

**On approval of the rules for voluntary anonymous and (or) confidential medical examination and counseling on HIV infection within the guaranteed volume of free medical care in public health organizations operating in the field of HIV prevention**

Order of the Minister of Health of the Republic of Kazakhstan dated November 25, 2020 No. ҚР ДСМ-204/2020. Registered with the Ministry of Justice of the Republic of Kazakhstan on November 27, 2020 No. 21682.

In accordance with paragraph 1 of Article 162 of the Code of the Republic of Kazakhstan dated July 7, 2020 "On the health of the people and the healthcare system", I ORDER:

1. Approve the rules for voluntary anonymous and (or) confidential medical examination and counseling on HIV infection within the guaranteed volume of free medical care in public health organizations operating in the field of HIV prevention, in accordance with the annex to this order.

2. Recognize as invalid:

1) Order of the Minister of Health and Social Development of the Republic of Kazakhstan dated April 22, 2015 No. 246 "On approval of the Rules for voluntary anonymous and (or) confidential medical examination and consultation of citizens of the Republic of Kazakhstan, repatriates, foreigners and stateless persons permanently residing in the territory of the Republic of Kazakhstan on issues of HIV infection on a free basis" (registered in the Register of State Registration of Regulatory Legal Acts under No. 11145, published on April 30, 2016 in the newspaper "Kazakhstanskaya Pravda" No. 82 (28208));

2) paragraph 3 of the List of some orders of the Ministry of Health of the Republic of Kazakhstan, which are amended and supplemented, approved by order of the Minister of Health of the Republic of Kazakhstan and Social Development of the Republic of Kazakhstan dated May 4, 2019 No. ҚР ДСМ-62 "On amendments and additions to some orders of the Ministry Health and Social Development of the Republic of Kazakhstan" (registered in the Register of State Registration of Regulatory Legal Acts under No. 18637, published on May 23, 2019 in the Reference Control Bank of Regulatory Legal Acts of the Republic of Kazakhstan).

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

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

2) placement of this order on the Internet resource of the Ministry of Health of the Republic of Kazakhstan after its official publication;

3) within ten calendar days after the state registration of this order with the Ministry of Justice of the Republic of Kazakhstan, submission to the Legal Department of the Ministry of Health of the Republic of Kazakhstan of information on the implementation of the measures provided for in subparagraphs 1) and 2) of this paragraph.

4. To impose control over the execution of this order on the supervising Vice Minister of Health of the Republic of Kazakhstan.

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

|  |  |
| --- | --- |
| *Minister of Health*  *of the Republic of Kazakhstan* | *A. Tsoi* |

|  |  |
| --- | --- |
|  | Approved by order  of the Minister of Health  of the Republic of Kazakhstan  dated November 25, 2020  No. ҚР ДСМ-204/2020 |

**Rules for voluntary anonymous and (or) confidential medical examination and counseling on HIV infection within the guaranteed volume of free medical care in public health organizations operating in the field of HIV prevention**

**Chapter 1. Basic Provisions**

1. These rules for voluntary anonymous and (or) confidential medical examination and counseling on HIV infection within the guaranteed volume of free medical care (hereinafter referred to as the Rules) are developed in accordance with paragraph 1 of Article 162 of the Code of the Republic of Kazakhstan dated July 7, 2020 "On health of the people and the healthcare system" (hereinafter referred to as the Code) and determine the procedure for conducting a voluntary anonymous and (or) confidential medical examination and counseling on HIV infection for citizens of the Republic of Kazakhstan, kandas, foreigners, stateless persons, refugees and asylum seekers, permanently and temporarily residing on the territory of the Republic of Kazakhstan, within the framework of the guaranteed volume of free medical care in state healthcare organizations operating in the field of HIV prevention.

2. The following concepts are used in these Rules:

1) HIV infection - a chronic infectious disease caused by the human immunodeficiency virus (hereinafter referred to as HIV), characterized by a specific lesion of the immune system and leading to its slow destruction to the formation of acquired immunodeficiency syndrome;

2) anonymous examination - a voluntary medical examination of a person without personal identification;

3) public health organization engaged in activities in the field of HIV prevention - an organization that conducts mandatory, voluntary anonymous and (or) confidential medical examination and counseling on HIV infection;

4) the Republican State Health Organization, carrying out activities in the field of HIV prevention (hereinafter - RPHO) - a healthcare organization that conducts screening, expert, arbitration tests for HIV and other laboratory tests;

5) confidential medical examination - an examination based on the observance of the secrecy of a medical worker and the preservation of information about the identity of the person being examined.

