# Analysis of national protocols for HIV testing service delivery

in 7 countries of Eastern Europe and Central Asia

**2023**

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## List of abbreviations

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| AIDS | acquired immunodeficiency syndrome |
| ART | antiretroviral therapy |
| ECLA | immunochemiluminescent assay/electrochemiluminescent analysis |
| EECA | Eastern Europe and Central Asia |
| ELISA | enzyme-linked immunosorbent assay |
| ET/RT | rapid test |
| HIV | human immunodeficiency virus |
| HTS | HIV testing services |
| MSM | men who have sex with men |
| NGOs | non-governmental / non-profit organizations |
| PCR | polymerase chain reaction |
| PLHIV | people living with HIV |
| PWID | people who inject drugs |
| STIs | sexually transmitted infections |
| UN | United Nations |
| UNAIDS | Joint United Nations Program on HIV/AIDS |
| VL | viral load |
| WB/IB | immunoblotting (western blot) |
| WHO | World Health Organization |

## Introduction

HIV testing services (HTS) are a pathway to prevention, care and treatment for those with HIV infection. Despite advances in scaling up and disseminating HTS in recent years, UNAIDS estimates[1], that in 2021 only 85% (75%-97%) of people living with HIV (PLHIV) were aware of their status. There were 1.5 million [1.1 million–2.0 million] new HIV infections in 2021, of which key populations (sex workers and their clients, gay men and other men who have sex) relationships with men, people who inject drugs, transgender women) and their sexual partners accounted for 70% of new HIV cases worldwide. To ensure effective implementation of HTS, they should be focused on PLHIV who are unaware of their diagnosis, as well as HIV-negative individuals at risk who could benefit from prevention program services.

Complementary and more targeted approaches to HTS delivery are critical to achieving the UNAIDS 95-95-95 global targets, in which the first 95 targets 95% of all HIV patients who know they are HIV positive up to 2030[2]. To achieve this, decentralization of services and simplification of testing procedures should be ensured to increase access and increase coverage of those who need it most; reduce the time to establish the final diagnosis; ensure prompt and effective ART prescription without loss of patients from medical observation; ensure the quality of testing and the accuracy of the results.

To effectively implement HTS and achieve the Sustainable Development Goals and the UNAIDS response to AIDS, at the global level and in each country separately, during 2015-2021, WHO published recommendations on the development of national strategies/policies for HIV testing and testing. At the same time, suboptimal testing strategies outlined in the national HIV testing policy can be the cause of ineffective HTS delivery, as well as an obstacle to achieving goals.

[1] https://www.unaids.org/ru/resources/fact-sheet

[2] https://www.unaids.org/ru/AIDS_SDGs

To study the level of implementation of WHO recommendations on HTS at the level of countries in Eastern Europe and Central Asia (EECA), an analysis of national HIV testing policies was conducted among 7 WHO member countries (Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Tajikistan, Uzbekistan). Data were collected on whether these countries have a national AIDS prevention and control strategy/policy, what approaches are envisaged for the provision of HTS (including whether communities, non-governmental organizations are involved in the provision of such services, whether lay workers can conduct express -HIV testing, is HIV self-testing available, is the use of dual rapid tests for simultaneous detection of HIV/syphilis serological markers part of a national strategy to expand sexually transmitted infection (STI) testing services to key populations). The national HIV testing strategy, testing algorithms, and testing quality assurance in each country were also reviewed for compliance with WHO recommendations.

## Methodology and structure of the report

The report contains summary information on 7 countries of Eastern Europe and Central Asia (EECA) (Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Tajikistan, Uzbekistan).

To analyze the compliance of national policies with WHO recommendations, a form developed and proposed by WHO was used. It consisted of several parts, namely:

• Basic information:

- Availability of National HIV testing strategy;
- Regulatory act/ MoH order, last year of revision;
- Is testing strategy part of National HIV/AIDS strategy

• Testing approaches used in the country:

- Self-testing implemented;
- Country has a written national policy on HIV self-testing;
- Assisted HIV partner notification included in national policy;
- National policy or strategy on linking HIV testing and counseling and enrollment in care;
- National policy or strategy on linking HIV testing and prevention following an HIV-negative diagnosis;
- Provider-initiated testing and counseling;
- Dual HIV/syphilis rapid diagnostic tests for key populations included in national policy;
- Social network-based HIV testing service approaches included in national policy;
- Lay provider testing;
- Community-based testing;
- General reflections on alignment with latest WHO guidelines

• HIV testing algorithm and quality assurance:

- Three test strategy is implemented;
- RDTs recommended as screening tests;
- Western Blotting used as a confirmatory test;
- Tests pre-qualified by WHO;
- Procedures for confirming the quality of HIV tests provided;
- External quality assurance scheme;
- Retesting before enrollment into ART

• Main gaps;

• Main recommendations.

The form involves entering information to assess the compliance of national HIV testing strategies/approaches and their algorithms with the WHO 2021 recommendations[3] in the form of "Yes" or "No" answers. The evaluation was carried out on the basis:

- available for analysis of the current (most relevant) legal documents governing the organization and provision of HIV testing services in each country obtained from open sources;
- analysis of national recommendations on treatment, testing, prevention of HIV infection and the provision of such medical services for compliance with the recommendations of the World Health Organization, implemented by national specialists in the field of HIV treatment of 7 countries (information provided by WHO);
- data on analytics and legislation and policies of countries presented on the website of UNAIDS and WHO[4].

The report is structured as follows: after the introduction and methodology, there are brief descriptions of the main findings, conclusions and recommendations (taking into account the latest WHO recommendations, 2021) for each of the 6 countries induded in the analysis. Basically, the brief descriptions of the situation for each of the countries correspond to the items from which the WHO questionnaire form consisted. As far as possible, the information was grouped into thematic blocks. Brief country summaries are followed by general conclusions and recommendations from the review of national HIV testing protocols in all 7 countries. Annex 1 contains the complet information collected by each country separately in the form proposed by WHO (it is presented in the table in excel).

[3] Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach July 2021 - https://www.who.int/publications/i/item/9789240031593

[4] https://lawsandpolicies.unaids.org/selectdataresult?lan=ru

# Belarus

In Belarus, the clinical protocol “Provision of medical care to patients with HIV infection” (CP HIV 2022) was taken as the basis for the analysis for compliance with the WHO 2021 recommendations. Most of the issues considered in the WHO recommendations are regulated by this document. At the same time, a number of issues included in the WHO recommendations are not regulated in it: including some issues of organizing the work of programs and services, some procedural issues. To assess the regulation of access to and provision of HIV testing services, the following documents were analyzed:

1. RESOLUTION OF THE MINISTRY OF HEALTH OF THE REPUBLIC OF BELARUS dated July 25, 2022 No. 73 On the approval of the clinical protocol "Providing medical care to patients with HIV infection"
2. DECISION OF THE MINISTRY OF HEALTH OF THE REPUBLIC OF BELARUS July 12, 2012 No. 97 On the establishment of clinical indications for which persons are subject to mandatory medical examination, and the list of other categories of persons subject to mandatory medical examination
3. RESOLUTION OF THE MINISTRY OF HEALTH OF THE REPUBLIC OF BELARUS November 8, 2017 No. 93 On approval of the Instruction on the procedure for organizing the provision of medical care to persons infected with the human immunodeficiency virus
4. Decree of the Ministry of Health of the Republic of Belarus of June 27, 2013 No. 57 Instructions on the procedure for pre-test and post-test counseling with the provision of psychological assistance during a medical examination for the detection of human immunodeficiency virus
5. Order of the Ministry of Health of the Republic of Belarus dated March 20, 2019 No. 345 On approval of the work procedure
6. RESOLUTION OF THE MINISTRY OF HEALTH OF THE REPUBLIC OF BELARUS December 1, 2017 No. 106 On approval of the Instructions on the procedure for carrying out preventive measures to prevent the spread of socially dangerous diseases, the human immunodeficiency virus anonymously
7. RECOMMENDATIONS FOR CONDUCTING VOLUNTARY COUNSELING AND TESTING FOR HIV instructions for use, approved by the Ministry of Health of the Republic of Belarus on December 23, 2011 Registration No. 134-1211
8. Decree of the Ministry of Health of the Republic of Belarus dated July 24, 2012 No. 112. On some issues of medical examination for the detection of diseases that pose a danger to public health, the human immunodeficiency virus
9. DECISION OF THE MINISTRY OF INTERNAL AFFAIRS OF THE REPUBLIC OF BELARUS AND THE MINISTRY OF HEALTH OF THE REPUBLIC OF BELARUS May 21, 2012 No. 145/50 On the procedure for the delivery of a person in respect of whom there are sufficient grounds to believe that he has a socially dangerous disease, human immunodeficiency virus or a socially dangerous disease subject to compulsory medical examination or compulsory hospitalization and treatment, to a state healthcare organization

National recommendations for diagnosing HIV infection do not fully comply with the WHO 2021 recommendations. Taking into account the identified inconsistencies and gaps in regulation, it should be recommended that the national health authorities of the Republic of Belarus develop harmonized national protocols in accordance with modern WHO recommendations on the points listed below (the main results of the analysis and recommendations to improve the quality of HIV testing services provided are presented below in table).

