BIOMEX

Fresh Frozen Apheresis Plasma*

DEFINITION
Liquid part of human blood remaining after separation of the cellular elements from blood collected by continuous centrifugation of anticoagulated blood in an apheresis procedure; it is intended for the manufacture of plasma-derived products.

PRODUCTION

DONORS
Only a carefully selected, healthy donor who, as far as can be ascertained after medical examination, laboratory blood tests and a study of the donor's medical history, is free from detectable agents of infection transmissible by plasma-derived products may be used. Recommendations in this field are made by the Council of Europe [Recommendation No. R (95) 15 on the preparation, use and quality assurance of blood components, or subsequent revision]; a directive of the European Union also deals with the matter: Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components.

RECORDS
Records of donors and donations made are kept in such a way that, while maintaining the required degree of confidentiality concerning the donor's identity, the origin of each donation in a plasma pool and the results of the corresponding acceptance procedures and laboratory tests can be traced.

LABORATORY TESTS
Laboratory tests are carried out for each donation to detect the following viral markers:

1. Antibodies against human immunodeficiency virus 1/2 (anti-HIV-1/2);
2. Antibodies against human immunodeficiency virus 2 (anti-HIV-2);
3. Hepatitis B surface antigen (HBsAg);
4. Antibodies against hepatitis C virus (anti-HCV).

The test methods used are of suitable sensitivity and specificity and comply with the regulations in force. If a repeat-reactive result is found in any of these tests, the donation is not accepted.

INDIVIDUAL PLASMA UNITS
The plasma is prepared by a method that removes cells and cell debris as completely as possible. Whether prepared from whole blood or by plasmapheresis, the plasma is separated from the cells by a method designed to prevent the introduction of micro-organisms. No antibacterial or antifungal agent is added to the plasma. The containers comply with the requirements for plastic containers for blood and blood components (European Pharmacopeia 3.2.3). The containers are closed so as to prevent any possibility of contamination.

The plasma was obtained by plasmapheresis, plasma intended for the recovery of proteins that are labile in plasma is frozen within 30 min of collection by cooling rapidly in conditions validated to ensure that a temperature of −40 °C or below is attained at the core of each plasma unit within 1 h of placing in the freezing apparatus.
When plasma is obtained from a suitable donor and using the intended proportion of anticoagulant solution, a total protein content complying with the limit of 50 g/L is obtained. The aim of good manufacturing practice must be to achieve the prescribed limit for all normal donations.
Preservation of human coagulation factor VIII in the donation depends on the collection procedure and the subsequent handling of the blood and plasma. With good practice, 0.7 IU/mL can usually be achieved, but units of plasma with a lower activity may still be suitable for use in the production of coagulation factor concentrates. The aim of all steps taken during production of plasma is to obtain plasma of the intended quality and to conserve labile proteins as much as possible.

TOTAL PROTEIN
Carry out the test using every 5th donation at a single unit base. The total protein content is not less than 50 g/L.
Human coagulation factor VIII (2.7.4). Carry out the test using a pool of not fewer than 10 units. Thaw the samples to be examined, if necessary, at 37 °C. Carry out the assay using a reference plasma calibrated against the International Standard for human coagulation factor VIII in plasma. The activity is not less than 0.7 IU/mL.

STORAGE AND TRANSPORT
Frozen plasma is stored and transported in conditions designed to maintain the temperature at or below −20 °C;

NAT TESTING
The plasma pool is also tested for hepatitis C virus RNA using a validated nucleic acid amplification technique (European Pharmacopeia 3.2.3). The plasma pool is also tested for HIV-RNA and HBV-DNA if needed.

CHARACTERS
Before freezing: clear or slightly turbid liquid without visible signs of haemolysis; it may vary in colour from light yellow to green.

LABELLING
The label enables each individual unit to be traced to a specific donor.

ADVANTAGES
- Highly stabilized proteins by flash freezing
- Manufacturing according to European Pharmacopeia 3.2.3
- Donor selection and testing according to German Transfusion Act and according to German Guidelines

* according to European Pharmacopeia 3.2.3

Other Negative Control Material

Negative Plasma/Serum

Human Single Donor Serum/Plasma
Anti-HIV 1/2 negative
Anti-HBsAG negative
Anti-HCV negative
Anti-Toxoplasmose negative
Anti-Rubella IgG/IgM negative
Anti-ToRCH IgG negative
Human Serum Processed
Defibrinated - fibrin removed (stripped) from human plasma
Defibrinated & Cross-Flow-Filtration - as above, additionally: low molecular constituents are separated by membrane technology
Defibrinated & Delipidized - fibrin and lipids removed (stripped) from human plasma
Defibrinated, Delipidized and Charcoal Treated - as above, additionally: treated with charcoal to remove steroids
Human Serum Off the Clot (Pooled) - supernatant of naturally clotted human plasma
Other Human Serum Proteins
Human Gammaglobulin
Human Albumin - solution (diagnostic grade)
Human Albumin - lyophilisate (diagnostic grade)

VOLUME:

Single units up to 860 mL

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