

16.3 Tests applicable to factor IX concentrates

16.3.1 Potency

Each filling lot shall be assayed for factor IX activity by a test approved by the national control authority, using a standard calibrated against the International Standard for Human Blood Coagulation Factors II, IX, and X in Concentrates.

Other coagulation factors may also be present in the final product, depending on the method of production, and products shall be assayed for all coagulation factors claimed to be present at a therapeutic level, including factors II, VII and X. The assay methods used for these factors shall be approved by the national control authority.

16.3.2 Presence of activated coagulation factors

A test for the presence of activated coagulation factors shall be carried out by a method approved by the national control authority.

In some countries, the non-activated partial thromboplastin times of normal plasma are measured after the addition of an equal volume of a number of different dilutions of the product under test.

In some countries, a test for the presence of thrombin is carried out by mixing equal volumes of the product under test and fibrinogen solution. The mixture is held at 37°C and should not coagulate within 6 h. The usual range of concentrations of fibrinogen solution is 3–10 g/l.

16.3.3 Alloantibodies

A test shall be made for the presence of alloantibodies A and B by a method approved by the national control authority.

It is not possible to be specific about the tests for alloantibodies or to specify an upper limit for the titre.

16.4 Test applicable to fibrinogen

Each filling lot shall be assayed for clottable protein by a test approved by the national control authority.

Not less than 70% of the total protein should be clottable by thrombin.

16.5 Identity test

An identity test shall be performed on at least one labelled container from each filling lot of coagulation-factor concentrate to verify that the preparation is of human origin. The test shall be one approved by the national control authority.

For albumin and plasma protein fraction, additional tests shall be made to determine that the protein is predominantly albumin.

The methods in most common use are radial immunodiffusion and electrophoresis.

16.6 Records

The requirements of Good Manufacturing Practices for Biological Products (8, pages 27-28) shall apply.

16.7 Samples

The requirements of Good Manufacturing Practices for Biological Products (8, page 29, paragraph 9.5) shall apply.

16.8 Labelling

The requirements of Good Manufacturing Practices for Biological Products (8, pages 26-27) shall apply.

In addition, the label on the container shall state:

- the content of the coagulation factor expressed in International Units, where they exist;
- the amount of protein in the container;
- the volume of diluent needed for reconstitution;
- a reference to a package insert giving instructions for use, warnings about the possible transmission of infectious agents and precautions.

16.9 Distribution and shipping

The requirements of Good Manufacturing Practices for Biological Products (8) shall apply.

16.10 Storage and shelf-life

The requirements of Good Manufacturing Practices for Biological Products (8, pages 26-27) shall apply.

Final containers of freeze-dried preparations of factor VIII and factor IX shall have a maximum shelf-life of two years if they are stored at 5 ± 3 °C. Final containers of fibrinogen shall have a maximum shelf-life of five years if they are stored at 5 ± 3 °C.

Other storage conditions and shelf-lives may be approved by the national control authority provided that they are consistent with the data on the stability of the products.

Part D. National control requirements

17. General

The general requirements for control laboratories in the Guidelines for National Authorities on Quality Assurance for Biological Products (6) shall apply.

The national control authority shall provide the standards and reference preparations necessary for the quality control of human blood and blood

products. Where appropriate, these standards should be calibrated against the relevant International Standard.

The national control authority shall have authority to approve the production and control methods used and settle all matters left for its decision or approval in Parts A, B and C.

The national control authority shall also have authority to approve the use of materials that carry potential risk and shall approve any new method of production and the preparation of any new product.

New products or products prepared by new production methods may be monitored to confirm their efficacy and safety.

18. Release and certification

Human blood and blood products shall be released only if they satisfy the requirements of Parts A, B and C, wherever applicable.