**Chapter 2. Procedure for conducting a voluntary anonymous and (or) confidential medical examination on HIV infection**

3. Citizens of the Republic of Kazakhstan, kandas, foreigners and stateless persons, refugees and asylum seekers permanently and temporarily residing in the territory of the Republic of Kazakhstan, who have expressed a desire to undergo a voluntary medical examination for HIV infection, are examined at their choice:

1) anonymously (documents are not required);

2) confidentially (identity document, home address, phone number are provided).

4. Voluntary anonymous examination for HIV infection is carried out using rapid tests (hereinafter referred to as ET) that detect the p24 viral antigen and antibodies to HIV of the first and second types in blood, serum, plasma, gingival fluid (transudate from the oral mucosa) or rapid tests for the diagnosis of HIV infection, intended for self-testing in public health organizations operating in the field of HIV prevention.

In a voluntary anonymous examination, the subject is assigned a unique identification code.

5. Based on the results of the rapid test, the subject is given a post-test consultation with oral information about the test result.

In the case of a negative result of the rapid test, the subject is re-examined for HIV infection after 3 (three) months in the presence of risk factors for infection.

In the event of a positive result of the express test, with the informed consent of the person being tested, an examination for HIV infection is carried out in accordance with the procedure for diagnosing HIV infection in adults in accordance with paragraphs 8-22 of these Rules.

6. Voluntary confidential medical examination for the presence of HIV infection is carried out by state health organizations engaged in the prevention of HIV infection, the WPHA in accordance with the procedure for diagnosing HIV infection in adults in accordance with paragraphs 8 to 22 of these Rules.

7. Blood sampling for testing for the presence of HIV infection is carried out by healthcare organizations, regardless of the form of ownership and departmental affiliation, upon presentation of an identity document. Blood is taken into a vacuum tube with a separating gel and a coagulation activator with a volume of at least 5 (five) milliliters (hereinafter referred to as ml). The blood sample is sent to the laboratory of the territorial public health organization that carries out activities in the field of HIV prevention, conducts a test for HIV infection, at a temperature of + 2o - + 8oC and is used for serological studies within 5 (five) calendar days from the date of blood sampling . A referral is attached to the blood sample in the form approved in accordance with subparagraph 31) of Article 7 of the Code.

8. The procedure for diagnosing HIV infection in adults includes two stages - the first and confirming.

9. The first stage: in the primary study (hereinafter - T1), the p24 viral antigen and antibodies to HIV of the first and second types are simultaneously determined by the method of enzyme-linked immunosorbent assay (hereinafter - ELISA) or immunochemiluminescent analysis (hereinafter - ICLA), or electrochemiluminescent analysis (hereinafter - ECLA ).

At the first stage, test systems with a diagnostic sensitivity of 100% are used (the lower limit of the 95% confidence interval is at least 99%); diagnostic specificity - not less than 99% (the lower limit of the 95% confidence interval - not less than 98%); analytical sensitivity - no more than 2 IU / ml (the minimum amount of p24 antigen). With each setting for the determination of markers of HIV infection by the serological method, in addition to the control samples attached to the set, a setting is carried out inside the laboratory control with a positivity coefficient (OD / ODcrit) in the range of 2.0–2.5 to assess the stability of the process.

10. Upon receipt of a negative T1 result, the subject is given the result "HIV negative". The subject receives a negative result at the place of blood sampling upon presentation of an identity document within 3 (three) working days from the moment the blood sample for analysis is received by the laboratory. Post-test counseling is carried out before the result is issued.

11. Upon receipt of a positive T1 result, a second study (hereinafter referred to as T2) is performed using a test system that differs from T1, or ET. Tests of the third and fourth generations are used.

12. If the T2 result is negative, the same sample is retested using the T1 and T2 tests.

13. If two negative results are obtained in a repeat study, the result "HIV negative" is issued.

14. Upon receipt of two positive test results, a serum sample with a volume of at least 1 (one) ml is sent to the RPHO laboratory for confirmatory studies no later than three working days from the date of the last statement.

15. When receiving conflicting research results (T1+, T2-), the result is considered doubtful. After 14 (fourteen) calendar days, a second blood sampling and a test for HIV infection is carried out, according to the first stage of the procedure for diagnosing HIV infection in adults prevention of HIV infection, for re-examination for HIV infection).

16. Upon receipt of a repeated doubtful result for HIV infection after 14 (fourteen) calendar days, additional studies are carried out using other serological tests. A negative result is issued for two negative results from three studies. A positive result is issued on two positive results from three studies. In the case of examination of pregnant women, molecular biological tests are additionally used (quantitative determination of HIV ribonucleic acid (hereinafter referred to as RNA) with a test sensitivity of not more than 50 copies / ml or determination of proviral deoxyribonucleic acid (hereinafter referred to as pDNA) HIV).

