

CBB Survey 2015 WO-1360

CBB Survey 2015

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| 1. General Information | |
| Name of CBB | St.Eugenio Hospital |
| CBB Director | Italo |
| CBB Director | De Meis |
| Address | piazzale dell'Umanesimo 10 |
| Address | 00144 |
| Address | Rome |
| Phone Number | 0039 06 51002259 |
| Website | cordbloodbank@aslrmc.it |
| Date CBB Started Collecting Cord Blood Units (month/day/year) | 03/01/1995 |
| Number of Public Cord Blood Units | 846 |
| Planned Number of Public Cord Blood Units Stored in 2015 | 70 |
| Lists on BMDW | Yes |
| Affiliated with National Stem Cell Donor Registry | Yes |
| Registry Affiliation | ITALIAN BONE MARROW DONOR REGISTRY IBMDR |
| 2. Cord Blood Units in Inventory | |
| Current Processing Method | Liquid+ plasma only |
| Year Current Process Method Started | 2010 |
| Percent of Units Plasma and RBC Reduced (manual) | 30 |
| Percent of Units No Volume Reduction | 70 |
| 3. Accreditations, Licenses and Certifications | |
| FACT-Netcord | No |
| AABB | No |
| Competent Authority/ National Health Authority | Yes |
| Name of Competent Authority | Centro Nazionale Sangue-Centro Nazionale Trapianti |
| Audited by National Stem Cell Registry | No |
| ISO | Yes |
| 4. Cord Blood Collection | |
| Current Collection Practice Is the collection In/Ex -Utero or both? | Both |
| Current Antiseptic | Betadine |
| Collection Bag | Double needle |

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| Agitation during Collection | Manual |
| 5. Conditioning/Transport from Collection Site to CBB | |
| Secondary Bag Used | Yes |
| Transport Conditions | Qualified transporter |
| Transport Conditions | Unqualified transporter |
| Transport Conditions | Active refrigeration system |
| Transport Conditions | Passive refrigeration system |
| Transport Conditions | Electronic temperature probe |
| Transport Conditions | Ground transport |
| Temp. for Storage and Transport | Other (lower limit +1-35°C, higher limit +6-30°C) |
| 6. Pre-Processing Evaluation | |
| Completed Prior to Accepting a CBU | Medical history, collection report, informed consent |
| Completed Prior to Accepting a CBU | Transport report |
| Current Threshold for Accepting a CBU | Viability threshold CD45 |
| Method for CD34 Remuneration | ISHAGE guidelines |
| External Proficiency Testing for QC of FACS Lab | UKNEQAS |
| Post Processing/ Pre Freeze CD34+ Cell Count | Yes |
| Time from Collection to Processing | up to 48H |
| 7. Processing and Packaging | |
| Pre Freeze Processing Methods- Unit in Inventory | No processing |
| Pre Freeze Processing Methods- Unit in Inventory | Optipress |
| Pre Freeze Processing Methods- Unit in Inventory | Other: Volume reduction manual |
| Pre Freeze Processing Methods- Current | Other: Volume reduction manual |
| Additives Currently in Use | No additive |
| Current Cryopreservation Method | Conventional CRF |
| Current Cryoprotectant Additive | DMSO |
| Current Cryobag | Single bag (one fraction) |
| Current Cryobag | Other: Two bags 50:50 |
| Current Target Cryopreservation Volume (mL) | 130.0 |
| Current Packaging for Storage | Overwrap |
| Current Packaging for Storage | Canister |
| Current Packaging for Storage | More than one segment |
| Current Packaging for Storage | Additional separate segments |
| 8. Testing | |
| PCR Performed on IgM+ Result | CMV |
| Extra Material Currently Stored | Cord blood DNA |
| Extra Material Currently Stored | Cord blood material for DNA extraction |
| Extra Material Currently Stored | Plasma/cord blood |
| Extra Material Currently Stored | Maternal DNA |
| Extra Material Currently Stored | Maternal material for DNA extraction |

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| Extra Material Currently Stored | Maternal plasma/serum |
| Current Post Processing Threshold for Accepting a CBU for Public Use TNC | 120 |
| Current Post Processing Threshold for Accepting a CBU for Public Use CD34 (10^6) Single Platform | NA |
| Current Post Processing Threshold for Accepting a CBU for Public Use CD34 (10^6) Double Platform | NA |
| Current Post Processing Threshold for Accepting a CBU for Public Use CFU-GM | NA |
| Current Post Processing Threshold for Accepting a CBU for Public Use Viability | 80 |
| 9. Storage | |
| Type of Storage Container Used | Conventional tank liquid phase |
| Monitoring of Storage | Alarm on individual tanks only |
| Monitoring of Storage | Centralized system remote monitoring |
| Monitoring of Storage | LN2 level |
| Monitoring of Storage | Lid opening |
| Monitoring of Storage | Temperature monitoring |
| 10. HLA Typing | |
| Current Level of HLA Typing at Time of Listing HLA-A | LR |
| Current Level of HLA Typing at Time of Listing HLA-B | LR |
| Current Level of HLA Typing at Time of Listing HLA-C | LR |
| Current Level of HLA Typing at Time of Listing HLA-DRB1 | HR |
| Current Level of HLA Typing at Time of Listing HLA-DQB1 | |
| Current Level of HLA Typing at Time of Listing HLA-DPB1 | |
| Accreditation of HLA Lab | EFI accredited lab |
| Average Turnaround Time for Extended HLA Typing Results in days | 9 |
| Attached Segment Used for Confirmatory/ Verification Typing | Yes |
| Units Listed without Attached Segment and have not been Previously Typed on Attached Segment | Yes |
| Percentage of CBUs that have an Attached Segment | below 50% |
| Confirmatory/ Verification Typing on an Attached Segment is Pre-Release Requirement | Yes |
| 11. Reservation and Cancellation Policies | |
| What Point is a CBU Reserved for a Patient | Reservation request |
| Length of Time a CBU can be Reserved in days | 30 |
| Reservation Fee | No |
| Reservation Cancellation Fee in Absence of Shipment Request | No |
| Can Reservation be Extended | Yes |
| Is a Unit Report Provided on a Unit that is Reserved for Another Patient | No |

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| 12. Release and Shipment | |
| Hemoglobinopathy Screening Performed Prior to Release | Yes |
| Criteria to Ship a CBU Viability and Cell Count | >40% / >50% |
| Criteria to Ship a CBU HLA Identity Testing | Yes |
| Current Packaging for Shipment to TC | Metal canister |
| Current Packaging for Shipment to TC | One attached segment |
| Current Packaging for Shipment to TC | Overwrap |
| Current Packaging for Shipment to TC | Separate segment |
| Time Between Shipment Request and Sending CBU | 1-2 weeks |
| Fee for Shipment Cancellation | No |
| Dry Shippers Validated to Maintain Temperature of at least -150 for 48 hours Beyond Expected Arrival | Yes |
| Electronic Temperature Data Logger on All Dry Shippers | Yes |
| Who Selects Transport Company | CBB |
| Who Selects Transport Company | WORLD COURIER |
| Shape of Transport Container | Other |
| Shape of Transport Container | cylindrical in the cubic container |
| 13. Adverse Events Reporting | |
| Who are S(P)EARS Reported To Competent Authority | Yes |
| Who are S(P)EARS Reported To National Registry | Yes |
| Who are S(P)EARS Reported To Transplant Center | Yes |

14. Pictures of cord blood units in the inventory

15. Infectious Disease Marker (IDM) CURRENTLY performed.



WO-1360-IDM-2015.pdf

Holiday Calendar

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| Team Calendars |
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