

3C30073001

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CUTTER BIOLOGICAL QUALITY ASSURANCE DOCUMENT	Document No.:	Rev.:
	CSOP 300:	2
	Date:	AUG 30 1984
Document Type:	Prepared By:	GRO-C
SUBJECT:	Approved By:	GRO-C
SPECIAL PLASMA	Approved By:	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_c antibody testing are known. 72

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. 72
- 2.2 Do not determine Donor Code until HB_c antibody results are known.
- 2.3 Repeat donors who have been sampled for HB_c Antibody testing but whose HB_c Antibody results are still unknown must remain plasma type S and be assigned a set of brown Control Numbers that has not been highlighted in order to indicate HB_c Antibody testing is not required.
- 2.4 An HB₂Ag sample requiring HB_c Antibody testing (highlighted Control Numbers), must be 9" 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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- 2.5 Record H_c Antibody sample taken on form 81-9711 (Donor Record).
- 2.6 The Special Testing Laboratory will notify the plasma center of results of H_c Antibody testing.
- 2.7 Record results on form 81-9711 (Donor Record).
 - 2.7.1 Donors testing H_c antibody positive are permanently assigned to Special plasma program, plasma type S. R
 - 2.7.1 a. H_c antibody positive donors may be assigned to another plasma type only upon authorization from Manager, Plasma Procurement, Cutter Biological. R
 - 2.7.2 Donors testing H_c antibody negative must be converted to Normal plasma or, if all requirements are met, a hyperimmune plasma type before they donate again. R
- 2.8 Repeat donors who are not permanently classified as Special Plasma donors must be retested for H_c Antibody at the time of their 4-month review. R
 - 2.8.1 When 4-month H_c Antibody test sample is due (CSOP 152), the Control Number set, whatever its color: Black, red, etc; must be highlighted in green as described in 2.1.1 above.
 - 2.8.2 H_cAg sample must be 9" long including a heat-sealed segment at one end 2-1/2" - 3" long for H_c Antibody test.
 - 2.8.3 Affix highlighted Control Numbers to both segments of sample as described in 2.4.1 above.
 - 2.8.4 Record H_c Antibody sample taken on form 81-9711 (Donor Record).
 - 2.8.5 Pack unit to be tested with other units of same Plasma Type and Donor Code; do not pack with plasma type S. R
 - 2.8.6 If a normal Tetanus or Pertussis donor tests H_c Antibody positive change the Plasma Type designation Form 81-9711 (Donor Record) by placing a brown letter "S" in Plasma Type box (CSOP 401). On donor's next donation plasma will be classified as Type S Plasma (brown Control Number labels). R
 - 2.8.7 H_c Antibody positive units from Normal, Tetanus and Pertussis donors, and any units drawn subsequently, must be removed from original cartons, relabeled and repacked as Special Plasma. R

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- a. Highlight, by circling, any HB_e Antibody positive units on original Plasma Packing and Hepatitis Report form. R
- b. Make another copy of any original Plasma Packing and Hepatitis Report form that lists unit(s) of HB_e Antibody positive plasma. Do not line out HB_e Antibody positive units until this copy is made. R
- c. Remove from original cartons all units, and any subsequent units, collected from donors who tested HB_e Antibody positive. R
- d. 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. R
- e. Repack units in cartons labeled with brown shipping labels. R
- f. Line out HB_e 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 bags/case. R
- 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 all HB_e Antibody negative units. R
- 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 HB_eA₁ results to original Plasma Packing and Hepatitis Report form for new case. R

RESPONSIBILITY: Centrifuge Technician

3. Labeling

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

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