

# (archived) CBB Survey 2015 WO-1370

## CBB Survey 2015

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|                                                                  |                                                    |
|------------------------------------------------------------------|----------------------------------------------------|
| <b>1. General Information</b>                                    |                                                    |
| Name of CBB                                                      | MD Anderson Cord Blood Bank                        |
| CBB Director                                                     | EJ                                                 |
| CBB Director                                                     | Shpall                                             |
| Address                                                          | Unit 1170                                          |
| Address                                                          | The University of Texas MD Anderson Cancer Center  |
| Address                                                          | 1841 Old Spanish Trail                             |
| Address                                                          | 77054                                              |
| Address                                                          | Houston                                            |
| Phone Number                                                     | 1-713-563-8000                                     |
| Date CBB Started Collecting Cord Blood Units<br>(month/day/year) | 04/16/2005                                         |
| Number of Public Cord Blood Units                                | 21,479                                             |
| Planned Number of Public Cord Blood Units Stored in 2015         | 3,000                                              |
| Lists on BMDW                                                    | No                                                 |
| Affiliated with National Stem Cell Donor Registry                | Yes                                                |
| Registry Affiliation                                             | Be The Match, National Marrow Donor program (NMDP) |
| <b>2. Cord Blood Units in Inventory</b>                          |                                                    |
| Current Processing Method                                        | Liquid+ red auto                                   |
| Previous Processing Method                                       | Liquid+ red manual                                 |
| Year Current Process Method Started                              | 2006                                               |
| Percent of Units Plasma and RBC Reduced (manual)                 | 9                                                  |
| Percent of Units Plasma and RBC Reduced (automated)              | 91                                                 |
| Percent of Units RBC Reduced Only                                | 0                                                  |
| Percent of Units No Volume Reduction                             | 0                                                  |
| <b>3. Accreditations, Licenses and Certifications</b>            |                                                    |
| FACT-Netcord                                                     | Yes                                                |
| AABB                                                             | No                                                 |
| Competent Authority/ National Health Authority                   | No                                                 |
| Audited by National Stem Cell Registry                           | Yes                                                |
| ISO                                                              | No                                                 |
| <b>4. Cord Blood Collection</b>                                  |                                                    |

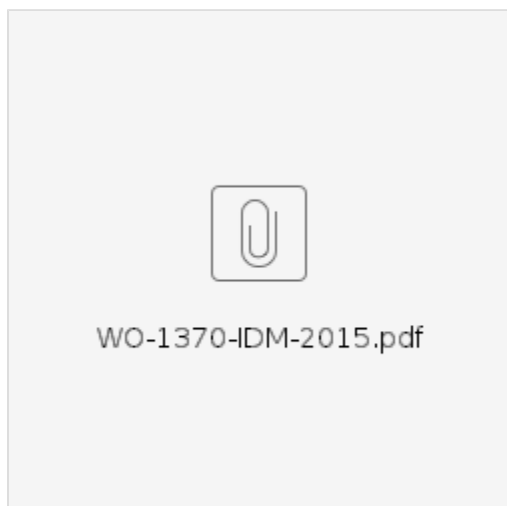
|                                                                             |                                                      |
|-----------------------------------------------------------------------------|------------------------------------------------------|
| Current Collection Practice<br>Is the collection In/Ex -Utero or both?      | Both                                                 |
| Current Antiseptic                                                          | Chlorhexidine                                        |
| Current Antiseptic                                                          | Betadine                                             |
| Collection Bag                                                              | Add second needle to collection bag                  |
| 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                                                        | Non-electronic temperature probe                     |
| Transport Conditions                                                        | Electronic temperature probe                         |
| Transport Conditions                                                        | Air transport                                        |
| Transport Conditions                                                        | Ground transport                                     |
| Temp. for Storage and Transport                                             | Room temperature                                     |
| <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                             | Stem cell technology, CAP                            |
| 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                                                  | HES                                                  |
| Current Cryopreservation Method                                             | BioArchive                                           |
| 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>                                                           |                                                      |
| 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 | 90                                                   |

|                                                                                                     |                                      |
|-----------------------------------------------------------------------------------------------------|--------------------------------------|
| Current Post Processing Threshold for Accepting a CBU for Public Use<br>CD34 (10^6) Single Platform | 1.25                                 |
| 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                         | 0.1x10e6                             |
| Current Post Processing Threshold for Accepting a CBU for Public Use<br>Viability                   | 85                                   |
| <b>9. Storage</b>                                                                                   |                                      |
| Type of Storage Container Used                                                                      | BioArchive                           |
| Monitoring of Storage                                                                               | Centralized system remote monitoring |
| Monitoring of Storage                                                                               | LN2 level                            |
| <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                                          |                                      |
| 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                                  | 5                                    |
| 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                  |
| Length of Time a CBU can be Reserved<br>in days                                                     | 60                                   |
| 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                                   |
| <b>12. Release and Shipment</b>                                                                     |                                      |
| Hemoglobinopathy Screening Performed Prior to Release                                               | Yes                                  |
| Criteria to Ship a CBU<br>Viability and Cell Count                                                  | >=70                                 |

|                                                                                                      |                        |
|------------------------------------------------------------------------------------------------------|------------------------|
| 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                                                        | 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                                                                        | CBB                    |
| Who Selects Transport Company                                                                        | Quick or World Courier |
| 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

Team Calendars

