INCA
INSTITUTO NACIONAL DE CÂNCER

# MANUAL
# TRANSPLANT CENTERS

REDOME
INSTITUTO NACIONAL DE CÂNCER

Brazilian Registry of Voluntary Bone Marrow Donors (REDOME)
Instituto Nacional de Câncer José Alencar Gomes da Silva (INCA)
MINISTRY OF HEALTH

# SUMMARY

# Presentation

Created in 1993, REDOME (Registry of Voluntary Bone Marrow Donors) has consolidated its position as the third largest registry of voluntary bone marrow donors in the world and this success must be shared with the entire network that has worked to ensure access to potential donors and patients to the registry throughout the Brazilian territory.

However, maintaining a nationwide registry in a country the size of Brazil is a major challenge, especially in the contact with this donor after the registration and in the steps that involve complementary tests for identification and confirmation of compatibility, fundamental to the success of hematopoietic progenitor cell (HPC) transplantation, highlighting, in this scenario, the work of blood centers and histocompatibility laboratories.

The displacement of selected donors to specialized collection centers and the assurance of a humanized and safe environment in the evaluation of these donors is also a result of REDOME's work with the various professionals who receive them.

Throughout its history, REDOME has endeavored to keep up with the technical and scientific changes that have promoted a significant improvement in transplant results for patients who find in the voluntary donors of our registry, the renewal of their hopes for a full and healthy life.

Guided by values such as ethics, transparency, cooperation and innovation, we thank the successful partnership with blood centers, histocompatibility laboratories, transplant and collection centers and present in this document some general guidelines that seek to strengthen this activity for the benefit of our donors and patients.

Dr. Danielli Oliveira

REDOME's Technical Coordinator

## Introduction

REDOME developed this manual with the purpose of offering information and guidance on good practices in the steps of filling out the registration of patients and prescription of cell products collection for transplantation in order to ensure the best care for patients awaiting hematopoietic stem cell transplantation with an unrelated donor.

The topic of correct labeling of the material was also addressed as a strategy that seeks safety in the use of these products.

At the end, we presented guidelines on the confidentiality breaking process between donor and patient that must take place in an environment that ensures the respect and safety of all involved.

We hope that the several collaborators working in the transplant centers can use this information in a way to benefit all those who benefit from this important activity.

# 1. Privacy and Data Security

REDOME works to ensure the privacy of all users of its computerized systems, patients and donors, and advises that all information available in the identification process of a compatible donor for allogeneic transplantation, respects the privacy of patients and donors, according to REDOME's Privacy Policy and in accordance with the General Law of Data Protection.

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

# 2. Registration in REDOMENET

## 2.1. Patient Registration in REDOMENET

Patients who are candidates for transplantation must be registered in the REDOMENET system, through the website link: https://redomenet.inca.gov.br, by the physician responsible for that patient.

The manuals and video classes guiding the registration of patients are available on the links below:

https://redomenet-manual.inca.gov.br/pt-br/fluxos_paciente

https://redomenet-manual.inca.gov.br/pt-br/video_aulas

## 2.2 Physicians Registration in REDOMENET

Access to the REDOMENET system is restricted to users previously registered in the system, using a personal username and password to access the restricted area of the register through the link on the site: https://redomenet.inca.gov.br

The manuals and video lessons about physician registration are available in the links below:

https://redomenet-manual.inca.gov.br

https://redomenet-manual.inca.gov.br/pt-br/video_aulas

## 3. Guidance for Filling Prescriptions

The prescription is a key document to request hematopoietic progenitor cell products of donors and for the success of the transplant.

When failures occur at filling the prescription, it is necessary to send the document again, which affects the efficiency of the process, affecting the patient in question, but also impacts other patients awaiting this procedure.

For these reasons, REDOME has prepared basic guidelines in order to elucidate the filling of prescription requests. This orientation does not dispense the clarification of doubts by REDOME for filling the requests, it only seeks to guide the basic information to be filled.

The deadline for sending the requests is a key aspect at this stage, as it must consider the donor's availability and the possibility of interstate travel, in addition to the availability of a collection center.

**REDOME recommends that the prescriptions be sent at least 45 days in advance, so that they can be fulfilled without prejudice to the patient or the donor.**

**In case the product is expected to be cryopreserved for later infusion, this information must be filled in the respective fields and the infusion deadline must be as short as possible, in order to ensure the real use of this product, considering the respect for the voluntary donor and the impact of unnecessary logistics in the collection centers.**

**It is important to highlight that if the transplant occurs in a private service, through a health insurance, the insurance authorization must be sent together with the prescription so that the process can be started.**

Cases of subsequent HSC donation from national or international donors must be requested by sending a new prescription and medical report justifying the new collection. This report will be evaluated by REDOME's technical coordination, which may request additional information.

