

**DUKE****DOCUMENT NUMBER:** COMM-QA-039 JA8**DOCUMENT TITLE:**

Audit Guidance - Cord Blood Collection Site JA8

DOCUMENT NOTES:**Document Information****Revision:** 04**Vault:** COMM-QA-rel**Status:** Release**Document Type:** COMM-QA**Date Information****Creation Date:** 02 Jun 2023**Release Date:** 10 Jul 2023**Effective Date:** 10 Jul 2023**Expiration Date:****Control Information****Author:** BAKER133**Owner:** WOOD0081**Previous Number:** COMM-QA-039 JA8 Rev 03 **Change Number:** CCBB-CCR-2018

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SITE: _____

DATE: _____

PERSONNEL: _____

☒ = Observed and performed successfully ☒ = Observed and NOT performed successfully – Add Notes
 NA = Not Applicable NO = Not Observed

EVENT MANAGEMENT	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	NA	NO
1. DEV/INVs identified and reported to QSU per <i>COMM-QA-042 Deviations and Investigations</i>	<input type="checkbox"/>		
2. CAPAs identified and reported to QSU per <i>COMM-QA-076 Corrective and Preventive Actions</i>	<input type="checkbox"/>		
NOTES:			
COLLECTION SITE EQUIPMENT MANAGEMENT AT HEAD OFFICE	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	NA	NO
3. Monthly cleaning of local shipping containers per <i>CCBB-COL-032 Quality Control and Cleaning of Equipment Used in the Collection and Transportation of Umbilical Cord Blood</i> or remote shippers per <i>CCBB-COL-019 Remote Shipper Quality Control and Cleaning</i>	<input type="checkbox"/>		
4. Annual deep cleaning of local shipping containers	<input type="checkbox"/>		
5. Annual Genesis weight measurement calibration confirmed and documented	<input type="checkbox"/>		
NOTES:			
PERSONNEL/TRAINING	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	NA	NO
6. Duties are performed by qualified staff according to policies/procedures per <i>CCBB-TRN-004 Cord Blood Collection and Transport Training Overview</i>	<input type="checkbox"/>		
7. Thorough training process demonstrated by competence on the job	<input type="checkbox"/>		
8. Personnel/training files are current and complete	<input type="checkbox"/>		
9. Documentation of cGMP training present	<input type="checkbox"/>		
NOTES:			
FACILITY	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	NA	NO
10. Secure storage and preparation area with limited access to unauthorized personnel	<input type="checkbox"/>		
11. Facilities are clean and well organized	<input type="checkbox"/>		
12. Eye wash accessible to the collection room/Eye Protection available	<input type="checkbox"/>		
13. Adequate space for collection procedures, documentation and storage of supplies	<input type="checkbox"/>		
NOTES:			
EQUIPMENT MANAGEMENT <i>CCBB-COL-032 Quality Control and Cleaning of Equipment Used in the Collection and Transportation of Umbilical Cord Blood</i>	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	NA	NO
14. Equipment qualifications documented with manuals available	<input type="checkbox"/>		
15. Shipping containers labeled as appropriate per <i>CCBB-COL-009 Storage and Transport of Cord Blood Units</i> or <i>CCBB-COL-019 Remote Shipper Quality Control and Cleaning</i>	<input type="checkbox"/>		
16. Thorough and accurate Log/Trouble Shooting /Corrective Actions documentation	<input type="checkbox"/>		

