**On approval of the Regulations on the activities of organizations and (or) structural divisions of healthcare organizations that carry out laboratory diagnostics, as well as the volume and types of research conducted by them**

Order of the Minister of Health and Social Development of the Republic of Kazakhstan dated September 28, 2015 No. 758. Registered with the Ministry of Justice of the Republic of Kazakhstan on October 28, 2015 No. 12207

     In accordance with subparagraph 100) paragraph 1 of article 7 of the Code of the Republic of Kazakhstan dated September 18, 2009 "On the health of the people and the healthcare system" **I ORDER:**
     1. Approve:
     1) Regulations on the activities of organizations and (or) structural units of healthcare organizations that carry out laboratory diagnostics, in accordance with Appendix 1 to this order;
2) The scope and types of research conducted by organizations and (or) structural units of healthcare organizations that carry out laboratory diagnostics, in accordance with Appendix 2 to this order.
      2. The Department of Organization of Medical Care of the Ministry of Health and Social Development of the Republic of Kazakhstan in the manner prescribed by law to ensure:
      1) state registration of this order with the Ministry of Justice of the Republic of Kazakhstan;
     2) within ten calendar days after the state registration of this order with the Ministry of Justice of the Republic of Kazakhstan, referral for official publication in printed periodicals and the Adilet information and legal system;
     3) placement of this order on the Internet resource of the Ministry of Health and Social Development of the Republic of Kazakhstan;
     4) within ten working days after the state registration of this order with the Ministry of Justice of the Republic of Kazakhstan, submission to the Legal Service Department of the Ministry of Health and Social Development of the Republic of Kazakhstan of information on the implementation of the measures provided for in subparagraphs 1), 2) and 3) of this paragraph.
      4. To impose control over the execution of this order on the Vice-Minister of Health and Social Development of the Republic of Kazakhstan Tsoi A.V.
     5. This order shall enter into force ten calendar days after the day of its first official publication.

*Minister of Health and*
*social development*
*Republic of Kazakhstan                      T. Duisenova*

Appendix 1
to the order of the Minister of Health
and Social Development
Republic of Kazakhstan
dated September 28, 2015 No. 758

**Regulations on the activities of organizations and (or) structural**
**divisions of healthcare organizations that carry out**
**laboratory diagnostics**

