On the 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.ҚR DSM-204/2020. Registered with the Ministry of Justice of the Republic of Kazakhstan on November 27, 2020 No. 21682

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

1. To approve the rules for voluntary anonymous and (or) confidential medical examination and counseling on HIV infection within the framework of 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. To declare 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 counseling of citizens of the Republic of Kazakhstan, oralmans, foreigners and stateless persons permanently residing in the Republic of Kazakhstan. Kazakhstan, on HIV infection free of charge "(registered in the Register of State Registration of Normative Legal Acts under No. 11145, published on April 30, 2016 in the newspaper" Kazakhstanskaya Pravda "No. 82 (28208));

2) clause 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 DSM-62 "On Amendments and Additions to Certain Orders Ministry of 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 for Organization of Medical Aid of the Ministry of Health of the Republic of Kazakhstan, in the manner prescribed 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) posting 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 information on the implementation of the measures provided for in subparagraphs 1) and 2) of this paragraph.

4. Control over the execution of this order shall be entrusted to the supervising vice minister of health of the Republic of Kazakhstan.

5. This order comes into effect upon the expiration of 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 DSM-204/2020

Rules for voluntary anonymous and (or) confidential medical examination and counseling on HIV infection within the framework of 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 amount of free medical care (hereinafter - 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 the health of the people and the health care system "(hereinafter - the Code) and determine the procedure for conducting voluntary , anonymous and (or) confidential medical examination and counseling on HIV infection for citizens of the Republic of Kazakhstan, candidates, foreigners, stateless persons, refugees and persons seeking asylum for permanently and temporarily residing in the territory of the Republic of Kazakhstan, within the framework of the guaranteed volume of free medical care in state health 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 - HIV), characterized by a specific damage to the immune system and leading to its slow destruction until the formation of acquired immunodeficiency syndrome;

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

3) a state healthcare organization carrying out activities in the field of HIV infection prevention - an agency 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 infection prevention (hereinafter - RGOZ) - a health 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 the medical worker and the preservation of information about the identity of the examined person.

Chapter 2. The procedure for conducting voluntary anonymous and (or) confidential medical examination on HIV infection

3. Citizens of the Republic of Kazakhstan, candidates, 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 (no documents required);

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

4. Voluntary anonymous testing for HIV infection is carried out using express tests (hereinafter referred to as ET), detecting viral antigen p24 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, designed for self-testing in public health organizations working in the field of HIV prevention.

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

5. Based on the results of the express test, the subject is given post-test counseling with oral information about the test result.

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

In the case of a positive result of the express test, with the informed consent of the person being tested, a test 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 carrying out activities in the field of HIV prevention, the Russian State Humanitarian Health Organization, in accordance with the procedure for diagnosing HIV infection in adults in accordance with paragraphs 8-22 of these Rules.

7. Blood sampling for testing for 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 test tube with a separating gel and a coagulation activator with a volume of at least 5 (five) milliliters (hereinafter - ml). A blood sample is sent to the laboratory of the territorial state health organization carrying out activities in the field of HIV prevention, conducting HIV testing at a temperature of + 2° - + 8°C and used for serological tests within 5 (five) calendar days from the date of collection blood. 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 the confirming.

9. First stage: during the primary study (hereinafter - T1), the viral antigen p24 and antibodies to HIV of the first and second types are simultaneously determined by the method of enzyme immunoassay (hereinafter - ELISA) or chemiluminescence immunoanalysis (hereinafter - CLIA), or electrochemiluminescence 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 not less than 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 (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 inside the laboratory control is carried out with a positivity coefficient (OP / OP crit) in the range of 2.0–2.5 to assess the stability of the process.

10. If a negative T1 result is obtained, the subject is given the result "HIV negative". The test 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 is received for testing at the laboratory. Before issuing the result, post-test counseling is carried out.

11. If a positive T1 result is obtained, a second study (hereinafter - T2) is carried out using a test system different from T1, or ET. Tests of the third and fourth generations are used.

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

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

14. Upon receipt of the two positive serum sample results of studies of not less than one (1) ml sent to the laboratory WG CLEANUP to conduct confirmatory studies minutes in a period not later than three working days from the time the final formulation.

15. If conflicting research results (T1 +, T2-) are obtained, the result is considered doubtful. After 14 (fourteen) calendar days, a repeated blood sampling and testing for HIV infection is carried out, according to the first stage of the procedure for diagnosing HIV infection in adults (RGOZ transmits information about a dubious result for HIV infection to the territorial state health organization operating in in the field of HIV prevention, for retesting for HIV).

16. If a second questionable result for HIV infection is received after 14 (fourteen) calendar days, additional studies are carried out using other serological tests. A negative result is given for two negative results out of three studies conducted. A positive result is given for two positive results out of three studies conducted. In the case of examining pregnant women, molecular biological tests are additionally used (quantitative determination of HIV ribonucleic acid (hereinafter - RNA) with a test sensitivity of no more than 50 copies / ml or determination of proviral deoxyribonucleic acid (hereinafter e - pDNA) of HIV).

