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CUTTER BICLOGICAL	: Document ho.: : Rev.: : CSOP 3CO: : 2		
QUALITY ASSURANCE DOCUMENT	Eate: AUG 3 0 1984		
CUTTER SYSTEM OF PLASMAPMERESIS	: Prepared Ey: GRO-C .		
Suc, ect:	: Approved Ey: GRO-C		
SPECIAL PLASMA	GRO-C		

Responsibility: Manager or Designate

- 1. Selection of Donors.
 - 1.1 Determine if donor is acceptable plasmapheresis donor (CSOP 221, 222, and 403).
 - 1.2 Donors suspected of being At Risk for AIDS shall be assigned to Special Plasma Program at the discretion of Plasma Center personnel.
 - 1.3 In addition, Cutter Biological Special Testing Lab Identifies to plasma center those donors that are hepatitis core antibody positive (HB_c Antibody) and are to be classified as Special Plasma donors, plasma type S.
 - 1.4 New donors and donors returning after an absence of four months or longer must temporarily be classified as donors of Special plasma, plasma type S, until results of $HB_{\rm C}$ antibody testing are known.

Responsibility: Receptionist and Centrifuge Technician

- 2. Sampling
 - 2.1 Assign donor a set of brown (Special plasma) Control numbers that has been highlighted in green to the right hand side of all labels, to indicate HB_C Antibody testing is required.
 - 2.2 Do not determine Donor Code until $\ensuremath{\mathrm{HB}_{\mathrm{C}}}$ entibody results are known.
 - 2.3 Repeat donors who have been sampled for $HB_{\rm c}$ Antibody testing but whose $HB_{\rm c}$ Antibody results are still unknown must remain plasma type S and be assigned a set of brown Control Humbers that has not been highlighted in order to indicate $HB_{\rm c}$ Antibody testing is not required.
 - 2.4 An 18_2 Ag sample requiring 18_2 Antibody testing (highlighted Control Numbers), must be $9^{\rm th}$ long, including a heat-sealed segment at one end 2 1/2" 3" long.
 - 2.4-1 Affix highlighted Control Numbers to both segments of sample; the Control Number on the short segment must be close to the dividing heat seal; the Control Number on the large segment must be 2" from the end farthest from the dividing heat seal.

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a. Highlight, by circling, any HB_C Antibody positive units on original Plasma Packing and Hepatitis Report form.

Make another copy of any original Plasma Packing and Hezetitis Report form that lists unit(s) of ${\rm HB}_{\rm C}$ Antibody positive plasma. Do not line out ${\rm HB}_{\rm C}$ Antibody positive units until this copy is

Remove from original cartons all units, and any subsequent units, collected from donors who tested ${\rm HB}_{\rm C}$ Antibody positive.

Cut cautionary statement from the top of a brown Source Plasma (Human) label and affix it over the label on the unit so that the statement "Caution: FOR MANUFACTURING USE ONLY" is

Line out HB_C Antibody positive plasma unit on original Plasma Packing and Hepatitis Report form. (See CSOP 407 Item 13). Use ball-point pen so entry is still readable. Recalculate total volume and total begs/case.

g. On copy of Plasma Packing and Hepatitis Report form change Plasma Type to S, change Case Number to Case Number of S plasma in which unit is to be packed. Using ball-point pen, line out

e. Repack units in cartons labeled with brown shipping labels.

h. List converted unit on original Plasma Packing and Hepatitis Report form for carton in which it is to be packed giving Control Number, Donor Number, volume. Attach copy of Plasma Packing and Hepatitis Report form with the HS₂A₂ results to original Plasma Packing and Hepatitis Report form for new case. RESPONSIBILITY: Centrifuge Technician

QUALITY ASSURANCE DOCUMENT

completely covered.

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3. Labeling

Cocurent Type:

3.1 Use brown Source Plasme (human) Label for Plasma designated for use in manufacturing albumin, PPF, or globulin only.

all HBc Antibody negative units.

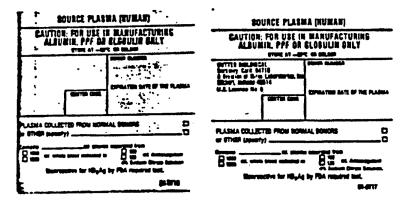
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(1) Non-Cutter-owned Centers

(2) Eutter-owned Centers



3.2 On Plasma Packing and Hepatitis Report form, enter Plasma Type S.

Responsibility: Receptionist

- 4. Convert Plasma Type \$ Donor to another Plasma Type.
 - 4.1 When donor tests HB_C Antibody negative, change the Plasma Type designation on form B1-9711 (Donor Record) lining out 5 and entering letter for appropriate plasma type (CSCP 214).
 - 4.2 Determine Donor Code of all donors converted to Plasma Types N and T. Record Donor Code on form 81-9711 (Donor Record).

Responsibility: Centrifuge Technician

- 5. Shipping
 - 5.1 Make sure shipping labels on carton of frozen plasma are brown.

PRECAUTIONS

- 1. If HB_C antibody testing is incomplete or a test sample is missing and a backup sample is unavailable, the donor's plasma is to be shipped as Type S until the donor's status with regard to this test can be determined.
- 2. Should a HB_C Antibody positive unit be inadvertently shipped as HB_C Antibody negative, i.e. other than as Plasma Type S, promptly report by phone to the National Plasma Center Operations Manager (415) 420-5151. Report must include Control Number, Donor Number, Date Drawn, Meek Number, Plasma Type, Donor Code, Case Number, date shipped and destination.

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