

Cord Blood Bank Technology Survey 2017

Response ID:71 Data

1.

1. General data

Name of the Cord Blood Bank:

Bayerische Stammzellbank gGmbH

2.

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

1998

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 Autologous. : 0

Cord Blood Units in inventory for Unrelated Allogeneic. : 4348

Cord Blood Units in inventory for Related Allogeneic (directed). : 53

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

In 2017 : 0

In 2018 : 0

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: ZKRD

3. Cord Blood Units in Inventory

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

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

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.

[10130047.JPG](#)

[10130065.JPG](#)

[11030007_Large.jpg](#)

[IMG_2221.jpg](#)

[IMG_2236.jpg](#)

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 : 2855

125 - 149 : 770

150 - 199 : 594

200 - 250 : 105

> 250 : 24

4. Accreditations-licenses-certifications

13. FACT-Netcord accreditation

Is your Cord Blood Bank FACT-Netcord accredited?

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:

2015

Name of the institution Competent Authority:

Regierung von Oberbayern and: Paul-Ehrlich-Institut

Link to the license website of the institution Competent Authority:

<http://www.regierung.oberbayern.bayern.de/aufgaben/umwelt/pharmazie/> and:

[http://www.pei.de/DE/arzneimittel/stammzellzubereitungen/stammzellzubereitungen-node.html?](http://www.pei.de/DE/arzneimittel/stammzellzubereitungen/stammzellzubereitungen-node.html?gts=3255748_list%253DpeiTeaserText_text_sort%252Basc)

[gts=3255748_list%253DpeiTeaserText_text_sort%252Basc](http://www.pei.de/DE/arzneimittel/stammzellzubereitungen/stammzellzubereitungen-node.html?gts=3255748_list%253DpeiTeaserText_text_sort%252Basc)

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.

Marketing Authorization (Paul-Ehrlich-Institut), WMDA

5. Cord Blood Collection

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

19. Current antiseptic. Check all that apply.

20. Collection bag

21. Agitation during collection

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)?

23. Transport conditions.

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

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

TNC (10E7) before processing

Viability CD45 positive cells (%)

Viability CD45 positive cells (method)

Viability CD34 positive cells (%)

Viability CD34 positive cells (method)

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.

27. Which method is used for CD34 enumeration?

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

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

30. Acceptable time from collection to processing.

8. Processing-Packaging

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

SEPAX

Manual- plasma and red cell reduction

RBC/plasma reduction with HES

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

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

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

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

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

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

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

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					
Hepatitis B core Antibody					
Hepatitis B Surface Antibody					
HBV NAT					
Hepatitis C Antibody					
HCV NAT					
HIV 1/2 Antibody					

HIV 1 and 2 + 0 Antibodies				
HIV p24 Antigen				
HIV NAT Antigen				
HTLV I/II Antibodies				
HTLV NAT				
CMV Antibody - IgG				
CMV Antibody - IgM				
CMV Antibody Total				
Syphilis				
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				

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

41. HLA typing at time of listing.

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

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

	Please specify threshold	Please provide method	Not performed
Minimum TNC (10E7)			
Minimum CD34 (10E6) single platform			
Minimum CD34 (10E6) double platform			
Total-CFU (10E5)			
Viability (10E5)			

10. Storage

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

Double walled liquid Nitrogen

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

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

11. Verification/Extended HLA Typing

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

EFI accredited lab

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

4 Days

12. Confirmatory/verification typing.

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

Yes

48. 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

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

90-100%

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

Yes

13. Reservation/cancellation policies

51. 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 HLA typing request
 At time of reservation request
 At time of shipment request

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

90 days

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

No

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

No

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

Yes

56. 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

57. 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

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

14. Release-Shipment

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

Yes

60. 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:		Trypan Blue	decision of transplant physician

61. 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: on request of TC all tests demanded (if possible due to volumes / type of reference samples)

Other, please describe: on request of TC all tests demanded (if possible due to volumes / type of reference samples)

62. Current packaging for shipment to transplant centre.

Metal Canister
Transport rack

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

Two or more attached segments

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

Less than one week

65. Is there a fee for cancellation of shipment?

Yes, always

66. 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

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

Yes

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

Cord Blood Bank or sending registry

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

Cubic

15. Adverse Events Reporting

70. Adverse Event Reporting

Competent authority
Internal report
Transplant centre
WMDA