## 3.1. For Request of National Donor

### 3.1.1. FOR027 - Prescription of Hematopoietic Stem Cells[1]

All fields must be filled legibly and without erasures. If these guidelines are not followed, the Work Up team is oriented to request a new filled prescription.

**RECEIVER IDENTIFICATION**: Fill out all the recipient's data, such as RMR, gender, age at the time of the transplant request, disease diagnosis (as registered in REDOMENET), history of previous transplants, ABO/Rh typing, and weight (in kilograms).

**TRANSPLANT CENTER**: Document the hospital requesting the transplant, city/state, and the deadline date for receiving the work-up results.

[1] Forms cited in this Manual will be made available by REDOME, as requested.

**DONOR IDENTIFICATION**: Record the DMR, ABO/Rh (there are cases that there is no record in the system, in these cases, indicate "Not informed" or "No Record". Do not leave blank!), sex and weight (in kilos) of the requested donor.

**PRODUCT REQUEST:** Record in the fields corresponding to the option, Bone Marrow or Mobilized Peripheral Blood, the preferred choice of cell source.

**There is no requirement to indicate two cell source options but restricting the choice to only one source can complicate the collection process by limiting the options of services available.**

Then record the respective doses and the total amount of cells requested, also taking into consideration the donor's weight limit. In case of weight incompatibility between patient and donor, especially in bone marrow collections, the requested target may not be reached.

**PERIPHERAL BLOOD SAMPLES TOGETHER WITH THE HSC COLLECTION** may be requested. The maximum volume of 50 ml has to be obeyed, considering also the sum of the volume of different tubes.

**REQUESTED DATES FOR BONE MARROW OR BLOOD SOURCE PERIPHERIC:** Inform different possible dates for the collection to be done, considering the expected date for transplantation. **It is important that there is an interval of at least one week between the options.**

**All prescriptions must bear the legible name of the ordering physician and be dated, signed and stamped.**

**Compatible donors and umbilical cord blood units selected for transplantation are considered “reserved” for a given patient for a period of 6 months, which may be renewed for another period of 6 months, after transplant center sending a justification including a probable date of the transplant. After 12 months, the selected donor will be released becoming available for other patients.**

## 3.2. For Request of International Donor

The forms used to apply for international registrations may vary according to the procedure established by the registry, but we describe below the guidelines related to the main international registry that works in this activity with REDOME: NMDP - National Marrow Donor Program - USA voluntary donor registry.

### 3.2.1. NMDP FORM 22 – Confirmation of Donor HLA Typing:

1. Recipient NMDP ID: RID (Patient Identification Number in the International Registry)
2. Recipient Last Name: patient's last name and corresponds to the names preceding the comma in the registry. E.g: DA SILVA, JOSÉ LUIZ → DA SILVA
3. Recipient Local ID: RMR XXXX (patient identification number in REDOMENET)
4. Donor NMDP ID: Donor identification number in the international registry
5. Confirmation Test Date: Report Date" date verified on the donor's CT report. Date in default Month/Day/Year.
6. HLA – Fill in loci A*, B*, C*, DRB1*, DQB1, and DPB1* with the typing released on the donor's CT report.

Note: The HLA typing to be filled out on the form must faithfully contain all the digits that appear on the report, including letters, if any. E.g.: A*02:01:01:02L should be transcribed as A*02:01:01:02L and not as 02:01.

NATIONAL MARROW DONOR PROGRAM®

## Confirmation of Donor HLA Typing

**Registry Use Only**

Sequence Number:

Date Received:

Recipient NMDP ID: 1 389-999-7 Phenotype Sequence ID:

Recipient Last Name: 2 DA SLIVA,

Recipient Local ID: 3 22222 TC Code:

Donor NMDP ID: — or — 4 2121-7880-5

Coop Reg Donor ID:

Confirmation Test Date: 5 06 (Month) 18 (Day) 2018 (Year) Coop Registry ID: *(see page 5 for codes)*

**A Form 22 must be completed for each donor requested to provide blood for Confirmatory Typing (CT). If the donor is being requested for work-up, the Form 22 must be submitted either prior to, or at the time of the work-up request.**

**Registry Use Only**

### HLA Typing by DNA Technology

Space is provided for reporting several possible alleles for each allele at a locus. If more space is needed, write the remainder of the alleles in the space above or below the box for that locus. A lab report may be attached to the completed report to provide additional information or typing result clarification for the form review process at the NMDP.

