



On approval of the rules for external assessment of the quality of measurements of laboratory research in reference laboratories

Unofficial translation

Order of the acting Minister of Health of the Republic of Kazakhstan dated December 21, 2020 No. ҚР ДСМ -295/2020. Registered in the Ministry of Justice of the Republic of Kazakhstan on December 22, 2020 No. 21845

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In accordance with paragraph 3 of Article 130 of the Code of the Republic of Kazakhstan dated July 7, 2020 "On people's health and health care system" I HEREBY ORDER:

1. To approve the attached rules for external assessment of the quality of measurements of laboratory research in reference laboratories.

2. The Department of organization of medical aid of the Ministry of Health of the Republic of Kazakhstan, in the manner prescribed by the legislation of the Republic of Kazakhstan, to ensure:

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

2) posting this order on the Internet resource of the Ministry of Health of the Republic of Kazakhstan;

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

3. The supervising vice minister of health of the Republic of Kazakhstan is authorized to control the execution of this order.

4. This order comes into effect upon the expiration of ten calendar days after the day of its first official publication.

*Acting minister of health of the
Republic of Kazakhstan*

M. Shoranov

Approved
by the order of the
acting minister of health of the
Republic of Kazakhstan
dated December 21, 2020
№ ҚР ДСМ-295/2020

Rules for external assessment of the quality of measurements of laboratory research in reference laboratories

Chapter 1. General provisions

1. These rules for external assessment of the quality of measurements of laboratory research in reference laboratories (hereinafter referred to as the Rules) are developed in accordance with paragraph 3 of Article 130 of the Code of the Republic of Kazakhstan dated July 7, 2020 "On people's health and health care system" (hereinafter referred to as the Code) and determine the procedure for external assessment of the quality of measurements of laboratory research in reference laboratories.

2. Reference laboratories are structural subdivisions of republican healthcare organizations and implement national programs for external quality assessment in the healthcare system.

3. The following concepts are used in these Rules:

1) external quality assessment (hereinafter - EQA) - a system of measures aimed at timely detection of violations of the quality of research, elimination of identified errors and improvement of the quality of laboratory diagnostics in the health care system;

2) participants in EQA programs - health care organizations that provide laboratory diagnostics, participating in EQA programs, implemented by reference laboratories and a competency (qualification) testing provider;

3) competence (qualification) testing provider - an organization accredited for compliance with ST RK ISO / IEC 17043-2012 "Conformity assessment. Basic requirements for qualification testing";

4) control samples for EQA - samples of control biological materials prepared by the reference laboratory for participants in the EQA program;

5) verification of competence (qualifications) - the EQA method, implemented by reference laboratories for participants in the EQA program, by examining professional tasks and (or) encrypted control samples;

6) reference laboratory - a laboratory of a healthcare organization that carries out organizational and methodological work to introduce an external quality assessment system and conduct research in diagnostically complex and expert cases in a certain area of laboratory diagnostics;

7) reference studies - laboratory research performed by reference laboratories in diagnostically complex and expert cases;

8) rechecking (retesting) - the EQA method, implemented by reference laboratories for participants in the EQA program, by repeated control measurement in order to recheck previously analyzed samples;

9) national EQA program - a program financed from state budgetary programs in order to improve the quality of laboratory research in laboratories of the health care system;

10) an authorized body in the field of health care - the central executive body that carries out management and inter-sectoral coordination in the field of health protection of citizens of

the Republic of Kazakhstan, medical and pharmaceutical science, medical and pharmaceutical education, sanitary and epidemiological welfare of the population, circulation of medicines and medical devices, quality of provision of medical services (assistance).

4. National EQA programs are implemented by reference laboratories and cover quality control of laboratory research in the field of diagnostics of infectious diseases (viral infections, highly dangerous infections, parasitic infections, bacterial infections and antibiotic resistance, tuberculosis, HIV infection, parenteral viral hepatitis), newly emerging infections, public health and blood services.

Chapter 2. Procedure for external assessment of quality of measurements of laboratory research in reference laboratories

5. The procedure for external assessment of the quality of measurements of laboratory research in reference laboratories is carried out by the following methods:

- 1) verification of competence (qualifications);
- 2) rechecking (retesting) of the analyzed samples;
- 3) on-site assessment.

6. Competence (qualification) testing includes the distribution of professional tasks and (or) encrypted control samples, programs, processing, comparison of research results by reference laboratories to participants in EQA and notification of participants about the results.

7. Re-checking (retesting) of analyzed samples involves re-measurement of previously analyzed samples of biological material and assessment of the match of the research results.

8. The on-site assessment method includes a monitoring visit to the laboratory to assess the laboratory's performance and study the documented processes and procedures in order to provide organizational, methodological and advisory assistance to participants in the EQA programs, based on the annual schedule approved by the reference laboratory and agreed with the authorized body in the field of health care or an order approved by the authorized body in the field of health care.

9. National EQA programs are implemented by reference laboratories cyclically, at regular intervals (monthly, quarterly, once every six months, and once a year).

At the end of the cycle of the national EQA program, the reference laboratory informs the participants about the results of the EQA and, no later than 15 working days after completion, sends them recommendations for improving the performance and quality of laboratory research in an arbitrary form of the EQA program report.

