

On approval of the rules for donation of blood and its components of a mandatory medical examination within the framework of a guaranteed amount of free medical care

Unofficial translation

Order of the Minister of Healthcare of the Republic of Kazakhstan dated September 16, 2020 № RK HM-102/2020. Registered with the Ministry of Justice of the Republic of Kazakhstan on September 17, 2020 № 21216.

Unofficial translation

In accordance with Article 207, paragraph 1, of the Code of the Republic of Kazakhstan dated July 7, 2020 "On public health and healthcare system," **I hereby ORDER:**

1. To approve the attached Rules for the donor to donate blood and its components of the mandatory medical examination within the framework of the guaranteed amount of free medical care.

2. To recognize the order of the Minister of Healthcare of the Republic of Kazakhstan as invalid dated September 10, 2019 № RK HM-125 "On approval of the Rules for medical examination of a donor before donation of blood and its components" (registered in the Register of State Registration of Regulatory Legal Acts under No. 19366, published on September 16, 2019 in the Reference Control Bank of Regulatory Legal Acts of the Republic of Kazakhstan in electronic form).

3. The Department of Medical Care Organization of the Ministry of Healthcare of the Republic of Kazakhstan, in accordance with the procedure established by the legislation of the Republic of Kazakhstan, shall:

1) ensure the state registration of this order with the Ministry of Justice of the Republic of Kazakhstan;

2) place this order on the Internet resource of the Ministry of Healthcare of the Republic of Kazakhstan;

3) within ten working days from the date of the state registration of this order, submit to the Legal Department of the Ministry of Healthcare of the Republic of Kazakhstan information on the implementation of measures provided for in subparagraphs 1) and 2) of this paragraph.

4. Control over the execution of this order shall be entrusted to the Vice-Minister of Healthcare of the Republic of Kazakhstan A. Giniyat.

5. This order shall enter into force upon expiry of ten calendar days after the date of its first official publication.

*Minister of Healthcare
of the Republic of Kazakhstan*

A. Tsoi

Approved

The rules for the donor to donate blood and its components of a mandatory medical examination within the framework of a guaranteed amount of free medical care Chapter 1. General provisions

1. These Rules for donor to donate blood and its components to compulsory medical examination within the guaranteed amount of free medical care (hereinafter referred to as the Rules) have been developed in accordance with Article 207, paragraph 1 of the Code of the Republic of Kazakhstan dated July 7, 2020 "On public health and healthcare system" (hereinafter referred to as the Code) and shall determine the procedure for donation of blood and its components of a mandatory medical examination within the framework of a guaranteed amount of free medical care (hereinafter – GAFMC).

2. Blood service organizations shall carry out donations of blood and its components of the following types: whole blood, plasma, blood cells, mixed.

Chapter 2. The procedure for donation of blood and its components of a mandatory medical examination within the framework of the GAFMC

3. The donor shall undergo a mandatory medical examination within the framework of the GAFMC before donation of blood and its components, which shall include the following stages:

- 1) donor admission and registration;
- 2) medical examination of the donor.

4. Reception, registration, medical examination of blood donor and its components in blood service organizations shall be carried out when a person who has reached the age of 18 years and has voluntarily expressed a desire to donate blood and its components for medical purposes, in accordance with Article 206, paragraph 1 of the Code.

5. According to the frequency and multiplicity of donations of blood and its components, donors shall be divided into the following categories:

primary - a person performing donation of blood and its components for the first time in life;

repeated - a person who had previously donated blood and its components;

regular - a person performing donation of blood and/or its components for the last 12 months with a multiplicity of 3 or more times.

6. Acceptance of donors is carried out on the basis of identity documents, or an electronic document from the digital document service (for identification) in accordance with the Law of

the Republic of Kazakhstan "On identity documents" or military registration documents for army conscripts.

Footnote. Paragraph 6 - as amended by the order of the Minister of Health of the Republic of Kazakhstan dated 07.12.2021 № ҚР ДСМ-125 (shall be enforced ten calendar days after the day of its first official publication).

7. Prior to donation of blood and its components, the registration of persons who shall not be subject to admission to blood donation and its components shall be checked in the electronic database.

In the absence of contraindications to blood donation and its components, the passport part of the donor's medical record shall be filled. In the medical record of the donor, shall be marked the verification of information.

8. Electronic database of persons not subject to blood donation and its components shall be formed on the basis of data sent from health organizations working in the field of prevention of human immunodeficiency virus/acquired immune deficiency syndrome (HIV) (hereinafter referred to as HIV Prevention organization), tuberculosis hospitals (dispensaries), drug treatment hospitals (dispensaries, centers for medical and social rehabilitation), skin and venereological hospitals (dispensaries), psychiatric hospitals (dispensaries), as well as according to the results of the examination for transfusion infections of persons who applied for donation of blood and its components to the organization of a blood service.

