

# CB banking specifics WO-1356

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## Section 1 General Info

| Question                                                                                           | CBB answer               |
|----------------------------------------------------------------------------------------------------|--------------------------|
| The information has been reviewed in year :                                                        |                          |
| Name of the cord blood bank:                                                                       | Calabria Cord Blood Bank |
| Number of cord blood units the cord blood bank plans to store for public use (unrelated patients): | 10 at year               |

## Section 2 Cord Blood Units in Inventory

| Question                                                                                                | CBB answer |
|---------------------------------------------------------------------------------------------------------|------------|
| Current processing method(s):                                                                           |            |
| Plasma and RBC reduced (automatic)                                                                      | checkfalse |
| Plasma reduction only                                                                                   | checkfalse |
| Plasma and RBC reduced (manual)                                                                         | checktrue  |
| RBC reduction only                                                                                      | checkfalse |
| Total Nucleated Cell Count (x10E7) of your cord blood units stored for Unrelated Patients (Public Use). |            |
| < 125 :                                                                                                 |            |
| 125 - 149 :                                                                                             |            |
| 150 - 199 :                                                                                             | 373        |
| 200 - 250 :                                                                                             | 475        |
| > 250 :                                                                                                 |            |

## Section 3 Cord Blood Collection

| Question                                    | CBB answer             |
|---------------------------------------------|------------------------|
| Current practice for collecting cord blood: | In-utero and ex-utero  |
| Current antiseptic:                         | Chlorhexidine betadine |
| Collection bag:                             | Other                  |
| Agitation during collection:                | Manual                 |

## Section 4 Conditioning and transport from Collection Centre to cord blood bank

| Question                                                                                         | CBB answer                     |
|--------------------------------------------------------------------------------------------------|--------------------------------|
| Secondary bag used by the cord blood bank (sealed, plastic bag or similar to avoid any leakage): | yes                            |
| Transport conditions:                                                                            |                                |
| Insulating transport container                                                                   | checktrue                      |
| Active refrigeration system                                                                      | checkfalse                     |
| Passive refrigeration system (gel, blocks)                                                       | checktrue                      |
| Electronic temperature probe                                                                     | checkfalse                     |
| Non-electronic temperature probe                                                                 | checkfalse                     |
| Qualified transporter                                                                            | checktrue                      |
| Unqualified transporter                                                                          | checkfalse                     |
| Air transport                                                                                    | checkfalse                     |
| Ground transport                                                                                 | checktrue                      |
| Other,                                                                                           | checkfalse                     |
| Temperature range for storage and transportation of fresh product:                               | Temperature between +2 to +8°C |

## Section 5 Evaluation

| Question                                                                                                               | CBB answer                                    |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| Pre-processing Evaluation:<br>Current threshold for accepting a cord blood unit for public use in the cord blood bank: |                                               |
| Net weight in grams (excluding bag and anticoagulant) before processing                                                | 80 - 89.99 grams                              |
| TNC (10E7) before processing                                                                                           | 150 - 199                                     |
| Viability CD45 positive cells (%)                                                                                      | 80 - 89%                                      |
| Viability CD45 positive cells (method)                                                                                 | 7AAD                                          |
| Viability CD34 positive cells (%)                                                                                      | 80 - 89%                                      |
| Viability CD34 positive cells (method)                                                                                 | 7AAD                                          |
| Criteria that are completed before accepting a cord blood unit for public use in the cord blood bank:                  |                                               |
| Medical History                                                                                                        | checktrue                                     |
| Collection Report                                                                                                      | checktrue                                     |
| Informed Consent                                                                                                       | checktrue                                     |
| Maternal IDM results                                                                                                   | checktrue                                     |
| Temperature and integrity of the bag                                                                                   | checktrue                                     |
| Other,                                                                                                                 | checkfalse                                    |
| Used method for CD34 enumeration:                                                                                      | ISHAGE                                        |
| The cord blood banks uses external proficiency testing for QC of the cord blood banks FACS lab:                        | yes                                           |
| The cord blood bank performs post processing/pre-freeze CD34 cell count:                                               | yes                                           |
| Acceptable time from collection to processing:                                                                         | 24-48H 72 h only in specific cases (dedicate) |

