# Regulatory Survey ION-7813



## General

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|---|---|
| The information has been reviewed in year : | |
| Organisation name: | Spanish Bone Marrow Donor Registry (REDMO) |
| Organisation ION: | ION-7813 |
| Country: | Spain |
| Year the registry started operations: | 1991 |

## Products

| | | comment |
|---|---|---|
| Do you provide HPC, Marrow? | yes | |
| Do you provide HPC, Apheresis? | yes | |
| Do you provide HPC, Cord Blood? | yes | |
| Do you provide MNC, Apheresis? | yes | |
| Do you provide NC, Whole Blood? | yes | |

## Product quantity

| Data valid for year | 2022 | |
|---|---|---|
| **Number of products** | **National** | **International** |
| HPC, Marrow products: | 13 | 16 |
| HPC, Apheresis: | 123 | 141 |
| HPC, Cord: | 7 | 95 |

## License

| | |
|---|---|
| Organisation is licensed/accredited by the Competent Authority: | yes |
| Comment: | |
| Name of Competent Authority: | Health Department - Servei Català de la Salut |
| Date of last inspection: | 2020/11/26 |
| Link to website of Competent Authority: | http://trasplantaments.gencat.cat/en/ocatt/guia_de_centres |
| Can you provide the Legal documentation from the Competent Authority that your organisation is allowed to operate as a registry ? | yes |
| Is your registry WMDA Certified, WMDA Qualified or WMDA Accredited? | WMDA Qualified |
| The registry is accredited by any other organisation: | no |
| If yes, by which organisation? | |

## Affiliation

| | |
|---|---|
| The registry works with the following number of affiliated donor centres: | 17 |
| The registry audits its donor centres: | Every 4 years (sooner if needed according to our Audit plan) |

| | |
|---|---|
| The registry works with the following numer of affiliated collection centres: | 29 |
| Ther registry audits its collection centres: | Every 4 years (sooner if needed according to our Audit plan) |
| The registry works with the following number of affiliated Cord Blood Banks: | 7 |
| The registry audits its Cord Blood Banks: | Every 4 years (sooner if needed according to our Audit plan) |
| The registry works with the following number of affiliated transplant centres: | 34 |
| The registry audits its transplant centres: | Every 4 years (sooner if needed according to our Audit plan) |
| The registry works with the following number of affiliated IDM Testing Laboratories: | 22 (affiated to DC) |
| The registry audits its IDM Testing Laboratories: | Every 4 years (sooner if needed according to our Audit plan) |
| The registry works with the following number of affiliated HLA/other DNA markers testing laboratories: | 17 (affiated to DC) |
| The registry audits its HLA/other DNA markers testing laboratories: | Every 4 years (sooner if needed according to our Audit plan) |
| The registry would be able to provide a full list of name/addresses of each affiliated and their licence /accreditation status, on request: | yes |
| The Cord Blood Banks are FACT-NetCord accredited: | yes |
| If yes, the following Cord Blood Bank(s) are accredited: | Andalucia CBB, Barcelona CBB, IVIDA |
| The registry is able to provide a copy of all the certificates: | yes |
| Affiliated centres comply with WMDA Standards and applicable national regulations: | yes |
| The registry has requirements for affiliated centres in addition to WMDA Standards and applicable national regulations: | yes |
| If yes, what are these requirements? | National Regulations/Laws |

## Donor policy

| | |
|---|---|
| All donors are unpaid volunteers: | yes |
| All donors are informed about donation process and associated risks: | yes |
| Donors sign a valid informed consent to donate in the presence of a medical doctor/health care personnel/registry staff: | yes |
| The registry has systems in place to protect and control access to donor/patient records: | yes |
| The registry maintains donor anonymity: | yes |
| The registry has detailed donor evaluation and exclusion criteria in place: | yes |
| The registry has donor evaluation and exclusion criteria that do meet or exceed the WMDA guidelines: | yes |

# IDM

| IDM | Tested | Method | Days between test and sampling/workup |
|---|---|---|---|
| ALT/ASTALT/AST ratio, De-Ritis-Quotient | Yes | | < 30 days |
| ChagasChagas, T. cruzi | On request | | < 30 days |
| CMV IgGCytomegalovirus (CMV) Antibody testing IgG | Yes | | < 30 days |
| CMV IgMCytomegalovirus (CMV) Antibody testing IgM | Yes | | < 30 days |
| CMV TotalCytomegalovirus Total | On request | | < 30 days |
| EBV IgGEpstein-Barr Virus Antibody testing IgG | Yes | | < 30 days |
| EBV IgMEpstein-Barr Virus Antibody testing IgM | Yes | | < 30 days |
| HAV (NAT)Anti-hepatitis A virus nucleic acid testing | On request | | < 30 days |