## Main results of the analysis and recommendations

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| **National HIV Testing Strategy** | The National HIV Testing Strategy, as well as the provision of unlimited access to HIV testing services, are part of the HIV/AIDS response strategy, which is also reflected in the Law of the Republic of Belarus dated January 7, 2012 "On Preventing the Spread of Diseases Dangerous to Public Health", human immunodeficiency virus. Depending on the grounds, the medical examination of the patient is divided into: voluntary; mandatory and mandatory. A voluntary medical examination may be conducted anonymously.<br>Mandatory medical examinations are subject to persons: specified in paragraph four of part one of Article 10 of this Law (donors of blood and (or) its components, donors of germ cells, living donors of organs and (or) human tissues (hereinafter referred to as donors), as well as employees of certain specialties (professions) for the presence of socially dangerous diseases, HIV); according to clinical indications established by the Ministry of Health of the Republic of Belarus; other categories of persons, the list of which is determined by the Ministry of Health of the Republic of Belarus.<br>Persons in respect of whom there are sufficient grounds to believe that they have a socially dangerous disease, HIV, are subject to compulsory medical examination. Sufficient grounds to believe that a person has HIV are: a direct indication of a person who has HIV to a person as a possible source of his HIV infection, or as a person who had sexual contact with him, or as a person who injected drugs with him, psychotropic substances intravenously with one syringe; results of clinical-instrumental and (or) laboratory studies indicating that a person has signs of HIV; a person evades a mandatory medical examination.<br><br>To establish HIV status in the country, **tests with a different set of antigenic, antibody determinants and high sensitivity (at least 99%) and specificity (at least 99%) are used.** However, **the HIV testing strategy does not fully comply with the 2021 WHO recommendations.**<br>To establish HIV-positive status, in addition to simple rapid tests and ELISA tests, the molecular genetic method (identification of HIV RNA) and the immune blot method are also used. |

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| **Testing approaches used in the country** | HIV testing services are provided both in hospitals and non-governmental organizations. Screening testing for HIV infection **using rapid tests** is carried out by medical workers in healthcare organizations, employees of HIV-service NGOs, as well as by **self-testing of the population with rapid tests**. At the same time, the national policy on self-testing, if it exists, was not available for analysis.<br>The regulatory documents selected for analysis **do not contain information about whether specialists without special medical education are allowed to test for HIV**.<br><br>The National Program **envisages linking testing programs with prevention programs for those members of key populations who are HIV negative (with the participation of NGOs) and with care and treatment programs for people living with HIV (PLHIV)**. To improve communication with HIV prevention and treatment programs, joint work of medical institutions and NGOs has been established.<br><br>**Information on the list of services provided within the framework of prevention programs for those who are HIV-negative can be obtained from individual sources** (**HIV 2022 CP** - Prescribing PrEP to people at high risk of HIV infection from among the following populations: people who use drugs; men who have sex with men, sex workers, transgender people, sexual partners of PLHIV who have not achieved viral suppression (undetectable VL), **order of the Ministry of Health of the Republic of Belarus dated December 1, 2017 No. 106 - carried out by state healthcare organizations and non-governmental non-profit organizations** implementing state social order in the field of carrying out preventive measures **to prevent the spread of diseases that pose a threat to public health, the human immunodeficiency virus, preventive measures to prevent the spread of socially dangerous diseases, HIV anonymous**, aimed at *ensuring wide access of clients to testing for HIV; formation of adherence to medical examination and treatment in HIV-positive clients; developing safe or less dangerous sexual and injecting behavior among clients; raising awareness among clients on issues related to HIV infection, parenteral viral hepatitis, tuberculosis; provides motivating consumables (syringes, needles, condoms, toothpaste, etc.)* to encourage clients to participate in preventive activities and contribute to the formation of safe behavior skills.<br>**Health care** for people living with HIV is based on clinical protocols or methods of care. It is provided in public health organizations at the place of residence (place of stay) according to the profile of the clinical manifestations of the disease. To receive consulting, informational, psychological, legal assistance, **to carry out activities to maintain high adherence to medical supervision and treatment,** referral and (or) support to specialized organizations to solve medical and social problems that worsen the quality of life and negatively affect health, **patients with HIV-positive status belonging to key populations,** if possible, are referred to the nearest office for the prevention of HIV infection among injecting drug users or anonymous counseling centers **based on HIV service NGOs.**<br><br>Regulatory documents during post-test counseling in case of a positive test result provide for assistance to PLHIV in communicating a positive test result to a sexual partner and correcting relations with him, discussing the possibility of sending a partner for testing. However, **there is no clear definition of whether partner services are provided for contact tracing, index testing** (contact tracing of PLHIV is carried out during epidemiological investigations). It does not contain documents of information about **whether it is possible to provide services based on social networks. The provision of HIV/syphilis testing services using dual tests has also not been reflected.** |

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| **HIV testing algorithm and quality assurane** | The HIV testing guidelines are part of the general order on the HIV 2022 CP. The HIV testing algorithm has its own characteristics, which **does not allow us to speak of its compliance with the WHO 2021 recommendations.**<br>In particular, the regulatory document provides for **several stages of testing - screening (using express tests in medical institutions or NGOs) and diagnostic (testing in laboratories in case of receiving reactive results at the screening stage)**. When performing diagnostic testing, parallel rather than sequential use of tests is assumed (at the first stage, biological material is tested to detect antibodies to HIV 1, 2 or antibodies, antigen and (or) antigens of HIV 1, 2 by ELISA or ICA, including with using two rapid blood tests with a different set of antigenic, antibody determinants and high sensitivity (at least 99%) and specificity (at least 99%).<br>If a **reactive (positive) result is obtained at the first stage** of diagnostic testing for HIV infection (positive ELISA or ICA **or positive one of two or both of the rapid tests performed**), at the second stage, the biological material is tested for the detection of **HIV RNA**.<br>In the case of a reactive (**positive**) result for the detection of **HIV RNA** at the second stage of diagnostic testing for HIV infection, the patient's **HIV-positive status is recorded**. In the case of a **non-reactive** (negative) result for the detection of **HIV RNA** at the second stage of diagnostic testing for HIV infection, a biological blood sample is taken again in tubes with EDTA and a **repeated laboratory test using the WB method** to determine the presence of antibodies to HIV antigens 1, 2 (if possible, the WB study is carried out using the same sample).<br>If a reactive **(positive) WB** result is obtained, the patient's **HIV-positive status is recorded**. In case of obtaining a non-reactive (**negative**) result of the study conducted by the **WB** method, the patient's **status is recorded as negative**. Upon receipt of **indeterminate results** of diagnostic testing for HIV infection, carried out using the **WB** method, **patients are referred for repeated diagnostic testing** for HIV infection **after 3 months** in order to finally determine their HIV status.<br><br>**Re-testing before ART is not included in the HIV treatment guidelines set out in the HIV 2022 CP**.<br><br>Documents available for analysis **do not contain requirements for purchasing WHO prequalified tests, conducting in-laboratory quality control programs, participating in external quality assessment programs for HIV testing, or conducting Procedures for confirming the quality of HIV tests provided.** |
| **Recommendations** | 1. Consider and harmonize with WHO recommendations all policies, strategies and algorithms for determining HIV status:<br>• simplify testing algorithms;<br>• include dual HIV/syphilis tests in testing algorithms for screening pregnant women in antenatal clinics and representatives of key populations;<br>• before starting ART, identify HIV-positive patients to eliminate possible laboratory errors at previous stages of testing;<br>• include in the regulations the requirements for assessing the characteristics of medical devices for HIV testing before their use in practice;<br>• include in regulations the requirement for the mandatory participation of all providers of HIV testing services in programs for external evaluation of the quality of testing.<br>2. Develop and conduct a procedure for verifying testing algorithms with subsequent revision (1 time in 2-3 years);<br>3. Consider the possibility of delegating authority to persons without special medical education to provide HIV testing services (including testing).<br>4. Consider the possibility of decentralizing HIV testing services, including using express tests, confirmatory testing to transfer such functions to the level of medical institutions, which will simplify logistics, significantly reduce the time to receive test results, and speed up the decision on the diagnosis HIV infection and treatment prescriptions. |

# Georgia

**Regulation of access to the provision of HIV testing services, as well as the testing strategy and algorithm in Georgia is carried out on the basis of legal acts. The following were analyzed for compliance with the WHO 2021 recommendations:**

**1. Resolution of the Government of Georgia No. 4 dated January 12, 2022 St. Tbilisi (draft) On Approval of State Health Programs for 2022, "HIV/AIDS Treatment", Appendix No. 7, (program code 270 30 207) (https://matsne.gov.ge/ka/document/view/5352433?publication =0)**

**2. Consolidated guidelines on the use of antiretroviral drugs for the prevention and treatment of HIV/AIDS, National Clinical Practice Recommendation (recommendation), 2021**

**3. Order of the Ministry of Health and Social Protection of the Government of Georgia dated September 18, 2020 No. 01-461 / O "HIV infection / Routine AIDS surveillance in Georgia" - public National recommendations on health protection (guidelines) "(Appendix 1) - bears advisory nature**

**National recommendations for diagnosing HIV infection do not fully comply with the WHO 2021 recommendations. Taking into account the identified inconsistencies and gaps in regulation, the national health authorities of Georgia should be recommended to develop harmonized national protocols in accordance with modern WHO recommendations on the points listed below (the main results of the analysis and recommendations to improve the quality of HIV testing services provided are presented in the table below).**

