 <p>St. Louis Cord Blood Bank SSM Health Cardinal Glennon Children's Hospital Saint Louis University Department of Pediatrics</p>	<p>DONOR AND FAMILY SCREENING BY THE COLLECTION TEAM</p>
<p>3662 Park Avenue, St. Louis MO 63110, 314-268-2787</p>	<p>CL.03.08</p>

PRINCIPLE:

The St. Louis Cord Blood Bank's goal is to prevent the transmission of diseases from the donor to recipient, and therefore provide the safest possible supply of hematopoietic stem cells for transplantation.

PURPOSE:

This policy describes the process for screening of cord blood donors/donations by the cord blood bank, the physician/midwife and the labor and delivery team to prevent disease transmission from donor to recipient. Screening should include both a medical chart review and physical exam.


BACKGROUND:

The St. Louis Cord Blood Bank (SLCBB) strives to provide the safest possible supply of hematopoietic stem cells to patients. With this in mind, the SLCBB actively uses the following donor screening and post-collection donor/product testing methods.

POLICY:

1. Physicians/midwives, clinical staff and office staff are the first line of screening to eliminate high-risk donors. Screening for high-risk behaviors is the best known method for limiting exposure to unknown pathogens. A medical history review will help to identify silent disease carriers. If a known high-risk factor is present, donation should not be recommended.
2. Interested delivering mothers are screened by the SLCBB's nurse coordinator/designee via the Medical History Questionnaire (CL.03A.XX; See Policy Notes below) utilizing the Comprehensive Medical Deferral Checklist CL.13A.XX. Please also refer to CL.13.XX, Assessment of Donor Eligibility by Cord Blood Bank.
3. Mothers have the option to self-defer at any point in the process.
4. Maternal blood samples are collected and tested for hepatitis, syphilis, HTLV-I/II, HIV, CMV, WNV, Chagas disease, and other infectious agents as mandated by the FDA. Testing is coordinated by the SLCBB.
5. The collection team is responsible for the following maternal assessments:
 - a. The obstetrical nurses who participate in the mother's labor & delivery and the delivering physician/midwife are responsible for the continuing assessment of the mother's suitability. This includes continued screening to eliminate mothers whose lifestyle includes high-risk behaviors. Screening for high-risk behaviors is the best known method for limiting exposure to unknown pathogens and silent disease carriers.
 - b. High-risk behaviors are defined as conduct that might expose the mother to any infectious pathogens. High-risk behaviors that need to be evaluated include: any

- (recreational) drug use with a needle, body piercing, accidental needle sticks, previous blood transfusions or organ transplants, money or drugs in exchange for sex. Other high-risk behaviors include having sex with someone who is: HIV positive, a hemophiliac, used IV drugs, was gay or bisexual.
- c. The nurse's physical assessment should also include noting if there are any signs of an active sexually transmitted disease.
 - d. Specific screening guidelines are provided on the back of the labor and delivery data sheet, (CL.03B,XX; See Policy Notes below) which is included with every cord blood collection kit. Physicians/midwives and collection teams need to be familiar with these guidelines. However, the SLCBB has the final responsibility in determining donor eligibility.
 - e. There are also situations that do not automatically cause the donor to be rejected or prevent the collection and storage of cord blood, however, they might impact donor eligibility or affect a transplant center's choice of a cord blood unit. Because the SLCBB strives to provide as much information as possible to the transplant center, the following items must be documented on the labor and delivery data form:
 - i. Meconium staining
 - ii. Maternal colonization with group B β streptococcus
 - iii. Prolonged ruptured membranes (greater than 24 hours) with no concern for infection
 - iv. Blood Transfusion after delivery
 - v. Elevated maternal/infant temperature and antibiotic administration – with no concern for infection
 - vi. History of Herpes or other sexually transmitted disease
 - f. During the actual cord blood collection, the collection site need to follow the aseptic techniques described in SOP CL.06.XX, Method of Collection of Cord Blood. These techniques are required to minimize bacteriological contamination.
 - g. In addition, all practices regarding proper labeling as found in SOP CL.07.XX, Labeling Maternal Samples and Cord Blood Unit at the Collection Site are to be practiced.

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Summary of Maternal & Donor Assessment:

Maternal & Donor Suitability assessed by:	Obstetrician / Midwife	Labor and Delivery Team	Cord Blood Bank Nurse Coordinator / Designee
Assessment	Evaluate for known high-risk factors.	Evaluate for high risk factors	Evaluate for high-risk behaviors, evidence of infection, and known exclusionary criteria on Medical History Questionnaire.
Action	If high-risk donor, not recommended for collection.	If high-risk factor donor is identified, cord blood should not be collected.	If high-risk donor, cord blood not processed. All collected blood products are quarantined until reviews are complete.
When	During prenatal visits	During Labor and the Birth Process	Throughout donation process and laboratory processing.
Documentation of assessment	Collection should not be performed	Labor and Delivery Data Sheet submitted with collection. (if performed)	RN initials and dates review of questionnaire. Documentation of follow up conversation on Medical History Questionnaire Review

POLICY NOTES:


1. All forms are available in Spanish (CL.03A-SPA.XX). For any other language barrier, utilization of the language line coordinated by SSM Health Cardinal Glennon Children's Hospital is available to SLCBB Nurses or the donor mother.
2. Currently, St. Louis Cord Blood Bank has an arrangement with Saint Luke's Cancer Institute of Kansas City for the collection of cord blood donations in the Kansas City area. A labor and delivery form (CL.03B_KC.XX) and a medical history questionnaire form (CL.03A_KC.XX) had been created to recognize the arrangement and is to be used for Kansas City area collections. The Kansas City version of the forms are not being actively printed, however, they may still be in circulation and will be acceptable.

MATERIALS:

Labor and Delivery Data Sheet
Medical History Questionnaire

PROCEDURAL NOTES:

Final determination of donor eligibility, using the documentation of information obtained through the assessment, review and follow up process, and evaluation of the infectious disease testing results is concluded by the Quality Unit.

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RELATED FORMS:

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|---------------|---|
| CL.03A.XX | Medical History Questionnaire (English Version) |
| CL.03A-SPA.XX | Medical History Questionnaire (Spanish Version) |
| CL.03A_KC.XX | Medical History Questionnaire Saint Luke's Cancer Institute
(Kansas City metro area) |
| CL.03B.XX | Labor and Delivery Data |
| CL.03B_KC.XX | Labor and Delivery Data Saint Luke's Cancer Institute
(Kansas City metro area) |
| CL.13A.XX | Comprehensive Medical Deferral Checklist |

RELATED POLICIES/PROCEDURES:

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| CL.06.XX | Method of Collection of Cord Blood |
| CL.07.XX | Labeling Maternal Samples and Cord Blood Units at the Collection Site |
| CL.13.XX | Assessment of Donor Eligibility by Cord Blood Bank |

REFERENCES:

- FACT-NetCord Standards for Cord Blood Collection, Processing, Testing, Banking, Selection and Release, Current Edition
- AABB Standards for Cellular Therapy Services, Current Edition
- NMDP Standards, Current Edition