A certificate signed by the appropriate official of the national control authority shall be provided at the request of the manufacturing establishment and shall state whether the product in question meets all national requirements as well as Parts A, B and C (whichever is relevant) of the present Requirements. The certificate shall also state the date of the last satisfactory potency test performed by the manufacturer, if applicable, the number under which the lot is released, and the number appearing on the labels of the containers. In addition, a copy of the official national release document shall be attached.

The purpose of this certificate is to facilitate the exchange of human blood and blood products between countries.

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Acknowledgements

Acknowledgements are due to the following experts for their comments and advice on the draft of these Requirements: Professor S. M. Ballester, Director Institute of Haematology and Immunology, Havana, Cuba; Ms M. Cone, Vice-President for Scientific Affairs, International Federation of Pharmaceutical Manufacturers Associations, Geneva, Switzerland; Dr I. Di Tommaso, Tuscan Institute for Serotherapy and Vaccine Production (SCLAVO), Siena, Italy; Dr J. Furesz, formerly Director, Bureau of Biologics, Ottawa, Ontario, Canada; Dr G. Fürst, German Association for the Establishment, Coordination and Working Method of Plasmapheresis Centres, Bonn, Germany; Dr W. N. Gibbs, Chief, Health Laboratory Technology and Blood Safety, WHO, Geneva, Switzerland; Dr A. Gonzaga, Chief, Brazilian Red Cross Blood Programme, Rio de Janeiro, Brazil; Mr J. Guley, Director, Regulatory Affairs, Alpha Therapeutic Corporation, CA, USA; Dr C. Guthrie, General Manager, Blood Products Division, CSL Ltd, Parkville, Victoria, Australia; Dr B. Habibi, National Blood Transfusion Centre, Paris, France; Dr K. Hannegren, National Bacteriological Laboratory, Stockholm, Sweden; Professor S. R. Hollán, National Institute of Haematology and Blood Transfusion, Budapest, Hungary; Dr F. C. Kothe, Head, Blood Programme, International Federation of Red Cross and Red Crescent Societies, Geneva, Switzerland; Mr B. Kubanck, Medical Director, Department of Transfusion Medicine, University of Ulm, Germany; Mrs S. F. Langlois, Director, Regulatory Affairs, Connaught Laboratories Ltd, Ontario, Canada; Mr P. Lemoine, Brussels, Belgium; Dr R. M. Lequin, Manager, Evaluation and Training Group, Organon Teknika, Turnhout, Belgium; Dr T. Matuhasi, Professor Emeritus, Okinaka Memorial Institute for Medical Research, University of Tokyo, Tokyo, Japan; Professor N. V. Medunitsin, Director, Tarasevich State Institute for the Standardization and Control of Medical Biological

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Appendix
Summary protocol for collection of source material

1. Name and address of collecting centre _____

2. Source material _____
3. Details of single donations, where applicable:
 - (a) Donor identification _____
 - (b) Date of collection _____
 - (c) Volume in container _____
 - (d) Results of tests for HBsAg _____
 - (e) Results of tests for anti-HIV _____
 - (f) Results of tests for anti-HCV _____
 - (g) If applicable, results of tests for antibody to hepatitis B core antigen _____
 - (h) If applicable, results of tests for alanine aminotransferase _____
4. Special information:
 - (a) Anticoagulant used _____
 - (b) Was the material collected for special purposes (e.g. as a source of specific antibodies)? _____
 - (c) Precautions to be taken when using the material _____
5. Conditions of storage _____
6. Does the donation comply with existing agreements between the supplier and manufacturer? _____
7. Does the donation comply with the Requirements for the Collection, Processing and Quality Control of Blood, Blood Components and Plasma Derivatives published by WHO? _____

Name and signature of responsible person _____

Date _____

STANDARD OPERATING PROCEDURE

(Name of the Blood Centre)

Number	Effective Date	Pages	Author	Authorised by
SP 001		3		
Version	Review Period	No. of Copies	Approved by	Date
1	1 Year			

LOCATION	SUBJECT
Donor Room	Criteria for Donor Selection
FUNCTION	DISTRIBUTION
Assessing suitability of donor for blood donation	- Medical Officer in charge of Donor Area - Master File

1. SCOPE & APPLICATION

This SOP describes the criteria for a donor to be accepted for blood donation, for ensuring safety of donor as well as recipient. The purpose of donor selection is to identify any factors that might make an individual unsuitable as a donor, either temporarily or permanently.