## Main results of the analysis and recommendations

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| **National HIV Testing Strategy** | The National HIV Testing Strategy, as well as the provision of unlimited access to HIV testing services, are part of the HIV/AIDS response strategy, which is also reflected in the State Health Program for 2022, approved by the Resolution of the Government of Georgia No. 4 dated January 12, 2022. St. Tbilisi (draft) "On the Approval of State Health Programs for 2022", "HIV/AIDS Treatment", Annex No. 7, (program code 27 03 02 07), where Article 2 provides that:<br>1. The beneficiaries of the program are citizens of Georgia. In addition, users of specific antiretroviral drugs required for treatment may be together with the persons referred to in this article:<br>a) citizens of foreign states or stateless persons permanently residing in Georgia, as well as persons applying for the said status, at the stage of carrying out the necessary procedures until obtaining the respective status;<br>b) holders of student status with a temporary residence permit in Georgia, studying at an authorized higher education institution of Georgia; Citizens of foreign states permanently residing in Georgia or stateless persons who are on probation (until the probation period is canceled and they leave the country);<br>c) persons working in diplomatic missions of foreign states operating in the territory of Georgia;<br>d) persons infected with coronavirus in the territory of Georgia, regardless of citizenship;<br>e) The population in the occupied territory of Abkhazia, regardless of citizenship.<br>2. Persons in correctional institutions, regardless of the lack of an official identity document.<br>3. High-risk groups (injecting drug users and their sexual partners, men who have sex with men (MSM), transgender people, people who have sex for any reward (sex workers) and their clients) identified in accordance with the order (with a 15-digit encrypted code) of the order of the Minister of Labour, Health and Social Protection of Georgia dated July 23, 2010 No. 217/O "On approval" of guidelines for routine AIDS surveillance.<br><br>The HIV testing strategy is reflected in the order of the Ministry of Health and Social Protection of the Government of Georgia dated September 18, 2020 No. 01-461 / O "HIV infection / Routine AIDS surveillance in Georgia - Public National recommendations on health protection (recommendations)" (Appendix 1) Three different ELISA tests are used for testing, including rapid tests, screening test A has high sensitivity (99% or more for rapid test and 100% for ELISA), tests B and C have high specificity ( 99% or more for both rapid test and enzyme immunoassay) **However, the HIV testing strategy does not fully comply with the WHO 2021 recommendations** - if the results of the 2nd and 3rd line tests do not match, the final conclusion of a positive HIV status is accepted based on the result of PCR RNA (DNA) At the same time, in accordance with WHO recommendations, in these cases, it is impossible to establish a diagnosis of HIV infection and the client is invited for a second examination after 14 days. In addition, the HIV viral load test is not diagnostic. |

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| **Testing approaches used in the country** | The issues of diagnosing HIV infection are reflected in the order of the Ministry of Health and Social Protection of the Government of Georgia dated September 18, 2020 No. 01-461 / O and in the State Program for 2022 "HIV / AIDS Treatment", Annex No.7, (program code 27 03 02 07). HIV testing services are provided both in hospitals and non-governmental organizations. **It is important to note that the country provides for an approach integrated with prevention programs to verify the diagnosis of HIV infection, which is carried out directly on the basis of the organization providing preventive services, centers and public organizations using the GeneXpert device (Cefeid) to determine viral RNA). This model of decentralized provision of HTS reduces the time it takes to determine HIV-positive status and connects PLHIV with treatment.**<br>In addition to HTS provided directly at health facilities or NGOs, the country **has a model of self-testing** with the provision of tests through various models (delivery through NGOs, medical organizations, ordering via the Internet, pharmacies, dispensing machines), integration into prevention programs (including PrEP); **HIV testing through social media,** when a person living with HIV or at high risk of contracting HIV invites members of their social network to get tested for HIV.<br>At the same time, national policies **did not reflect the possibility of testing for HIV by specialists without special medical education.** There is **no information** on whether accompanied **notification of partners about the potential risk of HIV infection** is provided, and approaches to index testing are not defined. **The provision of HIV/syphilis testing services using dual tests has also not been reflected.**<br>The state policy in the field of HTS **provides for linking testing programs with prevention programs for those members of key populations who are HIV negative (mainly with the participation of NGOs), and with care and treatment programs for people living with HIV (PLHIV).** Order of the Ministry of Health and Social Protection of the Government of Georgia dated September 18, 2020 No. 01-461/O contains recommendations on the application of best practices for their successful implementation, in accordance with WHO recommendations |
| **HIV testing algorithm and quality assurane** | The algorithm for testing for HIV using three tests is presented in the order of the Ministry of Health and Social Protection of the Government of Georgia dated September 18, 2020 No. 01-461/O and in the State Program for 2022 "Treatment of HIV Infection". /AIDS", Appendix No. 7, (program code 27 03 02 07). At the same time, the **presented algorithm does not allow us to speak of its full compliance with the WHO 2021 recommendations.**<br>In particular, the national HIV testing algorithm suggests using 2 additional tests for verification upon receiving a positive screening result and interpreting the results as follows: 2 negative responses indicate a negative result, and 2 reactive responses indicate that the patient is infected with HIV. **Upon receipt of 1 positive result and 1 negative result (result mismatch), the blood sample is verified by the HIV RNA (DNA) polymerase chain reaction method.** A negative PCR test result is considered HIV free, while a positive result indicates that the patient is HIV positive and will be offered entry into a treatment and care program.<br>The documents available for analysis contain information that **rapid tests and ELISA tests are used for HIV testing in both in medical institutions and in NGOs.**<br><br>**Retesting before ART** (determining the level of HIV-1 viral load) **is included** in the recommendations for the treatment of HIV infection, set out in the Consolidated recommendations for the use of antiretroviral drugs for the prevention and treatment of HIV/AIDS, National clinical practice recommendation (recommendation), 2021.<br><br>Documents available for review indicate that **each test used for both screening and confirmatory studies must be prequalified by WHO** (or be included in the Global Fund's recommended list). It is also noted that **quality control should also be carried out in relation to persons conducting testing (qualifications, skills)** and premises (area, equipment, workload, storage and logistics of testing, etc.). At the same time, the **requirements and procedure for conducting the Procedures for confirming the quality of HIV tests have not been approved.** |

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| **Recommendations** | 1. Consider harmonizing with the WHO 2021 guidelines on HIV testing strategies and algorithms for determining HIV status:<br>• The PCR testing strategy for verifying the diagnosis of HIV infection needs to be reviewed because the test to determine the level of HIV-1 viral load is not diagnostic, and if an HIV test result is indeterminate, the client is invited to retest after 14 days;<br>• include dual HIV/syphilis tests in testing algorithms for screening pregnant women in antenatal clinics and representatives of key populations;<br>• include in the manual a procedure for verifying testing algorithms with regular review (every 2-3 years), as well as requirements for assessing the characteristics of medical devices for HIV testing before they are used in practice by providers of such services.<br><br>2. Define the powers of persons without special medical education to provide HIV testing services (including the direct performance of the testing procedure). |

# Kazakhstan

**In the country, HIV testing is regulated by:**

1. **By order of the Minister of Health of the Republic of Kazakhstan dated November 27, 2020 No. KR DSM-211/2020, registered with the Ministry of Justice of the Republic of Kazakhstan on November 30, 2020 No. 21692 "On approval of the rules for mandatory confidential medical examination for the presence of HIV infection" (as amended on 26.01 .2022 No. ҚР ДСМ-6);**
2. **On approval of the rules for carrying out activities to prevent HIV infection Order of the Minister of Health of the Republic of Kazakhstan dated October 19, 2020 No. ҚР ДСМ-137/2020. Registered with the Ministry of Justice of the Republic of Kazakhstan on October 21, 2020 No. 21467;**
3. **Order of the Ministry of Health of the Republic of Kazakhstan No. KR DSM - 204/2020 dated November 25, 2020 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**
4. **Order "Clinical protocol "HIV infection in adults" No. 97 dated 06/11/2020, approved by protocol decision No. 97 dated 06/11/2020 by the Joint Commission on the quality of medical services of the Ministry of Health of the Republic of Kazakhstan.**

**National recommendations for diagnosing HIV infection do not fully comply with the WHO 2021 recommendations. Taking into account the identified inconsistencies and gaps in regulation, it should be recommended that the national health authorities of the Republic of Kazakhstan harmonize national protocols, bringing them into line with modern WHO recommendations on the points listed below (the main results of the analysis and recommendations for improving the quality of HIV testing services provided are presented below in the table).**

