

CB banking specifics WO-1832

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Section 1 General Info

| Question | CBB answer |
|--|------------------------|
| The information has been reviewed in year : | |
| Name of the cord blood bank: | Milano Cord Blood Bank |
| Number of cord blood units the cord blood bank plans to store for public use (unrelated patients): | 12.000 |

Section 2 Cord Blood Units in Inventory

| Question | CBB answer |
|---|------------|
| Current processing method(s): | |
| Plasma and RBC reduced (automatic) | checktrue |
| Plasma reduction only | checkfalse |
| Plasma and RBC reduced (manual) | checkfalse |
| RBC reduction only | checkfalse |
| Total Nucleated Cell Count (x10E7) of your cord blood units stored for Unrelated Patients (Public Use). | |
| < 125 : | 6754 |
| 125 - 149 : | 2077 |
| 150 - 199 : | 1452 |
| 200 - 250 : | 307 |
| > 250 : | 77 |

Section 3 Cord Blood Collection

| Question | CBB answer |
|---|-----------------------|
| Current practice for collecting cord blood: | In-utero and ex-utero |
| Current antiseptic: | Betadine |
| Collection bag: | Double needle |
| 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 | checkfalse |
| Active refrigeration system | checktrue |
| Passive refrigeration system (gel, blocks) | checktrue |
| Electronic temperature probe | checktrue |
| 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: | Defined (above +8°C) |

Section 5 Evaluation

| Question | CBB answer |
|--|----------------------------------|
| Pre-processing Evaluation: 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 | 60 - 69.99 grams |
| TNC (10E7) before processing | 150 - 199 |
| Viability CD45 positive cells (%) | NA- not evaluated pre-processing |
| Viability CD45 positive cells (method) | |
| Viability CD34 positive cells (%) | NA- not evaluated pre-processing |
| Viability CD34 positive cells (method) | |
| 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: | |
| 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 |

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 | checkfalse |
| RBC/plasma reduction with HES | checkfalse |
| Ficoll sedimentation | checkfalse |
| Centrifugation and volume reduction | checktrue |
| No processing | checktrue |
| Manual- plasma reduction only | checkfalse |
| Other, Compomat G4 | checkfalse |
| The current pre-freeze processing method(s): | |
| AXP | checkfalse |
| SEPAX | checkfalse |
| Optipress | checkfalse |
| Prepacyte | checkfalse |
| Manual- plasma and red cell reduction | checkfalse |
| RBC/plasma reduction with HES | checkfalse |
| Ficoll sedimentation | checkfalse |
| Centrifugation and volume reduction | checktrue |
| No processing | checkfalse |
| Manual- plasma reduction only | checkfalse |
| Other, Compomat G4 | checkfalse |
| Additives currently in use in addition to anticoagulants and DMSO during processing: | |
| HES | checkfalse |
| Prepacyte | checkfalse |
| Plasmalyte | checkfalse |
| Albumin | checkfalse |
| Isotonic salt solution NaCl (saline) | checkfalse |
| No additive | checktrue |
| Other, | checkfalse |
| Cryoprotectant additives currently in use: | DMSO- Dextran |
| Cryopreservation method currently in use: | |
| BioArchive | checkfalse |
| MVE 1850 Vapor freezer | checkfalse |
| Programmed cryopreservation with Air Liquid program (FREEZAL) | checkfalse |
| Programmed freezer | checktrue |
| 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 | checktrue |
| Separate segments detached from the bag, but stored with the CBU | checkfalse |
| 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 | checktrue |
| Maternal material for DNA extraction | checktrue |
| Maternal plasma/serum | checktrue |
| HLA typing at time of listing: | |
| HLA-A | High Resolution |
| HLA-B | High Resolution |
| HLA-C | High Resolution |
| HLA-DRB1 | High Resolution |
| 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 | checktrue |
| 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 | checktrue |
| Centralized system-local | checktrue |
| Centralized system-remote monitoring | checktrue |

| | |
|---------------------------|------------|
| LN2 level | checktrue |
| Lid opening | checktrue |
| System default | checktrue |
| 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 | checkfalse |

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| Question | CBB answer |
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| Name of the cord blood bank: | Milano Cord Blood Bank |
| Number of cord blood units the cord blood bank plans to store for public use (unrelated patients): | 12.000 |

Section 2 Cord Blood Units in Inventory

| Question | CBB answer |
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| Current processing method(s): | |
| Plasma and RBC reduced (automatic) | checktrue |
| Plasma reduction only | checkfalse |
| Plasma and RBC reduced (manual) | checkfalse |
| RBC reduction only | checkfalse |
| Total Nucleated Cell Count (x10E7) of your cord blood units stored for Unrelated Patients (Public Use). | |
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| Current antiseptic: | Betadine |
| Collection bag: | Double needle |
| Agitation during collection: | Manual |

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

| Question | CBB answer |
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| Secondary bag used by the cord blood bank (sealed, plastic bag or similar to avoid any leakage): | yes |
| Transport conditions: | |
| Insulating transport container | checkfalse |
| Active refrigeration system | checktrue |
| Passive refrigeration system (gel, blocks) | checktrue |
| Electronic temperature probe | checktrue |
| 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: | Defined (above +8°C) |

Section 5 Evaluation

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| Pre-processing Evaluation: Current threshold for accepting a cord blood unit for public use in the cord blood bank: | |
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| TNC (10E7) before processing | 150 - 199 |
| Viability CD45 positive cells (%) | NA- not evaluated pre-processing |
| Viability CD45 positive cells (method) | |

| | |
|---|----------------------------------|
| Viability CD34 positive cells (%) | NA- not evaluated pre-processing |
| Viability CD34 positive cells (method) | |
| 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: | |
| 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 |

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| 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 | checkfalse |
| RBC/plasma reduction with HES | checkfalse |
| Ficoll sedimentation | checkfalse |
| Centrifugation and volume reduction | checktrue |
| No processing | checktrue |
| Manual- plasma reduction only | checkfalse |
| Other, Compomat G4 | checkfalse |
| The current pre-freeze processing method(s): | |
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| No processing | checkfalse |
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| Cord blood material for DNA extraction | checktrue |
| Plasma/cord blood | checktrue |
| Maternal DNA | checktrue |
| Maternal material for DNA extraction | checktrue |
| Maternal plasma/serum | checktrue |
| HLA typing at time of listing: | |
| HLA-A | High Resolution |
| HLA-B | High Resolution |
| HLA-C | High Resolution |
| HLA-DRB1 | High Resolution |

| | |
|----------|---------------|
| 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: | |
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| Internal report | checktrue |
| National registry | checktrue |
| Transplant centre | checktrue |
| WMDA | checkfalse |