| | | | |
|---|---|---|---|
| HBV (NAT)Hepatitis B nucleic acid testing | Yes | | < 30 days |
| HBc AbHepatitis B core antibody testing | Yes | | < 30 days |
| HBs AgHepatitis B Surface antigen testing | Yes | | < 30 days |
| HCV (NAT)Hepatitis C nucleic acid testing | Yes | | < 30 days |
| HCV AbHepatitis C antibody testing | Yes | | < 30 days |
| HEV (NAT)Hepatitis E Virus nucleic acid testing | On request | | < 30 days |
| HIV (NAT)Human Immunodeficiency Virus nucleic acid testing | Yes | | < 30 days |
| HIV-1 AbHuman Immunodeficiency Virus HIV-1 antibody testing | Yes | | < 30 days |
| HIV-2 AbHuman Immunodeficiency Virus HIV-2 antibody testing | Yes | | < 30 days |
| HIV p24Human Immunodeficiency Virus p24 antigen testing | Yes | | < 30 days |
| HTLV-IHuman T-Lymphotropic Virus type I testing | Yes | | < 30 days |
| HTLV-IIHuman T-Lymphotropic Virus type II testing | Yes | | < 30 days |
| MalariaMalaria | On request | | < 30 days |
| HSVHerpes Simplex Virus | On request | | < 30 days |
| STSSerological tests for syphilis | Yes | | < 30 days |
| STS FTA-ABSSerological test for syphilis | On request | | < 30 days |
| ToxoplasmosisToxoplasmosis | Yes | | < 30 days |
| VZVVaricella Zoster Virus | On request | | < 30 days |
| WNV-NATWest Nile Virus nucleic acid testing | On request | | < 30 days |
| Other tests performed | On request | | < 30 days |

## Testing

| | |
|---|---|
| The physical and medical exam at donor workup is performed by a medical doctor: | yes |
| All donor testing (at workup) for infectious disease is performed in a laboratory certified/licensed by a Competent Authority: | yes |
| HLA typing for patient specific request is performed in an appropriately accredited laboratory: | yes |
| Sterility testing is performed on the adult donor product: | yes |
| Sterility testing is performed on the cord blood product: | yes |
| Screening questionnaire to exclude communicable disease: | yes |
| Screening questionnaire to exclude donors with 'high risk' lifestyles: | yes |
| Donor reliability identified by a medical doctor: | yes |

| | |
|---|---|
| Donor clearance to donate is confirmed by a medical doctor, following as a minimum the donor exclusion criteria in Annex 1 of EU Directive 2006/17/EC :<br>The party providing the cell product must exclude donors when:<br><br>• They are pregnant;<br>• They are breastfeeding;<br>• There is the potential for transmission of inherited conditions;<br>• There is evidence of any other risk factors for transmissible diseases on the basis of a risk assessment, taking into consideration *Donor travel and exposure history and local infectious disease prevalence*;<br>• There is presence on the donor's body of physical signs implying a risk of transmissible disease(s);<br>• There is a history of a disease of unknown aetiology;<br>• There is a risk of transmission of diseases caused by prions;<br>• There is systemic infection which is not controlled at the time of donation, including bacterial diseases, systemic viral, fungal or parasitic infections, or significant local infection in the tissues and cells to be donated;<br>• There is history of chronic, systemic autoimmune disease that could have a detrimental effect on the quality of the Cell Product;<br>• There is recent history of vaccination with a live attenuated virus where a risk of transmission is considered to exist;<br>• There is ingestion of, or exposure to, a substance (such as cyanide, lead, mercury, gold) that may be transmitted to recipients in a dose that could endanger their health. | y<br>es |

## Customs regulations

| | |
|---|---|
| Are there any customs regulations to follow, or customs paperwork required, to import cell products into the organisation country? If yes, please specify: | Yes, National Regulations |
| Are there any customs regulations to follow, or customs paperwork required, to export cell products from the organisation country? If yes, please specify: | Yes, National Regulations |
| Are there any import regulations to follow, or paperwork required, to import cell products into the organisation country? If yes, please specify: | Yes, National Regulations |
| Are there any export regulations to follow, or paperwork required, to export cell products from the organisation country? If yes, please specify: | Yes, National Regulations |

## Reporting of Serious Adverse Events

Please indicate which of the following schemes for reporting Serious Adverse Events relating to either the Donor or the product the Registry participates in:

| | |
|---|---|
| - Mandatory National Reporting Scheme | y<br>es |
| - Voluntary National Reporting Scheme | no |
| - WMDA SEAR/SPEAR Reporting Scheme | y<br>es |
| The registry will notify the receiving Registry within 24 hours of receiving information relating to any serious adverse event that could be considered to affect the patient receiving the product: | y<br>es |

## Quality management

| | |
|---|---|
| The registry does maintain Standard Operating Procedures for your work: | yes |
| The registry would be willing to provide these to WMDA or another registry upon request: | yes |
| The registry would be willing to provide WMDA or another registry, on request, with copies of any packaging the HPC product will arrive in: | yes |
| Donor records relating to the medical exam and HPC collection process are the following number(s) of year(s) retained: | on a permanent basis |