## Main results of the analysis and recommendations

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| **National HIV Testing Strategy** | The National HIV Testing Strategy, as well as the provision of unrestricted access to HIV testing services, are part of the HIV/AIDS response strategy, which is also reflected in the relevant legal acts. The National HIV Testing Strategy is targeted and includes programs/activities to meet the needs of key populations: sex workers (male and female); people who inject drugs; men who have sex with men.<br><br>The country has established rules for a **mandatory confidential medical examination** for the presence of HIV infection, which comply with the requirements of the Code of the Republic of Kazakhstan dated July 7, 2020 "On the health of the people and the healthcare system" (paragraph 2 of Article 162) and determine the procedure for conducting a mandatory confidential medical examination for the presence of HIV - infections within the framework of the guaranteed volume of free medical care in state healthcare organizations engaged in activities in the field of HIV prevention.<br><br>**Mandatory testing for HIV, as well as criminal liability for evading treatment and infecting others in accordance with Article 118 of the Criminal Code of the Republic of Kazakhstan, is provided for certain categories of the population.**<br><br>The HIV testing strategy in the Republic of Kazakhstan **does not comply** with the WHO 2021 recommendations and involves the use of two ELISA tests or an immunochemiluminescent assay or electrochemiluminescent analysis (ECLA) using test systems with a diagnostic sensitivity of 100% (lower limit 95% confidence interval - not less than 99%); diagnostic specificity - not less than 99% (the lower limit of the 95% confidence interval - not less than 98%); analytical sensitivity not more than 2 IU / ml (minimum amount of p24 antigen), or using fourth-generation rapid tests, as well as a **confirmatory immune blot (hereinafter referred to as WB)** or an immunochromatographic test with a profile of HIV proteins (2 ENV, GAG, LPO) in laboratories of Kazakhstan Scientific Center for Dermatology and Infections Diseases, Ministry of Health. |

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| **Testing approaches used in the country** | The rules for medical examination for the presence of HIV infection were developed in accordance with paragraphs 1 and 2 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" and determine the procedure for conducting a mandatory confidential medical examination for the presence of HIV infection within the guaranteed the volume of free medical care in public health organizations operating in the field of HIV prevention.<br>Services of voluntary anonymous and (or) confidential medical examination and counseling on HIV infection are provided for citizens of the Republic of Kazakhstan, kandas, foreigners, stateless persons, refugees and asylum seekers permanently and temporarily residing in the territory of the Republic of Kazakhstan.<br><br>HIV testing services (including anonymous testing) are provided by both hospitals and non-governmental organizations (using rapid tests), but testing is performed only by a medical professional. Medical institutions also take biological material for research, which is sent to the laboratories of state medical institutions of the country (including after receiving a reactive rapid test result).<br><br>Regulations/policies governing approaches to HTS provision **do not reflect the possibility of self-testing**. At the same time, there is the possibility of buying express tests at a pharmacy.<br><br>**The use of dual rapid tests for the diagnosis of HIV/syphilis** in pregnant women in antenatal clinics, as well as when examining representatives of key populations**, has not been reflected in national HIV testing policies.**<br><br>The country's national policies available for analysis **did not reflect the provision of partner services**, including approaches to index testing and social network-based approaches to HIV testing services. At the same time, in paragraph 23 of the order of the Minister of Health of the Republic of Kazakhstan dated November 27, 2020 No. ҚР ДСМ-211/2020 "On approval of the rules for mandatory confidential medical examination for the presence of HIV infection", the following is indicated: healthcare organizations that identified during the medical examination the fact of HIV infection, **notify the subject in writing** about the result obtained, inform about the need to take precautionary measures aimed at protecting their own health and the health of others, and also **warn about administrative and criminal liability for evading treatment and infecting other persons in accordance with Article 118 of the Criminal Code of the Republic Kazakhstan, with the patient signing a confidential interview sheet with a person infected with HIV in the form No. 095 / y, approved in accordance with order No. ҚR DSM-175/2020.**<br>Mandatory testing for the presence of HIV infection in sexual partners of HIV-infected, partners in the joint use of injecting drugs, children under 16 years of age in case of detection of HIV infection in the mother is provided according to epidemiological indications in accordance with the order of the Minister of Health of the Republic of Kazakhstan dated November 27, 2020 No. RK DSM-211/2020 "On approval of the rules for mandatory confidential medical examination for the presence of HIV infection" |
| **HIV testing algorithm and quality assurane** | The HIV testing algorithm in the Republic of Kazakhstan is provided for by the Order of the Minister of Health of the Republic of Kazakhstan dated November 27, 2020 No. ҚР ДСМ-211/2020 "On approval of the rules for mandatory confidential medical examination for the presence of HIV infection" and **does not comply** with the WHO 2021 recommendations. For HIV testing both instrumental methods and rapid tests are used, and the result of an **immune blot is also mandatory for verifying HIV-positive status**. In some cases, the testing algorithm for verifying the diagnosis also includes determining the level of HIV-1 viral load. At the same time, the HIV-1 viral load test is not diagnostic.<br><br>The rapid screening test (A0) can be performed both on the basis of a medical institution and an NGO (in this case, upon receipt of a reactive test result, the full testing algorithm is performed in the laboratory, and the screening test is considered triage).<br><br>***Tests to establish HIV-positive status are expected to be carried out only in state-*** |

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| | ***owned laboratories, and the final diagnosis can only be confirmed by one laboratory in the country. This practice has its drawbacks, since such centralization can lead to a delay in obtaining the final test result and timely involvement of PLHIV in treatment and care programs, as well as additional financial costs for providing logistics for biological material sent for research by medical institutions/laboratories.***<br><br>**There is no retesting before ART.**<br>In the country, the requirements for medical devices to be purchased are determined by the Decree of the Government of the Republic of Kazakhstan dated June 4, 2021 No. 375 "On approval of the Rules for organizing and conducting the procurement of medicines, medical devices and specialized medical devices within the guaranteed volume of free medical care and medical care and (or) in the system of compulsory social health insurance, pharmaceutical services and invalidation of certain decisions of the Government of the Republic of Kazakhstan". This regulation **does not require the procurement of only WHO prequalified medical devices.** In this regard, tests are purchased in the country in accordance with the requirements for their technical characteristics (sensitivity and specificity), defined in the order dated November 27, 2020 No. ҚР ДСМ-211/2020. Sensitivity and specificity values approved by country regulations are in line with WHO recommendations for tests used to diagnose HIV infection.<br><br>The same order dated November 27, 2020 No. ҚР ДСМ-211/2020 approved the requirements for conducting **intralaboratory quality control programs.**<br><br>The participation of laboratories in **programs for external quality assessment of HIV testing** is envisaged on an ongoing basis, however, the organization and conduct of such programs are carried out within the framework of the procedures of the quality management system of medical laboratories, and **not the regulatory legal acts**. In addition, such programs do not include the participation of NGOs or other medical institutions that use rapid HIV tests.<br><br>In the country, the requirements for the **Procedures for confirming the quality of HIV tests are not regulated by regulatory documents**, so the procedure is not unified and standardized. However, all laboratories carry out such verification in accordance with their own developed SOPs. |

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| **Recommendations** | 1. Review and align with WHO recommendations all policies, strategies and algorithms for determining HIV status:<br>• exclude the immune blot from the confirmatory testing algorithm;<br>• include dual testing for HIV/syphilis in testing algorithms for screening pregnant women at antenatal clinics and members of key populations;<br>• before starting ART, re-examine HIV-positive patients to rule out possible laboratory errors at previous stages of testing;<br>• include in national protocols the requirements for assessing the characteristics of medical devices for HIV testing before their use in practice;<br>• include in national protocols the requirement for the mandatory participation of all HIV testing providers in external programs for assessing the quality of testing.<br>2. Consider the possibility of delegating authority to persons without special medical education to provide HIV testing services.<br>3. Align national policy with WHO recommendations on introducing new innovative approaches such as HIV self-testing and partner services, including approaches to index testing and approaches to HIV testing services through social networks, and focus on specific health services, priority groups population and geographic conditions.<br>4. Consider the possibility of decentralizing HIV testing services, including using rapid tests, confirmatory testing with the transfer of such functions from the central to the regional (local) level, which will significantly reduce the time for obtaining test results, as well as speed up the decision-making on HIV diagnosis - Infections and treatment prescriptions. In addition, it will reduce the cost of transporting blood samples from hospitals to regional laboratories and from the regional level to the national reference laboratory. Ultimately, this will have a positive impact on the timely and rapid inclusion of a new patient in the ART program, prevent the loss of patients and time before starting ART, and reduce further transmission of HIV. |

# Kyrgyzstan

**Regulation of access to the provision of HIV testing services, as well as the testing strategy and algorithm in Kyrgyzstan is carried out on the basis of regulatory legal acts. The following were analyzed for compliance with the WHO 2021 recommendations:**

1. **Order of the Ministry of Health of the Kyrgyz Republic "Laboratory diagnosis of HIV infection", No. 87 dated February 4, 2016 / dated October 26, 2017 No. 964 / No. 303 dated April 28, 2018**
2. **Order of the Ministry of Health of the Kyrgyz Republic "On Approval of Clinical Protocols on HIV Infection" No. 335 dated March 16, 2022;**
3. **Order of the Ministry of Health of the Kyrgyz Republic Clinical protocols on HIV infection for outpatient and inpatient levels of medical care No. 903 dated 10.10.2017**

**In general, national policies and recommendations for the provision of HIV testing services are in line with the WHO 2021 recommendations. However, given the development of the WHO recommendations during the period 2015-2021, and given the identified inconsistencies and regulatory gaps, it should be recommended to national health authorities of the Kyrgyz Republic to harmonize national protocols, bringing them into line with modern WHO recommendations on the points listed below (the main results of the analysis and recommendations for improving the quality of HIV testing services provided are presented in the table below).**