**Class I**

| Locus | | Allele Designations (6) | Registry Use Only |
|---|---|---|---|
| 1. A ☐ not tested | First A* | Exemplo: 23:01 | |
| | Second A* | Exemplo: 30:02 | |
| 2. B ☐ not tested | First B* | Exemplo: 44:03 | |
| | Second B* | Exemplo: 08:01 | |
| 3. C ☐ not tested | First C* | Exemplo: 04:09N | |
| | Second C* | Exemplo: 07:18 | |

**Class II**

| Locus | | Allele Designations | Registry Use Only |
|---|---|---|---|
| 4. DRB1 ☐ not tested | First DRB1* | Exemplo: 03:01 | |
| | Second DRB1* | Exemplo: 07:01 | |

**Mail this form to:**
**The NMDP Registry**
**3001 Broadway St. N.E., Suite 100**
**Minneapolis, MN 55413**
**Retain a copy at the Transplant Center.**

NMDP Form 22 revision 9 (page 1 of 5) fillable pdf effective June 2011
*Internal use: Document number F00777 revision 1*

Recipient NMDP ID: 1 389-999-7

Donor NMDP ID: 4 2121-7880-5
— or —
Donor Cooperative Registry ID:

**Class II (Optional)**
Please provide the optional allele information if it is available from your laboratory.

| Locus | | Allele Designations | Registry Use Only |
|---|---|---|---|
| 5. DRB3 ☐ not tested | First DRB3* | | |
| | Second DRB3* | | |
| 6. DRB4 ☐ not tested | First DRB4* | | |
| | Second DRB4* | | |
| 7. DRB5 ☐ not tested | First DRB5* | | |
| | Second DRB5* | | |
| 8. DQB1 ☐ not tested | First DQB1* | 02:01 | |
| | Second DQB1* | 02:02 | |
| 9. DPB1 ☐ not tested | First DPB1* | 04:01 | |
| | Second DPB1* | 13:FNVU | |
| 10. DQA1 ☐ not tested | First DQA1* | | |
| | Second DQA1* | | |
| 11. DPA1 ☐ not tested | First DPA1* | | |
| | Second DPA1* | | |


HLA Services
180 Rustcraft Road
Suite 115
Dedham, MA 02026
(tel) 781-461-2148
(fax) 781-461-2269

Blood Services
East Division
ASHI# 10-1-MA-01-1
Director: Susan H. Hsu Ph.D.
CLIA# 22D0073830
Director: Jorge Rios, M.D

DA SILA, JOSÉ LUIZ
MRN RID#: 389-999-7
Stem Cell Recipient

**HLA Report**

Patient: 2 DA SILVA, JOSÉ LUIZ
DOB:
MRN: 1 RID#: 389-999-7
Category: Stem Cell Recipient
**Report Date:** 5 **06/18/2018**

Report to: Muniz Oliveira, Danielli
Rereme
Rua dos Invalidos, 212
Rio de Janiero, Brazil

**HLA Typing**

| Name / DOB/MRN / LID / Relation/ Source | Sample Dt / Receive Dt / Test Dt | 6 A* | B* | C* | DRB1* | DRB345* | DQA1* | 6 DQB1* | DPA1* | 6 DPB1* | Haplo |
|---|---|---|---|---|---|---|---|---|---|---|---|
| DA SILVA, JOSÉ LUIZ / RID#: 389-999-7 | | | | | | | | | | | |
| Patient / | | | | | | | | | | | |
| URD, 2121-7880-5 4 | 06/11/2018 | 23:01 | 44:03 | 04:09N | 03:01 | 3*02:02 | 05:01 | 02:01 | | 04:01 | |
| / | 06/13/2018 | 30:02 | 08:01 | 07:18 | 07:01 | 4*01:01 | 02:01 | 02:02 | | 13:FNVU | |
| R615041-1 | 06/13/2018 | | | | | | | | | | |
| Unrelated Donor / Blood | | | | | | | | | | | |

Allelic HLA typing was performed by PCR-SSOP, Sanger SBT, NGS. Low-Intermediate resolution HLA typing was performed by PCR-SSOP.