2. RESPONSIBILITY

The Medical Officer is responsible for determining the suitability of donor for blood donation. He/She should confirm that the criteria are fulfilled after evaluation of health history questionnaire and medical examination including the results of pre donation screening tests.

3. REFERENCES

Technical Manual of American Association of Blood Banks- 13th edition, 1999 pgs 90-97, 103-110.

4. MATERIAL REQUIRED

- Donor Questionnaire
- Donor Card

5. PROCEDURE

CRITERIA FOR SELECTION OF BLOOD DONORS

A. Accept only voluntary/replacement non-remunerated blood donors if following criteria are fulfilled.

The interval between blood donations should be no less than three months. The donor shall be in good health, mentally alert and physically fit and shall not be a jail inmate or a person having multiple sex partners or a drug-addict. The donors shall fulfill the following requirements, namely:-

1. The donor shall be in the age group of 18 to 60 years
2. The donor shall not be less than 45 kilograms
3. Temperature and pulse of the donor shall be normal
4. The systolic and diastolic blood pressures are within normal limits without medication
5. Haemoglobin shall not be less than 12.5 g/dL
6. The donor shall be free from acute respiratory diseases
7. The donor shall be free from any skin disease at the site of phlebotomy
8. The donor shall be free from any disease transmissible by blood transfusion, in so far as can be determined by history and examination indicated above
9. The arms and forearms of the donor shall be free from skin punctures or scars indicative of professional blood donors or addiction of self-injected narcotics

B. Defer the donor for the period mentioned as indicated in the following table:

CONDITIONS	PERIOD OF DEFERMENT
Abortion	6 months
History of blood transfusion	6 months
Surgery	12 months
Typhoid fever	12 months after recovery
History of Malaria duly treated	3 months (endemic) 3 years (non endemic area)
Tattoo	6 months
Breast feeding	12 months after delivery
Immunization (Cholera, Typhoid, Diphtheria, Tetanus, Plague, Gammaglobulin)	15 days
Rabies vaccination	1 year after vaccination
Hepatitis in family or close contact	12 months
Hepatitis Immune globulin	12 months

C. Defer the donor permanently if suffering from any of the following diseases:

1. Cancer
2. Heart disease
3. Abnormal bleeding tendencies
4. Unexplained weight loss
5. Diabetes
6. Hepatitis B infection
7. Chronic nephritis

Signs and symptoms, suggestive of AIDS

9. It is important to ask donors if they have been engaged in any risk behaviour. Allow sufficient time for discussion in the private cubicle. Try and identify result-seeking donors and refer them to VCTC (Voluntary Counseling and Testing Center). Reassure the donor that strict confidentiality is maintained.
- 10 Liver disease
- 11 Tuberculosis
- 12 Polycythemia Vera
- 13 Asthma
- 14 Epilepsy
- 15 Leprosy
- 16 Schizophrenia
- 17 Endocrine disorders

D. Private interview:

A detailed sexual history should be taken. Positive history should be recorded on confidential notebook.

E. Informed consent:

Provide information regarding:

1. Need for blood
2. Need for voluntary donation
3. Regarding transfusion transmissible infections
4. Need for questionnaire and honest answers
5. Safety of blood donation
6. How the donated blood is processed and used
7. Tests carried out on donated blood

N.B. This gives the donor an opportunity to give his/her consent if they feel they are safe donors

* Request the donors to sign on the donor card indicating that he is donating voluntarily.

6. DOCUMENTATION

Enter all details in the donor questionnaire form/card and computer