## Main results of the analysis and recommendations

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| **National HIV Testing Strategy** | The national HIV testing strategy, as well as the provision of unlimited access to HIV testing services, are part of the HIV/AIDS response strategy, which is also reflected in the relevant regulatory legal acts that are mandatory for implementation in accordance with the Law of the Kyrgyz Republic "On protection of the health of citizens in the Kyrgyz Republic" as amended on 22.08.2020. The National HIV Testing Strategy targets and includes programs/activities to meet the needs of key populations: migrants and asylum seekers, transgender people; sex workers (men and women); people who inject drugs; prisoners in prisons and other closed institutions; internally displaced persons.<br><br>The HIV testing strategy **fully complies with the WHO 2021 recommendations** and involves the use of three diagnostic test systems (ELISA or rapid tests) with sensitivity and specificity of at least 99%.<br><br>If positive results are obtained in all three tests, the diagnosis of HIV infection is considered final. |
| **Testing approaches used in the country** | HIV testing services are provided both in hospitals and non-governmental organizations. National policy documents **link testing programs with prevention programs for those members of key populations** who are HIV negative and **with care and treatment programs for people living with HIV (PLHIV)**.<br><br>**For testing for HIV, not only specialists with a medical education are involved, but also those who do not have a special medical education, but have undergone special training and received an appropriate certificate.**<br><br>However, the regulatory documents regulating approaches to the provision of HTS **do not reflect the possibility of self-testing**. At the same time, you can get free tests for self-testing, for example, through the website https://kabar.kg/news/teper-v-bishkeke-mozhno-zakazat-ekspress-testy-na-vich-onlain-i-besplatno/ It is obvious that the regulatory documents that define HTS policies need to be revised and updated.<br><br>**There is no information on the use of dual rapid tests for the diagnosis of HIV/syphilis and where they are used.**<br><br>**No information is available on partner services** that include partner notification, contact tracing, index testing of partners and family members to better detect new HIV infections.<br><br>National policies **have not reflected** the WHO recommendation on **social network - based approaches to HIV testing** as an approach to establishing contact with sexual or injecting partners, as well as social contacts of key populations. These approaches can also expand the scope of testing. |

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| **HIV testing algorithm and quality assurane** | By order of the Ministry of Health of the Kyrgyz Republic dated October 26, 2017 No. 964 "On approval of the guidelines "Laboratory diagnosis of HIV infection" and "Guidelines for the assessment of laboratories for the diagnosis of HIV infection", a **testing algorithm was approved using three tests, which is fully consistent with the WHO 2021 recommendations.** At the same time, HIV -positive status is confirmed by obtaining consecutive reactive results of three tests of different names and manufacturers, which differ in terms of sensitivity and specificity. For testing, both instrumental methods and quick tests are used. The screening test (A1) can be performed both on the basis of a medical institution and an NGO (in this case, upon receipt of a reactive test result, the full testing algorithm is performed in the laboratory, and the screening test is considered to be a triage test). ***Testing to establish HIV-positive status is supposed to be carried out only in a laboratory setting, which has its drawbacks and limitations, since such centralization can lead to a delay in obtaining the final test result and timely involvement of PLHIV in treatment and care programs.***<br><br>**Repeated testing before ART is also provided** for by the Order of the Ministry of Health of the Kyrgyz Republic dated October 26, 2017 No. 964. Rapid tests are used in medical and non-medical institutions, including NGOs. ET is carried out only by specialists who have undergone special training and received the appropriate certificate.<br><br>The same order **approved the requirements for the purchase of tests that have passed WHO prequalification, the conduct of in-laboratory quality control programs, participation in external quality assessment programs for HIV testing, as well as the Procedures for confirming the quality of HIV tests provided** (by the regulatory body, but not laboratories/testing sites, which does not fully comply with WHO recommendations). |
| **Recommendations** | 1. Consider the possibility and expediency of decentralizing services for determining HIV status using a full testing algorithm based on medical institutions, including using rapid tests;<br><br>2.Update regulations/policies to align with WHO 2021 recommendations, including on the use of dual tests for simultaneous detection of HIV and syphilis serological markers, provision of HIV testing services for self-testing, partnership services that include notification partners, contact tracing, index testing to reach partners of people living with HIV, social network-based approaches to HIV testing as an approach to contacting sexual or injecting partners, and social networking of key populations population;<br><br>3.Develop and implement procedures for reviewing available diagnostic tools for their performance in order to select optimal products before using them;<br><br>4. Provide for, when updating regulatory legal acts, the introduction of requirements for the mandatory participation of all providers of HIV testing services, including NGOs using rapid tests, in programs for external assessment of the quality of testing. |

# Moldova

**Regulation of access to the provision of HIV testing services, as well as the testing strategy and algorithm in Moldova is carried out on the basis of legal acts. The following were analyzed for compliance with the WHO 2021 recommendations:**

**1. National guidelines for the laboratory diagnosis of HIV infection, approved by the Order of the Ministry of Health, Labor and Social Protection No. 409 dated March 16, 2018;**

**2. National Clinical Protocol No. 211 "HIV infection in adults and adolescents" was approved by Order of the Ministry of Health No. 538 dated 07.06.2022.**

**In general, national policies and recommendations regarding the provision of HIV testing services are in line with the WHO 2021 recommendations. However, given the development of the WHO recommendations in the period 2015-2021 and taking into account the identified inconsistencies in the regulation, it should be recommended to the national health authorities of the Republic of Moldova to harmonize national protocols, bringing them into line with modern WHO recommendations on the points listed below (the main results of the analysis and recommendations for improving the quality of HIV testing services provided are presented in the table below).**

## Main results of the analysis and recommendations

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| **National HIV Testing Strategy** | The National HIV Testing Strategy, as well as the provision of unrestricted access to HIV testing services, are part of the HIV/AIDS response strategy, which is reflected in the relevant regulatory legal acts that are mandatory.<br><br>The National HIV Testing Strategy targets and includes programs/activities that address the needs of key populations (men who have sex with men; people who inject drugs; people who are in prison or pre-trial detention; sex workers; transgender people), as well as vulnerable groups (youth, orphans, people with disabilities, labor migrants, etc.).<br><br>The testing strategy **does not fully comply with WHO recommendations** and involves the use of two rapid tests or an ELISA and a test to determine the level of HIV-1 viral load to verify the diagnosis of HIV infection. At the same time, the HIV-1 viral load test is not diagnostic.<br>The sensitivity and specificity of the tests used in the HIV testing strategy are not quantified. It is only indicated that the first line of testing uses a rapid test with the highest possible sensitivity, later, in the case of a reactive test, the second line of testing (A2) uses a rapid test containing a different antigen (and higher specificity) than the one that used in A1 to avoid false cross-reactivity with A1. For confirmation (A3), a molecular genetic method is used (for example, Xpert Viral Load, Xpert Qual, etc.), and if HIV 2 infection is suspected, it is confirmed using a specific test. |

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| **Testing approaches used in the country** | HIV testing services are provided **both on the basis of medical organizations** (regional hospitals in Moldova, in the consultation rooms of the Centers of Family Doctors in Balti and Chisinau mun., as well as in the Hospital for Dermatology and Infectious Diseases) **and public organizations**. The importance and necessity of providing tailored HTS approaches for the following populations is emphasized:<br>• Newborns and children up to 18 months<br>• Pregnant women and their sexual partners<br>• Key populations (injecting drug users, men who have sex with men, sex workers, prisoners, etc.)<br>• General population<br><br>Priority groups for testing **in NGOs**, given the concentration of the epidemic in vulnerable groups (PWID, MSM, commercial sex workers), it is considered appropriate to test key populations with the creation of optimal conditions for the availability of these testing services for these groups.<br><br>National policy documents (policies) **provide for a procedure for accompanied notification of partners** about the potential risk of HIV infection, and clearly define the need to **link testing programs with HIV prevention and treatment programs** (the package of such services includes needle and syringe programs; opioid substitution therapy; HIV testing and counseling; HIV treatment and care; access to condoms; treatment of sexually transmitted infections, tuberculosis and viral hepatitis).<br><br>For HIV testing, **not only specialists with medical education** are involved, but also those who **do not have a special medical education**, but have received appropriate training (using express tests).<br><br>The testing procedure is provided for in two stages: the first stage (screening) - family medicine centers / other medical institutions or NGOs; the second stage (verification) – laboratories of regional/national levels.<br><br>The regulatory documents governing approaches to the provision of HTS, as well as service delivery models, **reflect the possibility of self-testing.** Rapid HIV tests are also available in the network of pharmacies in the country.<br><br>In the sources available for study (regulations) **there is no mention of the use of double rapid tests for the diagnosis of HIV / syphilis both in pregnant women** in antenatal clinics and when examining **representatives of key populations**.<br><br>National policies have **not reflected the WHO recommendation on social network-based approaches to HIV testing** as an approach to establishing contact with sexual or injecting partners, as well as social contacts of key populations. These approaches can also expand the scope of testing. |

