

# Cord Blood Bank Technology Survey 2017

Response ID:192 Data

1.

## 1. General data

### Name of the Cord Blood Bank:

ERCB-EMILIA ROMAGNA CORD BLOOD BANK

2.

### 2. In what year did your Cord Blood Bank start collecting cord blood units?

1997

### 3. Type of cord blood units in the inventory of your Cord Blood Bank (please note the number of cord blood units stored on December 31, 2016).

Cord Blood Units in inventory for Unrelated Allogeneic. : 4910

Cord Blood Units in inventory for Related Allogeneic (directed). : 132

Cord Blood Units in inventory for Autologous. : 14

### 4. How many cord blood units do you plan to store for public use (unrelated patients)?

In 2017 : 110

In 2018 : 110

### 5. Does your Cord Blood Bank list units in BMDW (www.bmdw.org)?

Yes

### 6. Is your Cord Blood Bank affiliated with a National Stem Cell Donor Registry? If yes, list the name of the registry.

Yes, please list the name of the registry: IBMDR

## 3. Cord Blood Units in Inventory

### 7. What is your current processing method? Check all that apply.

Plasma and RBC reduced (automatic)

### 8. What year did your Cord Blood Bank start using your current processes?

2008

### 9. If possible, please upload a picture of cord blood units in your inventory for your current practise in use. You can upload a maximum of five pictures per question.

[current\\_practise\\_use.pdf](#)

[current\\_practise\\_use.pdf](#)

### 10. If possible, please upload a picture of cord blood units in your inventory for volume reduction. You can upload a maximum of five pictures per question.

[bag\\_after\\_2008.pdf](#)

### 11. If possible, please upload a picture of cord blood units in your inventory for no volume reduction. You can upload a maximum of five pictures per question.

[bag\\_before\\_2008.pdf](#)

### 12. Total Nucleated Cell Count (x10E7) of your cord blood units stored for Unrelated Patients (Public Use).

Please specify the number of cord blood units per category.

< 125 : 1782  
125 - 149 : 1600  
150 - 199 : 1000  
200 - 250 : 400  
> 250 : 128

#### 4. Accreditations-licenses-certifications

##### 13. FACT-Netcord accreditation

**Is your Cord Blood Bank FACT-Netcord accredited?**

Yes

**Year of last on-site inspection (FACT):**

2016

**State year of your first accreditation:**

2013

##### 14. AABB accreditation

**Is your Cord Blood Bank AABB accredited?**

No

##### 15. Competent Authority/National Health Authority (state-based).

**Is your Cord Blood Bank licensed by a (state-based) Competent Authority?**

Yes

**Does the Competent Authority perform on-site inspections?**

Yes, please specify year of the last inspection.

**Year of last on-site inspection of your Competent Authority:**

2011

**Name of the institution Competent Authority:**

National Transplant Center and National Blood Center

**Link to the license website of the institution Competent Authority:**

<http://www.trapianti.salute.gov.it/cnt/cnt.htm>

**16. Does your National Stem Cell Donor Registry perform on-site inspections?**

No

**17. Please describe other accreditations, licenses, or certifications of your Cord Blood Bank.**

NMDP IND Annual Qualification

#### 5. Cord Blood Collection

**18. What is your current practice for collecting cord blood?**

In-utero

**19. Current antiseptic. Check all that apply.**

Chlorhexidine

Betadine

**20. Collection bag**

Double needle

**21. Agitation during collection**

Manual

#### 6. Conditioning and transport from Collection Centre to Cord Blood Bank.

**22. Do you use a secondary bag (sealed, plastic bag or similar to avoid any leakage)?**

Yes

**23. Transport conditions.**

Insulating transport container  
Passive refrigeration system (gel, blocks)  
Non-electronic temperature probe  
Qualified transporter  
Ground transport

**24. Specify temperature range for storage and transportation of fresh product.**

Defined (above +8°C)

**7. Evaluation**

**25. Pre-processing Evaluation**

**Please specify your current threshold for accepting a cord blood unit for public use in your cord blood bank.**

**Net weight in grams (excluding bag and anticoagulant) before processing**

50 - 59.99 grams

**TNC (10E7) before processing**

150 - 199

**Viability CD45 positive cells (%)**

70 - 79%

**Viability CD45 positive cells (method)**

7AAD

**Viability CD34 positive cells (%)**

70 - 79%

**Viability CD34 positive cells (method)**

7AAD

**26. Pre Processing Evaluation**

**Please mark the criteria that are completed before accepting a cord blood unit for public use in your Cord Blood Bank. Check all that apply.**

