Cutter

MILES

CUTTER BIOLOGICAL
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July 7, 1987

Plasmapheresis
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RE: Cutter System of Plasmapheresis

Dear Dr. Esber:

In response to your letter dated June 8, 1987, I am enclosing CSOP 262, Revision 7, for your review and comments. This has been changed to require notification of Cutter if any HIV positive units were shipped during the previous six months.

Also, CSOP 262, HBsAg, HIV, ALT and ANTI-D Test Results and Actions on Reactive Results, has been rewritten to incorporate the use of a Disposition Checklist.

Sin

GRO-C

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MMS/VH:dk

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CUTTER BIOLOGICAL PLASMA PROCUREMENT DOCUMENT	Document No: CSOP 262	Rev: 7
	Date:	
Document Type: CUTTER SYSTEM OF PLASMAPHERESIS	Prepared By:	GRO-C
Subject: HBsAg, HIV, ALT and ANTI-D TEST RESULTS and ACTIONS ON REACTIVE RESULTS	Approved By:	GRO-C
	Approved B:	GRO-C

Responsibility: Center Manager or Trained Designate

1. Receive telephone call from testing laboratory. The Special Testing Laboratory (STL) will telephone if any test is determined to be HBsAg, HIV, ALT or Anti-D reactive.

2. Record information from STL on Section 1 of Unacceptable Plasma - Disposition Checklist. (Form 81-9739). USE ONE FORM PER DONOR.

3. Use the Appendix to this procedure, entitled Action on Reactive Results, to determine action to be taken on donor and donor's plasma.

4. Identify from Donor's Record (Form 81-9711) by Donor Number and Control Number any other unacceptable units. Enter information on these units on Section 2 of Form 81-9739.

5. Perform actions listed in Section 3 of Form 81-9739, dating and initialing form as actions are completed.

6. Preferably within two hours of STL phone call, but no later than the start of the next business day, telephone Plasma Procurement, Cutter Biological, Berkeley, if any prior units have been shipped to Cutter from donors testing HIV or Anti-D reactive. (CSOP 268.) Send copy of Form 81-9739, so far completed, to Plasma Procurement, Berkeley, as written confirmation of phone call.

7. Within 24 hours of STL phone call, record reactive test result on Donor Record and permanently defer donor.

8. Within 24 hours of STL phone call, update permanent deferral files: "Viral" for HBsAg, HIV and ALT reactive donors.

9. Mark appropriate unit of plasma as reactive on photocopy of Plasma Packing and Test Report Form and draw a single line through entry. Initial and date line. Locate Plasma Packing and Test Report Forms for any units identified in Step 4 of this procedure and line them out as well.

10. Within 24 hours of STL phone call, remove all available units identified in Step 4 from their original cartons in the freezer.

11. Immediately deface Source Plasma label of unit(s) to be destroyed with a large X drawn with a felt-tipped pen.

12. Quarantine plasma schedule for destruction in a sealed or lockable container clearly marked "Possibly Reactive Plasma - DO NOT SHIP."

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13. Destroy reactive units within two working days of phone call from STL. (Plasma to be destroyed at a hazardous waste disposal facility must be picked up at first opportunity, preferably within seven working days of phone call from STL.)

14. Destroy plasma. (See CSOP 265.) Enter destruction information on reverse side of Unacceptable Plasma - Disposition Checklist.

15. Ensure HIV-reactive donors are counseled by physician or trained designate next visit.

16. Receive original Plasma Packing and Test Report form from STL containing HBsAg, HIV and ALT test results, and Titer Sample Packing List containing Anti-D results.

17. Compare original Plasma Packing and Test Report Forms with appropriate photocopies to be sure that testing is complete on all samples listed.

18. Ensure individual units of plasma on which HBsAg, HIV, ALT or Anti-D testing is incomplete, i.e., marked "QNS" or "sample missing", are not shipped until negative results are received.

19. Discard photocopy of Plasma Packing and Test Report form.

20. Plasma initially reported as QNS or sample missing, but later reported negative:

    20.1 If original cartons have been shipped, add unit(s) to another Plasma Packing and Test Report form of the sample Plasma Type and Donor Code and ship on next regular shipment. In space headed Results, write "HBsAg, HIV and ALT Negative." Initial and date line.

