Community Blood Bank
2646 Peach St. Erie, PA 16508

TITLE: **PLASMA FROM FEMALE DONOR**

PURPOSE/SCOPE:
In accordance with AABB recommendation for measures to reduce the potential occurrence of TRALI (Transfusion Related Acute Lung Injury), transfusable frozen plasma products (FFP and CSP) will be produced from male donors only. A Special Process (FEM) will be placed on female donors to disallow the production of FFP and CSP from female donors. (See exception: AB females)

MATERIALS/FORMS: SafeTrace Computer System
Donor History Questionnaire
Form: HLA Worksheet

Designations:
FFP- fresh frozen plasma
CSP- cryo reduced plasma

PROCEDURE:

A. AB females: females who have never been pregnant or females who have tested negative for HLA antibodies may be produced into FFP or CSP.

1. Donor Collections:
    a. Collect an extra red top tube on all AB female donors.
    b. Previously positive HLA antibodies will be documented in SafeTrace:
        i. Special Process of "NOFP".
        ii. Mark satellite collection bag with NOFP

2. Laboratory:
    a. Create AB FFP/PRECR (if not marked "NOFP") from females and place in physical quarantine
    b. Document on HLA worksheet:
        i. Unit Number: Place a unit number for each female AB collected and verify against Crystal report
        ii. Tube Check : verify against Crystal report
        iii. Card Review: verify against card
            There is an additional question (#48) on side 2 of the card.

            "FEMALES ONLY (circle one) HAVE YOU EVER BEEN PREGNANT?
            If Yes, Date of Last Pregnancy (MM/YY):_____"

        iv. If a female is/has been:
            1. Never pregnant:
                i. Acceptable for FFP/CSP production
                ii. Discard tube
                iii. Document "never pregnant" in comments column on HLA worksheet

            2. Previously tested HLA negative and has not been pregnant since testing
                i. Check SafeTrace for testing date:
                    1. =LA, TH
                    2. Unit # and Test (HLA). This will show last testing date
                ii. Acceptable for FFP/CSP
                iii. Discard tube
                iv. Document "HLAN" in comments column

3. Previously positive HLA testing:
    i. Discard tube
    ii. Convert any FFP/CSP to recovered plasma
    iii. Document “NOFP” in comments column

4. Previous pregnancy and never tested for HLA antibodies OR pregnancy since last HLA testing
    i. Check SafeTrace for testing date:
        1. =LA, TH
        2. Unit # and Test (HLA). This will show last testing date
    ii. Component remains in quarantine (physical and computer)
    iii. Tube sent for testing

i. Date tube sent for testing

c. Release of FFP/CSP from Quarantine (SafeTrace and Physical)

i. HLA worksheet will be given to supervisor performing review for commitment of HLA results and SafeTrace release of components
ii. When results are received:
    1. =LA, ET: enter result (HLA- either P-positive or N-negative)
    2. Supervisor will commit test result (=LA, OT) and release FFP for labeling in SafeTrace (=LA, CN)

3. QA review:

a. Data base administrator/designee will create Crystal report on AB female donors collected.
b. Perform review of female AB donors: check the HLA worksheet, SafeTrace and crystal report.

B. <u>Data Entry:</u> In the DN system of SafeTrace, the following steps will be taken for each female donor:

1. =DN
2. Select appropriate donor: Using either DS or DV
3. F4 to bring up window
4. Select (S) “Donor Special Processes”
5. Populate with “FEM”
6. F12 to update

C. Laboratory: **Do not override any prohibiting factors of AB female FFP or CSP**

1. FFP (E0701, E0707) already produced will automatically be placed in QPEN for female donors with "SPC-PRC Disallow" under "CY" screen.
   These components may be modified into Recovered Plasma (exception: AB female donors see A above). The following steps should be taken.
   a. =LA
   b. CA, tab, Unit #
   c. Under appropriate component , "W" to bring up the production menu. Note the following:
      i. Production date and time
      ii. Centrifuge
      iii. Tech/Staff
   d. F6 to exit the screens
   e. CF to modify to appropriate plasma product. Make sure that appropriate Create/Store dates and times are used along with centrifuge and tech.
   f. Place appropriate ISBT plasma label on product

2. CSP**:** when modifying from PRECR to CSP "Special Process Disallow" will pop up and production will not be allowed:

REPORTING & INTERPRETING RESULTS:

1. A special process is added for female donors as donor history cards are entered into SafeTrace. The special process will not allow transfusable plasma products from female donors, placing them in QPEN.

2. Female AB donors: FFP/CSP will be placed into QPEN automatically when created. Supervisory/QA review and release will be necessary to remove from QPEN

3. Daily Audit of Donor history card and SafeTrace is performed to assure all new female donors or female donors who have not donated since 2007 have special process "FEM" placed on them. The following process may be used:
   =DN
   a. DS/DV to locate donor
   b. DC to check special process screen.

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Original Effective Date	Revised by	Revision	Supersedes Revision #
2.12.07	D. Pirschel	ISBT: replaced Codabar product codes with ISBT codes	1.002
	D. Pirschel	Remove BRD Union Square address	1.003
	D. Pirschel	Deleted: AB FFP from female donors will be created if inventory levels indicate the need. These FFP will be released from QPEN by a master user (QA, TD, ED, DBA) by overriding the prohibiting factor and then releasing (CN) to general inventory	1.004
	D. Pirschel	Changed to incorporate testing of AB females for HLA antibodies	1.005

REVIEW/APPROVAL/IMPLEMENTATION

REVIEWED BY:			
Department Head	**Name**	**Signature**	**Date**
Data Base Administrator	Tracy Riedel	Tracy Riedel	3-24-14
Technical Director	Janet Vieyra	J. A Vieyra	3.25.14
APPROVED BY:			
Position	**Name**	**Signature**	**Date**
QA Director	Diane Pirschel	D. Pirschel	3/28/14
Medical Director	Jeffrey A. Richmond MD	Richmond	3-28-14
IMPLEMENTATION DATE:	APR 0 1 2014		

ANNUAL REVIEW			
MEDICAL DIRECTOR	DATE	MEDICAL DIRECTOR	DATE

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RETIRED SOP

SOP RETIRED BY	TITLE	SIGNATURE	DATE RETIRED

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LAB	**CBB**	**DBA**	**ED**	**DRC**