Danish Stem Cell Donors East: Rules and policies

Contact information:

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Registry Information:

ION: 7484
WMDA accredited
WSMS listed
EMDIS HUB: DS
Abbreviation: DSDE

All donors are voluntary and unpaid.

International searches:
Request can be submitted by EMDIS or secure E-mail:
WMDA forms or similar forms can be used.

The following information must be included in a request:
  – Patient initials and ID
  – Date of birth
  – Gender
  – Diagnosis
  – HLA typing (minimum HLA-A, B, C, DRB1 high resolution)
  – Invoice address

Diagnosis should be in accordance with the most recent EBMT recommendations.

A search report will be generated and returned.
It is possible to ask for mismatch search.
If the request is by e-mail only one search will be performed.

If the search is performed via EMDIS a repeated search is performed every night until the patient is inactivated.

Typing requests (extended typing):
Request can be submitted by EMDIS or secure E-mail.
WMDA forms or similar forms can be used.

All HLA typing requests are performed by our local laboratory, which holds an accreditation from European Federation for Immunogenetics (EFI).

Only DNA techniques are used including RT-PCR and NGS.
Low resolution (2 digits) and high resolution (4 digits) HLA typing are performed in accordance with the latest standards defined by EFI.
Loci: HLA-A,B,C,DRB1,DR3/4/5, DQA1,DQB1,DPA1, DPB1

Sample requests (verification typing (VT)):
Request can be submitted by EMDIS or secure E-mail.
WMDA forms or similar forms can be used.

Total volume of blood: Max 50 ml
IDM testing is performed at verification typing.
Date for blood draw and shipment will be notified.
Confirmation of donor HLA typing must be returned within 6 weeks.

Infectious disease markers:
Includes:
- CMV: IgG+IgM
- Hepatitis B: HBc Ab, HBsAg, HBs Ab
- Hepatitis C: HCV Ab
- HIV: Anti-HIV 1+2
- HTLV I+II

Donors can be further examined by nucleic acid testing (NAT)
Other IDMs can be tested upon request.
The laboratory holds an ISO15189 accreditation and is authorized by the national regulatory agency.

Donor reservation:
Typing request: 2 months
Sample request: 2 months
The reservation period is extended upon request

Work-up requests:
Work-up requests can be submitted by secure E-mail.
WMDA forms or similar forms can be used.
A confirmation of receipt will by returned during the following working day.
A confirmation on donor availability will be send in 1 or 2 working days.
In case of urgency it is possible to request a VT and work-up together, but the result of the VT must be submitted before the donor clearance can be obtained.
Full donor screening for infectious disease will be performed and completed 30 days prior to collection.
A physical exam and relevant donor testing are performed.
A sample for additional donor testing can be provided upon request.

The following information must be included in a work-up request:

- Patient identification
- Donor GRID
- High resolution VT HLA typing of patient and donor (minimum HLA-A, B, C, DRB1 high resolution)
- Preferred product (apheresis / bone marrow harvest) and cell dose.
- Preferred date of collection
- Latest date for donor clearance

Products:
HPC, Marrow
HPC, Apheresis
MNC, Apheresis
The product dosage limit is 20 ml/kg

Subsequent donations:
The requesting transplant center must explain the reason for the request and the need of a subsequent donation (incl. recipient disease, current status of recipient) and if the request is considered urgent.

Same recipient
- A donor should not provide more than two subsequent donations for a given recipient, of which only one may be an HPC (marrow or apheresis) donation.

Second recipient
- A donor should only be asked to provide an HPC donation for a second recipient if no other equally compatible donor is available and only if:
  o At least two years have elapsed since the first HPC donation.
- No donor shall provide more than two HPC in total.

A medical doctor from the DSDE registry department may authorize exceptions to this.
Requests for subsequent donations are handled as other requests unless it is stated to be of urgent matter.

Credentials of requesting registries / transplantation centres:
Requesting registries or transplant centres must be:
1. WMDA / EBMT /ASBMT member or similar *or*
2. Approved by a National Health Authority
A medical director from the DSDE registry department may authorize exceptions to this.

Donor / Recipient Contact:
The anonymity between recipient and donor must be maintained until at least 2 years after the donation/transplantation.
If the anonymity is subsequently to be repealed, there must be informed consent from both recipient and donor.

Exchange of anonymous information is allowed from after the donation / transplantation.
This is done via the registers, and all material for exchange is reviewed and corrected for information which may result in breach of anonymity.
Checks are performed by both registers.

Research Projects
Donors can be asked to participate in research protocols if:
1. Participation is without risk for the donor and can be contained within routine practice for collection of stem cells.
2. Information of the project including research protocol, information for the donor in Danish (English can be accepted if the donor agrees to this), and informed consent for the donor to sign.
3. Documented approval from the national institutional review board.
4. Copy of the signed informed consent of the patient (or a statement from the requesting registry that the patient has agreed to participate).

Based upon the information provided the medical directors at the DSDE registry department will decide if the donor can be asked to participate.