**1. General Provisions**

     1. This Regulation on the activities of organizations and (or) structural divisions of healthcare organizations that carry out laboratory diagnostics (hereinafter referred to as the Regulation) regulates the activities of medical laboratories and (or) structural divisions of healthcare organizations that carry out laboratory diagnostics, regardless of ownership and departmental affiliation.
     2. The medical laboratory, when performing work at its permanent location or in another place, outside its permanent location, complies with the requirements of the State Standard of the Republic of Kazakhstan ST RK ISO 15189-2008 “Medical Laboratories. Specific requirements for quality and competence” (hereinafter referred to as ST RK ISO 15189-2008).
     3. In this provision, the following concepts are used:
     1) proficiency testing provider - an organization engaged in the development and implementation of proficiency testing schemes in accordance with the State Standard of the Republic of Kazakhstan ST RK ISO / IEC 17043-2012 “Conformity assessment. Basic requirements for proficiency testing” (hereinafter referred to as the standard ST RK ISO / IEC 17043-2012);
     2) biological material (hereinafter - biomaterial) - a material of biological origin obtained from the human body;
     3) biomaterial collection and reception point (hereinafter referred to as PZ) - a structural subdivision of a medical organization of inpatient, outpatient levels, in which the patient's biomaterial is collected, received and laboratory tests are carried out using portable analyzers and rapid tests;
     4) a specialist in biosafety and biosecurity - a laboratory specialist with a higher education (medical, biomedical, medical and preventive, biological, chemical, chemical-biological, pharmaceutical, physical and mathematical) responsible for the development and implementation of an effective policy (program) of biological safety and biological protection of the laboratory;
     5) study at the place of treatment (hereinafter - IML) - a qualitative or quantitative laboratory study, which is performed directly at the patient's location on portable analyzers and rapid tests;
     6) laboratory diagnostics - a set of medical services aimed at establishing the fact of the presence or absence of a disease (condition) through laboratory studies of biomaterials obtained from a patient;
     7) laboratory research - a set of operations carried out in a medical laboratory, the object of which is to determine the value or characterize the properties of a biomaterial;
     8) stage of laboratory research - the time interval for performing a laboratory research;
     9) interlaboratory comparative tests (hereinafter - MLTS) - organization, conduct and evaluation of measurements or tests on the same or similar samples by two or more laboratories in accordance with previously defined conditions;
     10) clinical diagnostic laboratory (hereinafter - CDL) - a medical laboratory that carries out the production of planned laboratory tests (general clinical, biochemical, microbiological, immunological (serological), cytological and molecular biological) necessary for the diagnosis of various pathological conditions;
     11) transport logistics company - a company that has specially equipped vehicles and organizes the delivery of biomaterials from the PZ to the medical laboratory along the optimal route in compliance with the rules of triple packaging and temperature conditions in accordance with ST RK ISO 15189-2008;
     12) specialized medical laboratory (hereinafter - LSU) - a medical laboratory that carries out serial execution of planned laboratory tests for the differential diagnosis of diseases in a network of specialized medical organizations;
     13) medical laboratory - a legal entity or a structural subdivision of a healthcare organization that conducts laboratory studies of biomaterial in order to obtain information for the diagnosis, prevention or treatment of a disease or assess the state of human health and provide advice on aspects of the laboratory studies performed, including interpretation of the results;
     14) centralized medical laboratory (hereinafter - CML) - a medical laboratory that carries out serial production of scheduled and unscheduled laboratory tests (general clinical, biochemical, microbiological, immunological (serological), cytological and molecular biological), rare, expensive laboratory tests necessary for diagnostics of various pathological conditions;
     15) reference laboratory (hereinafter - RL) - a medical laboratory that carries out organizational and methodological work on the implementation of an external quality assessment system (hereinafter - EQA) and conducts research in diagnostically complex and expert cases;
     16) quality manager - a health care manager or laboratory specialist with a higher medical and (or) non-medical education, responsible for the implementation, provision and maintenance of the quality management system;
     17) expert laboratory (hereinafter - EL) - a medical laboratory that carries out coordination work on the implementation of centralization, the introduction of an external quality assessment system (hereinafter - EQA) and conducting expert research in the serviced region;
     18) pre-analytical stage - procedures that chronologically begin with the appointment of a study by a profile specialist, the inclusion of a study in the application, covering the preparation of the patient, taking the primary sample, transporting it to the laboratory and ending with the start of the study;
     19) analytical stage - procedures that chronologically begin after the receipt of the biomaterial in the laboratory, including the process of performing the study according to the appropriate analysis technique;
     20) post-analytical stage - procedures that chronologically begin after the examination, including systematization, formulation and interpretation, permission for issuance, registration and transfer of examination results and storage of the examined samples;
     21) analysis methodology - a detailed description of all conditions and operations that provide regulated characteristics of the error (convergence, reproducibility, correctness) when performing the analysis;
     22) rater (hereinafter referred to as rater) - a list of medical services with an indication of their cost, established in accordance with paragraph 5 of article 35 of the Code of the Republic of Kazakhstan dated September 18, 2009 "On the health of the people and the healthcare system".