Medical History  
Collection Report  
Informed Consent  
Maternal IDM results  
Temperature and integrity of the bag

**27. Which method is used for CD34 enumeration?**

ISHAGE guidelines

**28. Do you use external proficiency testing for QC of your FACS lab?**

Yes, please specify (e.g. UKNEQAS): UKNEQAS, STEMCELL PROFICIENCY

**29. Does your Cord Blood Bank perform post processing/pre-freeze CD34 cell count?**

Yes

**30. Acceptable time from collection to processing.**

24-48H

## 8. Processing-Packaging

**31. Please select the pre freeze processing methods you have used at any stage in time. Check all that apply.**

- SEPAX
- RBC/plasma reduction with HES
- Centrifugation and volume reduction
- Manual- plasma reduction only

**32. What are your current pre-freeze processing methods? Check all that apply.**

- SEPAX
- RBC/plasma reduction with HES

**33. Please specify additives currently in use in addition to anticoagulants and DMSO during processing. Check all that apply.**

- HES

**34. Please specify cryoprotectant additives currently in use. Check all that apply.**

- DMSO- Dextran

**35. Please specify cryopreservation method currently in use. Check all that apply.**

- Programmed freezer

**36. Please specify cryobag currently in use. Check all that apply.**

- Single bag (one fraction)

**37. What packaging is currently used when a unit is stored? Check all that apply.**

- Metal canister
- Overwrap

**38. How many segments do you currently store with the unit? Check all that apply.**

- Two or more attached segments
- Other samples

## 9. Testing

**39. Using the list below, indicate which Infectious Disease Marker (IDM) testing of the maternal donor and/or cord blood is CURRENTLY performed by your Cord Blood Bank.**

	Standard on Maternal Sample	Standard on cord blood sample	Testing available by request on maternal sample	Testing available by request on cord blood sample	Not done
Hepatitis B Surface Antigen	X	X			
Hepatitis B core Antibody	X	X			
Hepatitis B Surface Antibody				X	
HBV NAT	X	X			
Hepatitis C Antibody	X	X			
HCV NAT	X	X			
HIV 1/2 Antibody	X	X			
HIV 1 and 2 + 0 Antibodies					

HIV p24 Antigen	X	X		
HIV NAT Antigen	X	X		
HTLV I/II Antibodies	X	X		
HTLV NAT				
CMV Antibody - IgG	X	X		
CMV Antibody - IgM	X	X		
CMV Antibody Total				
Syphilis	X	X		
West Nile Virus NAT	X	X		
West Nile Virus Antibody			X	
T. Cruzi Antibody (Chagas Disease)			X	
EBV Antibody - IgG			X	
EBV Antibody - IgM			X	
EBV Antibody Total			X	
Toxoplasmosis Antibody - IgG	X	X		
Toxoplasmosis Antibody - IgM	X	X		
Toxoplasmosis Antibody Total				

**40. In case the Antibody - IgM is positive (for CMV, Toxoplasmosis or EBV) does your Cord Blood Bank perform a PCR? Please mark checkbox, when your Cord Blood Bank performs PCR testing. Check all that apply.**

- CMV
- Toxoplasmosis
- EBV

**41. Does your Cord Blood Bank currently store extra material?**

- Cord blood DNA
- Cord blood material for DNA extraction
- Plasma/cord blood
- Maternal DNA
- Maternal material for DNA extraction
- Maternal plasma/serum

**42. HLA typing at time of listing.**

	Low Resolution	Intermediate Resolution	High Resolution	Not performed
HLA-A			X	
HLA-B			X	
HLA-C			X	
HLA-DRB1			X	
HLA-DQB1				X
HLA-DPB1				X

**43. Current threshold for accepting a cord blood unit for public use (post processing)**

	Please specify threshold	Please provide method	Not performed
Minimum TNC (10E7)	160	DASIT Hemocytometer	
Minimum CD34 (10E6) single platform	2	STEM KIT BD (CD34+/CD45+/viable cells WITH FLOW CYTOMETER ANALYSIS)	
Minimum CD34 (10E6) double platform	NA		
Total-CFU (10E5)	growth	HSC-CFU CLONOGENIC ASSAY	
Viability (10E5)	20	7-Amino-Actinomycin D	

