REPORTING OF ABNORMAL LABORATORY TEST RESULTS PROCEDURE TEMPLATE

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PRINCIPLE:

The St. Louis Cord Blood Bank acts to ensure abnormal laboratory test results are communicated to the appropriate health care provider and to the donor family to ensure appropriate follow-up medical care is obtained if necessary.

PURPOSE:

This policy describes the notification policy of abnormal test results to the physician/midwife and family.

POLICY:

1. Abnormal laboratory results are reported, when indicated, to the donor (mother of baby) and/or the donor's primary physician (obstetrician/midwife and/or pediatrician) for further evaluation and recommendations for follow-up care.

2. There are certain positive blood tests that are required to be reported to the state. The medical director will identify such cases, and a program nurse will be responsible to complete the appropriate paperwork and submit to the Missouri or Illinois Department of Health.

3. In cases where bacterial or fungal cultures from the cord blood are positive, the biostatistician will evaluate data/information for trends in contamination frequency and this information will be provided to the Medical Director for monthly review. Upon discovery of significance in microbial contamination trend for a particular physician/midwife, phone and/or written communication will be initiated with the clinician to address the increase in contamination frequency.

4. In cases where maternal samples are positive for infectious viral markers, letters are sent to the delivering physician/midwife as well as directly to the donor. The intent of the donor letter is to inform of possible exposure to a particular infectious disease agent and the recommendation to follow up with a physician. The letter also includes the bank's phone number with the opportunity to contact personnel within the program for questions and/or counseling.

5. Abnormal hematology or pertinent microbiology results obtained on the cord blood by the technical staff are investigated by the nurse coordinator/designee through communication with the delivering unit, and discussed with the Medical Director. When appropriate, the infant's pediatrician will be notified.

6. Reports will include but are not limited to:

    - Positive or inconclusive viral screening markers, except for maternal total CMV antibody

7. **It is the responsibility of the health care provider to interpret the results with the patient's clinical presentations and history, and to contact the mother, if appropriate, for further follow-up care.**

8. A copy of the signed letter sent to the physician/midwife is preserved in the donor's confidential file.

MATERIALS:

None

RELATED FORMS:

Sample Letters: P:\Procedures\Collection Manual\Forms\Sample Letters CL.09.xx

REFERENCES:

NetCord-FACT International Standards for Cord Blood Collection, Processing, Testing, Banking, Selection and Release, Current Standards

AABB Standards for Cellular Therapy Product Services, Current Standards

Food and Drug Administration, 21 CFR 1271