10. The reference laboratories, no later than 15 working days after the completion of the cycle of the national EQA program, inform the authorized body in the field of healthcare about the results of the EQA in an arbitrary form of the report of the national EQA program.

11. Reference laboratories monitor the quality of laboratory research and eliminate inconsistencies identified in EQA programs during the implementation of subsequent EQA cycles.

12. The reference laboratory organizes EQA programs if accreditation for compliance with the ST RK ISO / IEC 17043-2012 standard “Conformity assessment. Basic requirements for qualification testing” is available.

13. The procedure for conducting EQA by the method of competence (qualification) testing of laboratory research includes:

1) planning of participants in EQA programs from among the laboratories of health care organizations performing laboratory diagnostics;

2) formation of EQA programs, with the establishment of the frequency of cycles (monthly, quarterly, once every six months, once a year) and the annual implementation schedule in accordance with the allocated funding;

3) informing participants of EQA programs about the annual schedule and frequency of EQA programs;

4) preparation of professional tasks and (or) encrypted control samples;

5) distribution of professional tasks and (or) encrypted control samples, and instructions for conducting control measurements to laboratories participating in the EQA; 6) a set and statistical processing of the results of control measurements obtained from laboratories participating in the EQA;

7) identification of problems associated with the use of incorrect procedures, measurements or tests, insufficient effectiveness of training and personnel management, or incorrect calibration of equipment;

8) establishing the effectiveness and comparability of research or measurement methods;

9) development of recommendations for improving performance following the results of the EQA;

10) notifying the laboratories participating in the EQA about the results of the competence (qualification) testing no later than 15 working days after the completion of the EQA program in an arbitrary form of the EQA program report;

11) notification of the authorized body in the field of health care about the results of the competence (qualification) testing of the laboratories participating in the EQA within 15 working days after the completion of the EQA program in an arbitrary form of the EQA program report;

12) monitoring the implementation of recommendations to improve the quality of laboratory research.

13. The procedure for rechecking (retesting) of the analyzed samples includes:

1) planning of participants in EQA programs from among the laboratories of health care organizations performing laboratory diagnostics;

2) formation of an annual rechecking (retesting) schedule with the determination of the frequency (monthly, quarterly, once every six months, once a year) and the number of samples in accordance with the allocated funding;

3) informing participants in EQA programs about the annual rechecking schedule, indicating the frequency and number of samples;

4) acceptance of samples sent for rechecking (retesting);

5) performing repeated research of the sent samples;

6) a set and statistical processing of the results of rechecking (retesting);

7) identifying problems associated with the use of incorrect procedures, measurements or tests, insufficient training and management of personnel, or incorrect calibration of equipment ;

8) establishing the effectiveness and comparability of research or measurement methods;

9) development of recommendations for improving performance based on the results of rechecking (retesting);

10) notifying the laboratories participating in the EQA about the results of rechecking (retesting) no later than 15 working days after the completion of the EQA program cycle in the form of an arbitrary report of the EQA program;

11) notifying the authorized body in the field of health care about the results of rechecking (retesting) of the laboratories participating in the EQA within 15 working days after the completion of the EQA program cycle in an arbitrary form of the EQA program report;

12) monitoring the implementation of recommendations to improve the quality of laboratory research.

14. The procedure for conducting monitoring visits (on-site assessment) includes:

1) planning the schedule of monitoring visits to the laboratories of health care organizations performing laboratory diagnostics;

2) coordination of the schedule of monitoring visits with the authorized body in the field of health care in accordance with the allocated funding;

3) informing the participants of the EQA programs about the annual schedule of monitoring visits;

4) visit to the location of the laboratory, to assess the laboratory's activities and provide it with organizational, methodological and advisory assistance;

5) submission of a report to the laboratory participating in the EQA program on the monitoring visit, indicating recommendations for improving the laboratory's performance, no later than 15 working days after the completion of the monitoring visit;

6) notifying the authorized body in the field of health care about the results of monitoring visits to laboratories participating in the EQA program no later than 15 working days after the completion of the monitoring visit;

15. The procedure for participation in EQA for laboratories participating in the EQA program includes: 1) planning of participation in EQA programs (by competence (qualifications) testing, rechecking (retesting) samples, monitoring visits to the location of the laboratory);

2) formation of an application for consumables and reagents for participation in EQA programs;

3) formation of an application for transportation of samples of biological material to the reference laboratory for rechecking (retesting);

4) analysis of the results of participation in the EQA, development of a plan for quality improvement, a plan to eliminate inconsistencies identified as a result of participation in the EQA program;

5) informing the management of the healthcare organization on the results of participation in EQA programs;

6) use of EQA results to confirm competence (qualification).

16. Health care organizations performing laboratory diagnostics:

1) support the participation of laboratories in national EQA programs implemented by the reference laboratory;

2) account and control the results of EQA of laboratories;

3) include the costs for research and logistics of samples in development plans;

4) determine a list of administrative persons in charge of the work on participation of laboratories in EQA;

5) control the elimination of the causes of errors in laboratories according to the results of the EQA.