Code Translation:
FNVU - 13:01/107:01

**Comments**
DPB1*04:01, DPB1*13:01 is ambiguous with DPB1*133:01, DPB1*350:01
.

*Nome do paciente e códigos de identificação fictícios criados para esse informativo, em respeito a política de confidencialidade do REDOME

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### 3.2.2. NMDP FORM 117 – Final Recipient HLA Typing

1. Recipient NMDP ID: **RID** (Patient Identification Number in the International Registry);
2. Recipient Last Name: patient's last name and corresponds to the names preceding the comma in the registry. E.g: DA SILVA, JOSÉ LUIZ → DA SILVA;
3. Recipient Local ID: RMR XXXX (patient identification number in REDOMENET);
4. Confirmation Test Date: Date of release of the patient's CT report. Attention, the date must be registered in the American standard Month/Day/Year;

5. Full name of the laboratory that performed the patient's CT
6. HLA – Fill in the loci A*, B*, C*, DRB1* and DQB1* with the typing released in the patient's CT report, including if there are letters P and G, they must also be inserted according to what is written in the report.

Note: The HLA typing to be filled out on the form must faithfully contain all the digits that appear on the report, including letters, if any. E.g.: A*02:01:01:02L should be transcribed as A*02:01:01:02L and not as 02:01.

NATIONAL MARROW DONOR PROGRAM®

# Final Recipient HLA Typing

Registry Use Only

Sequence Number:

Date Received:

Recipient NMDP ID: 1 389-999-7 Phenotype Sequence ID:

Recipient Last Name: 2 DA SLIVA,

Recipient Local ID: 3 22222

Confirmation Test Date: 4 06 (Month) 07 (Day) 2018 (Year) TC Code:

**A Form 117 must be submitted either prior to, or at the same time as, a donor is requested for work-up.**

1. Name of Laboratory: 5 Nome COMPLETO do Laboratório *(please print)* — Registry Use Only

## HLA Typing by DNA Technology

Space is provided for reporting several possible alleles for each allele at a locus. If more space is needed, write the remainder of the alleles in the space above or below the box for that locus. A lab report may be attached to the completed report to provide additional information or typing result clarification for the form review process at the NMDP.

**Class I**

| Locus | | Allele Designations (6) | Registry Use Only |
|---|---|---|---|
| 2. A ☐ not tested | First A* | 02:01P | |
| | Second A* | 02:01P | |
| 3. B ☐ not tested | First B* | 51:01 | |
| | Second B* | 51:01 | |
| 4. C ☐ not tested | First C* | 51:01 | |
| | Second C* | 51:01 | |

**Class II**

| Locus | | Allele Designations | Registry Use Only |
|---|---|---|---|
| 5. DRB1 ☐ not tested | First DRB1* | 14:02 | |
| | Second DRB1* | 14:02 | |

**Mail this form to:**
**The NMDP Registry**
**3001 Broadway St. N.E., Suite 100**
**Minneapolis, MN 55413**
**Retain a copy at the Transplant Center.**

