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CUTTER BIOLOGICAL QUALITY ASSURANCE DOCUMENT	Document No.: CSOP 300	Rev.: N/C
	Date: MAR 14 1984	
Document Type: CUTTER SYSTEM OF PLASMAPHERESIS	Prepared By: GRO-C	
Subject: SPECIAL PLASMA	Approved By: GRO-C	
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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 center those donors that are hepatitis core antibody positive (HB_c Antibody) donors and are to be classified as Special Plasma donors, Plasma type S.

Responsibility: Receptionist and Centrifuge Technician

2. Sampling

   2.1 New donors, other than those who have been classified as donors of Special Plasma (see item 1.2 above) must be classified as donors of Normal plasma, Code X, until results of HB_c antibody testing are known.

   2.1.1 Plasma drawn from first time donor's must be listed on a separate Plasma Packing and Hepatitis Report form. The word "NEW" should be entered in large green letters immediately above spaces designated as Plasma Type and Donor Code and last digit of Control Number label affixed to HB_sAg sample must be highlighted in green.

   2.1.2 HB_sAg sample must be 9" long including a heat-sealed segment at one end exactly 2-1/2" long that will be used for the HB_c Antibody test.

   2.1.3 Record HB_c Antibody sample taken on form 81-9711 (Donor Record).

   2.2 Repeat donors who are not classified as Special Plasma donors must be sampled at the time of their 4-month review.

   2.2.1 When 4-month Special Plasma test sample is due, the Control Number on the Plasma Packing and Hepatitis Report form should be highlighted in green and the last digit of Control Number label affixed to the HB_sAg sample must be highlighted in green.

   2.2.2 HB_sAg sample must be 9" long including a heat-sealed segment at one end exactly 2-1/2" long for HB_c Antibody test.

   2.2.3 Record HB_c Antibody sample taken on form 81-9711 (Donor Record).

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QUALITY ASSURANCE DOCUMENT	: Document No.: : CSOP 300	: Rev.: : N/C
Document Type: CUTTER SYSTEM OF PLASMAPHERESIS	: Date: :	MAR 14 1984

2.3 Results of HB_c Antibody testing will be mailed to you by the Special Testing Laboratory.

2.4 Record results on form 81-9711 (Donor Record).

Responsibility: Receptionist or Prep Technician

3. Convert Normal or hyperimmune donor to Special Plasma donor.

3.1 Change the Plasma Type designation on Form 81-9711 (Donor Record) by placing a brown letter "S" in Plasma Type box (CSOP 401).

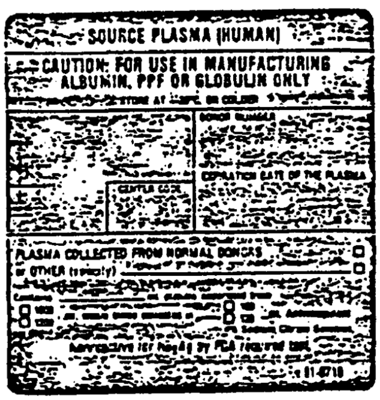
3.2 On donor's next donation plasma will be classified as Type S Plasma (brown Control Number labels).

Responsibility: Centrifuge Technician

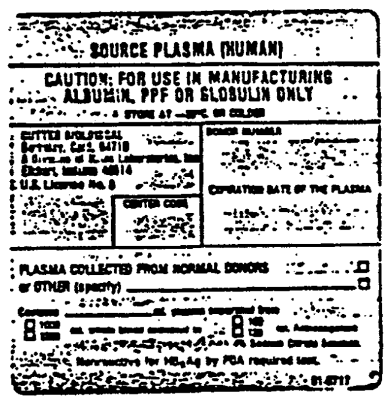
4. Labeling

4.1 Use brown Source Plasma (Human) label for plasma designated for use in manufacturing albumin, PPF, or globulin only.

(1) Non-Cutter-owned Centers



(2) Cutter-owned Centers



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

Responsibility: Center Manager or Assistant Manager ONLY

5. Segregation of Plasma

5.1 Receive copy of Plasma Packing and Hepatitis Report forms from testing laboratory containing the HB_c Antibody testing results.

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QUALITY ASSURANCE DOCUMENT	Document No.: CSOP 300	Rev.: N/C
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5.2 Compare Plasma Packing and Hepatitis Report forms with center's photocopies to ascertain that HB_c Antibody Testing is complete on all samples listed.

5.3 Remove from original cartons all units, and any subsequent units, drawn from donors who tested HB_c Antibody positive.

5.4 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 completely covered.

5.5 Repack units in cartons labeled with brown shipping labels.

5.6 Make another copy of original Plasma Packing and Hepatitis Report form that lists a unit of HB_c Antibody positive plasma.

5.7 Line out HB_c Antibody positive plasma unit on original Plasma Packing and Hepatitis Report form.

5.8 Highlight HB_c Antibody positive plasma unit(s) on copy of Plasma Packing and Hepatitis Report form; change Plasma Type to S; line out Donor Code; change Case Number.

5.8.1 It is possible to have up to 12 copies of Plasma Packing and Hepatitis Report forms per case of newly-designated Type S plasma.

Responsibility: Centrifuge Technician

6. Shipping

6.1 Make sure shipping labels on carton of frozen plasma are brown.

PRECAUTIONS

1. DO NOT SHIP any plasma, on which HB_c Antibody testing is incomplete.

2. DO NOT SHIP any plasma collected from a donor who has donated previous units on which the HB_c Antibody testing is incomplete.

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