17. Confirmatory stage: confirmation of primary-positive samples from territorial state health organizations carrying out activities in the field of HIV infection prevention is carried out by ELISA or CLIA or ET and a confirmatory immune blot (hereinafter - IB) or immunochromatographic test with an HIV protein profile (2 ENV , GAG , POL) in the laboratory of the Russian Geographical Society.

When the RGOZ laboratory receives a biomaterial from a blood service organization with a positive polymerase chain reaction (hereinafter - PCR) and a negative or dubious result of ELISA or CLIA or ECLA, an additional study is carried out using molecular biological tests to identify HIV infection during the seronegative window ... The examined donor is undergoing serocontrol at the territorial state healthcare organization, which carries out activities in the field of HIV prevention until the diagnosis is confirmed or excluded.

18. Upon receipt of a negative result in ELISA or CLIA or ET in the laboratory of the Russian State Pedagogical University, the information is transferred to the

territorial state health organization carrying out activities in the field of HIV prevention, for repeated blood sampling and HIV testing after 14 (fourteen) calendar days, according to the procedure for diagnosing HIV infection in adults (stage 1).

19. If a positive result is obtained in ELISA, CLIA, or ET, a confirmatory test is carried out in the laboratory of the Russian Geological Society: IB or immunochromatographic test with a profile of HIV proteins (2 ENV, GAG, and POL).

20. If 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 CLIA or ET is obtained, a second study is carried out after 1 (one) or 3 (three) months, according to the procedure diagnosis of HIV infection in adults, consistently, starting from the first stage. In the absence of positive dynamics of titers of antibodies to HIV in ELISA or CLIA and negative IB after 3 (three) months, a PCR study is performed.

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

In the absence of positive dynamics of titers of antibodies to HIV in IF A or CLIA and doubtful IB after 1 (one) month, a PCR study is carried out. At the first questionable result of IB of pregnant women in the late stages of testing, the issue of additional testing is decided on an individual basis.

In case of a negative PCR result (HIV RNA), a second study is carried out 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 titers of antibodies to HIV in ELISA or CLIA and IB and a negative result of PCR, within a period of no more than 3 (three) months, the issue of a nonspecific reaction to antibodies to HIV or setting for serocontrol is resolved.

22. If a positive IB result or an immunochromatographic test with a HIV protein profile (2 ENV, GAG, and POL) is obtained, the result "HIV antibodies detected" is issued to the territorial state health organization that carries out activities in the field of HIV prevention. In the result form, intended for the medical organization, where the blood sample of the examined person was taken, the IB number and the date of its issue are entered.

The IB result is issued within 15 (fifteen) working days from the moment the blood sample is received by the laboratory that performs the initial test for HIV infection.

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

24. Voluntary medical confidential HIV testing of minors aged 16 (sixteen) 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 research for markers of HIV infection in the form in accordance with the appendix to these Rules is issued by state healthcare organizations carrying out activities in the field of HIV infection prevention, RGOZ 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 counseling.

27. Pre-test counseling is provided through visual campaigns that are displayed in waiting areas.

28. Pre-test counseling includes:

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

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

3) a brief description of the methods of prevention and examination of a partner with a positive HIV test result;

4) guarantee of confidentiality of test results.

29. Post-test counseling is carried out with the aim of informing the counselor about the test result (negative, positive and uncertain), the meaning of the result and the counselor's motivation for 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 stay in the seronegative window (with an undefined 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 healthcare organization operating in the field of HIV prevention, notifies the examinee in writing about a positive result for HIV infection, conducts crisis counseling of the patient, which includes:

1) provision of psychological assistance;

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

3) informing about the need for dynamic observation 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 observe precautionary measures aimed at protecting one's own health and the health of others, as well as warning about administrative and criminal liability for infecting other persons;

6) options for prevention and establishment of contact persons for examination for HIV infection;

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

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

32. In case of a positive test result 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, data from the epidemiological history are entered into the electronic tracking system.

Appendix to the rules for
voluntary anonymous and
(or) confidential
medical examination and
counseling on
HIV infection within the framework of the
guaranteed volume of
free medical
care in public
health organizations
operating in the
field of HIV prevention
The form

CERTIFICATE
of absence of HIV infection markers

I am)_____
/ name of doctor
here by certify that)
_____
/name of patient)
_____
(date of birth of patient)
was tested on _____
(date)
For the presence in his/her blood of HIV infection markers and that there result of the test was NEGATIVE)
Certificate is valid for three months since the testing day.
Stamp:
Signature:

Note (for clarification on filling out the certificate):

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

2. The certificate is filled in with block letters.

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

4. The certificate is signed by a specialist of the state health organization carrying out activities in the field of HIV prevention or RGOZ and is certified by the organization's round seal.