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

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Guideline for
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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
concurrency 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

Plasmaphoresis is limited to once per week except that the frequency of plasmaphoresis 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/NIM
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
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 CBIR prior to use.
Bibliography


International Air Transportation Association. Dangerous goods regulations, Montreal, Quebec, January 1, 1988.

International Civil Aviation Organization. Technical instruction for the safe transport of dangerous goods by air, Montreal, Quebec, 1989-1990. Available from American Label Mark, 5724 N. Pulaski Road, Chicago, IL 60646.


Occupational Safety and Health Administration, OSHA, Instruction CPL 2-2-444, August 15, 1988. Enforcement procedures for occupational exposure to Hepatitis B Virus (HBV) and Human Immunodeficiency Virus (HIV).


APPENDIX

Biosafety Resources

Centers for Disease Control
Office of Biosafety
1600 Clifton Road
Atlanta, GA 30333
Tel. No. 404-639-3383
775-256-3383

Department of Agriculture
APHIS
Federal Bldg., Rm 410
6205 Belcrest Road
Bowie, MD 20725
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. 202-366-4418

Environmental Protection Agency
Infectious Waste Management Program
52240
401 N Street, S.W.
Washington, D.C. 20460
Tel. No. 202-564-9364
202-260-3000

Division of Blood and Blood Products
Center for Biologics
Evaluation and Research
Food and Drug Administration
8800 Rockville Pike
Building 29, Room 222
Bethesda, MD 20892
Tel. No. 301-496-6196
301-402-0290

International Air Transportation Association
2000 Peel Street
Montreal, Quebec
Canada B3J 2B4
Tel. No. 514-444-6311

International Civil Aviation Organization
100 Sherbrook Street W
Suite 400
Montreal, Quebec
Canada H3A 2S3
Tel. No. 514-285-7626

National Institutes of Health
Division of Safety
Safety Operations Section
Bethesda, Maryland 20892
Tel. No. 301-496-3246
301-496-3354 (Import/Export)

National Institute for Occupational Safety and Health
Robert A. Taft Laboratory
4676 Columbia Parkway
Cincinnati, OH 45226
Tel. No. 513-533-8139

Occupational Safety and Health Administration
Office of Information Consumer Affairs
703 Department of Labor
Room H-3647
200 Constitution Avenue, N.W.
Washington, D.C. 20210
Tel. No. 202-523-8551
202-523-8557 (Standards)
202-523-8536 (Inspections)

U.S. Postal Service
Office of Safety and Health
475 L'Enfant Plaza
Washington, D.C. 20260
Tel. No. 202-268-3632