC and 2005/62/EC setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC
- JORF FrenchOfficial Journal No. 105 of 5 May 2002 Page 8703 Text No. 129 Decree of 24 April 2002 on the approval of the Regulation on best practices for transporting samples, and products derived from human blood samples

4. Terms, definitions, abbreviations

ECRIN: European Clinical Research Infrastructures Network

WHO: World Health Organisation

SOP: Standard Operation Procedure

Sample: sampling substance (blood and its components, tissue and fluid tissue, biopsies, urine, feces,secreta,etc.) if needed pretreated (centrifuged, pipetted, aliquoted, purified, etc.) and conditioning (tube, aluminum foil, etc.), ready to be sent to the laboratory performing the assay.

Primary containers are: tubes, bottles, swab holders,etc. which are all watertight and labeled.

5. Documentation

SOPNUTR0001 BLOOD SAMPLE COLLECTION v00

SOPNUT0003 ADIPOSE TISSUE NEEDLE ASPIRATION BIOPSY v00

6. General

The purpose of this Standard Operation Procedure is to ensure that the process of samples transport for Nutrition Centres is performed under standardised conditions.

7. Safety Considerations

- A white laboratory coat or tunic is worn and fastened to the top.

- Gloves must be worn when handling samples.
- Any member of staff handling blood samples are advised to be vaccinated against Hepatitis B.
- Safety glasses should be available for staff if required.
- Discard used items into the appropriate category of waste.
- Remove all personal protective equipment before leaving the laboratory or work area.

8. Sample Requirements

The sample preparation, if necessary (centrifugation, aliquoted, cryogenic, etc.) is made by the person responsible for collecting the samples (blood, tissue, etc.).
The samples are kept at the correct temperature according to the analysis and the local laboratory guidelines.
- At room temperature (bench e.g. DNA)
- At 4 ° C in the laboratory refrigerator.
- At -20 ° C in the freezer.
- At -80 ° C in the freezer.

9. Materials

The equipment required includes:

- A supply of sample tubes within the expiration date.
- Well fitting, non-sterile gloves.
- refrigerated centrifuge
- crushed ice
- liquid nitrogen
- dry ice
- polystyrene box

- Laboratory sample labels
- Leak proof transportation bags and containers
- Dispatch note
- Laboratory forms

10. Sample Identification (Name, DOB, Hospital No.)

- Recheck the labels on the tubes and the forms for accuracy before dispatch. The label must be clearly written with the information required by the local laboratory, the subject's first and last names, hospital number, date of birth and date and time when the sample was collected. Never proceed with samples if there is a discrepancy.
- If there are any concerns regarding the procedure, discuss the concerns with the relevant manager before continuing with the procedure.

11. Transport of samples

After the pre-analytical processing locally, samples are transferred in isothermal packing within predefined temperature limits to the Laboratory for analysis.

If road transport is required, ADR regulations must be complied with by the person or the provider in charge of transport.

Traceability of the cold chain must be provided by a control system with temperature recording device. The data collected by the system must be stored in the laboratory and traceable.

Transport documents are attached to all the samples and archived in the laboratory.

12. Packaging

This section details the correct method of packing the samples, so they reach the laboratory undamaged and within acceptable temperature limits.

It include: packaging, equipment to ensure the proper temperature, temperature indicators, labeling, dispatch note and instructions to people in charge of transport.

The sender is responsible for the packaging of products that must be performed in its premises and staff.

a. Samples sent to the laboratory of the centre for immediate testing

- For not frozen samples

  Tube(s) are shipped in a plastic leak-proof bag or box with an outside compartment for the required documents.

  Tubes should be wrapped with absorbent material in sufficient quantity to absorb the entire contents in case of breakage.

  If there are multiple tubes placed in a single leak-proof bag, they are either individually wrapped or separated using rack or padded holder to prevent contact between them.

- For frozen samples at -20°C

  Tube(s) will be put in a plastic leak-proof bag or box with crushed ice and transported quickly.

  Tubes should be wrapped with absorbent material in sufficient quantity to absorb the entire contents in case of breakage.

  The tubes will be accompanied by the required documents.

  Well indicate the samples are stored at - 20 °C.

- For frozen samples at -80°C

  Sample immersed in a nitrogen tank will be transported along with the required documents.

  Well indicate the samples are stored at - 80 °C.

b. **Samples sent to a laboratory outside the centre implying road transport**

Plan the delivery time for the samples to arrive one business day.
In case of frozen samples plan to order dry ice or liquid nitrogen in advance.

ADR regulations should be followed. Biological samples for analysis are classified as UN 3373 "Biological substance, Category B". The triple packaging system is used.

An outer container will be added to the corresponding packaging of paragraph a.
The outer container should be of adequate strength against external damage (shock or water) for transit protection, and with at least one surface having minimum dimensions of 100 mm × 100 mm;

Eutectic must be sufficient to maintain the package in the desired temperature. Their position within the package must maintain a uniform temperature throughout the volume of the parcel
Temperature indicators should be placed in the thermostatically enclosure.

Each package shall be properly marked, labeled and accompanied by specific transport documents (as applicable).

The packaging must be closed to ensure the integrity of goods transported during the period of their delivery.

13. Blood cold chain during transport

Temperature variations during transport can cause a deterioration of the products.
Transport arrangements must guarantee conformance to temperature range specifications.

A local procedure establishes a program of thermal controls to monitor the integrity of the cold chain temperature throughout the shipping process.

To validate the temperature conditions during transport, traceability of the cold chain must be provided by a control system with temperature recording device.
The data collected by the system must be stored in the laboratory and traceable.

If an intermediate storage area involved, it must allow recording of temperature and have an alarm and appropriate hygiene procedures.

14. Reception of the products

The recipient verifies compliance of transport conditions, including:

- The integrity of the packages;
- The respect of the hygiene conditions of the parcels
- The respect of the conditions of transport temperature;
- The respect for the duration of transport.

Please note! If any discrepancies contact the sender immediately

15. Limitations & Pitfalls of the Examination

16. Method Validation

- ADR Regulation for transport
- Local validation procedures for cold chain management

17. Procedure Notes & Other Pertinent Information

Safety procedures training staff

18. Appendices

- Appendix 1: MINIMUM MANDATORY INFORMATION REQUIRED ON THE LABELS OF THE OUTER CONTAINER

- Appendix 2: SAFETY INSTRUCTIONS FOR TRANSPORT

Appendix 1

MINIMUM MANDATORY INFORMATION REQUIRED ON THE LABELS OF THE OUTER CONTAINER

- Name, address, telephone number and fax number of the sender
- Name, address, telephone number and fax number of the recipient
- The word "IN CASE OF ACCIDENT OR INCIDENT DURING TRANSPORT, INFORM SENDER IMMEDIATELY"
- Logo UN 3373 "Biological substance, Category B"
- Eventually, the conduct during the transport (temperature, duration of transport not to be exceed ...).
- Possibly the action to be taken on receipt (eg "AT RECEIPT, TRANSFER PRODUCTS A + 4 ° C");
- Biohazard label can be added following local regulation

Appendix 2

SAFETY INSTRUCTIONS FOR TRANSPORT

Nature and threat posed by the products transported;

Preventive measures;

Measures to be taken if product leaks; if contact with the products.

Material for protections and absorption;

Details of the sender or the security service to contact.