NMDP Form 117 revision 8 (page 1 of 4) fillable pdf effective June 2011



*Internal use: Document number F00775 revision 1*

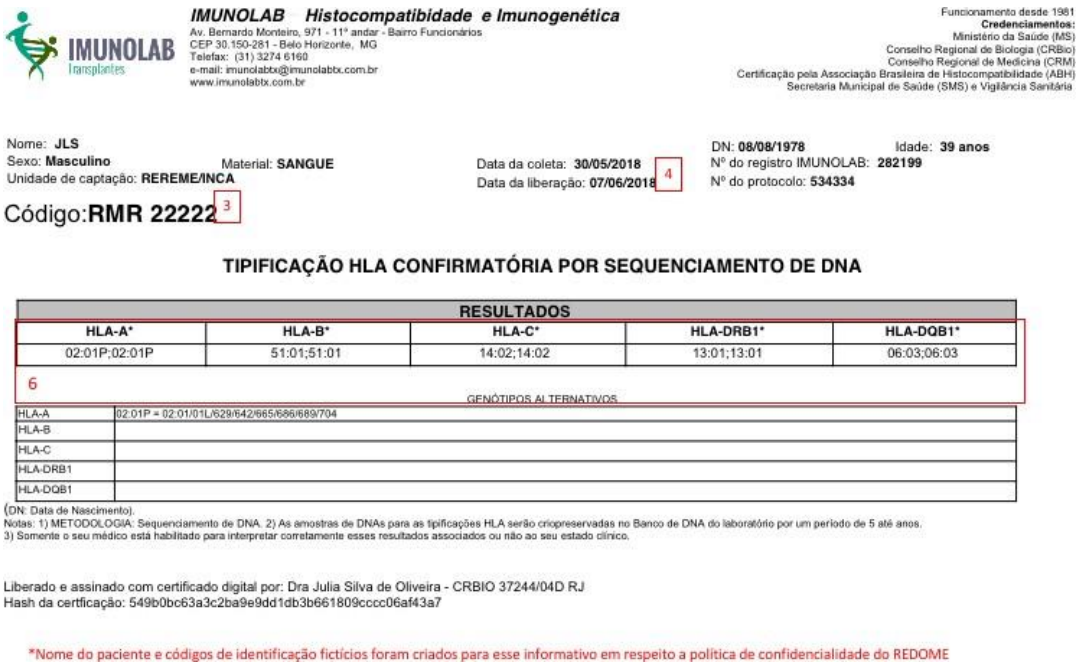
Recipient NMDP ID: 1 389-999-7

Recipient Last Name: 2 DA SLIVA,

**Class II (Optional)**

Please provide the optional allele information if it is available from your laboratory.

| Locus | | Allele Designations | Registry Use Only |
|---|---|---|---|
| 6. DRB3 ☐ not tested | First DRB3* | | |
| | Second DRB3* | | |
| 7. DRB4 ☐ not tested | First DRB4* | | |
| | Second DRB4* | | |
| 8. DRB5 ☐ not tested | First DRB5* | | |
| | Second DRB5* | | |
| 9. DQB1 ☐ not tested | First DQB1* | | |
| | Second DQB1* | 6 06:03 | |
| 10. DPB1 ☐ not tested | First DPB1* | 6 06:03 | |
| | Second DPB1* | 6 * Se disponivel | |
| 11. DQA1 ☐ not tested | First DQA1* | 6 * Se disponivel | |
| | Second DQA1* | | |
| 12. DPA1 ☐ not tested | First DPA1* | | |
| | Second DPA1* | | |



IMUNOLAB Histocompatibidade e Imunogenética
Av. Bernardo Monteiro, 971 - 11º andar - Bairro Funcionários
CEP 30.150-281 - Belo Horizonte, MG
Telefax: (31) 3274 6160
e-mail: imunolabtx@imunolabtx.com.br
www.imunolabtx.com.br

Funcionamento desde 1981
Credenciamentos:
Ministério da Saúde (MS)
Conselho Regional de Biologia (CRBio)
Conselho Regional de Medicina (CRM)
Certificação pela Associação Brasileira de Histocompatibilidade (ABH)
Secretaria Municipal de Saúde (SMS) e Vigilância Sanitária

Nome: **JLS**
Sexo: **Masculino** Material: **SANGUE**
Unidade de captação: **REREME/INCA**

Data da coleta: **30/05/2018**
Data da liberação: **07/06/2018** 4

DN: **08/08/1978** Idade: **39 anos**
Nº do registro IMUNOLAB: **282199**
Nº do protocolo: **534334**

Código:**RMR 22222** 3

**TIPIFICAÇÃO HLA CONFIRMATÓRIA POR SEQUENCIAMENTO DE DNA**

| RESULTADOS | | | | |
|---|---|---|---|---|
| HLA-A* | HLA-B* | HLA-C* | HLA-DRB1* | HLA-DQB1* |
| 02:01P;02:01P | 51:01;51:01 | 14:02;14:02 | 13:01;13:01 | 06:03;06:03 |

6

GENÓTIPOS ALTERNATIVOS

| | |
|---|---|
| HLA-A | 02:01P = 02:01/01L/629/642/665/686/689/704 |
| HLA-B | |
| HLA-C | |
| HLA-DRB1 | |
| HLA-DQB1 | |

(DN: Data de Nascimento).
Notas: 1) METODOLOGIA: Sequenciamento de DNA. 2) As amostras de DNAs para as tipificações HLA serão criopreservadas no Banco de DNA do laboratório por um período de 5 até anos.
3) Somente o seu médico está habilitado para interpretar corretamente esses resultados associados ou não ao seu estado clínico.

Liberado e assinado com certificado digital por: Dra Julia Silva de Oliveira - CRBIO 37244/04D RJ
Hash da certficação: 549b0bc63a3c2ba9e9dd1db3b661809cccc06af43a7

*Nome do paciente e códigos de identificação fictícios foram criados para esse informativo em respeito a política de confidencialidade do REDOME

### 3.2.3. F00475 – Donor Work Up Request

The prescription document must be filled out completely with patient and donor information, preferred source, amount of cells, and requested collection date, as well as delivery information (address, phone number, and responsible person).

