

# CBB Survey 2015 WO-1369

## CBB Survey 2015

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|--|---|
| <b>1. General Information</b>  |   |
| Name of CBB  | Umbilical Cord Blood Bank of Hospital de Clínicas de Porto Alegre |
| CBB Director   | Tor   |
| CBB Director   | Onsten  |
| Address  | Rua São Manoel 543  |
| Address  | 90620-110   |
| Address  | Porto Alegre  |
| Phone Number   | 55 51 33567676  |
| Date CBB Started Collecting Cord Blood Units<br>(month/day/year)       | 07/04/2011  |
| Number of Public Cord Blood Units                                      | 691   |
| Planned Number of Public Cord Blood Units Stored in 2015               | 360   |
| Lists on BMDW  | Yes   |
| Affiliated with National Stem Cell Donor Registry                      | Yes   |
| Registry Affiliation   | REDOME  |
| <b>2. Cord Blood Units in Inventory</b>                                |   |
| Current Processing Method  | Liquid+ red manual  |
| Current Processing Method  | Liquid+ red auto  |
| Year Current Process Method Started                                    | 2011  |
| <b>3. Accreditations, Licenses and Certifications</b>                  |   |
| FACT-Netcord   | No  |
| AABB   | No  |
| Competent Authority/ National Health Authority                         | Yes   |
| Name of Competent Authority  | Agência Nacional de Vigilância Sanitária (ANVISA)                 |
| Audited by National Stem Cell Registry                                 | Yes   |
| ISO  | No  |
| Other  | Joint Commission International                                    |
| <b>4. Cord Blood Collection</b>  |   |
| Current Collection Practice<br>Is the collection In/Ex -Utero or both? | Ex-utero  |
| Current Antiseptic   | Chlorhexidine   |
| Current Antiseptic   | Alcohol   |
| Collection Bag   | Single needle   |

|   |  |
|---|--|
| Agitation during Collection   | Automatic  |
| <b>5. Conditioning/Transport from Collection Site to CBB</b>  |  |
| 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 |
| Method for CD34 Remuneration  | ISHAGE guidelines                                    |
| External Proficiency Testing for QC of FACS Lab   | UKNEQAS  |
| External Proficiency Testing for QC of FACS Lab   | UKNEQAS and Controllab                               |
| 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- Unit in Inventory  | Volume reduction with HES-Manual                     |
| Pre Freeze Processing Methods- Current  | SEPAX  |
| Additives Currently in Use  | No additive  |
| Current Cryopreservation Method   | BioArchive   |
| Current Cryoprotectant Additive   | Ready for use DMSO-Dextran                           |
| Current Target Cryopreservation Volume (mL)   | 25.0   |
| Current Packaging for Storage   | Overwrap   |
| Current Packaging for Storage   | Canister   |
| Current Packaging for Storage   | One attached segment                                 |
| Current Packaging for Storage   | Additional separate segments                         |
| <b>8. Testing</b>   |  |
| 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                         | 50   |
| 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>CD34 (10^6) Double 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                   | NA   |
| <b>9. Storage</b>   |  |

|  |                                |
|--|--------------------------------|
| Type of Storage Container Used   | BioArchive                     |
| Monitoring of Storage  | Centralized alarm system local |
| Monitoring of Storage  | LN2 level                      |
| 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  |                                |
| Current Level of HLA Typing at Time of Listing<br>HLA-DRB1   | LR                             |
| 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   | ASHI 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         | No                             |
| Percentage of CBUs that have an Attached Segment   | 90-100%                        |
| 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            |
| Reservation Fee  | No                             |
| Reservation Cancellation Fee in Absence of Shipment Request  | No                             |
| Can Reservation be Extended  | No                             |
| Is a Unit Report Provided on a Unit that is Reserved for Another Patient                             | No                             |
| <b>12. Release and Shipment</b>  |                                |
| Hemoglobinopathy Screening Performed Prior to Release  | Yes                            |
| Criteria to Ship a CBU<br>Viability and Cell Count   | NA/50 x 10e7                   |
| Criteria to Ship a CBU<br>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   | Protective sleeve              |
| Time Between Shipment Request and Sending CBU  | 4 days-1 week                  |
| 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                          | Requesting transplant centre |
| Shape of Transport Container                           | Mushroom                     |
| <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                          |

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

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



#### Holiday Calendar

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