Guideline for Collection of Blood or Blood Products From Donors With Positive Tests for Infectious Disease Markers ("High Risk" Donors)

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These procedures replace the March/August 1981 guidelines for collection of Source Plasma from HBsAg reactive donors. The Center for Biologics Evaluation and Research has received many requests from licensed blood establishments to approve collection of plasma twice a week from healthy, asymptomatic, HBsAg reactive donors. These requests are currently being approved with the concurrence of the donor's personal physician. The blood or plasma center medical director's approval is acceptable in those cases where he is the donor's personal physician of record.

In addition, there are rare circumstances wherein it is appropriate to collect blood products from donors with other disease markers, e.g., anti-HIV-1 positive plasma for research use. The following information is provided to assist manufacturers in preparing the required license amendment submission when requesting an exemption under 21 CFR 640.75 to permit collection of plasma for special purposes from donors known to have positive tests for infectious disease markers or known risk factors for HIV-1 infection.

DONOR QUALIFICATIONS

1. Donors should qualify as regular donors except:

   a. for HBsAg programs, they may give a history of hepatitis but are free of symptoms of hepatitis at the times of donation, and

   b. men who have had sex with other men, or persons having other risk factors for HIV-1 infection may be acceptable upon specific CBER approval. Intravenous drug users (past or present) are not generally acceptable for any current program.

2. Donors should receive and document understanding at each donation of specifically designed AIDS educational materials related to the special program involved. Informed consent for each donation should include language consistent with that in the 30 October 1986 memorandum (or subsequent updated recommendations relative to HIV-1 and blood safety), including a final modifying phrase, e.g.,

   "I have reviewed and understand the information provided to me regarding the spread of the AIDS virus by donated blood and plasma and, if I consider myself to be a person at risk for spreading the virus known to cause AIDS, I agree not to donate blood or plasma for

transfusion to another person or for further manufacture, except for (specifically approved indication)."

3. Donor screening and processing should be done with adequate precautions to prevent disease transmission to other donors or to establishment personnel. Biosafety level 2 applies. Consult DHHS Publication No. (CDC) 88-8395 for additional information.

4. Donors should have written permission from their personal physician for the volume and schedule of products to be collected.

5. Laboratory testing of donors should include, in addition to the other requirements of 21 CFR 640.63:

   a. serum protein electrophoresis initially and every two months; continued donation with abnormal results requires the written approval of the donor's personal physician.

   b. for HBsAg reactive or anti-HB core positive donors, ALT measurements initially and every month. If ALT levels exceed two times the upper limit of normal values, the donor must be deferred until acceptable level occurs and a physician reinstates the donor.

   c. except for known anti-HIV-1 positive donors in special programs, anti-HIV-1 testing is performed in accordance with 21 CFR 610.45.

6. Medical evaluation of donors is performed by a licensed physician every month of donation including a physical examination, review of laboratory reports, and recertification of donor suitability. This responsibility may not be delegated to a physician substitute or to any other person.

FREQUENCY OF PLASMAPHERESIS

Plasmapheresis is limited to once per week except that the frequency of plasmapheresis may be increased to twice per week only with written approval from the donor's personal physician.

MANNER OF COLLECTION

Plasma may be collected manually, by use of membrane filtration automated collection devices, or by other automated collection devices if these devices are dedicated to use only for the one specific program, provided that the collection is undertaken in as safe a manner as possible and in compliance with CDC/NIH

Biosafety Level 2 Guidelines. Specifically:

1. The collection is done by trained personnel in a physically or temporally isolated manner and all products are handled separately. Staff may not work concurrently with both normal and high risk donors. It is recommended that the number of staff involved be limited as much as is practical.

2. An approved collection system that is functionally closed is used. If manual centrifugation is done, double overwraps are used.

3. Adequate cleaning and disinfection of the area, equipment, etc., both for routine operation and for accidental spills, is documented. Detailed procedures for disinfection must be part of standard operating procedures.

4. Storage and disposal of all collection materials, including laboratory samples upon completion of required testing, is done in a manner consistent with CDC Biosafety Level 2 guidelines and etiologic agent packaging requirements if transportation will occur. Autoclaving for 1 hour at 121°C or incineration are the only currently recognized safe procedures for disposal of blood products or other contaminated materials.

5. Plasma collected from donors with infectious disease markers is:

   a. physically isolated from other source plasma during both collection and storage.

   b. adequately labelled and distributed only for purposes known to comply with restrictions on use, with periodic reporting to the CBER in accordance with 21 CFR 610.40(d)(1) and (2).

   c. made available for manufacturing use only if all applicable FDA donor suitability and testing criteria are met. Unsuitable units are destroyed by autoclaving or incineration or used only for research purposes; product disposition is documented. Record keeping and donor deferral procedures are in accordance with all other applicable FDA recommendations and requirements.

6. Laboratory samples are labelled conspicuously with the biohazard symbol. Repeat laboratory testing for known reactive donors is NOT required nor recommended.

7. Packing for shipment of laboratory samples and plasma is in compliance with biohazard/etiologic agent requirements and conforms to federal recommendations for shipment of

etiologic agents. (42 CFR 72 and 49 CFR 173.386/387)

WASTE DISPOSAL

All material contaminated with blood from donors known to have positive tests for disease markers should be handled and disposed of in accordance with all requirements for etiologic agents.

PERSONNEL PROTECTION

1. The SOP includes:

   a. written personnel safety instructions in compliance with current CDC and/or OSHA standards with specific directions regarding handwashing between donors, and safe use and disposal of protective equipment, including gowns, gloves, goggles, and masks.

   b. written procedures for treatment, notification of management, and documentation of follow-up when inadvertent injury to employees occurs during collection and handling of plasma from these donors.

2. Written records are maintained showing that all personnel have been adequately trained in safety procedures, including retraining as necessary to maintain skills required for current responsibilities.

3. Active immunization is offered to personnel susceptible to possible infection by hepatitis B virus.

4. Safety program plans are periodically reviewed and updated as necessary.

LABELING

1. Labeling conforms to 21 CFR 640.70, or if appropriate 606.121(g), and 610.40, EXCEPT SUBPARTS 640.70(a)(7),(8) and (11) DO NOT APPLY. In addition, CDC labeling requirements for etiologic agents are met.

2. Language acceptable for labeling is either:

   a. "This product is reactive when tested for ..., and may transmit infectious agents," or

   b. "This product was collected from a donor known to be reactive for ..., and may transmit infectious agents".

3. Labeling is submitted to and accepted by CBER prior to use.

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APPENDIX

Biosafety Resources

Centers for Disease Control
Office of Biosafety
1600 Clifton Road
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Tel. No. 404-639-3883
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Department of Agriculture
APHIS
Federal Bldg. Rm 810
6505 Bellcrest Road
Hyattsville, MD 20782
Tel. No. 301-436-5453

Department of Transportation
Office of Hazardous Materials Transportation
Research and Special Programs Administration
400 7th Street, N.W.
Washington, D.C. 20590
Tel. No. 202-366-4488

Environmental Protection Agency
Infectious Waste Management Program
SE240
401 M Street, S.W.
Washington, D.C. 20460
Tel. No. 800-424-9346
202-382-3000

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1000 Sherbrook Street W
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