INSTITUTO NACIONAL DE CÂNCER

GUIDELINES FOR HPC TRANSPORTATION

REDOME
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Brazilian Registry of Volunteer Bone Marrow Donors (REDOME)
José Alencar Gomes da Silva National Cancer Institute (INCA)
MINISTRY OF HEALTH

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Presentation

Founded in 1993, REDOME (the Brazilian Registry of Volunteer Bone Marrow Donors) has established itself as the third largest registry of volunteer bone marrow donors in the world. This success must be shared with the entire network that has been working to enable potential donors and patients to access the registry throughout the Brazilian territory.

However, maintaining a nationwide registry in a country as vast as Brazil represents a major challenge, especially considering the follow-up procedures upon locating a donor, and all the steps requiring complementary tests to assess and confirm compatibility, which is critical for the successful transplantation of hematopoietic stem cells; this scenario highlights the role of blood centers and histocompatibility laboratories.

Transferring selected donors to specialized collection centers and guaranteeing a humane, safe environment for their assessment is also a result of REDOME's work with the various professionals who welcome them.

Throughout its history, REDOME has made efforts to keep up with technical and scientific advances, with a view to promoting a significant improvement in transplant results for our patients, who find renewed hopes of leading a full, healthy life in the volunteer donors in our registry.

Inspired by values such as ethics, transparency, cooperation and innovation, we are grateful for our successful partnership with blood centers, histocompatibility laboratories, transplant and collection centers; accordingly, this document presents some general guidelines intended to consolidate our activities for the benefit of our donors and patients.

Dr. Danielli Oliveira

REDOME Technical Coordinator

Introduction

Hematopoietic Progenitor Cells (HPCs) are extremely sensitive to temperature conditions, which may affect their viability. In this sense, the proper transportation of this material is critical to guarantee the safety of the transplant procedure, and the guidelines for each type of material to be transported must be respected.

1. Material Preparation

The material must be prepared for transport according to its specificity, observing the transport verifications required by the shipping center and/or courier company.

The material must also:

- Be identified with the DMR or GRID (donor identification code);
- Be identified with the name of the product;
- Include a record of the collection date;
- Include a record of the collection completion time;
- Include the name and volume of any anticoagulant;
- Include a record of the recommended temperature for transport;
- Be properly sealed and prepared for transport.

2. Transport case

- Thermal transport bags must be individually identified, verified and periodically assessed for to their capacity to maintain the desired temperature;

- Their evaluation and verification must contain, at least, the maximum capacity (volume) of the material to be transported, and how long they can maintain the intended temperature;
- All thermometers used for verification and transport must be calibrated annually, or checked for their thermal accuracy;
- All supporting documents required for the validation of the items described above must be available for consultation.

3. Identification of the Thermal Transport Case

The outside of the thermal bag must bear the following information, according to the material:

- Biohazard Labels;
- “Do not irradiate / Do not expose to X-ray” warnings;
- "Human Cells for Transplant" or equivalent warnings;
- Date of collection;
- Name and address of the recipient health facility;
- Name and contact telephone number of the patient's transplant center;
- Name, address and contact telephone number of the collection center.

4. Labeling

The material must be prepared and labeled following current regulatory standards and all requirements of the accreditation bodies, including the WMDA.

The labels of all released products must be inviolable and remain intact throughout the storage period, until the product's expiration date, and contain the following information:

- Total cell volume;
- DMR or GRID identification;
- Recipient RMR;
- Expiration date and time, within 48 hours;
- Date and time of collection;
- Anticoagulant volume;
- Temperature at 2-24°C;
- “Do not radiate”;
- “Do not use leukocyte filter”.

Further details about the product must be included in the collection form attached thereto[1] (**FOR029 - Transport Report** or **C10 - Collection Report).**

5. Couriers

- People responsible for carrying biological materials intended for transplantation must be trained to meet the requirements set forth by national, international and REDOME transportation standards;
- Couriers must be associated at some degree with the company responsible for the transport or institution picking up the material;
- Couriers must undertake to comply with all guidelines for transporting biological materials, aiming at the safety of donors, patients, the couriers themselves, and their communities, as well as to maintain the confidentiality required by the process;

[1]The forms mentioned in this Manual will be provided by REDOME, upon request.

- REDOME must receive all identifying details pertaining to the transport of these materials, including a contact telephone number, having also provided its own means of contact;
- Couriers must inform REDOME of any intercurrence or issue during the transportation of materials, using the indicated means of contact.
- It is critical to keep a record of the entire process, such as the corresponding collection and transport reports.

6. Transportation

- The transportation process must observe the specificity of each type of material;
- Transportation data must contain, at least: a record of the temperature of the material throughout the entire transport, date and time of packaging and receipt at the transplant center, as well as identifying details and the signature of the person responsible for storing, transporting and receiving the material;
- Couriers must have an alternative travel plan, should the need arise;
- All supporting documents must be sent to REDOME, as soon as the transportation is completed.

7. Documentation

A collection report (**FOR030 - HPC Quantification Report** or **FORMC010 - Collection Report**) containing all information concerning the material will be provided by the collection center; the report must be completely filled and kept by the courier, until the material is delivery to the transplant center.

Every document pertaining to the transportation of cells, such as the courier's identification letter and guiding statements so that the material can be shipped without going through an X-ray, will be provided by REDOME.

REDOME is responsible for requesting authorization from the National Transplant Center (CNT), allowing the material to enter flights, as required.

For cells of foreign origins arriving in the national territory, REDOME will request authorization from ANVISA to inspect them, forwarding the supporting documents to the courier.

8. Cryopreserved cells

Cryopreserved HPCs from volunteer donors or umbilical cord blood units are carried out in a specific container (*Dryshipper*), provided by the collection center or transport company.

This material is dispatched as cargo with specific documents for customs clearance, which will be prepared by REDOME, jointly with the competent health authorities, and then sent to the transport company.

After the material is delivered to the transplant center, the *dryshipper* must be returned to its place of origin by the transport company.

9. Data Privacy and Security

REDOME works to guarantee the privacy of all users of its computerized systems, patients and donors, and provides for that the confidentiality of all patient and donor information made available within the scope of the process of identifying compatible donors for allogeneic transplantation is respected, according to the REDOME Privacy Policy and the General Data Protection Law (LGPD) - LAW No. 13,709, OF AUGUST 14, 2018.

All employees involved in this activity must be informed about their responsibility in the process.

10. Final thoughts

We have described some good practices in the transportation of biological materials, in addition to the supporting documents provided by each agency.

REDOME values a good relationship with its service providers, and remains available for further clarification through the following channels:

Email: rereme@inca.gov.br

Telephone: (21) 3207 - 4707

Website: http://redome.inca.gov.br/

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Developers:

Adriana Santos Nunes

Maria Fernanda Carneiro Machado

Reviewer:

Douglas do Amaral Vidmontiene

Approver:

Danielli Cristina Muniz de Oliveira