 **2. Organization of activities of medical laboratories**

4. Laboratory diagnostics is carried out by specialists (head of the laboratory, laboratory specialist, laboratory assistant) who meet the qualification characteristics approved by the order of the Acting Minister of Health of the Republic of Kazakhstan dated November 26, 2009 No. registration of normative legal acts under No. 5945).
5. Ensuring the quality management system in the medical laboratory is the responsibility of the quality manager. A biosafety specialist is introduced into the laboratory staff (if the staff of the laboratory staff is less than twenty positions, the function is assigned to the quality manager).
6. The states of the medical laboratory staff are established in accordance with the staffing standards approved by the order of the Minister of Health of the Republic of Kazakhstan dated April 7, 2010 No. 238 “On approval of model staffing and staffing standards for healthcare organizations” (registered in the Register of State Registration of Regulatory Legal Acts under No. 6173 ).
7. The medical laboratory is located in specially equipped, isolated rooms that meet the sanitary and epidemiological requirements approved by the order of the Acting Minister of the National Economy of the Republic of Kazakhstan dated February 24, 2015 No. 127 “On approval of the Sanitary Rules “Sanitary and epidemiological requirements for healthcare facilities” (registered in the Register of State Registration of Regulatory Legal Acts under No. 10713) and the Order of the Acting Minister of the National Economy of the Republic of Kazakhstan dated April 15, 2015 No. 338 “On Approval of the Sanitary Rules “Sanitary and Epidemiological Requirements for Laboratories Using Potentially Hazardous Chemical and Biological Substances” (registered in the Register of State Registration of Normative Legal Acts under No. 11099).
8. The medical laboratory, regardless of the form of ownership and departmental affiliation, maintains medical records approved by the order of the Acting Minister of Health of the Republic of Kazakhstan dated November 23, 2010 No. 907 "On approval of the forms of primary medical documentation of healthcare organizations" No. 6697).
9. The medical laboratory maintains statistical reports on forms and submits reports on time, in accordance with the order of the Minister of Health of the Republic of Kazakhstan dated March 6, 2013 No. 128 "On approval of forms intended for the collection of administrative data of healthcare subjects" (registered in the Register of State Registration legal acts under No. 8421).
10. A medical laboratory for an effective system for managing information about patients and research results uses laboratory information systems (hereinafter referred to as LIS).
11. When organizing a laboratory study, a medical laboratory performs processes for managing the quality of clinical laboratory studies according to the principle of stages, which includes the pre-analytical, analytical and post-analytical stages of a laboratory study.
12. Medical laboratories use equipment certified and registered in the Republic of Kazakhstan, diagnostic reagent kits, test systems and consumables, except for cases of state testing of the specified equipment, consumables or reagent kits.
13. Medical laboratory technologies used in the work of a medical laboratory are determined by the Nomenclature of clinical laboratory methods in accordance with the appendix to this Regulation.
14. To ensure the quality of all types of laboratory research, the medical laboratory conducts intralaboratory quality control and participates in external quality control programs, including in the form of MLSI, conducted by an accredited proficiency testing provider. The procedure for conducting the MLSI is regulated by the standard ST RK ISO/IEC 17043-2012.
15. Organizational and methodological assistance and coordination of the activities of medical laboratories is carried out by local public health authorities of regions, cities of republican significance and the capital.
The coordination of the activities of the reference laboratory is carried out by the authorized body in the field of healthcare.

**3. Tasks of the medical laboratory**

16. The tasks of the medical laboratory are:
1) centralization of laboratory research to ensure the availability of a wide range of services in the field of laboratory diagnostics to the population within the guaranteed volume of free medical care;
2) achieving, maintaining, improving the accuracy, timeliness of results to ensure the quality of laboratory research;
3) quality management at all stages of laboratory research, standardization of the technological process, implementation of measures to implement a quality management system, ensure biological safety in accordance with ST RK ISO 15189-2008;
4) introduction of reagent-free biomaterial research technology for conducting research at the place of patient treatment;
5) organization and conduct of work on the training of qualified specialists of medical laboratories.