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17. All equipment is within calibration due date, as applicable	<input type="checkbox"/>		
18. Daily maintenance of the collection room documented	<input type="checkbox"/>		
19. Daily calibration and documentation of Genesis Blood Collection Rocker/ Mixer	<input type="checkbox"/>		
20. Daily refrigerator temperature recorded, if applicable	<input type="checkbox"/>		
21. Daily temperature & humidity in collection room documented	<input type="checkbox"/>		
22. Weekly Activate 5000 Bleach Dilution System tested	<input type="checkbox"/>		
23. Weekly Activate 5000 Bleach Dilution System reviewed	<input type="checkbox"/>		
24. Post collection bleach maintained surface contact for at least 4 minutes per SOP	<input type="checkbox"/>		
25. Post collection cleaning per SOP	<input type="checkbox"/>		
26. Post collection cleaning of Genesis Blood Collection Rocker/Mixer	<input type="checkbox"/>		
27. Post use shipping and storage containers inspected in collection room	<input type="checkbox"/>		
NOTES:			
PROCESS MANAGEMENT/CONTROL	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	NA	NO
28. Consent Process CCB-B-COL-003 Obtaining Informed Consent			
• Patient prescreened for eligibility and in a condition to give informed consent	<input type="checkbox"/>		
• Collection consent presented and signed, if applicable	<input type="checkbox"/>		
• Universal consent presented and signed, if applicable	<input type="checkbox"/>		
• Preliminary consent presented and signed, if applicable	<input type="checkbox"/>		
• Full informed consent thoroughly presented	<input type="checkbox"/>		
• Consents labeled, signed and dated by donor and staff member	<input type="checkbox"/>		
• Confidential Packet assigned to donor	<input type="checkbox"/>		
• Consents distributed to donor and chart	<input type="checkbox"/>		
• If surrogate mother, consent obtained from both surrogate & genetic mother	<input type="checkbox"/>		
NOTES:			
29. Maternal Samples CCB-B-COL-025 Maternal Sample Labeling			
• Verified maternal sample tubes correct and in-date	<input type="checkbox"/>		
• Drew, or requested maternal blood draw, after consent, within 7 days of birth	<input type="checkbox"/>		
• Verified identity of donor and linked with confidential packet documents and barcodes	<input type="checkbox"/>		
• Verified 2L of fluid not given to donor within 1 hour of maternal sample draw (VCBDIF FRM3)	<input type="checkbox"/>		
• Blood transfusion not received within 48 hours of maternal sample blood draw	<input type="checkbox"/>		
• Completed VCBDIF FRM 4 to verify identification	<input type="checkbox"/>		
• Switched maternal labels with barcodes and placed appropriately	<input type="checkbox"/>		
• Completed Maternal Sample and IDT forms	<input type="checkbox"/>		
• Stored maternal samples in designated area and container	<input type="checkbox"/>		
• Discarded and documented samples per SOP	<input type="checkbox"/>		
• Notified CCB-B lab if maternal samples were previously sent and should be discarded	<input type="checkbox"/>		
• Explained redraw procedure and referenced SOP	<input type="checkbox"/>		

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NOTES:			
30. CCBB In & Ex Utero Collection in the Collection Room and Delivery Room <i>CCBB-COL-008 Ex Utero Cord Blood Collection Procedure, CCBB-COL-010 In Utero Collection of Cord Blood by CCBB Staff, CCBB-COL-046 Ex Utero Collection of Cord Blood in the Delivery Room</i>			<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> NA NO
• Consent obtained prior to collection	<input type="checkbox"/>		
• Verified donor's name on placenta container/CBU bag, VCBDF FRM2 and Confidential Packet	<input type="checkbox"/>		
• Wore protective clothing	<input type="checkbox"/>		
• Assessed placenta and cord for 3 vessels and intact	<input type="checkbox"/>		
• Barcoded or placed maternal label on CBU collection bag	<input type="checkbox"/>		
• Cleaned cord using aseptic technique	<input type="checkbox"/>		
• Collected per SOP	<input type="checkbox"/>		
• Stripped and heat sealed CBU bag tubes	<input type="checkbox"/>		
• Accurate calculation of post collection CBU bag weight	<input type="checkbox"/>		
• Demand 128 barcoded and completed accurately	<input type="checkbox"/>		
• Collection documents completed and entered into EMMES	<input type="checkbox"/>		
• Collection stand and equipment thoroughly cleaned	<input type="checkbox"/>		
• Collection stand set up	<input type="checkbox"/>		
• CBU stored in designated container for transport or discarded per SOP and hospital policy	<input type="checkbox"/>		
NOTES:			
31. CBU In Utero Collection by Provider			<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> NA NO
• Prepared collection kit for consented donor per <i>CCBB-COL-022 Assembly of Non-CCBB Staff Collection Kits</i>	<input type="checkbox"/>		
• Collected kit placed in designated storage container	<input type="checkbox"/>		
• CBU bag tubes stripped and heat sealed	<input type="checkbox"/>		
• CBU weighed	<input type="checkbox"/>		
• Documents checked and completed per <i>CCBB-COL-024 Non-CCBB Staff Collection Confidentiality and Linkage</i>	<input type="checkbox"/>		
NOTES:			
32. Collection of Cord Tissue <i>CCBB-COL-047 Ex Utero Collection of Cord Tissue</i>			<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> NA NO
• Donor identification verified, full consent and Opt In	<input type="checkbox"/>		
• Identified receiving bottle	<input type="checkbox"/>		
• Collected cord blood, cleaned and cut cord, placed cord in receiving bottle	<input type="checkbox"/>		
• Weighed cord blood and if ≥30 mL proceed, if <30mL cord blood and cord tissue discarded	<input type="checkbox"/>		
• Labeled with blue sticker per SOP	<input type="checkbox"/>		
• Placed ISBT barcodes and completed documentation per SOP	<input type="checkbox"/>		
• Stored in refrigerator and Shipping Log completed	<input type="checkbox"/>		
• Emailed Robertson GMP lab and shipped cord with courier on ice	<input type="checkbox"/>		

