

(archived) CBB Survey 2015 WO-1361

CBB Survey 2015

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| 1. General Information | |
| Name of CBB | GenCure: Texas Cord Blood Bank |
| CBB Director | Mary Ellen |
| CBB Director | Mooney |
| Address | 6211 IH 10 West |
| Address | 78201 |
| Address | San Antonio |
| Phone Number | 210-757-9425 |
| Website | www.gencure.org |
| Date CBB Started Collecting Cord Blood Units (month/day/year) | 06/22/2005 |
| Number of Public Cord Blood Units | 10,207 |
| Planned Number of Public Cord Blood Units Stored in 2015 | 1,528 |
| Lists on BMDW | No |
| Affiliated with National Stem Cell Donor Registry | Yes |
| Registry Affiliation | Be The Match Registry (NMDP) |
| 2. Cord Blood Units in Inventory | |
| Current Processing Method | Liquid+ red auto |
| Current Processing Method | Vapour+ red auto |
| Previous Processing Method | Vapour+ red manual |
| Year Current Process Method Started | 2008 |
| Percent of Units Plasma and RBC Reduced (manual) | 30 |
| Percent of Units Plasma and RBC Reduced (automated) | 70 |
| 3. Accreditations, Licenses and Certifications | |
| FACT-Netcord | No |
| AABB | Yes |
| Competent Authority/ National Health Authority | No |
| Audited by National Stem Cell Registry | Yes |
| ISO | Yes |
| 4. Cord Blood Collection | |
| Current Collection Practice Is the collection In/Ex -Utero or both? | In-utero |
| Current Antiseptic | Chlorhexidine |
| Collection Bag | Single 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 | Insulating transport container |
| Transport Conditions | Passive refrigeration system |
| Transport Conditions | Air 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 | Collection report, informed consent |
| Completed Prior to Accepting a CBU | Maternal Eligibility Pre-Screening |
| Method for CD34 Remuneration | ISHAGE guidelines |
| External Proficiency Testing for QC of FACS Lab | CAP |
| 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 | SEPAX |
| Pre Freeze Processing Methods- Unit in Inventory | Volume reduction with HES-Manual |
| Pre Freeze Processing Methods- Current | SEPAX |
| Additives Currently in Use | HES |
| Current Cryopreservation Method | BioArchive |
| Current Cryoprotectant Additive | Other: Sterile 0.9% NaCl (Saline) |
| 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 |
| 8. Testing | |
| 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 |
| Extra Material Currently Stored | Maternal plasma/serum |
| Current Post Processing Threshold for Accepting a CBU for Public Use TNC | 29 |
| Current Post Processing Threshold for Accepting a CBU for Public Use CD34 (10^6) Single Platform | 0.10 |
| 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 | 10 |

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| Current Post Processing Threshold for Accepting a CBU for Public Use CFU | 0 - 999 |
| Current Post Processing Threshold for Accepting a CBU for Public Use Viability | 85 |
| 9. Storage | |
| Type of Storage Container Used | BioArchive |
| Type of Storage Container Used | Conventional storage tank vapor phase |
| Monitoring of Storage | Centralized alarm system local |
| 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 | IR |
| Current Level of HLA Typing at Time of Listing HLA-B | IR |
| Current Level of HLA Typing at Time of Listing HLA-C | IR |
| Current Level of HLA Typing at Time of Listing HLA-DRB1 | HR |
| Current Level of HLA Typing at Time of Listing HLA-DQB1 | IR |
| Current Level of HLA Typing at Time of Listing HLA-DPB1 | IR |
| Accreditation of HLA Lab | ASHI accredited lab |
| Average Turnaround Time for Extended HLA Typing Results 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 |
| 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 | Other |
| Length of Time a CBU can be Reserved in days | Until NMDP indicates release |
| 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 |
| 12. Release and Shipment | |
| Hemoglobinopathy Screening Performed Prior to Release | Yes |
| Criteria to Ship a CBU Viability and Cell Count | NA |

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| 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 | Transport rack |
| Time Between Shipment Request and Sending CBU | 0-3 days |
| 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 |
| 13. Adverse Events Reporting | |
| Who are S(P)EARS Reported To Internal Report | Yes |
| Who are S(P)EARS Reported To National Registry | Yes |

14. Pictures of cord blood units in the inventory



15. Infectious Disease Marker (IDM) CURRENTLY performed.



WO-1361-IDM-2015.pdf

Holiday Calendar

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| Team Calendars |
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