**4. Types of medical laboratories**

17. Medical laboratories:
1) according to the form of ownership are divided into:
state;
private;
2) according to the types and scope of research, functional powers are divided into:
clinical diagnostic laboratory;
centralized medical laboratory;
specialized medical laboratory;
expert laboratory;
reference laboratory (national, republican).
18. To ensure the availability of laboratory diagnostics in outpatient and inpatient health care organizations, PZs are organized.
The PP provides for rooms for blood sampling, a room for receiving biological material, a room for sample preparation and temporary storage of biological material.
Biomaterial is taken and received, stored, centrifuged, biomaterial is prepared for transportation to the medical laboratory and the patient's data is registered in the laboratory information system in the PZ.
Transportation of biomaterial, including by road, air and rail, is carried out in compliance with the rules of triple packaging and temperature conditions in accordance with ST RK ISO 15189-2008.
The health facility with IML at the outpatient level functions during the working day in accordance with the working hours of the medical organization.
19. In medical organizations providing primary health care (medical and feldsher-obstetric stations, outpatient clinics, family health centers, polyclinics), personnel with secondary medical education (nurse, paramedic) conduct research on the diagnosis of emergency conditions using portable analyzers on test strips drop by drop of biomaterial.
In medical organizations providing inpatient care, maternity hospitals and perinatal centers, the laboratory staff consists of personnel with higher medical education, higher non-medical education and secondary medical education (medical assistant, laboratory assistant).
20. In hospitals that have a surgical department, resuscitation and intensive care, laboratory diagnostics of emergency conditions of a surgical and therapeutic profile is carried out around the clock. For an emergency assessment of the pathological condition of patients, general clinical and biochemical studies are carried out, including rapid tests using bedside technologies.
21. IML, including for emergency laboratory tests, is carried out:
in medical organizations providing primary health care (medical and feldsher-obstetric stations, medical outpatient clinics, family health centers, polyclinics) - blood glucose tests are carried out, blood hemoglobin, cardiac markers, preeclampsia test, viral hepatitis B and C test, urine protein test;
in medical organizations providing inpatient care, maternity hospitals and perinatal centers - a general blood test, a general urinalysis, a urinalysis according to Nechiporenko, a urinalysis according to Zimnitsky, coagulograms - prothrombin (hereinafter - PT), thrombin time, international normalized ratio ( hereinafter - INR), activated partial thromboplastin time (hereinafter - APTT), fibrinogen, soluble fibrin monomer complex (hereinafter - SFMC), D-dimer; biochemical studies - total protein, urea, creatinine, blood glucose, alanine aminotransferase (hereinafter - ALT), aspartate aminotransferase (hereinafter - AST), total bilirubin, direct bilirubin, total and pancreatic amylase, creatinine kinase (hereinafter - CK), myoglobin, troponin, electrolytes ; test for preeclampsia, determination of urine protein, analysis of acid-base state (hereinafter referred to as acid-base balance), tests for viral hepatitis, microprecipitation reactions (microreaction), rapid diagnosis of HIV / AIDS.
22. The head of the centralized laboratory organizes the activities of the PZ with IML, organized in medical organizations.

**5. Clinical diagnostic laboratory**

23. CDL is organized as a legal entity or is a structural subdivision of a healthcare organization.
24. CDL provides the PZ with disposable, sterile means for collecting biomaterial, consumables for storing and transporting biomaterial.
25. CDL carries out the organization of activities and control over compliance with the conditions and requirements for the collection, acceptance, storage of biomaterial and provides logistics and transportation of biomaterial from the PZ, including with the involvement of transport logistics companies.
26. The tasks of the CDL are:
1) standardization of the process of performing laboratory tests, the continuity of the results of laboratory analysis;
2) ensuring the quality of laboratory research by achieving accuracy, reliability, timeliness of issuing research results, conducting intralaboratory quality control and participating in external quality assessment;
3) the introduction of highly informative technologies, automation and informatization of the laboratory process.