Highlighted below are some instructions. If you have any questions, please contact the REDOME team.

## Donor Workup Request

International or NMDP Recipient ID: RID ..... RID Fornecido pela técnica responsável TC Code: 301

GRID: Informar o número do doador indicado pela Técnica responsável International or NMDP Donor ID: _____

**1. Recipient Information**

1.1. Current diagnosis: _____

If acute leukemia, CML or SAA, complete the following:

**a. For AML, ALL, or other acute leukemia**, indicate current disease status **and** number of remissions: _____

○ Primary induction failure ○ Complete remission ○ Relapse ○ Induction therapy in progress

**b. For CML**, indicate the current status of the leukemia (check one)

○ Chronic phase ○ Accelerated phase ○ Blastic phase

**c. For Severe Aplastic Anemia**, has recipient been transfused?

○ Yes ○ No

1.2. Classify workup based on patient clinical condition:

○ Standard ○ Urgent

**2. Stem Cell Choice**

2.1. First Choice

○ HPC, Marrow → complete section 4

○ HPC, Apheresis → complete section 5

2.2 Second Choice (**Must Select One**)

○ HPC, Marrow → complete section 4

○ HPC, Apheresis → complete section 5

○ None

**3. Pre-Collection Samples**

Do not include samples related to a transplant center research study that requires NMDP IRB approval. Instead, complete the *Request for NMDP Donor to Participate in a Research Study* form.

3.1. Do you require pre-collection samples to be drawn?

◉ No manter sempre essa opção selecionada. Pois não fazemos importação de amostras

○ Yes

3.2. Pre-Collection blood samples: **50 mls** is the maximum volume that can be requested.

**NOTE**: For non-U.S. donors, the maximum volume is **35 mls**.

_____ ml Red Top (No Anticoagulant) _____ ml Yellow Top (ACD)

_____ ml Green Top (Sodium Heparin) _____ ml Purple Top (EDTA)

**Pre-Collection Sample Shipping Information**

Attn/Name: _____

Center Name: _____

Address Line 1: _____

Address Line 2 : _____

City, State, Province: _____

Zip code, Country: _____

Telephone: _____

3.3. Specify when samples should be collected: *(optional)* _____

## Donor Workup Request

International or NMDP Recipient ID: RID ..... TC Code: 301

GRID: _____ NMDP Donor ID: _____

**4. HPC, Marrow [HPC(M)] Collection**

4.1. Length of patient's preparative regimen in days: _____

4.2. Specify number of nucleated cells below:

| | | | |
|---|---|---|---|
| 1. | Nucleated cells per kg (uncorrected): | | _____.__ x $10^8$/kg |
| 2. | Recipient weight: | x | _____.__ kg |
| 3. | Total nucleated cells for recipient: | = | 0.00 x $10^8$ |
| 4. | Nucleated cells for quality assurance: | + | ___._ x $10^8$ |
| 5. | TOTAL nucleated cells requested: | = | 0.00 x $10^8$ |

4.3. Enter at least one proposed collection and corresponding donor clearance dates:

| | Proposed Collection Date (mm/dd/yy) | Clearance needed by (mm/dd/yy) |
|---|---|---|
| **First Choice - Required** | data que desejada para coleta | mínimo de 10 dias antes da coleta (data proposta) |
| Second Choice - Optional | data que desejada para coleta | mínimo de 10 dias antes da coleta (data proposta) |
| Third Choice - Optional | data que desejada para coleta | mínimo de 10 dias antes da coleta (data proposta) |

4.4. Marrow collection within the NMDP network must be aspirated, filtered and mixed with anticoagulant in quantities sufficient to prevent coagulation. Does your transplant center require special instructions regarding anticoagulant to be added to the marrow either during or after the aspiration?
○ No ○ Yes

a. If yes, specify the anticoagulant including the units, ratio or amount as appropriate:
Anticoagulant: _____ Amount or Ratio: _____

4.5. Specify HPC(M) storage and transport conditions (Select one): ○ Room Temperature ⊙ Cooled

**5. HPC, Apheresis [HPC(A)] Collection**

5.1. Length of patient's preparative regimen in days: _____

5.2. Specify number of desired CD34+ cells:

| | | | |
|---|---|---|---|
| 1. | CD34+ cells per kg: | | _____.__ x $10^6$/kg |
| 2. | Recipient weight: | x | _____.__ kg |
| 3. | Total CD34+ cells for recipient: | = | 0.00 x $10^6$ |
| 4. | CD34+ cells for quality assurance : | + | ___.__ x $10^6$ |
| 5. | TOTAL CD34+ cells requested: | = | 0.00 x $10^6$ |

Reminder: HPC(A) will be stored and transported cooled.