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| **HIV testing algorithm and quality assurane** | Order of the Ministry of Health, Labor and Social Protection No. 409 dated March 16, 2018 approved a testing algorithm using three tests, which **partially complies with the WHO 2021 recommendations**, since the testing algorithm uses both tests to detect HIV serological markers (mainly rapid tests) and tests for determining HIV nucleic acids (quantitative - determining the viral load of HIV-1). To establish HIV status, two blood samples are used: at the primary level (family medicine centers, other medical institutions, the penitentiary sector, NGOs (in this case, the screening test is considered triage)) using only rapid tests, in case of a reactive test result, sampling is carried out another blood sample and sent to laboratories (regional and national), where both rapid tests and instrumental methods are used (national level).<br><br>HIV-positive status is confirmed by obtaining consecutive reactive results from two serological tests and a test performed by PCR (quantitative determination of HIV nucleic acids). If the HIV test result is considered indeterminate (inconsistent test results), a **retest is scheduled after 3 months, which is different from the WHO recommendation of testing after 14 days.** ***Testing to establish HIV-positive status is expected to be carried out only in a laboratory setting, which has its drawbacks, since such centralization can lead to a delay in obtaining the final test result and timely involvement of PLHIV in treatment and care programs. In addition, the HIV-1 viral load test is not diagnostic, but is used to monitor the effectiveness of HIV treatment.***<br><br>**Re-testing before ART is not envisaged** because two samples of biological material are used to establish HIV-positive status.<br><br>Accessible regulations **do not require the use of WHO prequalified medical goods** for HIV testing. At the same time, tests used to determine HIV-1 viral load that are compatible with the GeneXpert instrument are WHO prequalified.<br><br>Order No. 409 of March 16, 2018 **approved the requirements for conducting intralaboratory quality control programs, participation of laboratories in programs for external quality assessment of HIV testing, as well as for conducting Procedures for confirming the quality of HIV tests provided.** Evaluation of HIV testing activities and quality audits are carried out in accordance with the current regulations of the Dermatological and Infectious Diseases Hospital, the institution responsible for the implementation of activities - the National Center for HIV / AIDS and STIs. |
| **Recommendations** | 1.Consider the possibility and feasibility of decentralizing services for determining HIV status using a complete testing algorithm based on medical institutions, which will reduce the time to receive a result from 4 days to 1 day;<br><br>2.Update regulations/policies to align with WHO 2021 recommendations, including for repeat testing for indeterminate HIV status, reducing the period from 3 months to 14 days; the use of dual tests for the simultaneous detection of HIV and syphilis serological markers, social network-based approaches to HIV testing;<br><br>3. Provide for, when updating regulatory legal acts, the introduction of requirements for the mandatory participation of all providers of HIV testing services, including NGOs, in programs for external assessment of the quality of testing. |

# Tajikistan

**Regulation Regulation of access to the provision of HIV testing services, as well as the testing strategy and algorithm in Tajikistan is carried out on the basis of legal acts. The following were analyzed for compliance with the WHO 2021 recommendations:**

**1. GUIDELINES for laboratory diagnosis of HIV infection in the Republic of Tajikistan, order of the Ministry of Health and Social Protection of the Population of the Republic of Tajikistan, 2022 (draft);**

**2. Order of the Ministry of Health of the Republic of Tajikistan Republican Center for the Prevention and Control of AIDS No. 354 dated July 17, 2012 GUIDELINES FOR HIV COUNSELING AND TESTING;**

**3. DECISION of the Government of the Republic of Tajikistan dated February 27, 2021 No. 50 On the National Program to Combat the Epidemic of the Human Immunodeficiency Virus and Acquired Immunodeficiency Syndrome in the Republic of Tajikistan for 2021-2025**

**4. Order of the Ministry of Health of the Republic of Tajikistan dated August 23, 2012 No. 415 "On amendments and additions to the order of the Ministry of Health of the Republic of Tajikistan dated February 13, 2008 No. 60 "On improving the prevention of the spread of HIV / AIDS among vulnerable groups in the Republic of Tajikistan";**

**5. Order of the Ministry of Health of the Republic of Tajikistan dated 05.09.2019 No. 657 On the introduction of an express test to detect infection with the human immunodeficiency virus in the Republic of Tajikistan by self-testing;**

**6. Order of the Ministry of Health of the Republic of Tajikistan dated September 30, 2015 No. 832 On expanding the coverage of the population with the diagnosis of the human immunodeficiency virus;**

**7. Clinical protocol for primary, secondary and tertiary care for children with HIV infection in the Republic of Tajikistan, 2021**

**In general, national policies and recommendations regarding the provision of HIV testing services are in line with the WHO 2021 recommendations. However, given the development of the WHO recommendations in the period 2015-2021 and taking into account the identified inconsistencies in the regulation, it should be recommended to the national health authorities of the Republic of Tajikistan to harmonize national protocols, bringing them into line with modern WHO recommendations on the points listed below (the main results of the analysis and recommendations for improving the quality of HIV testing services provided are presented in the table below).**

## Main results of the analysis and recommendations

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| **National HIV Testing Strategy** | The National HIV Testing Strategy, as well as the provision of unrestricted access to HIV testing services, are part of the HIV/AIDS response strategy, which is also reflected in the relevant legal acts. The National HIV Testing Strategy aims and includes programs/activities that primarily address the needs of key (people who inject drugs, sex workers, men who have sex with men, prisoners) and vulnerable (migrant workers) populations.<br>The HIV testing strategy **fully complies with the 2021 WHO recommendations** and involves the use of three diagnostic test systems (ELISA or rapid tests) with sensitivity rates of at least 99% and specificity of at least 98%.<br>If positive results are obtained in all three tests, the diagnosis of HIV infection is considered final. |
| **Testing approaches used in the country** | HIV testing services **are provided both in hospitals and non-governmental organizations**. National policy documents **link testing programs with prevention programs for those members of key populations who are HIV negative and with care and treatment programs for people living with HIV (PLHIV)**.<br><br>For testing for HIV, **not only specialists with a medical education are involved, but also those who do not have a special medical education**, but have undergone special training.<br><br>National policies **include a self-testing approach** to providing HTS. At the same time, this service is available for sexual partners of PLHIV and injecting drug users, as well as some representatives of vulnerable groups of the population either on the basis of an NGO or in a medical institution, which was reflected in the order of the Ministry of Health of the Republic of Tajikistan dated 05.09.2019 No. 657.<br><br>**There is no information on the use of dual rapid tests for the diagnosis of HIV/syphilis and where they are used.**<br><br>National policies **do not reflected the WHO recommendation on social network-based approaches to HIV testing** as an approach to establishing contact with sexual or injecting partners, **as well as social contacts of key populations**. These approaches can also expand the scope of testing. |
| **HIV testing algorithm and quality assurane** | Guidelines for laboratory diagnosis of HIV infection in Tajikistan (draft order of the Ministry of Health of the Republic of Tajikistan) defines the use of an **HIV testing strategy and algorithm that is fully consistent with the WHO 2021 recommendation**. To achieve at least 99% positive predictive value, it is important that:<br>• the first test (T1) identified all HIV-infected people and had a high sensitivity (>99%).<br>• The second and third tests (T2, T3) must prevent any false positive test results. For this reason, both assay kits used for both T2 and T3 should have high specificity (>98%).<br>• The first (T1), second (T2), and third (T3) tests must be different to avoid false positives<br>The testing algorithm uses both express tests and instrumental methods (at least 1 test in the testing algorithm). **The screening test (T1) can be carried out both at a medical institution and in an NGO (in this case,** when a reactive test result is obtained, a complete HIV test is performed in the laboratory, and the **screening test is considered a triage test)**. **In NGOs, ET is carried out only by specialists who have undergone special training**.<br>Confirmation of HIV-positive status is carried out only in the laboratory, which has certain limitations, since such centralization may delay the final result of HIV detection and the involvement of PLHIV in treatment.<br><br>**Re-testing before ART is also provided** for by the draft order of the Ministry of Health of the Republic of Tajikistan. |

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| | The same draft sets out the **requirements for the purchase of tests that have passed WHO prequalification**, the implementation of intralaboratory quality control programs, **the mandatory participation in the program of external quality assessment of HIV testing not only for all HIV diagnostic laboratories, but also for medical and non-medical HIV testing organizations.** It also **provides for the need to assess the quality of test systems imported into the republic**. This assessment is provided by the Republican AIDS Center of the Ministry of Health with the Pharmaceutical Activity Service of the Ministry of Health and Social Protection for quality control of test systems. Based on the results obtained, the State Institution "RCAIDS" gives recommendations on their use. At the same time, **all HIV testing sites should have procedures for evaluating the effectiveness of tests prior to routine testing**. |
| **Recommendations** | 1. Consider the possibility and expediency of decentralizing services for determining HIV status using a complete testing algorithm based on medical institutions, including using rapid tests.<br>2. Develop and implement procedures for input control of the characteristics of tests used for HIV testing by all HTS providers before their practical use.<br>3. Consider the acceptability of social network-based approaches to HIV testing for establishing contacts with sexual or injecting partners, as well as for social contacts of key populations.<br>4. Include in national policies the use of dual HIV/syphilis tests for testing pregnant women and members of key populations.<br>5. Consider providing free access to tests for self-testing, for example, by purchasing tests through a pharmacy network. |

# Uzbekistan

**Regulation of access to the provision of HIV testing services, as well as the testing strategy and algorithm in Uzbekistan is carried out on the basis of regulatory legal acts. The following were analyzed for compliance with the WHO 2021 recommendations:**

**1. Law of the Republic of Uzbekistan "On counteracting the spread of the disease caused by the human immunodeficiency virus (HIV)", 22.08.2013**

**2. Order of the Ministry of Health of the Republic of Uzbekistan dated May 24, 2018 No. 336 "On measures to prevent HIV infection in the Republic of Uzbekistan and further improve the organization of medical care";**

