CUTTER BIOLOGICAL PLASMA PROCUREMENT DOCUMENT	Document No.: CSOP 262	Rev.: 6
	Date: September 19, 1986	
Document Type: CUTTER SYSTEM OF PLASMAPHERESIS	Prepared By: GRO-C	
Subject: HBsAg, HTLV-III, ALT AND ANTI-D TEST REPORTS	Approved By: GRO-C	
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Responsibility: Center Manager or Responsible Designate

1. Receive telephone call from testing laboratory.

   1.1 Special Testing Laboratory (STL) will telephone if any test is determined to be HBsAg, HTLV-III, ALT or Anti-D reactive.

   1.2 Obtain the reactive Donor's Record(s) from the active files and use the Appendix of this procedure to identify the action to be taken for the donor(s) and the plasma donation(s).

   1.3 Mark the appropriate unit(s) 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 additional Plasma Packing and Test Report Forms for any units identified in Step 1.2. of this procedure and line them out as well.

   1.4 Immediately deface Source Plasma label of unit to be destroyed by drawing a large X with a felt tipped pen on it. Quarantine reactive unit of plasma, and any units of plasma identified in 1.2 above, in a separate freezer operating at -20°C or colder or in a sealed or lockable container clearly marked "Possibly HBsAg, HTLV-III, ALT or Anti-D Reactive Plasma, DO NOT SHIP." Destroy reactive units within two working days of phone call from STL.

   1.5 Record reactive test result on Donor Record and permanently defer donor.

   1.6 Update permanent deferral files.

   1.7 HTLV-III and Anti-D reactive donors:

      1.7.1 Examine the appropriate Donor Record to determine if there were any units of plasma donated during six weeks prior to notification of reactive unit. Promptly report these donations by phone (see CSOP 268, Item 5.1.5).

      1.7.2 At the donor's next visit refer HTLV-III reactive donor to physician, or designate, for counseling (see CSOP 269).

2. Receive Plasma Packing and Test Report Form from STL containing HBsAg, HTLV-III, and ALT test results, and Titer Sample Packing List containing Anti-D results.

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

2.2 Individual units of plasma on which HBsAg, HTLV-III, ALT or Anti-D testing is incomplete; i.e., marked "QNS" or "sample missing":

2.2.1 Remove unit and any subsequent units collected from same donor from original carton(s) and quarantine in container labeled "Possibly HBsAg, HTLV-III, ALT or Anti-D Reactive Plasma, DO NOT SHIP."

2.3 Discard photocopy of Plasma Packing and Test Report Form.

2.4 Plasma initially reported as QNS or sample missing but later reported negative.

2.4.1 Remove unit and any subsequent units collected from same donor from quarantine and return to original carton(s), if available.

2.4.2 If original cartons have been shipped, add unit(s) to another Plasma Packing and Test Report Form of the same Plasma Type and Donor Code and ship on next regular shipment. In space headed Results, write "HBsAg, HTLV-III and ALT Negative." Initial and date shipment.

2.4.3 Attach original of "HBsAg/HTLV-III/ALT Negative" test results to Plasma Packing and Test Report Form containing the appropriate unit(s).

2.4.4 Reinstate donor to active donor status.

3. Sort quarantined plasma

3.1 Double check 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 and Donor Record to indicate double checks have been performed; therefore, two initials required. The double check for accuracy and completeness of the Donor Record, Plasma Packing and Test Report Forms is a vital step in this procedure, and must be done promptly and carefully.

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

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

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

QUALITY ASSURANCE DOCUMENT	Document No.: CSOP 262	Rev.: 6
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4. Records

4.1 Retain, on permanent file, photocopies of completed Plasma Packing and Test Report Forms and any results of tests received from STL.

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!.

5. Appendix

5.1 ACTION on REACTIVE RESULTS.