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<ul style="list-style-type: none"> Courier signed Shipping Log and date stamped Shipping Log on arrival at CCBB lab 	<input type="checkbox"/>		
<ul style="list-style-type: none"> Robertson GMP lab signed Shipping Log when cord tissue received 	<input type="checkbox"/>		
NOTES:			
33. NEOVII Placenta Collection	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	NA	NO
<ul style="list-style-type: none"> Donor identification verified, full consent and Opt In 	<input type="checkbox"/>		
<ul style="list-style-type: none"> After cord blood and/or tissue collection, placenta is sealed per <i>NEOV-GEN-002 Packaging of Placenta at Collection Site</i> 	<input type="checkbox"/>		
<ul style="list-style-type: none"> Placed a Demand 128 “Placenta, Human” label on foil bag and package 	<input type="checkbox"/>		
<ul style="list-style-type: none"> Completed <i>NEOV-GEN-003 FRM1 Placenta Shipping Log</i> and shipped with courier 	<input type="checkbox"/>		
NOTES:			
Donor Medical History <i>CCBB-COL-005 Obtaining Donor Medical History Procedure</i>	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	NA	NO
<ul style="list-style-type: none"> Medical history completed after <u>full</u> consent – interview or self-administered 	<input type="checkbox"/>		
<ul style="list-style-type: none"> Reaffirmed every question and resigned if completed more than 14 days prior to delivery 	<input type="checkbox"/>		
<ul style="list-style-type: none"> Reviewed all asterisk questions with mother in auditory privacy 	<input type="checkbox"/>		
<ul style="list-style-type: none"> Signature on medical history matched informed consent 	<input type="checkbox"/>		
<ul style="list-style-type: none"> Date on donor signature page matched date on front of FMH 	<input type="checkbox"/>		
<ul style="list-style-type: none"> Donor Risk Questionnaire Addendum(s) completed 	<input type="checkbox"/>		
<ul style="list-style-type: none"> Medical history Addendum and Approvals Form completed 	<input type="checkbox"/>		
<ul style="list-style-type: none"> ISBT barcode label attached to each odd-numbered pages of FMH and MRQ 	<input type="checkbox"/>		
<ul style="list-style-type: none"> Instruction page removed and shredded 	<input type="checkbox"/>		
<ul style="list-style-type: none"> Patient signature page detached from medical history 	<input type="checkbox"/>		
<ul style="list-style-type: none"> Exclusion notification sent to CCBB lab, if necessary 	<input type="checkbox"/>		
<ul style="list-style-type: none"> Front of the Confidential Packet completed 	<input type="checkbox"/>		
NOTES:			
34. Postpartum Follow Up	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	NA	NO
<ul style="list-style-type: none"> Recorded pre-processing TNCC from EMMES 	<input type="checkbox"/>		
<ul style="list-style-type: none"> Screened infant and mother donor’s medical history – electronically or chart 	<input type="checkbox"/>		
<ul style="list-style-type: none"> Completed <i>CCBB-COL-008 FRM1 Donor and Delivery Information</i> for infant and donor’s postpartum health 	<input type="checkbox"/>		
NOTES:			
35. CBU and Maternal Sample Storage and Transport with Local Courier <i>CCBB-COL-009 Storage and Transport of Cord Blood Units</i>	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	NA	NO
<ul style="list-style-type: none"> CBUs/maternal samples stored in designated, secure, temperature monitored environment 	<input type="checkbox"/>		
<ul style="list-style-type: none"> Inspected validated transport containers for correct labels, cleanliness and intact condition 	<input type="checkbox"/>		
<ul style="list-style-type: none"> Inspected each sample and document for accuracy 	<input type="checkbox"/>		
<ul style="list-style-type: none"> Completed Shipping Log with barcodes 	<input type="checkbox"/>		

