

# (archived) CBB Survey 2015 WO-1389

## CBB Survey 2015

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|                                                                        |                                           |
|------------------------------------------------------------------------|-------------------------------------------|
| <b>1. General Information</b>                                          |                                           |
| Name of CBB                                                            | CYCORD PACBB                              |
| CBB Director                                                           | PAUL                                      |
| CBB Director                                                           | COSTEAS                                   |
| Address                                                                | OLD ROAD NICOSIA-LIMASSOL                 |
| Address                                                                | NICOSIA GENERAL HOSPITAL                  |
| Address                                                                | 2029                                      |
| Address                                                                | NICOSIA                                   |
| Phone Number                                                           | 0035722603246                             |
| Date CBB Started Collecting Cord Blood Units<br>(month/day/year)       | 11/19/2005                                |
| Number of Public Cord Blood Units                                      | 2,634                                     |
| Planned Number of Public Cord Blood Units Stored in 2015               | 400                                       |
| Lists on BMDW                                                          | Yes                                       |
| Affiliated with National Stem Cell Donor Registry                      | Yes                                       |
| Registry Affiliation                                                   | CYPRUS BONE MARROW DONOR REGISTRY, CYBMDR |
| <b>2. Cord Blood Units in Inventory</b>                                |                                           |
| Current Processing Method                                              | Vapour+ red auto                          |
| Previous Processing Method                                             | Liquid+ red auto                          |
| Year Current Process Method Started                                    | 2008                                      |
| Percent of Units Plasma and RBC Reduced (automated)                    | 71                                        |
| Percent of Units No Volume Reduction                                   | 29                                        |
| <b>3. Accreditations, Licenses and Certifications</b>                  |                                           |
| FACT-Netcord                                                           | Yes                                       |
| AABB                                                                   | No                                        |
| Competent Authority/ National Health Authority                         | Yes                                       |
| Name of Competent Authority                                            | MINISTRY OF HEALTH                        |
| Audited by National Stem Cell Registry                                 | Yes                                       |
| ISO                                                                    | No                                        |
| <b>4. Cord Blood Collection</b>                                        |                                           |
| Current Collection Practice<br>Is the collection In/Ex -Utero or both? | In-utero                                  |
| Current Antiseptic                                                     | Betadine                                  |

|                                                                                                                 |                                                      |
|-----------------------------------------------------------------------------------------------------------------|------------------------------------------------------|
| Collection Bag                                                                                                  | Double needle                                        |
| Agitation during Collection                                                                                     | None                                                 |
| <b>5. Conditioning/Transport from Collection Site to CBB</b>                                                    |                                                      |
| Secondary Bag Used                                                                                              | Yes                                                  |
| Transport Conditions                                                                                            | Unqualified transporter                              |
| Transport Conditions                                                                                            | Passive refrigeration system                         |
| Transport Conditions                                                                                            | Electronic temperature probe                         |
| Transport Conditions                                                                                            | Ground transport                                     |
| Temp. for Storage and Transport                                                                                 | Defined (above +8°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                                                                | No processing                                        |
| 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 80:20                                     |
| Current Target Cryopreservation Volume (mL)                                                                     | 27.0                                                 |
| Current Packaging for Storage                                                                                   | Overwrap                                             |
| Current Packaging for Storage                                                                                   | Canister                                             |
| Current Packaging for Storage                                                                                   | More than one segment                                |
| <b>8. Testing</b>                                                                                               |                                                      |
| Extra Material Currently Stored                                                                                 | Cord blood DNA                                       |
| Extra Material Currently Stored                                                                                 | Plasma/cord blood                                    |
| Extra Material Currently Stored                                                                                 | Maternal DNA                                         |
| Extra Material Currently Stored                                                                                 | Maternal plasma/serum                                |
| Current Post Processing Threshold for Accepting a CBU for Public Use<br>TNC                                     | 100                                                  |
| Current Post Processing Threshold for Accepting a CBU for Public Use<br>CD34 (10 <sup>6</sup> ) Single Platform | 1.00                                                 |
| Current Post Processing Threshold for Accepting a CBU for Public Use<br>CD34 (10 <sup>6</sup> ) 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            | 75                                    |
| <b>9. Storage</b>                                                                            |                                       |
| Type of Storage Container Used                                                               | Conventional storage tank vapor phase |
| 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                |
| <b>10. HLA Typing</b>                                                                        |                                       |
| Current Level of HLA Typing at Time of Listing<br>HLA-A                                      | IR                                    |
| Current Level of HLA Typing at Time of Listing<br>HLA-B                                      | IR                                    |
| Current Level of HLA Typing at Time of Listing<br>HLA-C                                      | IR                                    |
| Current Level of HLA Typing at Time of Listing<br>HLA-DRB1                                   | IR                                    |
| Current Level of HLA Typing at Time of Listing<br>HLA-DQB1                                   | IR                                    |
| Current Level of HLA Typing at Time of Listing<br>HLA-DPB1                                   | LR                                    |
| 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                                             | 75-90%                                |
| Confirmatory/ Verification Typing on an Attached Segment is Pre-Release Requirement          | No                                    |
| <b>11. Reservation and Cancellation Policies</b>                                             |                                       |
| What Point is a CBU Reserved for a Patient                                                   | HLA typing request                    |
| Length of Time a CBU can be Reserved<br>in days                                              | 90                                    |
| 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                                           | 65                                    |

|                                                                                                      |                              |
|------------------------------------------------------------------------------------------------------|------------------------------|
| 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                                                                 | Separate segment             |
| Current Packaging for Shipment to TC                                                                 | 2 attached segments          |
| 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                                                                        | 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>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.



#### Holiday Calendar

Team Calendars