Blood service organizations shall be provided with information about HIV-infected persons in the republic with subsequent updating of information about newly identified persons by organizations for the prevention of HIV in regions, cities of national importance and the capital.

Information about convalescent patients who are potential donors of immune plasma shall be transmitted by medical organizations at the request of the blood service organization in the service region for the possibility of organizing the procurement of immune plasma.

Footnote. Paragraph 8 as amended by order of the Minister of Healthcare of the Republic of Kazakhstan dated 02.08.2022 № ҚР ДСМ-73 (shall come into effect ten calendar days after the day of its first official publication).

9. Before each donation of blood and its components, the donor shall be surveyed using a list of questions to identify additional information that limits or prevents admission to donation in accordance with Annex 1 to these Rules.

In this case, the donor shall confirm or deny the presence of circumstances limiting or preventing admission to donation.

The questionnaire shall be filled out by the donor independently or with the participation of a medical registrar.

Footnote. Paragraph 9 - as amended by the order of the Minister of Healthcare of the Republic of Kazakhstan dated 02.08.2022 № ҚР ДСМ-73 (shall come into effect upon the expiration of ten calendar days after the day of its first official publication).

10. Before a medical examination, a preliminary laboratory examination of a potential donor shall be carried out to obtain information about the state of his/her (the donor's) health.

Preliminary laboratory examination shall include:

determination of haemoglobin (for all donors);

determination of alanine aminotransferase (hereinafter referred to as ALT) activity (for all donors);

additionally:

determination of platelet count in platelet donors and hematocrit in apheresis platelet donors;

level of total protein in apheresis plasma donors;

determination of blood clotting time before donation of blood components on automatic separators;

the presence of specific antibodies in immune plasma donors.

Footnote. Paragraph 10 - as amended by the order of the Minister of Healthcare of the Republic of Kazakhstan dated 02.08.2022 № ҚР ДСМ-73 (shall come into effect ten calendar days after the day of its first official publication).

11. The result of the ALT test shall be taken into account only when a donor is allowed to donate and shall not be used to determine the suitability of the product for use.

A study of the titer of specific immune antibodies after donation during production control shall be performed in the absence of diagnostics before donation.

The results of the study of the titer of specific immune antibodies shall not be taken into account when determining the suitability of products for use.

The titer of specific immune antibodies shall be indicated on the label of the finished product.

Footnote. Paragraph 11 - as amended by the order of the Minister of Healthcare of the Republic of Kazakhstan dated 02.08.2022 № ҚР ДСМ-73 (shall come into effect upon the expiration of ten calendar days after the day of its first official publication).

12. Before donation, group affiliation shall be determined by ABO system, rhesus of affiliation and presence of K antigen of Kell system, if donor blood type is not established and result is not registered in automated information system.

13. Laboratory research shall be carried out by methods registered on the territory of the Republic of Kazakhstan, including dry chemistry methods, on equipment registered by the state body in the field of circulation of medicines and medical devices in accordance with Article 10, paragraph 7 of the Code.

14. Regular donors shall be examined additionally. At least once a year, a study of the composition of peripheral blood (haemoglobin (hematocrit), erythrocytes, leukocytes, platelets, erythrocyte sedimentation rate, and leukocyte formula) shall be carried out.

Footnote. Paragraph 14 - as amended by the order of the Minister of Healthcare of the Republic of Kazakhstan dated 02.08.2022 № ҚР ДСМ-73 (shall come into effect upon the expiration of ten calendar days after the day of its first official publication).

15. Before donating blood and its components, the donor shall be given the following information orally:

on the guarantee of confidentiality of personal information and the right to receive information about the results of the survey;

about infections transmitted by blood and its components (HIV, viral hepatitis with parenteral transmission);

about the purposes of laboratory examination of donor blood, the importance of obtaining reliable medical history data and the importance of voluntary informed consent for donation of blood and its components.

Footnote. Paragraph 15 - as amended by the order of the Minister of Healthcare of the Republic of Kazakhstan dated 02.08.2022 № ҚР ДСМ-73 (shall come into effect upon the expiration of ten calendar days after the day of its first official publication).

16. During a medical examination and donation of blood and (or) its components on working days, an employee shall be exempt from work while maintaining the average salary in accordance with paragraph 1 of Article 208 of the Code.

Footnote. Paragraph 16 - as amended by the order of the Minister of Healthcare of the Republic of Kazakhstan dated 02.08.2022 № ҚР ДСМ-73 (shall come into effect upon the expiration of ten calendar days after the day of its first official publication).