**3. SOP on the mechanism for the provision of ARVs and diagnostic kits (Appendix No. 3 to Order No. 277 of the Ministry of Health of the Republic of Uzbekistan dated April 30, 2018);**

**4. Draft order of the Ministry of Health of the Republic of Uzbekistan dated 2022 on the approval of regulations on the organization and implementation of anti-epidemic, diagnostic, preventive and psychosocial measures for HIV infection, as well as on providing assistance to patients living with HIV (provided by WHO for evaluation).**

**In general, the National Guidelines for the Diagnosis of HIV Infection do not fully comply with the WHO 2021 recommendations. Taking into account the identified inconsistencies and gaps in regulation, it should be recommended that the national health authorities of the Republic of Uzbekistan harmonize national protocols, bringing them into line with modern WHO recommendations on the points listed below (the main results of the analysis and recommendations for improving the quality of HIV testing services provided are presented below in the table).**

## Main results of the analysis and recommendations

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| **National HIV Testing Strategy** | The National HIV Testing Strategy, as well as the provision of unlimited access to HIV testing services, are part of the HIV/AIDS response strategy, which is also reflected in the relevant legal acts:<br>Law of the Republic of Uzbekistan "On counteracting the spread of the disease caused by the human immunodeficiency virus (HIV)", August 22, 2013;<br>Resolution "On measures to implement the National goals and objectives in the field of sustainable development for the period up to 2030".<br>Order of the Ministry of Health of the Republic of Uzbekistan "Rules for medical examination for the human immunodeficiency virus".<br><br>All citizens of Uzbekistan and persons who are not residents of the republic are subject to a medical examination for HIV infection in accordance with the indications determined in the relevant regulations.<br><br>Categories of social order survey:<br>• Voluntary<br>• Mandatory<br>• Forced<br>Target populations for HTS provision include individuals<br>- with a high risk of HIV infection due to their lifestyle and behavior.<br>injecting drug users (PWID);<br>- men who have sex with men<br>- persons providing sexual services for remuneration<br>- persons with sexually transmitted diseases (STDs);<br>- sexual partners of people who inject drugs, etc.<br>- other vulnerable groups of the population.<br><br>HIV testing strategy **not in line** with WHO 2021 guidelines.<br>For the diagnosis of HIV infection, the third strategy is used - double confirmation of a positive result: Primary study (screening): by ELISA (using 3-4 generation test systems) or using rapid testing; Confirmatory study: carried out by ELISA (using 4-generation test systems) and the final confirmatory WB test or confirmatory test (ELISA-ELISA or ELISA-rapid test) (at the last stage). In the latest version of the draft order (Appendix 2), there are no clear indications that tests should have different sensitivity and specificity indicators, be of different names and manufacturers. |

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| **Testing approaches used in the country** | HIV testing services (including anonymous ones) are provided, in accordance with the WHO 2021 recommendations, both on the basis of medical institutions and non-governmental organizations, with the involvement of a specialist with a non-medical education, but who has undergone appropriate training (assisted self-testing using rapid tests). Medical institutions collect biological material for testing, which is sent to the country's laboratories (including after receiving a reactive rapid test result).<br><br>HIV testing is provided both on a paid basis and free of charge. The following persons who returned to Uzbekistan after a long stay abroad (more than 3 months) are subject to free testing: victims of human trafficking; key populations (PWID, PWID, men who have sex with men); persons with AIDS-indicator diseases (tuberculosis, tumors, candidiasis, etc.); pregnant women; persons under 18 years of age and over 60 years of age; persons released from penitentiary institutions; persons deported from foreign countries; persons who underwent surgery abroad; recipients of blood and its components, organs and tissues; sexual partners of HIV-positive people.<br><br>In other cases, the costs associated with HIV testing of citizens who returned to Uzbekistan after a long stay in foreign countries (more than 3 months) are covered by paid services at the expense of the person being tested.<br>Married persons are also subject to free testing, subject to testing at the place of residence.<br><br>The regulations/policies governing approaches to HTS provision reflect the model of assisted self-testing based on NGOs, but **do not reflect the possibility of self-testing**. Only medical organizations can buy express tests in a pharmacy.<br><br>The **use of dual rapid tests for the diagnosis of HIV/syphilis** in pregnant women in antenatal clinics, as well as when examining representatives of key populations, **has not been reflected in national HIV testing policies.**<br><br>There is **no information** in the national regulations available for analysis whether **accompanied notification of partners about the potential risk of HIV infection is provided**. At the same time, Annex 1 of the draft order of the Ministry of Health of the Republic of Uzbekistan (submitted for evaluation by WHO) provides for the completion of the "Warning sheet on criminal liability for infecting another person with HIV infection", which contains a recommendation for a person with HIV-positive status to his sexual (or injecting) partners be sure to undergo an HIV test and maintain confidentiality.<br><br>**The linkage of HIV testing programs with prevention programs is provided** for representatives of key populations and groups at high risk of infection who are HIV negative; for people living with HIV (PLHIV) **there is also a link to care and treatment programs.**<br><br>**There is no information** on the possibility of obtaining information on the provision of HTS through **social networks, on partner services, including notification of partners, contact tracing, index testing of partners and family members to reach partners of people living with HIV.** |

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| **HIV testing algorithm and quality assurane** | HIV testing algorithm **does not comply** with WHO 2021 recommendations.<br>For the diagnosis of HIV infection, the third strategy is used - double confirmation of a positive result: Primary study (screening): by ELISA (using 3-4 generation test systems) or using rapid testing; Confirmatory study: carried out by ELISA (using 4-generation test systems) and the final confirmatory WB test or confirmatory test (ELISA-ELISA or ELISA-rapid test) (at the last stage).<br><br>There are no clear indications that the tests should be of different names and manufacturers. The algorithm uses both ELISA tests (RTs), immunoblot, and PCR (determination of HIV-1 viral load). At the same time, the viral load test is not a diagnostic test, as indicated in the manufacturer's instructions for its use.<br><br>The testing algorithm **provides for the use of rapid tests** (medical organizations for HIV testing of persons at high risk of infection, NGOs (A0) in models of assisted self-testing services). Rapid tests are also used in laboratories when testing blood samples from patients delivered by medical facilities for HIV.<br><br>The 2021 WHO **recommendations on the use of WHO prequalified HIV tests are not included in the regulations**.<br><br>The WHO 2021 recommendations **on checking the performance of tests prior to their use in routine HIV testing are only reflected in saliva tests** used in models of HTS delivery – assisted self-testing. Thus, the draft order of the Ministry of Health of the Republic of Uzbekistan (Appendix 7) provides for the verification of the operation of test systems in the AIDS centers: in the laboratories of the AIDS centers, each time a new batch of test systems arrives, an input control is carried out by verifying with the previous series.<br>Verification is carried out in accordance with the developed verification SOP:<br>• Before using test systems with a new lot/series;<br>• Before using test kits from a new supplier/manufacturer.<br>For other medical devices, this WHO 2021 recommendation was not reflected in the regulatory documents of the Republic of Uzbekistan.<br><br>**The national policy of the Republic of Uzbekistan stipulates that an external assessment of the quality of HIV testing by laboratories** is carried out annually jointly with the staff of the Reference Laboratory of the Ministry of Health and the Republican AIDS Center. However, for all service providers, including NGOs when using rapid tests, such a procedure is not provided for by national policies.<br><br>The 2021 WHO **recommendations to retest all HIV-infected people before starting ART** to confirm the correct diagnosis of HIV infection are **not included** in national programs. |

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| **Recommendations** | 1. Consider access to testing services, providing a free service to all who need it;<br>2. Bring the strategy and algorithms of HIV testing in line with WHO recommendations; abandon Western blotting as a mandatory test for verifying HIV-positive status;<br>3. Develop and conduct a procedure for testing testing algorithms with subsequent revision (1 time in 2-3 years);<br>4. Introduce dual testing for HIV/syphilis in antenatal clinics to test pregnant women at the first visit due to pregnancy, as well as for key populations;<br>5. Consider decentralizing the provision of HIV testing and HIV-positive status services to primary health care, specialized and highly specialized clinics, using rapid tests to reduce the time for obtaining test results and prompt involvement of people living with HIV, in treatment and care;<br>6. Develop and implement entry control procedures for all tests used to diagnose HIV infection, and not just for rapid tests (assisted self-testing);<br>7. Develop and implement programs for external quality assurance of HIV testing, involving the participation of all providers of such services, including medical and non-medical employees who use rapid tests for testing;<br>8. Include in national policies recommendations for information on HTS delivery through social network, partnership services, including partner notification, contact tracing, index testing and family-level index testing to reach partners of people living with HIV. |

## Key Findings and Recommendations

*This section contains the main conclusions and recommendations based on the results of the analysis. They are of a collective and descriptive nature, and their main purpose is to reflect some general trends that are more or less characteristic of the countries included in the analysis.*

### Recommendation 1.

**When reviewing/updating national HIV testing policies and protocols in countries where necessary, emphasize the need to move towards a unified HIV testing strategy**

One of the key WHO 2021 recommendations for achieving at least 99% positive predictive value in HIV testing is to move to a single three-test strategy, which means that all people seeking HIV testing services should have three consecutive positive test results to confirm HIV-positive status. In order to scale up HIV testing, prevention and treatment, reduce the time to test results, and involve PLHIV in treatment and care programs, WHO also recommends that Western blot and linear immunoassays be phased out of their national testing strategies or algorithms in favor of simpler and more less expensive rapid diagnostic tests and/or enzyme immunoassays. WHO also recommends that all HIV testing algorithms use a combination of tests with >99% sensitivity and >98% specificity. The first test in an HIV testing strategy and algorithm should have the highest sensitivity, followed by the second and third tests with the highest specificity.

