

Cord Blood Bank Technology Survey 2017

Response ID:166 Data

1.

1. General data

Name of the Cord Blood Bank:

Jeevan Public Cord Blood Bank

2.

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

2008

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. : 5552

Cord Blood Units in inventory for Related Allogeneic (directed). : 13

Cord Blood Units in inventory for Autologous. : 248

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

In 2017 : 6500

In 2018 : 7500

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.

No

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.

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.

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.

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 : 4533

125 - 149 : 526

150 - 199 : 375

200 - 250 : 97

> 250 : 21

4. Accreditations-licenses-certifications

13. FACT-Netcord accreditation

Is your Cord Blood Bank FACT-Netcord accredited?

No

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:

2016

Name of the institution Competent Authority:

Central Drugs Standard Control Organisation (CDSCO)

Link to the license website of the institution Competent Authority:

www.cdscsco.nic.in

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

- 1) ISO Certification
- 2) NABL -National Accreditation Board for Laboratories - HLA Lab - ongoing
- 3) EFI Accreditation - HLA Lab - Application submitted

5. Cord Blood Collection

17. What is your current practice for collecting cord blood?

In-utero

18. Current antiseptic. Check all that apply.

Betadine
Alcohol

19. Collection bag

Single needle

20. Agitation during collection

Manual

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

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

No

22. Transport conditions.

Insulating transport container
Passive refrigeration system (gel, blocks)
Qualified transporter
Air transport
Ground transport

23. Specify temperature range for storage and transportation of fresh product.

Defined (above +8°C)

7. Evaluation

24. 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

60 - 69.99 grams

TNC (10E7) before processing

< 125

Viability CD45 positive cells (%)

80 - 89%

Viability CD45 positive cells (method)

7AAD

Viability CD34 positive cells (%)

80 - 89%

Viability CD34 positive cells (method)

7AAD

25. 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

Other, please describe:: Family History and current pregnancy details including history of blood transfusion

26. Which method is used for CD34 enumeration?

ISHAGE guidelines

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

Yes, please specify (e.g. UKNEQAS): UK NEQAS

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

Yes

29. Acceptable time from collection to processing.

Other, please specify: Samples must reach us within 40 hours from time of collection.

8. Processing-Packaging

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

SEPAX

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

SEPAX

32. Please specify additives currently in use in addition to anticoagulants and DMSO during processing.

Check all that apply.

HES

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

DMSO- Dextran

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

MVE 1850 Vapor freezer

35. Please specify cryobag currently in use. Check all that apply.

Single bag (two fractions)

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

Metal canister

Overwrap

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

Two or more attached segments

9. Testing

38. 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				
Hepatitis B core Antibody					
Hepatitis B Surface Antibody					
HBV NAT		X			
Hepatitis C Antibody	X				
HCV NAT		X			
HIV 1/2 Antibody					
HIV 1 and 2 + 0 Antibodies	X				
HIV p24 Antigen	X				
HIV NAT Antigen		X			
HTLV I/II Antibodies	X				
HTLV NAT					
CMV Antibody - IgG					
CMV Antibody - IgM	X			X	
CMV Anitbody Total					

Syphilis	X				
West Nile Virus NAT					
West Nile Virus Antibody					
T. Cruzi Antibody (Chagas Disease)					
EBV Antibody - IgG					
EBV Antibody - IgM					
EBV Antibody Total					
Toxoplasmosis Antibody - IgG					
Toxoplasmosis Antibody - IgM					
Toxoplasmosis Antibody Total					

39. Does your Cord Blood Bank currently store extra material?

Cord blood DNA

Cord blood material for DNA extraction

40. 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				

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

	Please specify threshold	Please provide method	Not performed
Minimum TNC (10E7)	100	7AAD	
Minimum CD34 (10E6) single platform	2.4	7AAD	
Minimum CD34 (10E6) double platform			
Total-CFU (10E5)	1	Methocult -IMDM	
Viability (10E5)	8500 or 85%	7AAD	

10. Storage

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

Conventional storage tank-Vapor phase

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

Alarm on individual tanks only

LN2 level

Temperature monitoring

11. Verification/Extended HLA Typing

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

No accredited lab

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

5 Days

12. Confirmatory/verification typing.

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

Yes

47. 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?

No

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

90-100%

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

Yes

13. Reservation/cancellation policies

50. 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

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

90 days

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

No

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

No

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

Yes

55. 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

56. 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

57. 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	X	X	X	X	X
Upon request when CBU is reserved					
Upon request when verification typing is performed					
Only once shipment is requested					
Not performed					

14. Release-Shipment

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

Yes

59. 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:	Viability of equal or > 85%	7AAD	

60. 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: NAT on cord blood for HBV, HCV and HIV - any others if specifically requested outside India

61. Current packaging for shipment to transplant centre.

Metal Canister

Overwrap

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

One attached segment

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

2-3 weeks

64. Is there a fee for cancellation of shipment?

Yes, if release testing has begun

65. Does your Cord Blood Bank validate its dry shippers to ensure they maintain the temperature at $\leq -150^{\circ}\text{C}$ at least 48 hours beyond the expected arrival time at the receiving facility?

Yes

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

Yes

67. Who typically chooses the courier company for international transports?

Cord Blood Bank or sending registry

68. Please specify the shape of the transport container you currently use.

Upright positioner

15. Adverse Events Reporting

69. Adverse Event Reporting

Internal report