17. Confirmatory stage: confirmation of primary positive samples from territorial public health organizations operating in the field of HIV prevention is carried out by ELISA or ELISA or ET and a confirmatory immune blot (hereinafter referred to as IB) or an immunochromatographic test with a profile of HIV proteins (2 ENV, GAG, POL) in the WPHA laboratory.

Upon receipt of a biomaterial from a blood service organization with a positive result of a polymerase chain reaction (hereinafter - PCR) and a negative or doubtful result of ELISA or ELISA or ELECTR, an additional study is carried out using molecular biological tests to identify HIV infection during the period of the seronegative window. The examined donor is under serocontrol in the territorial public health organization that carries out activities in the field of HIV prevention until the diagnosis is confirmed or excluded.

18. Upon receipt of a negative result in the ELISA or IHLA or ET in the laboratory of the RPHD, the information is transmitted to the territorial state health organization engaged in the prevention of HIV infection, for re-blood sampling and testing for HIV after 14 (fourteen) calendar days, according to the procedure for diagnosing HIV infection in adults (stage 1).

19. Upon receipt of a positive result in ELISA or ELISA or ET, a confirmatory test is performed in the laboratory of the RPHD: IB or immunochromatographic test with a profile of HIV proteins (2 ENV, GAG, POL).

20. Upon receipt of a negative result of IB or an immunochromatographic test with a profile of HIV proteins (2 ENV, GAG, POL) and a positive result in ELISA or ELISA or ET, a second examination is performed after 1 (one) or 3 (three) months, according to the procedure for conducting diagnostics HIV infections in adults, consecutively, starting with the first stage. In the absence of positive dynamics of antibody titers to HIV in ELISA or ELISA and negative IB, a PCR test is performed after 3 (three) months.

21. Upon receipt of a doubtful result of IB or an immunochromatographic test with a profile of HIV proteins (2 ENV, GAG, POL) and a positive result in ELISA or ELISA or ET, a second study is carried out after 14 (fourteen) calendar days or 1 (one) month, in in accordance with the procedure for diagnosing HIV infection in adults, sequentially, starting from the first stage.

In the absence of positive dynamics of antibody titers to HIV in ELISA or CLLA and doubtful IB after 1 (one) month, a PCR test is performed. With the first doubtful result of IB in pregnant women at the later stages of testing, the issue of conducting additional testing on an individual basis is decided.

If the PCR result (HIV RNA) is negative, a second test is performed after 14 (fourteen) calendar days.

With a positive result of PCR (HIV RNA) in pregnant women in the third trimester, antiretroviral therapy is prescribed.

In the absence of positive dynamics of antibody titers to HIV in ELISA or CLLA and IB and a negative PCR result, the issue of a non-specific reaction to antibodies to HIV or serocontrol is resolved within a period of not more than 3 (three) months.

22. Upon receipt of a positive result of IB or an immunochromatographic test with a profile of HIV proteins (2 ENV, GAG, POL), the result "Anti-HIV antibodies detected" is issued to the territorial state health organization engaged in the prevention of HIV infection. In the result form intended for the medical organization where the blood of the examined person was taken, the number of the IB and the date of its issue are entered.

The IB result is issued within 15 (fifteen) working days from the moment the blood sample arrives at the laboratory performing the initial HIV test.

23. Persons with a previously established diagnosis of HIV infection are excluded from conducting a re-test with a confirmatory test (IB or immunochromatographic test with a profile of HIV proteins (2 ENV, GAG, POL)) as part of the guaranteed volume of free medical care.

24. Voluntary medical confidential testing for HIV infection of minors from 16 (sixteen) years of age and older is carried out at their request, incapacitated persons - with the consent of their legal representatives, in accordance with paragraph 2, Article 78 of the Code. When HIV infection is detected in a person under the age of 18 (eighteen) years, his parents or legal representatives are notified. Children under 16 (sixteen) years of age are examined with the informed consent of one of the parents or legal representative.

25. A certificate of testing for markers of HIV infection in the form in accordance with the appendix to these Rules is issued by state health organizations engaged in activities in the field of HIV prevention, RPHO to persons traveling outside the Republic of Kazakhstan. The certificate is valid for 3 (three) months.

26. When testing for HIV infection, test persons are provided with information related to pre-test and post-test counselling.