In all national HIV testing protocols included in the analysis, countries use rapid tests and/or enzyme immunoassays for HIV testing. In all protocols, it is noted that the first-line tests should be as sensitive as possible, and the second and third lines should be as specific as possible. At the same time, the national protocols for HIV testing in most countries (Belarus, Georgia, Kazakhstan, Kyrgyzstan, Tajikistan) specify the requirements for sensitivity and specificity (at least 99%) of tests. The national protocol of Moldova does not contain clear requirements for the technical characteristics of tests (indicators of their sensitivity and specificity) used for HIV testing. In the national protocol of Uzbekistan, there is no definition at all of the need to use different tests with different technical characteristics at certain stages of testing. Of all the national HIV testing protocols included in the analysis, only the testing strategy of Kyrgyzstan fully complies with the WHO 2021 recommendations, despite the fact that the last revision of the document was carried out in 2018. Belarus, Kazakhstan and Uzbekistan continue to use the immune blot, which is a mandatory test for Kazakhstan and Uzbekistan to confirm the diagnosis of HIV infection. At the same time, in Kazakhstan, such studies are carried out by the only laboratory in the country. Moldova and Belarus to verify the diagnosis as a mandatory confirmatory test, Georgia - upon receipt of inconsistent test results at the previous stage of testing, use molecular genetic studies to determine the level of HIV-1 viral load, which is not intended for diagnostic purposes in accordance with the instructions of the test manufacturer to their use.

Therefore, at the next review of national protocols, countries, where appropriate, should review their HIV testing strategy and algorithms and align it with the WHO 2021 recommendations.

### Recommendation 2.

**When reviewing/updating national HIV testing policies and protocols, take into account the updated WHO recommendations (2021) in the area of expanding access of key populations to HIV testing services, detecting new HIV infections, reducing the time to receive test results, and also provide the possibility of providing HTS by non-medical workers in testing for HIV infection, as well as the decentralization of HTS.**

In the area of improving the quality of HIV testing services provided, and increasing access to them for all who need them, WHO recommends that countries implement approaches that would, among other things, improve communication with health care after an HIV-positive status is established. Among these activities are the following:

- HIV self-testing as an approach to HIV testing;
- Use of dual rapid HIV/syphilis tests, which could be the first test in HIV testing strategies and algorithms for diagnosing HIV infection and STIs;
- Partner services to notify partners of PLHIV, contact tracing, index testing of partners and family members of PLHIV;

• Introducing new innovative approaches such as index testing and social networking approaches to HIV testing services and focusing on specific health services, population priority and geographical conditions;

• Reducing the time to diagnose HIV infection by decentralizing the provision of HIV testing services and involving PLHIV in medical treatment and care programs;

• Involving non-medical workers – representatives of public organizations in the provision of HIV testing services.

All national protocols included in the analysis contain some or other of the recommendations proposed by WHO, however, there are points that should be taken into account when revising the current recommendations for the provision of HIV testing services, namely:

• updated WHO guidance on offering self-testing as an approach to HIV testing. Access to self-testing is provided in a number of countries (Georgia, Moldova, Kyrgyzstan, Kazakhstan, Tajikistan, Belarus). Tests can be obtained from medical institutions or NGOs (Georgia, Tajikistan), or purchased through a pharmacy chain, or obtained free of charge from an NGO (Kyrgyzstan). At the same time, only in the national protocols of Georgia, Moldova and Tajikistan there is an indication that self-testing for HIV is offered as an additional method/approach to HIV testing services. In Uzbekistan, the self-testing service is not provided – rapid tests through the pharmacy network can only be purchased by medical organizations;

• recommendations regarding the involvement of non-governmental organizations in the testing process: "professional medical workers who have received special training, under the supervision of specialists, can conduct safe and effective HIV testing on their own using rapid diagnostic tests", use of partner services to notify partners of PLHIV, index testing. All national protocols included in the analysis noted the importance of involving NGOs in the provision of HIV testing services. At the same time, only Kyrgyzstan, Tajikistan and Moldova, through their national policies, determine the possibility of participation of specialists with non-medical education, who have undergone appropriate training, in the provision of testing services on the basis of NGOs (rapid test - triage). The national protocol of Uzbekistan provides for the so-called assisted self-testing with the participation of an NGO representative. At the same time, its role is reduced to a greater extent to the provision of advisory services. In Kazakhstan, HIV testing is provided exclusively on the basis of medical institutions; Georgian and Belarusian national policies do not reflect opportunities for non-medical professionals to test for HIV;

• recommendations for reducing the time to establish a diagnosis of HIV infection. A barrier to wide involvement in ART in a number of countries may be the length and complexity of the testing algorithm (use of WB as a confirmatory test, limited use of ET) and the length of the chain from testing to providing treatment (logistics of the client/patient's movement from the point of initial testing to the point of providing therapy). In addition, the long chain from testing to treatment in a number of countries (Kazakhstan, Uzbekistan, Belarus) is also due to the involvement of an excessive number of specialists (different people conduct pre-test counseling during testing, reporting the test result, conducting an epidemiological investigation and subsequent medical care). Conducting research to establish HIV-positive status in all countries (except Georgia) is expected only in the conditions of state-owned laboratories, and the final diagnosis, in some cases, can only be confirmed in one laboratory in the country (Kazakhstan). This practice, as well as the immune blot as a mandatory test to verify the diagnosis of HIV infection (Kazakhstan, Uzbekistan), has its drawbacks, since such centralization of testing to establish HIV-positive status and the use of a suboptimal HIV testing algorithm may lead to a delay in obtaining the final result. testing and timely involvement of PLHIV in treatment and care programs, as well as additional financial costs for providing logistics for biological material sent for research by medical institutions/laboratories. Progressive practice regarding the establishment of HIV-positive status is noted in Georgia, which provides for the implementation of this stage directly on the basis of the organization providing preventive services, centers and public organizations using the GeneXpert (Cefeid) device for the determination of viral RNA. This model of decentralized provision of HTS reduces the time it takes to determine HIV-positive status and connects PLHIV with treatment.

Where appropriate, national protocols should include measures to expand and streamline approaches to organizing and delivering HIV testing services to all who need them, as well as to reduce the time to establish HIV-positive status.

## Recommendation 3.

**Where appropriate, national protocols should include sections on quality assurance.**

Quality assurance through quality management systems is essential for all testing services, from HIV testing in laboratories and health care facilities to community organizations, including rapid tests performed by lay people. In addition, the

provision of HIV testing services must ensure that only high-quality diagnostic tools and equipment are used. Therefore, in order to select the optimal products, it is essential to analyze the available diagnostic tools for their performance and operational characteristics before they are put into practice.

All of the national protocols included in the analysis note the importance of quality assurance in testing to obtain correct results (Belarus). Georgia, in particular, in the testing manual notes the recommendations on the periodic validation of HIV testing algorithms, on the implementation of quality control of the tests used; quality control should also be carried out in relation to the persons conducting the test (qualifications, skills) and premises (space, equipment, workload, storage and logistics of tests, etc. (appropriate conditions). Some politicians (Kazakhstan) contain separate elements of testing quality assurance (intralaboratory quality control), but do not contain sections on the procedure for assessing the characteristics of tests before their use for HIV testing, as well as on organizing and conducting programs for external assessment of the quality of HIV testing. The national protocols for HIV testing in Moldova, Tajikistan and Kyrgyzstan approved the requirements for the use of tests that have passed WHO prequalification, the conduct of in-laboratory quality control programs, the participation of laboratories in external quality assessment programs for HIV testing, as well as the assessment of the technical characteristics of medical devices for HIV testing (Kyrgyzstan assumes such an assessment by the regulatory body, but not by laboratories / testing sites, which does not fully comply with WHO recommendations). In turn, the national HIV testing protocol of the Republic of Uzbekistan provides for an input control of test systems with each arrival of a new batch of test systems by verifying with the previous batch, however, this procedure applies only to rapid tests used in assisted self-testing models, and not all medical devices used for HIV testing, which does not fully reflect WHO recommendations. There are also requirements for the implementation of internal laboratory quality control programs and the participation of laboratories in external quality assessment programs.

At the same time, ensuring the quality of testing is of paramount importance not only when it comes to laboratories, but also when specialists from other medical institutions are involved in HIV testing services, including using rapid tests, as well as non-governmental organizations. Therefore, all HIV testing providers are responsible for ensuring the quality of HIV testing. Only the national protocol of Tajikistan mentions the requirement for mandatory participation in the programs of external quality assessment of HIV testing not only all laboratories for diagnosing HIV infection, but also for medical and non-medical organizations that carry out HIV testing.

Where appropriate, national protocols should include sections on quality assurance of HIV testing services in line with the latest WHO recommendations, from HIV testing conducted in laboratories and health care facilities to community organizations, including rapid tests conducted by non-professionals.