## Section 6 Processing-Packaging

| Question                                                                             | CBB answer |
|--------------------------------------------------------------------------------------|------------|
| The pre-freeze processing method(s) cord blood bank uses at any stage in time:       |            |
| AXP                                                                                  | checkfalse |
| SEPAX                                                                                | checkfalse |
| Optipress                                                                            | checkfalse |
| Prepacyte                                                                            | checkfalse |
| Manual- plasma and red cell reduction                                                | checktrue  |
| RBC/plasma reduction with HES                                                        | checkfalse |
| Ficoll sedimentation                                                                 | checkfalse |
| Centrifugation and volume reduction                                                  | checktrue  |
| No processing                                                                        | checkfalse |
| Manual- plasma reduction only                                                        | checkfalse |
| Other,                                                                               | checkfalse |
| The current pre-freeze processing method(s):                                         |            |
| AXP                                                                                  | checkfalse |
| SEPAX                                                                                | checkfalse |
| Optipress                                                                            | checkfalse |
| Prepacyte                                                                            | checkfalse |
| Manual- plasma and red cell reduction                                                | checktrue  |
| RBC/plasma reduction with HES                                                        | checkfalse |
| Ficoll sedimentation                                                                 | checkfalse |
| Centrifugation and volume reduction                                                  | checktrue  |
| No processing                                                                        | checkfalse |
| Manual- plasma reduction only                                                        | checkfalse |
| Other,                                                                               | checkfalse |
| Additives currently in use in addition to anticoagulants and DMSO during processing: |            |
| HES                                                                                  | checkfalse |
| Prepacyte                                                                            | checkfalse |
| Plasmalyte                                                                           | checkfalse |
| Albumin                                                                              | checktrue  |
| Isotonic salt solution NaCl (saline)                                                 | checktrue  |
| No additive                                                                          | checkfalse |
| Other,                                                                               | checkfalse |
| Cryoprotectant additives currently in use:                                           | DMSO       |
| Cryopreservation method currently in use:                                            |            |
| BioArchive                                                                           | checkfalse |
| MVE 1850 Vapor freezer                                                               | checkfalse |
| Programmed cryopreservation with Air Liquid program (FREEZAL)                        | checktrue  |
| Programmed freezer                                                                   | checkfalse |
| Two-step (equilibrium) freezing                                                      | checkfalse |

|                                                                  |                             |
|------------------------------------------------------------------|-----------------------------|
| Cryobag currently in use:                                        | Single bag (one fraction)   |
| Currently used packaging when a unit is stored:                  | Metal canister and overwrap |
| Segments currently stored with the unit by the cord blood bank:  |                             |
| One attached segment                                             | checkfalse                  |
| Two or more attached segments                                    | checkfalse                  |
| Separate segments detached from the bag, but stored with the CBU | checktrue                   |
| Other samples                                                    | checkfalse                  |
| None                                                             | checkfalse                  |

## Section 7 Testing

| Question                                                  | CBB answer      |
|-----------------------------------------------------------|-----------------|
| Does your cord blood bank currently store extra material? |                 |
| Cord blood DNA                                            | checktrue       |
| Cord blood material for DNA extraction                    | checktrue       |
| Plasma/cord blood                                         | checktrue       |
| Maternal DNA                                              | checkfalse      |
| Maternal material for DNA extraction                      | checkfalse      |
| Maternal plasma/serum                                     | checktrue       |
| HLA typing at time of listing:                            |                 |
| HLA-A                                                     | High Resolution |
| HLA-B                                                     | High Resolution |
| HLA-C                                                     | Not performed   |
| HLA-DRB1                                                  | Not performed   |
| HLA-DRB2                                                  | Not performed   |
| HLA-DPB1                                                  | Not performed   |

## Section 8 Storage

| Question                                                                             | CBB answer |
|--------------------------------------------------------------------------------------|------------|
| The following type(s) of storage container is currently used by the cord blood bank: |            |
| BioArchive tank                                                                      | checkfalse |
| Conventional storage tank-Vapor phase                                                | checkfalse |
| Conventional tank-Liquid phase                                                       | checktrue  |
| Double walled liquid Nitrogen                                                        | checkfalse |
| Type following type(s) of storage monitoring is currently by the cord blood bank:    |            |
| Alarm on individual tanks only                                                       | checkfalse |
| Centralized system-local                                                             | checktrue  |
| Centralized system-remote monitoring                                                 | checktrue  |

|                           |            |
|---------------------------|------------|
| LN2 level                 | checktrue  |
| Lid opening               | checkfalse |
| System default            | checkfalse |
| Temperature monitoring    | checktrue  |
| No temperature monitoring | checkfalse |

## Section 9 Adverse Events Reporting

| Question                                             | CBB answer |
|------------------------------------------------------|------------|
| Adverse Event Reporting used by the cord blood bank: |            |
| Competent authority                                  | checktrue  |
| Internal report                                      | checktrue  |
| National registry                                    | checktrue  |
| Transplant centre                                    | checktrue  |
| WMDA                                                 | checktrue  |