

# (archived) CBB Survey 2015 WO-1354

## CBB Survey 2015

These data are submitted by the cord blood bank to the WMDA in February 2015. The WMDA makes no representations or express or implied warranties regarding any information on this site or obtained through these links; expressly disclaims all legal liability and responsibility for the accuracy, completeness, currency, suitability, validity, or usefulness of such information; and is not and will not be liable for any statements, errors, or omissions in posted information, or for any losses, injuries, or damages that arise or are alleged to arise from such information. Use of any information provided on this site does not and is not intended to create a contractual or other relationship. All information is on an as-is basis. The data cannot be updated.

|                                                                        |                                                     |
|------------------------------------------------------------------------|-----------------------------------------------------|
| <b>1. General Information</b>                                          |                                                     |
| Name of CBB                                                            | ERCB ( Emilia Romagna Cord Blood Bank)              |
| CBB Director                                                           | Claudio                                             |
| CBB Director                                                           | Velati                                              |
| Address                                                                | via Massarenti 9                                    |
| Address                                                                | 40138                                               |
| Address                                                                | Bologna                                             |
| Phone Number                                                           | +39 051 2143011                                     |
| Date CBB Started Collecting Cord Blood Units<br>(month/day/year)       | 11/01/1997                                          |
| Number of Public Cord Blood Units                                      | 4,606                                               |
| Planned Number of Public Cord Blood Units Stored in 2015               | 300                                                 |
| Lists on BMDW                                                          | Yes                                                 |
| Affiliated with National Stem Cell Donor Registry                      | No                                                  |
| <b>2. Cord Blood Units in Inventory</b>                                |                                                     |
| Current Processing Method                                              | Liquid+ red auto                                    |
| Current Processing Method                                              | Vapour+ red auto                                    |
| Previous Processing Method                                             | Liquid- red manual                                  |
| Previous Processing Method                                             | Liquid- plasma only                                 |
| Year Current Process Method Started                                    | 2007                                                |
| Percent of Units Plasma and RBC Reduced (manual)                       | 5                                                   |
| Percent of Units Plasma and RBC Reduced (automated)                    | 43                                                  |
| Percent of Units No Volume Reduction                                   | 52                                                  |
| <b>3. Accreditations, Licenses and Certifications</b>                  |                                                     |
| FACT-Netcord                                                           | Yes                                                 |
| AABB                                                                   | No                                                  |
| Competent Authority/ National Health Authority                         | Yes                                                 |
| Name of Competent Authority                                            | National Blood Center ( Italian Ministry of health) |
| ISO                                                                    | No                                                  |
| <b>4. Cord Blood Collection</b>                                        |                                                     |
| Current Collection Practice<br>Is the collection In/Ex -Utero or both? | In-utero                                            |
| Current Antiseptic                                                     | Chlorhexidine                                       |
| Collection Bag                                                         | Double needle                                       |

|                                                                                                     |                                                      |
|-----------------------------------------------------------------------------------------------------|------------------------------------------------------|
| Agitation during Collection                                                                         | Manual                                               |
| <b>5. Conditioning/Transport from Collection Site to CBB</b>                                        |                                                      |
| Secondary Bag Used                                                                                  | Yes                                                  |
| Transport Conditions                                                                                | Qualified transporter                                |
| Transport Conditions                                                                                | Insulating transport container                       |
| Transport Conditions                                                                                | Passive refrigeration system                         |
| Temp. for Storage and Transport                                                                     | Other (lower limit +1-35°C, higher limit +6-30°C)    |
| <b>6. Pre-Processing Evaluation</b>                                                                 |                                                      |
| Completed Prior to Accepting a CBU                                                                  | Medical history, collection report, informed consent |
| 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                                            |
| <b>7. Processing and Packaging</b>                                                                  |                                                      |
| Pre Freeze Processing Methods- Unit in Inventory                                                    | SEPAX                                                |
| Pre Freeze Processing Methods- Current                                                              | SEPAX                                                |
| Additives Currently in Use                                                                          | HES                                                  |
| Current Cryopreservation Method                                                                     | Conventional CRF                                     |
| Current Cryoprotectant Additive                                                                     | Ready for use DMSO-Dextran                           |
| Current Cryobag                                                                                     | Single bag (one fraction)                            |
| Current Target Cryopreservation Volume (mL)                                                         | 26.5                                                 |
| 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                         |
| <b>8. Testing</b>                                                                                   |                                                      |
| PCR Performed on IgM+ Result                                                                        | CMV                                                  |
| PCR Performed on IgM+ Result                                                                        | EBV                                                  |
| 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 material for DNA extraction                 |
| Extra Material Currently Stored                                                                     | Maternal plasma/serum                                |
| Current Post Processing Threshold for Accepting a CBU for Public Use<br>TNC                         | 120                                                  |
| Current Post Processing Threshold for Accepting a CBU for Public Use<br>CD34 (10^6) Single Platform | NA                                                   |
| Current Post Processing Threshold for Accepting a CBU for Public Use<br>CFU-GM                      | NA                                                   |