5.3. Enter at least one proposed collection and corresponding donor clearance dates:

| | Proposed Collection Date 1 (Required) (mm/dd/yy) | Proposed Collection Date 2 (Optional) (mm/dd/yy) | Clearance needed by (mm/dd/yy) |
|---|---|---|---|
| **First Choice** - Required | data que desejada para coleta | data que desejada para coleta | mínimo de 10 dias antes da coleta (data proposta) |
| Second Choice (Optional) | data que desejada para coleta | data que desejada para coleta | |
| Third Choice (Optional) | data que desejada para coleta | data que desejada para coleta | |

When CD34+ counts are not available, the Apheresis Center collects based on recipient weight as outlined below:

- Recipient weight ≤ 35kg . . . . . One 12-liter Apheresis procedure performed.
- Recipient weight 36 – 45kg . . . . . One 15-liter Apheresis procedure performed.
- Recipient weight 46 – 55kg . . . . . One 18-liter **or** two 12-liter Apheresis procedure(s) performed.
- Recipient weight 56 – 65kg . . . . . One 22-liter **or** two 12-liter Apheresis procedure(s) performed.
- Recipient weight > 65kg . . . . . One 30-liter **or** two 12-liter Apheresis procedure(s) performed.

## Donor Workup Request

International or NMDP Recipient ID: RID ..... TC Code: 301

GRID: _____ NMDP Donor ID: _____

**6. Day of Collection Samples**

**A minimum of 10 mls of donor peripheral blood must accompany each product collected** (used for ABO and Rh confirmation).

Indicate the type of tube(s) required by the transplant center:

| | Peripheral Blood | | Product | |
|---|---|---|---|---|
| | **Day 1** HPC(M) & HPC(A) | **Day 2** HPC(A) only | **Day 1** HPC(M) & HPC(A) | **Day 2** HPC(A) only |
| Red Top (No Anticoagulant) | ml | ml | ml | ml |
| Yellow Top (ACD) | ml | ml | ml | ml |
| Green Top (Sodium Heparin) | ml | ml | ml | ml |
| Purple Top (EDTA) | ml | ml | ml | ml |

6.1. **Apheresis Center: Fax CD34+ results to the following number:** _____

**7. All Transplant Centers Must Complete:**

*Regarding the donor designated above, I verify that the ABO type, degree of HLA match, compatibility testing results and infectious disease results are acceptable to proceed with stem cell collection for above patient.*

| Apenas o nome | data real de envio ao REDOME | Apenas o nome |
|---|---|---|
| Form Completed By | (mm/dd/yy) | Ordering Physician |

**8. Product Transport /Delivery Information**

**Name:** A responsible party at the receiving facility — Nome do Centro de Transplante

**Receiving Facility Name:** NMDP Transplant Center or other delivery site name — Local de entrega

**Street Address:** Street address for product delivery

**City, State and Country:** Information for product delivery

**Telephone Number:** A telephone number for the receiving facility — Responsável por receber as células

## Donor Workup Request

International or NMDP Recipient ID: RID ..... TC Code: 301

GRID: _____ NMDP Donor ID: _____

**9. Outstanding Requests**

9.1. If there are outstanding requests for donor or cord typing, should they be cancelled*?

- ○ No
- ○ Yes → Please indicate below:

☐ NMDP Donor ☐ Cooperative Registry Donor
☐ NMDP Cord ☐ Cooperative Registry Cord

*It may not be possible to cancel request for typing in progress or for donors with an appointment scheduled in the next 2-3 days. The transplant center is financially responsible for the services that cannot be cancelled.

**10. Held for Workup**

10.1. Donors requested as Held for Workup?

- ○ No
- ○ Yes

When ID numbers are listed below, the donor(s) are categorized as "held for workup". After the first choice donor is "cleared to donate", the held for workup donor(s) are released. The *Confirmation of Donor HLA Typing* (Form 22) must be submitted to request a donor to be held for workup.

NMDP Donor ID: _____ GRID: _____

NMDP Donor ID: _____ GRID: _____

**11. Comments** (optional):

_____

_____

_____

**Information on this page is for NMDP Case Management use only and is not to be shared with the donor center.**

### 3.2.4. F 10 – Formal Request and Prescription for HPC Marrow; HPC Apheresis and/or MNC Apheresis

The form must be completely filled out and without erasures.