    20.2 Attach original test results to Plasma Packing and Test Report Form containing the appropriate unit(s).

21. Sort quarantined plasma by double-checking that all reactive units and any other indicated units have been removed from original cartons and that reactive result is entered in Donor Record. Person performing double checks must be someone other than person who removed unit. Initial and date entries on Plasma Packing and Test Report Form, Donor Record, Unacceptable Plasma - Disposition Checklist and Plasma Destruction Record to indicate double checks have been performed; therefore, two initials required. The double checks for accuracy and completeness are a vital step in this procedure and must be done promptly and carefully.

22. Transfer all plasma with negative test results from quarantine area of freezer to portion of walk-in freezer reserved for plasma to be shipped.

23. Ship complete week numbers of plasma on next regular shipping day, or as directed by Manager, Plasma Procurement, Cutter Biological.

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24. Retain in quarantine area of freezer all plasma with incomplete test results and any plasma collected subsequently from the same donor.

25. Retain, on permanent file, photocopies of completed Plasma Packing and Test Report Forms, any test results received from the STL, and two copies of Unacceptable Plasma - Disposition Checklist: the original to be filed in donor's chart and one copy to be maintained as a Plasma Destruction Record. In addition, copies of the form should be attached to each Plasma Packing and Test Report Form from which units listed on the form have been deleted, even if the form is only partially completed at time of shipment.

26. Send report of reactive test result to Public Health Department, if required.

PRECAUTION: Checking for accuracy and completeness of original Plasma Packing and Test Report Forms with retained photocopy of Plasma Packing and Test Report Forms is a vital step in this procedure, and must be done promptly and carefully!

27. APPENDIX

27.1 Unacceptable Plasma - Disposition Checklist (Form 81-9739).

27.2 ACTION ON REACTIVE RESULTS

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Cutter Biological
UNACCEPTABLE PLASMA — DISPOSITION CHECKLIST

Telephone/Other Report From: _____ Taken by: _____

Date: _____ Time: _____

1

DONATION DATE	DONOR NO.	CONTROL NO.	PLASMA TYPE	WEEK NO.	CARTON NO.

HBsAg + HIV + ALT + ANTI-D + (Circle as appropriate) OTHER (specify) _____

Prior and Subsequent Units to be disposed of by Plasma Center or by Cutter:

2

DATE OF DONATION	DONOR NO.	CONTROL NO.	PLASMA TYPE	WEEK NO.	CARTON NO.	SHIPPING DATE

3

ACTION:	DATE:	INITIALS:	DOUBLE CHECK INITIALS:
Telephone Call to Plasma Procurement (Prior HIV and Anti-D Units):			
Donor Record Updated:			
Donor Suspended:			
Donor Added to Permanent Reject File By:			
Copy of Packing List(s) Revised:			
Plasma Removed from Original Case:			
Plasma Unit Label Defaced:			
Plasma Quarantined:			
Plasma Destroyed (Run No.): *OR*			
Picked Up by Hazardous Waste Company:			
MD Counseled HIV + Donor:			
Plasma Packing and Test Report Form(s) Received & Checked:			
Plasma Packing and Test Report Form(s) Revised:			
Report Sent to Public Health Department By:			

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81-9739 (Rev 6-87)

Please complete Plasma Destruction Record (over).

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PLASMA DESTRUCTION RECORD

(Minimum 15 PSI for 2 Hours)

Donor ______________________

Date	Date Plasma Collected	Control Number	Run Number	Time of Day		Pressure in PSI at			Heat Off	Total Time	Initials	Double Check Initials
				Heat Start	Reach 15 PSI	30 Min	60 Min	120 Min				

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ACTION ON REACTIVE RESULTS

	HBsAg	HIV	ALT Reactive (>5)	(ALT 2-5)	Anti-D Reactive
PLASMA					
1. Reactive unit:	Destroy	Destroy	Destroy or divert from Cutter	Destroy or divert from Cutter	Destroy or divert from Cutter
2. Subsequent units:	Destroy	Destroy	Destroy or divert from Cutter	If unit(s) are non-reactive and donor has tested reactive for first time in 30 days: No action. Even if unit(s) are non-reactive, if donor has tested reactive for second time in 30 days: Destroy or divert from Cutter	Destroy or divert from Cutter
3. Previous units:	No action	Destroy units in-house. Call Cutter if any units were shipped to Cutter during previous 6 months.	No action	No action	Destroy or divert from Cutter all units in-house and call Cutter on any other units donated previously.
DONOR					
1. First Reactive	Permanent Deferral	Permanent Deferral	Permanent Deferral	No action	Permanent Deferral
2. Second Reactive within 30 days	N/A	N/A	N/A	Permanent Deferral	N/A
3. Second Reactive > 30 days apart	N/A	N/A	N/A	No action	N/A

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