17. The donor, on the basis of a written application, shall be issued an archival certificate on the types and scope of donations carried out by him, which shall be drawn up on the blood service organization form signed by the first head.

18. In blood service organizations, a laboratory examination of a donor without subsequent donation shall be carried out to obtain research results to resolve the possibility of restoring donor rights or indefinitely diverting persons from blood donation and its components who previously had undefined or positive research results on markers of hemotransmissible infections, as well as other laboratory studies provided for blood donors of its components.

Annex 1 to the Rules
for the donor to donate blood and
its components of a mandatory medical
examination within the framework
of the guaranteed amount of medical care

List of questions to identify additional information that limits or prevents admission to donation:

Footnote. Annex 1 - as amended by the order of the Minister of Healthcare of the Republic of Kazakhstan dated 02.08.2022 № ҚР ДСМ-73 (shall come into effect ten calendar days after the day of its first official publication).

1. Have you consumed alcohol in the last 48 hours.
2. Has there been any tooth extraction in the last 10 days.
3. Have you taken any medications in the last month.
4. Have you been vaccinated against hepatitis B, influenza, COVID, tetanus, diphtheria, brucellosis, etc. in the last month.
5. Have you taken medications to prevent HIV infection in the last 4 months.
6. Have you had acupuncture, tattoos, piercings, or injections in the last 4 months.
7. Have there been any household contacts with patients with hepatitis A, B, C, or HIV over the past 6 months.
8. Have you sought medical help in the last 6 months.
9. Have there been any donor blood transfusions in the last 12 months.
10. Have there been any surgical interventions or cosmetic procedures in the last 12 months.
11. Have you had promiscuous sexual relations with heterosexual or homosexual partners in the last 12 months.
12. Have you had an irregular relationship with a homosexual partner(s) in the last 12 months.
13. Have you had a regular relationship with a regular homosexual partner over the past 12 months.
14. Have you been in prison in the last 12 months.
15. Have you been provided sexual services in the last 12 months.
16. Was there any contact of someone else's blood with the mucous membrane or skin, including damage caused by piercing objects.
17. Have you used injecting drugs in the last 12 months.
18. Have the following signs appeared, including briefly, over the past 12 months: discharge from the genital organs, growths and (or) sores in the genital area, burning sensation in the genital area, pain when urinating, enlarged inguinal lymph nodes.
19. Have you stayed for more than 4 months in countries with tropical and subtropical climates in the last 12 months.
20. Have there been frequent changes in blood pressure over the past 12 months.
21. Have you had any unexplained fevers, weight loss, fainting(s), night sweats, or headaches in the last 12 months.
22. Is there currently a disability group or dispensary registration for the disease.
23. Have you had or currently have the following infectious diseases: HIV, syphilis or other sexually transmitted diseases, hepatitis B or C, brucellosis, tuberculosis (all forms), typhus, tularemia, and leprosy.
24. Have you had or currently have the following non-infectious diseases: heart, lungs, kidneys, liver, nervous, reproductive system, severe allergies, bronchial asthma, congenital defects, seizures (epileptic).

25. Have you had any parasitic diseases during your life or currently have them.
26. Have you ever had or currently have chronic skin diseases.
27. Were foreign stem cells introduced, or was there a cornea or dura mater transplant.
28. Have there been any operations involving the removal of a limb and (or) organ during your life.
29. Have there been positive results of tests for the presence of markers of HBV, HCV, syphilis, and HIV during your life or are there currently.
- Additionally, for females:
30. Has there been any pregnancy, childbirth, lactation, or medical abortion in the last 12 months.
31. Are you currently breastfeeding.
32. Is hormonal contraception currently used.

Annex 2 to the Rules
for the donor to donate blood and
its components of a mandatory medical
examination within the framework
of the guaranteed amount of medical care

“Form of informed voluntary consent for donation of blood and its components”

Footnote. The Rules are supplemented by Annex 2 in accordance with the order of the Minister of Healthcare of the Republic of Kazakhstan dated 02.08.2022 No. ҚР ДСМ-73 (shall come into effect ten calendar days after the day of its first official publication).

I _____
hereby confirm that I give voluntary, free consent to the donation of blood or its components for medical use.

I hereby agree to:

- 1) processing of my data through an automated information system in the electronic database of blood donors and its components;
- 2) to examine the blood I donated for markers of HIV infection, syphilis, hepatitis B and C;
- 3) to use in an anonymized form a sample of my blood obtained during donation, during scientific research;
- 4) transfer of my data to a medical organization at the place of my attachments when determining positive results of my blood test for markers of infections;
- 5) to receive newsletters for invitations to participate in a donation via mobile phone or email.

Donor's signature _____

Doctor's signature _____

Date of completion _____

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