The following fields are highlighted on the WMDA Form:

- **PATIENT DATA**: Filling in patient data;
- **DONOR DATA**: Filling in donor data;
- **PRODUCT SHIPPING ADRESS:** Address of the Collection Center for delivery of the cells;
- **PRODUCT REQUEST:** Definition of the chosen product;
- **TRANSPLANT HISTORY:** History of previous transplants;
- **PREFERRED DATES:** preferred dates for collection (put three dates and their respective infusion dates);
- **PRE-COLLECTION SAMPLES:** In general, we do not request pre-collection samples and exceptional cases should be informed to the REDOME team;
- **PRE-COLLECTION SAMPLES TO BE SHIPPED TO**: In general, we do not request pre-collection samples;
- **STEM CELL AND/OR LYMPHOCYTE COLLECTION:** fill in to signal quantity of cells desired and do not exceed the safety margin set for donor;
- **ADDITIONAL SAMPLES TO ACCOMPANY STEM CELL OR LYMPHOCYTE PRODUCT:** Fill in if you want some sample to accompany the collection.

# 4. Guidelines for Labeling and Releasing HPC

The labeling, completion of documentation, and proper release of Hematopoietic Progenitor Cells (HPC) is extremely important for the transport and maintenance of the integrity of the collected material in order to ensure the safety of the patient for whom it is intended.

## 4.1. Labeling

The material must be prepared labeled according to current regulatory standards, accreditation body requirements, including the WMDA.

The released product labels must be tamper-proof and remain intact throughout the storage period, until the expiration date of the product, and contain the following information:

- Total cell volume;
- DMR or GRID ID;
- Receiving RMR;
- Expiration date and time 48 h;
- Date and time of collection;
- Volume of anticoagulant;
- Temperature at 2-24ºC;
- Do not irradiate;
- Do not use leukocyte filter.

Other information about the product must be described in the collection form that must accompany the product (FOR029 - Transport Report or C10 - Collection Report).

## 4.2. Documentation for Product Transportation

All products released, must be accompanied by the corresponding documentation to be delivered to the person responsible for receiving the product:

- **FOR029 – Transport Report** (National);
- **FOR030 – CPH Quantification Report** (National);
- **Collection Report in the template for the place of origin** (for import);
- **Transport Report in the template for the place of origin** (for import).

The adequate filling out of these forms is also important to ensure the safety of the transport and use of the product, and they must be received clearly and completely filled out.

In case the form presents inconsistent information, REDOME should be immediately communicated in order to inform the collection center or international registry about the occurrence.

## 4.3. Courier

The person responsible for transporting the material is trained to meet the requirements established in national and international standards.

It is important to highlight that the couriers for international collections are foreigners, and it is important that the person responsible for receiving the material is able to receive and communicate with this professional.

If a second collection day is required or there is any incident that delays the release of the product, REDOME will contact the transplant center to inform about the changes in the logistics of travel and delivery.

After the delivery of the material, REDOME will send the thermal reading report regarding the temperature control during the transportation of the material.

To finalize the process, we request that you send the form **FOR023 - Transport of HSC from international donor or FOR029 - Transport report (national)** with the consent of delivery and forecast for infusion of the product.

## 5. Post-transplant

After six months from the date of the infusion, the donor may request information about the health status of the recipient. In this sense, we count on the collaboration of the transplant centers to provide us with updated health information of the recipient when requested.

The same occurs in cases of breach of confidentiality (disclosure) between donor and recipient, a process that begins eighteen months after the confirmation of the transplant date and culminates in the meeting between patient and donor. For this purpose, we will also need an updated medical report and the contact information of the recipient or his guardian to start the disclosure process.

The international registries also request information from the recipient through a specific Follow-up form, and, for this reason, we will routinely send this document to the transplant center teams for completion.

Whenever desirable and respecting the established deadlines described above, the collection center or transplant center may encourage its recipient or donor to contact us through the e-mail postransplante@inca.gov.br with the purpose of initiating the news request process, correspondence exchange or disclosure.

## Final Remarks

Some descriptions of the proper handling and filling of documents in the HPC request process were presented.

These guidelines do not dispense the clarification of doubts by the REDOME team for the correct use of requests and forms.

Contact the REDOME team through:

Email: rereme@inca.gov.br

Telephone: (21) 3207 – 4707

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

## References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