27. Pre-test counseling is provided through visual aids that are displayed at the waiting areas.

28. Pre-test counseling includes:

1) information on the benefits of HIV testing, transmission routes and the significance of HIV-positive and HIV-negative test results;

2) an explanation of the services available in case of an HIV-positive diagnosis, including an explanation of free antiretroviral therapy;

3) a brief description of the methods of prevention and examination of the partner in case of a positive test result for HIV infection;

4) a guarantee of the confidentiality of the test results.

29. Post-test counseling is carried out in order to inform the counselee about the result of the examination (negative, positive and indeterminate), the significance of the result and the motivation of the counselor to conduct behavior that minimizes the risk of HIV infection.

30. Post-test counseling includes:

1) communication to the patient of the test result and the value of the result;

2) informing about the possible presence in the seronegative window (with an uncertain or negative result) and the need for re-examination for HIV infection;

3) explaining how to reduce the risk of infection through behavior change;

4) informing about the possibilities of additional medical care for key populations, psycho-social assistance;

5) psychological help and support.

31. When confirming the status of HIV infection, a doctor or psychologist of a state health organization engaged in the prevention of HIV infection notifies the subject in writing of a positive result for HIV infection, conducts crisis counseling of the patient, which includes:

1) provision of psychological assistance;

2) informing about the features and clinical stages of HIV infection, the possibility of free treatment with antiretroviral drugs, the ways of transmission and the necessary preventive measures to prevent the transmission of HIV to others;

3) informing about the need for dynamic monitoring in the state healthcare organization carrying out activities in the field of HIV prevention;

4) informing about additional medical and social assistance in healthcare organizations, non-governmental organizations;

5) informing in writing about the need to comply with precautionary measures aimed at protecting their own health and the health of others, as well as warning about administrative and criminal liability for infecting other persons;

6) prevention options and identification of contact persons for testing for HIV infection;

7) guarantee of confidentiality of test results and any information;

8) signing by the patient of a sheet of confidential interview with a person infected with HIV in the form developed in accordance with subparagraph 31) of Article 7 of the Code.

32. With a positive result of testing for HIV infection, an informed consent is signed to enter personal data into the electronic tracking system. In case of refusal to enter personal data, the number and date of the IB result, initials, date of birth, and epidemiological history data are entered into the electronic tracking system.

|  |  |
| --- | --- |
|  | Appendix to the Rules for  Voluntary Anonymous and  (or) Confidential  Medical Examination and  Counseling on  HIV Issues within the  Guaranteed Volume of  Free Medical  Care in Public  Health Organizations  Operating in  the Field of HIV Prevention |
|  | The form |

**markerlerinin**   
**bolmauy turaly**   
**S E R T I F I K A T**   
**CERTIFICATE**   
**of**   
**absence of HIV infection markers**

Men (I / I am) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   
dәrigerdіn tegі, ati, аkesіnің ati (Bulgan zhagdayda) / surname, name, patronymic   
(if any) of the doctor) / name of doctor

Osymen kelesіnі rastaymyn (I hereby confirm / here by certify that)   
\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   
(patient tags, ati, әkesіnіңaty (Bulgan zhagdayda) latin аrіpterіmen /   
/ surname, name, patronymic (if any) of the patient in Latin letters / name of patient)   
\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   
( patient tags, ati, аkesіnіңы (Bulgan zhagdayda) ati, әkesіnің ati (Bulgan zhagdaida) Cyrillic / surname, name, patronymic   
(if any) of the patient in Cyrillic) name of patient

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   
(patient tugan datasy / date of birth of the patient / date of birth of patient)

Tekserildі /has been examined/ was tested on \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   
(date/date)

AITV-infection son markerleri boluyna teris natizhemen (   
for the presence in his/her blood of HIV infection   
markers and that there result of the test was NEGATIVE)

Atalgan certificate zertteu zhүrgіzіlgen kүnnen bastap ush ai boyi zharamdy.   
The certificate is valid for three months from the date of examination. The certificate is valid for   
three months since the testing day.

Mөr (Print/Stamp):

Coles (Signature/Signature):

Note (explanation on filling out the certificate certificate):

1. The certificate is issued only to one person, the issuance of collective certificates is not allowed.

2. The certificate must be completed in block Latin letters.

3. The dates of the study and birth are filled in the following sequence: day, month, year, the name of the month is written in letters, not numbers.

4. The certificate is signed by a specialist of the state healthcare organization engaged in the prevention of HIV infection or the WPHA and is certified by the round seal of the organization.

© 2012. RSE on REM "Institute of Legislation and Legal Information of the Republic of Kazakhstan" of the Ministry of Justice of the Republic of Kazakhstan