|                                                                                              |                                      |
|----------------------------------------------------------------------------------------------|--------------------------------------|
| Current Post Processing Threshold for Accepting a CBU for Public Use<br>CFU                  | NA                                   |
| Current Post Processing Threshold for Accepting a CBU for Public Use<br>Viability            | 80                                   |
| <b>9. Storage</b>                                                                            |                                      |
| Type of Storage Container Used                                                               | Conventional tank liquid phase       |
| Monitoring of Storage                                                                        | Centralized system remote monitoring |
| Monitoring of Storage                                                                        | LN2 level                            |
| Monitoring of Storage                                                                        | Lid opening                          |
| Monitoring of Storage                                                                        | System default                       |
| Monitoring of Storage                                                                        | Temperature monitoring               |
| <b>10. HLA Typing</b>                                                                        |                                      |
| Current Level of HLA Typing at Time of Listing<br>HLA-A                                      | LR                                   |
| Current Level of HLA Typing at Time of Listing<br>HLA-B                                      | LR                                   |
| Current Level of HLA Typing at Time of Listing<br>HLA-C                                      | LR                                   |
| Current Level of HLA Typing at Time of Listing<br>HLA-DRB1                                   | HR                                   |
| Current Level of HLA Typing at Time of Listing<br>HLA-DQB1                                   |                                      |
| Current Level of HLA Typing at Time of Listing<br>HLA-DPB1                                   |                                      |
| Accreditation of HLA Lab                                                                     | EFI accredited lab                   |
| Average Turnaround Time for Extended HLA Typing Results<br>in days                           | ?10                                  |
| 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                                             | 50-75%                               |
| Confirmatory/ Verification Typing on an Attached Segment is Pre-Release Requirement          | Yes                                  |
| <b>11. Reservation and Cancellation Policies</b>                                             |                                      |
| What Point is a CBU Reserved for a Patient                                                   | Reservation request                  |
| Length of Time a CBU can be Reserved<br>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                                   |
| Is TC Informed when CBU is Released                                                          | Yes                                  |
| <b>12. Release and Shipment</b>                                                              |                                      |
| Hemoglobinopathy Screening Performed Prior to Release                                        | Yes                                  |
| Criteria to Ship a CBU<br>Viability and Cell Count                                           | 40                                   |
| Criteria to Ship a CBU<br>HLA Identity Testing                                               | Yes                                  |

|                                                                                                      |                |
|------------------------------------------------------------------------------------------------------|----------------|
| Current Packaging for Shipment to TC                                                                 | Metal canister |
| Current Packaging for Shipment to TC                                                                 | Overwrap       |
| Current Packaging for Shipment to TC                                                                 | Transport rack |
| Time Between Shipment Request and Sending CBU                                                        | 2-3 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                                                                         | Cubic          |
| <b>13. Adverse Events Reporting</b>                                                                  |                |
| Who are S(P)EARS Reported To<br>Competent Authority                                                  | Yes            |
| Who are S(P)EARS Reported To<br>Internal Report                                                      | Yes            |
| Who are S(P)EARS Reported To<br>National Registry                                                    | Yes            |
| Who are S(P)EARS Reported To<br>Transplant Center                                                    | Yes            |
| Who are S(P)EARS Reported To<br>WMDA                                                                 | Yes            |

#### 14. Pictures of cord blood units in the inventory



#### 15. Infectious Disease Marker (IDM) CURRENTLY performed.





WO-1354-IDM-2015.pdf

---

## Holiday Calendar

|                |
|----------------|
| Team Calendars |
|----------------|