

# (archived) CBB Survey 2015 WO-1380

## CBB Survey 2015

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| <b>1. General Information</b>                                    |  |
| Name of CBB  | Bedomaich Chayi CBB  |
| CBB Director   | Gideon   |
| CBB Director   | Bach   |
| Address  | 5 HaMarpe St.  |
| Address  | P.O.B. 50220   |
| Address  | 91056  |
| Address  | Jerusalem  |
| Phone Number   | +972-2-6499899   |
| Website  | <a href="http://www.cordblood.org.il">www.cordblood.org.il</a>   |
| Date CBB Started Collecting Cord Blood Units<br>(month/day/year) | 01/01/2006   |
| Number of Public Cord Blood Units                                | 4,784  |
| Planned Number of Public Cord Blood Units Stored in 2015         | 600  |
| Lists on BMDW  | Yes  |
| Affiliated with National Stem Cell Donor Registry                | Yes  |
| Registry Affiliation   | Hadassah Bone Marrow and CB registry, Jerusalem, Israel  |
| <b>2. Cord Blood Units in Inventory</b>                          |  |
| Current Processing Method  | Vapour+ red manual   |
| Current Processing Method  | Vapour+ red auto   |
| Year Current Process Method Started                              | 2006   |
| Percent of Units Plasma and RBC Reduced (manual)                 | 85   |
| Percent of Units Plasma and RBC Reduced (automated)              | 15   |
| <b>3. Accreditations, Licenses and Certifications</b>            |  |
| FACT-Netcord   | No   |
| AABB   | No   |
| Competent Authority/ National Health Authority                   | Yes  |
| Name of Competent Authority                                      | Israeli ministry of health   |
| Audited by National Stem Cell Registry                           | Yes  |
| ISO  | No   |
| Other  | GMP Certificate by the Institute for the Standardization and Control of Pharmaceuticals, Ministry of Health, Jerusalem, Israel |
| <b>4. Cord Blood Collection</b>                                  |  |

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| Current Collection Practice<br>Is the collection In/Ex -Utero or both? | In-utero   |
| Current Antiseptic   | Chlorhexidine  |
| Current Antiseptic   | Alcohol  |
| Collection Bag   | Single 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                         |
| 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)    |
| <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  |
| 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  |
| Pre Freeze Processing Methods- Current                                 | Volume reduction with HES manual                     |
| 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)                            | 25.0   |
| Current Packaging for Storage  | Overwrap   |
| Current Packaging for Storage  | Canister   |
| Current Packaging for Storage  | More than one segment                                |
| <b>8. Testing</b>  |  |
| PCR Performed on IgM+ Result   | CMV  |
| PCR Performed on IgM+ Result   | EBV  |
| Extra Material Currently Stored  | Cord blood material for DNA extraction               |
| Extra Material Currently Stored  | Plasma/cord blood                                    |
| Extra Material Currently Stored  | Maternal plasma/serum                                |

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| 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 (10^6) Single Platform | 1.50   |
| 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>Viability                   | 80   |
| <b>9. Storage</b>   |  |
| Type of Storage Container Used  | Conventional storage tank vapor phase  |
| Monitoring of Storage   | Centralized alarm system local   |
| Monitoring of Storage   | Centralized system remote monitoring   |
| 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   | 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   |  |
| 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  |  |
| 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                                  | 3  |
| 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  |
| What Point is a CBU Reserved for a Patient  | Shipment request   |
| Length of Time a CBU can be Reserved<br>in days   | Other  |
| Length of Time a CBU can be Reserved<br>in days   | reservation can be extended by request. a fee is charged for extending the reservation and it is discounted from the CBU release fee |
| Reservation Fee   | No   |

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| 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  |
| <b>12. Release and Shipment</b>  |   |
| Hemoglobinopathy Screening Performed Prior to Release  | Yes   |
| Criteria to Ship a CBU<br><small>Viability and Cell Count</small>                                    | Minimum 60% TNC recovery and 60% Viability  |
| Criteria to Ship a CBU<br><small>HLA Identity Testing</small>  | Yes   |
| Current Packaging for Shipment to TC   | Metal canister  |
| Current Packaging for Shipment to TC   | One attached segment  |
| Current Packaging for Shipment to TC   | Transport rack  |
| Time Between Shipment Request and Sending CBU  | Other   |
| Time to Prepare a Cord Blood Unit for Shipment   | CBUs can be shipped within 3-4 days. it is recommended to request a CBU at least 14 days in advance for completing a CFU assay on a frozen sample from the attached segment |
| Fee for Shipment Cancellation  | Yes   |
| 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><small>Competent Authority</small>                                   | Yes   |
| Who are S(P)EARS Reported To<br><small>Internal Report</small>                                       | Yes   |
| Who are S(P)EARS Reported To<br><small>National Registry</small>                                     | Yes   |
| Who are S(P)EARS Reported To<br><small>Transplant Center</small>                                     | Yes   |
| Who are S(P)EARS Reported To<br><small>WMDA</small>  | Yes   |

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



15. Infectious Disease Marker (IDM) CURRENTLY performed.



WO-1380-IDM-2015.pdf

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## Holiday Calendar

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| Team Calendars |
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