**10. Storage**

**44. What type of storage container is currently used in your cord blood bank?**

Conventional storage tank-Vapor phase  
 Conventional tank-Liquid phase

**45. What type of storage monitoring is currently used in your cord blood bank?**

Centralized system-local  
 Centralized system-remote monitoring  
 LN2 level  
 Lid opening  
 System default  
 Temperature monitoring

**11. Verification/Extended HLA Typing**

**46. Is extended/verification typing performed at an ASHI, EFI or CAP accredited lab?**

EFI accredited lab

**47. What is the average turnaround time for extended HLA typing results?**

10 Days or more

**12. Confirmatory/verification typing.**

**48. Does your Cord Blood Bank use an attached (contiguous) segment (if available) for confirmatory/verification HLA typing currently?**

Yes

**49. Does your Cord Blood Bank list cord blood units that do NOT have attached segments and have NOT previously been confirmatory typed on attached segments?**

Yes

50. What is the percentage of cord blood units in your inventory that will be sent with attached segment?

50-75%

51. Is your current practice to perform confirmatory/verification typing on all cord blood units prior to release?

Yes

### 13. Reservation/cancellation policies

52. At what point is a cord blood unit reserved for a patient and not available for other patients? Check all that apply.

At time of reservation request

53. What is the length of time a cord blood unit can be reserved?

60 days

54. Is there a fee to reserve a cord blood unit?

No

55. Is there a fee to cancel the reservation for a cord blood unit in the absence of a subsequent request for shipment?

No

56. Do you allow for an extension on a reservation of a cord blood unit?

Yes

57. Will your Cord Blood Bank provide a cord blood unit report on a cord blood unit that is already reserved for another patient (and thus not available) without specifying that the cord blood unit is already reserved?

No

58. If your Cord Blood Bank releases a cord blood unit from a patient's search (as opposed to the transplant centre indicating that the cord blood unit may be released), do you inform the transplant centre of the release?

Yes

59. Using the list below, please indicate which tests are currently performed by your Cord Blood Bank on a thawed attached segment and at which stage.

	TNC count	Total viable CD34 count	% viability of CD34	% viability of CD45	CFUs
As standard when verification typing is performed					
As standard when CBU is reserved					
Upon request when CBU is reserved					
Upon request when verification typing is performed					
Only once shipment is requested	X	X	X	X	X
Not performed					

### 14. Release-Shipment

60. Does your Cord Blood Bank perform hemoglobinopathy screening before release?

Yes

**61. Criteria to allow a Cord Blood Unit to be shipped to transplant centres. See Appendix V of FACT Netcord Standards 6th Edition.**

	Acceptable range of values	Please provide method	Please provide additional information
Viability / cell count:	TNC viability ≥ 40%	STEM KIT Number of CD34+/CD45+/viable cells 7AAD WITH FLOW CYTOMETER ANALYSIS	

**62. Criteria to allow a cord blood unit to be shipped to transplant centres. See Appendix V of FACT Netcord Standards 6th Edition.**

**What do you perform at the time a cord blood unit is released to be shipped to a transplant centre? Check all that apply.**

- Identity testing with HLA
- IDMs not performed prior to listing, please describe: hemoglobinopathy screening

**63. Current packaging for shipment to transplant centre.**

- Metal Canister
- Overwrap
- Transport rack

**64. How many segments do you currently send with the unit?**

- None

**65. How much time is required from the date the shipment order is placed until the unit is shipped?**

- 2-3 weeks

**66. Is there a fee for cancellation of shipment?**

- Yes, always

**67. Does your Cord Blood Bank validate its dry shippers to ensure they maintain the temperature at ≤ -150 °C at least 48 hours beyond the expected arrival time at the receiving facility?**

- Yes

**68. Do all dry shippers used by your Cord Blood Bank contain an electronic temperature data logger?**

- Yes

**69. Who typically chooses the courier company for international transports?**

- Cord Blood Bank or sending registry

**70. Please specify the shape of the transport container you currently use.**

- Mushroom

**15. Adverse Events Reporting**

**71. Adverse Event Reporting**

- Competent authority
- Internal report
- National registry
- Transplant centre
- WMDA