# DE and Collection Questions, February 22, 2012 - Ducord

**BLA 125407**
**Additional Information Request: DE and collection questions for Duke (02-22-12)**

1. Please describe how CCBB and non-CBBB staff is trained on the donor pre-screening procedures. We note that you have submitted information regarding the training for collection of cord blood.

2. Please confirm whether CCBB staff or hospital staff is responsible for performing the collections at the remote hospitals (e.g. collection site in Boston).

3. According to SOP COL-021, non-CCBB staff can perform collections when CCBB staff is not available. The collector is instructed to label the collection bag with the hospital generated maternal label and leave the unit in the platelet shipper in the collection room designated area. The SOP does not explain who is responsible for obtaining the maternal samples, subsequent labeling and shipment of the unit. Please submit the revised SOP that describes the entire procedure.

4. Please provide the following clarification regarding shipment of the maternal specimens:

- For collections at fixed sites, SOP COL-009 does not include instructions for packing the maternal specimens but the shipping log (COL-009-FRM1) has checkboxes for maternal specimens. If specimens are shipped along with the cord blood units, please submit the revised SOP.
- Are the instructions in SOP COL-025 for preparing maternal samples for transportation from the processing laboratory to the (b)(4) testing laboratory or from the collection sites to the processing laboratory?
  - Step 8.6 provides instructions for preparing sample for (b)(4) testing lab but step 8.7 refers to packing the samples for transport to the processing laboratory.
  - According to the instructions, samples are placed in a “soft-sided” cooler with cups of ice (SOP COL-025). Is this the transportation instructions from the testing lab? What is the testing lab’s acceptable temperature range for specimen transportation?

5. In several SOPs (ex: COL-025) you refer to “--(b)(4)-- collection sites”. Please clarify what this is referring to and are units collected at “--(b)(4)-- collection sites” accepted for banking.

6. In SOP COL-025, page 8 and on COL-009-FRM1 there are references to shipment of -(b)(4)-. Please explain why is the -(b)(4)- collected and shipped. We also understand that the -(b)(4)- can be packaged in the same shipper along with the collected cord units but there are no instructions for packaging of the -(b)(4)-. Also, your

transportation validation only included shipment of maximum of (b)(4) cord blood units. Please provide further explanation.

7. Please describe how the ISBT assigned to the birth mother differs from the one assigned to the cord blood unit.

8. In CCBB-DIST-026, you refer to the Cord Blood Unit Detail Report (page 2, 8.2.1). If this report is provided to the transplant center and includes the donor screening and the infectious disease test results, please submit the report or any other report that includes this information.

9. In SOP CCBB-COL-002, the donor prescreening and family medical history in sections 8.1.2.1, and 8.1.2.2 refers to the "biological mother". Since you may accept donations from surrogate mothers (step 8.1.2.7), please confirm that donor screening and family medical history are obtained from the "birth mother". We recommend that you make the clarification that all "birth mothers" are screened and tested for the relevant communicable diseases.

10. We understand that you may accept cord blood units from birth mothers who are surrogates or pregnancies that involve donated egg or sperm as long as the medical records of the egg/sperm donor are available. In SOP COL-005-JA1, it is stated that the sperm/egg donation must come from an AATB accredited banks but in COL-102 JA1, it is stated that the donation must come from a FDA regulated banks. We suggest that you address the discrepancy in your SOPs (AATB vs FDA) and also clarify the statement regarding "FDA regulated banks". For example, do you confirm that the sperm/egg came from a bank that is registered with the FDA? Also, please note that FDA registration does not necessarily mean that the bank is compliant with applicable FDA regulations.

**Follow-up questions/comments regarding responses to the filing letter:**

11. Response to question #5 related to the acceptable temperature for storage of the collection kit by the birth mother upon receipt of the kit- You stated that the birth mother is instructed to keep everything in the kit at room temperature after she receives it. However, we have noted the Donor Letter (COL-014 FRM1) and the Donor Envelope Label ( COL-014 FRM4) only refers to room temperature storage after the sample and cord blood unit have been collected. We recommend that you add the storage instructions for the kit prior to the collection to the two forms.

12. Response to question #8 related to the syphilis testing- You explained that you are currently using ------(b)(4)------- donor screening test- ---(b)(4)--- and are revising the SOPs to correct references to (b)(4) testing. However, we also note that in the submitted batch records (e.g. #7 & #8), (b)(4) is listed on the test result report that you received from the (b)(4) testing laboratory. Please address the discrepancy on the test result reports as well.

You also explained that if the initial syphilis screening results is positive, the donor is considered ineligible and the unit is not acceptable for release. We understand that you are revising SOPs COL-002, COL-025 and LAB-018 to clarify the syphilis test results. Please note that SOPs should specify that units from such ineligible donors are not released to the search inventory.

13. Response to question #9a & #9b related to the confirmatory/discriminatory tests- You explained that donors with positive screening results for HBc, HTLV I/II, HIV-1, HCV and HBV are not released to the search inventory regardless of the confirmatory or discriminatory tests. SOPs LAB-018 and LAB-020 only state that donor is considered ineligible. Since in some cases, you release units from ineligible donors (e.g. "yes" responses to questions 55 & 56 on maternal history questionnaire), SOP LAB-018 and LAB-020 should clearly state that units with positive screening results for HBc, HTLV I/II, HIV-1, HCV and HBV are not released to the search inventory. Please submit the revised SOPs.

Response to question #10 related to the donor eligibility determination- You have described the review process and we understand that you are revising SOP QA-045. Please note that the Donor Screening and Evaluation (SOP COL-002) does not specifically address the following:

a. Criteria for "eligible" donors based on the review of the medical history questionnaire, medical and physical examination records and the donor testing results. SOP should also specify that only units from eligible donors are acceptable for licensure.

b. List of risk factors identified during the review of the medical history questionnaire, medical and physical examination records and the donor testing results that would make a donor "ineligible". SOP should specify whether units from the ineligible donors are discarded or kept in the inventory for release under the IND, if there is documented urgent medical need.

c. Criteria for donors for whom donor eligibility has not been completed (example: missing response to a donor history questionnaire, missing test result). SOP should specify whether units from the donors for whom donor eligibility has not been completed are discarded or kept in the inventory for release under the IND, if there is documented urgent medical need.

d. Documentation of the final donor eligibility determination after completion of the above review. We note that on the Cord Blood Unit Specifications FRM2 (DIST-002 FRM2), Medical Director approves a unit for release under and IND or license; however the final donor eligibility determination is not documented. We recommend that you include the final donor eligibility determination to this form and in your SOP(s) describe how the reason for ineligibility or incomplete donor eligibility determination is documented.

We recommend that you clearly define the donor eligibility determination criteria and documentation either in COL-002 or the SOP QA-045 that is currently under revision.

Page Last Updated: 09/24/2013
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