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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB 18467-2011

Whole blood and component donor selection requirements

献血者健康检查要求

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Foreword

Chapter 4 of this standard, Chapter 5, Chapter 9, Chapter 10, Section 8.2,

8.3 are mandatory, the rest are recommended. This standard was drafted in accordance with GB/T 1.1-2009 given rules. This standard replaces GB 18467-2001 "donor health inspection requirements", compared with GB 18467-2001, the major technological change as follows:

- Adjust the standard structure, increase directory, reference documents, informed consent of donors, delete the original Appendix C;
- Adjust normative technical provisions of chapter structure; the relevant provisions of the adjusted blood donation immunization, vaccine production process according to classification management;
- Adjust mandatory provisions, in addition to the original pre-donation testing, blood volume and blood donation interval, donated blood testing requirements, increased blood Informed consent;
- Increase blood donors about life experiences and travel experience health consultation;
- Deleting content blood test about the method to detect markers Once blood;
- Adjust blood donation age, blood volume, hemoglobin standard, platelets and blood collection standard spacing;
- Amendment ophthalmic disorders, homosexuality and the relevant provisions of the post-vaccination blood donation;

- Revised Appendix A blood donor consent and Health Questionnaire related content;
- Revised Appendix B before blood tests and blood donation records related content. This standard is proposed and administered by the People's Republic of China Ministry of Health. Drafting of this standard. Beijing Red Cross Blood Center. The main drafters of this standard. High Tung Ying, Liu Jiang, Dai Suna, Guo Jin, Zhou Qian, Chen Xiao, Liu Zhiyong, Jiang Feng, Zhao Dongyan, Zhuangguang Yan. This standard replaces the standards previously issued as follows:
- GB 18467-2001. Donor health inspection requirements

1 Scope

GB 18467-2011 is the Chinese national standard on whole blood and component donor selection requirements, in the field of health care technology. It carries no /T suffix, which in the Chinese system means compliance is mandatory: a product or a practice within its scope has to meet it to be lawfully made, sold or carried out in China. It was issued on 30 December 2011 by the Ministry of Health of the People's Republic of China; Standardization Administration of China, and has been in force since 1 July 2012. Classification: ICS 11.020, CCS C05. This page is published from the official record of the standard held by the Chinese standards administration: the identification, the dates, the classification and the issuing body are taken from there. The clause text, the tables and the numeric limits are in the document itself, which is delivered complete in English translation.

This standard specifies the general requirements for blood donors and project health check. This standard applies to general health screening blood for blood donors. This standard does not apply to blood stem cell donation, blood storage and its own therapeutic apheresis.

2 Normative references

The following documents for the application of this document is essential. For dated references, only the dated version suitable for use herein Member. For undated references, the latest edition (including any amendments) applies to this document.

GB 18469 of whole blood and blood components quality

3 Terms and Definitions

GB 18469 and defined by the following terms and definitions apply to this document.

3.1 Fixed blood donors regularnon-remuneratedvoluntaryblooddonor Offered at least three times the blood, and the blood at least once in the last 12 months.

3.2 After forecasting platelet count predictedpost-donationplateletcount After the body of the remaining collection donor platelet count lower control limit for verifying the platelet

collection scheme.

4 General

4.1 before collecting blood donors should obtain informed consent, and its necessary health consultation, general examination and blood tests. written Log files, see Appendix A, Appendix B. General examination and blood tests

4.2 blood donors before blood results should prevail, valid for 14d.

4.3 pre-donation medical examination Results for judging whether a suitable blood donors, not suitable for diagnostics donor health status or disease.

4.4 pairs by inappropriate health check blood donors should be given appropriate explanation and attention to the protection of their personal information.

5 Donors informed consent

5.1 Obligation Blood bank staff should be in front of the blood donors to fulfill this obligation in writing and made donors signed informed consent.

5.2 inform content

5.2.1 Motivation to donate blood Blood donation is motivated by altruism, it aims to help patients requiring transfusion. Do not donate blood for the testing and. Countries Free HIV counseling and free HIV antibody testing services, if necessary, please contact your local Center for Disease Control (electrical contact Words can query the National Public Health Public hotline 12320).

5.2.2 The importance of safe blood donors Unsafe blood to endanger life and health of the patient. Donors should not donate blood with a high-risk behavior such as intravenous drug history, MSM Behavior or with blood-borne diseases (AIDS, hepatitis C, hepatitis B, syphilis and other) risks.

5.2.3 has a risk behavior deliberately donation responsibility Infectious blood donors donate blood recipients will be dangerous, should bear the moral responsibility of the recipient. According to "People's Republic of China Disease Prevention Act" Article 77, "AIDS Prevention Act," Article 38 and Article 62 of the high-risk offer Deliberately blood donation, resulting in the spread of infectious diseases, epidemic, he shall bear civil liability; constitute a crime, be held criminally responsible.

5.2.4 real-name system to donate blood According to "Blood management approach", donors before blood donation should produce a real and effective identification, blood should be checked and registered. Fraudulent use of another person's identity to donate blood, should be held accountable in accordance with relevant laws and regulations.

5.2.5 donors after donation report back If you think there may be blood donors have

donated blood safety hazard, it shall inform the blood bank as quickly as possible. Blood should provide contact phone number.

5.2.6 Donating Blood Reaction In most cases, blood donation is safe, but individuals may occasionally occur such as dizziness, cold sweats, puncture site bruising, hematoma, pain And discomfort, very few may appear more serious blood reactions such as syncope. Medical personnel should be disposed of promptly reaction donation, blood donation Caution should follow before and after blood donation and blood donation, blood donation to reduce the probability of occurrence of the reaction.

5.2.7 health consultation and examination Under the "Blood Donation Law of People's Republic of China" shall consult healthy blood donors and general examination, blood donors must fill out Health Status Questionnaire. Fill untrue who donated blood due to adverse effects caused by the recipient, should bear in accordance with relevant laws and regulations responsibility.

5.2.8 Blood tests Blood donors will comply with state regulations for blood to detect blood-borne diseases, blood tested and will be used for clinical failure Blood will be disposed of in accordance with national regulations. Blood test results show only failed to donate blood do not meet national standards of blood, not for Of infection or disease diagnosis.

5.2.9 epidemic reporting According to relevant regulations, "People's Republic of China Disease Prevention Act" and so on, will be the local blood bank CDC reported HIV disease Results such as testing positive for virus infection and its profile.

5.3 donors informed consent Donors should carefully read the information related to informed consent, and signed informed consent.

6.1 Donors have the following circumstances can not donate blood

6.1.1 respiratory diseases, such as including chronic bronchitis, bronchiectasis, bronchial asthma, emphysema, and pulmonary function not congruent.

6.1.2 circulatory system diseases, such as various heart diseases, hypertension, hypotension, limb atherosclerosis, thrombotic phlebitis.

6.1.3 digestive diseases, such as chronic gastroenteritis, treated with active or recurrent gastric and duodenal ulcers, chronic pancreas Inflammation, nonspecific ulcerative colitis.

6.1.4 patients with urinary system diseases, such as acute and chronic glomerulonephritis, chronic pyelonephritis, nephrotic syndrome, acute and chronic urinary tract infections Chronic renal insufficiency.

6.1.5 patients with blood disorders such as anemia (iron deficiency anemia, megaloblastic anemia except healer), polycythemia vera, grain Cell deficiency, leukemias, lymphomas and various publications, blood clotting disorders.