

<p>St. Louis  <b>Cord Blood Bank</b>  <small>SSM Health Cardinal Glennon Children's Hospital  Saint Louis University Department of Pediatrics</small></p>	<p><b>LABELING MATERNAL SAMPLES  AND CORD BLOOD UNIT AT THE  COLLECTION SITE</b></p>
<p>3662 Park Avenue, St. Louis MO 63110, 314-268-2787</p>	<p><b>CL.07.08</b></p>

**PRINCIPLE:**

The St. Louis Cord Blood Bank acts to ensure that all cord blood units, maternal blood samples and collection paperwork are labeled accurately with complete identifiers.

**PURPOSE:**

This policy describes the policy for labeling of cord blood collections, maternal tubes and paperwork.

**BACKGROUND:**

The AABB, NetCord-FACT (the Foundation for the Accreditation of Cellular Therapy), and the FDA have developed specific standards for blood product labeling. They require that collected specimens be labeled with *two* unique patient identifiers, plus the date/time of collection and the initials of the collector.

The St. Louis Cord Blood Bank requires that **each** specimen be labeled with *two* unique patient identifiers, as well as the date/time of collection and the initials of the collector. Two of the three unique identifiers listed below are required on specimens collected for the St. Louis Cord Blood Bank.

- Mother's complete name
- Maternal date of birth
- Maternal medical history number

These unique identifiers are already on the maternal label. The nurse at the delivery hospital ensures that these identifiers match those on the maternal armband and documents this verification on the Labor and Delivery Data Sheet (CL.03B). These identifiers will also allow the unit to be associated with the Maternal History Questionnaire and Labor and Delivery Data Sheet and will be verified by the nurse coordinator/designee.

**POLICY:**

1. Maternal Blood Samples:

After collection of the three maternal blood samples (1-red top, 1-white top, 1-purple top), label tubes with maternal labels. Be sure to note the date and time of collection and collector's initials on each label. Place the samples in the biohazard specimen bag provided. The samples must be collected in the tubes provided in the cord blood collection kit. The three tubes used are:

- Red top - no additives
- White top - EDTA + gel
- Purple top – EDTA

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2. Cord Blood:

After the collection of the cord blood unit, place a maternal label on the collection bag. This will allow the unit to be associated with the maternal delivery information, family history, test results, and to all records describing the handling and final disposition of that cord blood unit. Label should include the date and time of the collection and the collector's initials and/or the initials of the nurse who documents the collection.

3. When collection of the cord blood unit is complete, the primary collection bag shall bear the following information:

1) Maternal label which includes:

- name of donating mother with unique identifiers
- date and time of collection and the collector's initials and/or the initials of the nurse who documents the collection

2) Collection Bag which includes:

- HPC, Cord Blood
- <210 ml umbilical cord blood
- 35 ml CPD
- Do not irradiate
- Warning: This product may transmit infectious agents.

4. Place collected maternal samples and the cord blood collection bag into the biohazard specimen bag. Seal the specimen bag and place it in the cord blood collection kit box.

5. Paperwork:

Complete the Labor and Delivery Data Sheet and place it in the collection kit box along with the signed consent. Include completed medical history questionnaire if not previously sent in.

6. Cord Blood Collection Kit

After all specimens and paperwork are in the collection kit box, close and seal the box. The transport information is printed on the outside of the collection kit box and includes the following information:

- a) Cord Blood for Transplantation
- b) Do Not Expose to Radiation
- c) Store at Room Temperature 18-26°C (64-80° F)
- d) BIOHAZARD label
- e) Name and Address of collection center
- f) Address and telephone number of St. Louis Cord Blood Bank
- g) Attn: Processing Laboratory

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7. See SOP CL.08.XX, Storage of Cord Blood at the Collection Site before Transportation to the St. Louis Cord Blood Bank for instructions on how to store the cord blood before transport to the St. Louis Cord Blood Bank.

**QUALITY CONTROL:**

Mislabeled samples will require the St. Louis Cord Blood Bank, upon receipt, to investigate how critical characteristics can be assured. If these characteristics cannot be assured, mislabeling will likely result in specimen rejection. The St. Louis Cord Blood Bank will notify collection hospitals liaisons of labeling conformance deficiencies periodically so that prudent corrective action can be implemented.

**MATERIALS:**

Maternal label (provided by the hospital)

**RELATED FORMS:**

None

**RELATED POLICIES/PROCEDURES:**

- CL.04.XX Protection of Maternal and Donor Privacy
- CL.06.XX Method of Collection of Cord Blood
- CL.08.XX Storage of Cord Blood at the Collection Site Before Transport to the St. Louis Cord Blood Bank
- TE.01.XX Receiving Weighing and Labeling Umbilical Cord Blood Units

**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

CAP standards GEN.40491, GEN.40492, and COM.06100, COM.06300

Food and Drug Administration, 21 CFR 1271