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<ul style="list-style-type: none"> Insured absorbent pad and TSPs in the bottom of the transport container 	<input type="checkbox"/>		
<ul style="list-style-type: none"> Placed maternal samples/CBUs in transport containers, with max. of 6 per transport container 	<input type="checkbox"/>		
<ul style="list-style-type: none"> Placed a second absorbent pad and TSP on the top of the samples 	<input type="checkbox"/>		
<ul style="list-style-type: none"> Activated temperature tracking device and placed in the transport container with a closed lid 	<input type="checkbox"/>		
<ul style="list-style-type: none"> CCBB site courier picked-up and documented date and time of transport on the Shipping Log 	<input type="checkbox"/>		
NOTES:			
36. Remote Shipping Using Red Box Shipper CCB-B-COL-009 Storage and Transport of Cord Blood Units			
	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	NA	NO
<ul style="list-style-type: none"> Inspected validated transport container for correct labels, cleanliness and intact condition 	<input type="checkbox"/>		
<ul style="list-style-type: none"> Absorbent pad and TSP placed inside at the bottom of the Red Box 	<input type="checkbox"/>		
<ul style="list-style-type: none"> Inspected each sample and documented for accuracy 	<input type="checkbox"/>		
<ul style="list-style-type: none"> Completed Shipping Log 	<input type="checkbox"/>		
<ul style="list-style-type: none"> Insured absorbent pad and TSP are in the bottom of the transport container 	<input type="checkbox"/>		
<ul style="list-style-type: none"> Placed maternal samples/CBUs in transport container, with a maximum of 6 in combination 	<input type="checkbox"/>		
<ul style="list-style-type: none"> Started and placed the Electronic Data Logger (EDL) on top of samples – not expired 	<input type="checkbox"/>		
<ul style="list-style-type: none"> Placed a second absorbent pad and TSP on the top of the samples 	<input type="checkbox"/>		
<ul style="list-style-type: none"> Placed silver lid on top of contents 	<input type="checkbox"/>		
<ul style="list-style-type: none"> Placed Shipping Log and other documents on top of silver lid 	<input type="checkbox"/>		
<ul style="list-style-type: none"> Sealed box and affixed completed air bill on outside of box 	<input type="checkbox"/>		
<ul style="list-style-type: none"> Transported to designated and approved courier pick-up point 	<input type="checkbox"/>		
<ul style="list-style-type: none"> Emailed scanned information to CCB-B Processing Lab. Retained copy. 	<input type="checkbox"/>		
NOTES:			
DOCUMENT CONTROL/RECORDS MANAGEMENT			
	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	NA	NO
37. Approved SOPs available to personnel	<input type="checkbox"/>		
38. Documentation is completed consistently, accurately, legibly & thoroughly	<input type="checkbox"/>		
39. Data entered accurately into EMMES for all relevant documents	<input type="checkbox"/>		
40. Donor recruitment information entered into database daily or weekly	<input type="checkbox"/>		
41. First and second checks completed on Confidential Packets	<input type="checkbox"/>		
42. Label Release Log completed accurately and thoroughly	<input type="checkbox"/>		
NOTES:			
INVENTORY CONTROL/SUPPLY MANAGEMENT			
<i>CCBB-COL-036 Management of Supplies at Collection Sites</i>			
	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	NA	NO
43. Supplies ordered online prior to deadline	<input type="checkbox"/>		
44. Supplies transported and inspected, received and checked in per SOP	<input type="checkbox"/>		
45. Supplies stored in temperature monitored room with oldest supplies at the back	<input type="checkbox"/>		
46. Supplies with expired dates discarded	<input type="checkbox"/>		
NOTES:			

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DIRECTED DONATIONS	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	NA	NO
<i>CCBB-COL-044 Directed Donation at CCBB Collection Sites</i>	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	NA	NO
47. Approved Directed Donation SOPs available to personnel	<input type="checkbox"/>		
48. Received approval from the medical director	<input type="checkbox"/>		
49. Completed contract with patient	<input type="checkbox"/>		
50. Collected and labeled the CBU and maternal samples per SOP	<input type="checkbox"/>		
NOTES:			
ADDITIONAL ITEMS	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	NA	NO
51.	<input type="checkbox"/>		
52.	<input type="checkbox"/>		
NOTES:			

INSTRUCTIONS FOR USE

- This document is used as a guide when preparing for/or conducting a collection site audit.
- Reference the site being audited, and the date of audit, at the beginning of the Audit Guidance.
- List all collection site staff present at site during audit.
- If an item is not relevant to the site being audited mark the “NA” column for that item.
- If an item is not observed during the audit, mark the “NO” column for that item.
- If an item is successfully demonstrated, check ☒ the relevant box alongside the item.
- If an item is not successfully demonstrated, circle alongside the box and mark ☒ and add explanatory notes at the end of that section under NOTES.
- Additional notes may be appended to this form as needed.
- After the Audit Guidance has been completed and the Audit Report completed the Audit Guidance may be shredded.

Signature Manifest

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All dates and times are in Eastern Time.

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Document Release

Name/Signature	Title	Date	Meaning/Reason
Sandra Mulligan (MULLI026)		20 Jun 2023, 12:05:16 AM	Approved