**6. Centralized medical laboratory**

27. CML is organized by decision of the local health authorities as an independent organization and (or) on the basis of medical laboratories of multidisciplinary district hospitals, regional and city clinical diagnostic centers, hospitals, as well as on the basis of polyclinics of cities of republican significance and the capital.
28. CML is created with the aim of:
1) standardizing the process of performing laboratory tests, the continuity of the results of laboratory analysis;
2) improving the quality of laboratory research;
3) introduction of highly informative technologies, automation and informatization of the laboratory process;
4) fully meet the needs of organizations and patients by expanding the range of laboratory tests;
5) economic efficiency with minimization of the cost of research by reducing the cost of purchasing reagents and consumables, purchasing and maintaining equipment and increasing the flow of research;
6) reduction of terms of performance of laboratory researches.
29. CML provides PZs with IML with disposable, sterile means for collecting biomaterial, consumables for storing and transporting biomaterial.
30. CML organizes activities and monitors compliance with the conditions and requirements for the collection, acceptance, storage of biomaterial and provides logistics and transportation of biomaterial from the PZ, including with the involvement of transport logistics companies.
31. The CML, with a high capacity of the laboratory and conducting research for hospitals and emergency services, operates around the clock.
32. CML at the district, city and regional level, in accordance with the tariff set, conducts the following types of research:
general clinical;
hematological;
cyto-histological;
biochemical;
coagulological;
chemical-toxicological;
immunological and isoserological;
microbiological;
molecular genetic.
33. CML is organized by local health authorities on the basis of an existing laboratory, taking into account:
1) the development of the laboratory infrastructure (the level of material and technical equipment, qualified personnel), including the possibility of redistributing existing high-tech equipment for the purpose of effective use;
2) the production capabilities of the laboratory to fully meet the needs of organizations and patients in laboratory research in its service area, the ability to comply with the stages of laboratory research and the conditions for transporting biomaterials;
3) ensuring laboratory quality: accuracy, reliability and timeliness of issuing research results;
4) the volume of needs for laboratory research of medical organizations located in the proposed centralization zone.
34. The organization of the activities of a private laboratory, when participating in the provision of services for medical organizations under a subcontract agreement, is provided in accordance with the activities of a centralized and (or) specialized medical laboratory.

**7. Specialized medical laboratory**

35. LSU is organized by decision of the authorized body in the field of healthcare or local healthcare authorities as an independent organization and (or) on the basis of laboratories in the place of the main localization of a specialized service as a structural unit of specialized medical organizations.
LSU at the district, city, regional, republican level, in accordance with the tariff set, conducts the following types of research:
immunohematological;
cytological;
serological;
microbiological (bacteriological);
molecular genetic.
36. LSU carries out centralized provision of disposable, sterile means for collecting biomaterial, consumables for storing and transporting biomaterial.
37. LSU carries out the organization of activities and control over compliance with the conditions and requirements for the collection, acceptance, storage of biomaterial and provides logistics and transportation of biomaterial from the PZ at the expense of its own fleet of special vehicles. It is acceptable to involve transport logistics companies.
38. LSU carries out activities in accordance with the legislation on the health of the people and the healthcare system.

**8. Expert laboratory**

39. EL is created by the decision of the authorized body in the field of healthcare on the basis of centralized and specialized medical laboratories in regional centers and the capital, equipped, highly efficient laboratories with a high level of performance indicators and quality control results and a quality management system.
40. Tasks of the EL:
1) organization of activities for the implementation of external quality control programs in the form of interlaboratory comparative comparisons;
2) introduction of new technologies for laboratory diagnostics, development and expert evaluation of programs for the modernization of diagnostic laboratories;
3) analysis of the work of the laboratory diagnostics service of the served regions in order to improve the quality of the examination, rational use of staff and laboratory equipment;
4) conducting expert studies in case of diagnostic complexity, resolving controversial issues in laboratory diagnostics.

**9. Reference laboratory (national, republican)**

41. The RL is created by the decision of the authorized body in the field of healthcare on the basis of scientific and republican specialized centers, research institutes with an implemented and operating quality management system, having an accreditation certificate for compliance with national and international standards, participating in international projects and scientific programs in the field of healthcare .
42. Tasks of the RL:
1) creation and organization of a national system of laboratory research in the form of MLSI in accordance with the standard ST RK ISO/IEC 17043-2012 in the presence of accreditation of the proficiency testing provider;
2) coordination of the activities of medical laboratories for participation in the FQA research program carried out by external organizations, including foreign ones;
3) providing organizational and methodological work to medical laboratories in an objective assessment of the quality of research performed;
4) introduction and conduct of rare laboratory tests using high-tech methods and equipment;
5) carrying out research work on the development of reference intervals for laboratory studies;
6) training and advanced training of laboratory service specialists.
43. The organization of the national system of EQA for laboratory research includes:
1) development and improvement of technologies for managing the quality of laboratory research;
2) integration with international organizations involved in the assessment and improvement of quality management systems for laboratory research;
3) use of the results of the WQA for the rejection of methods, equipment, technologies;
4) assistance in the development of regional, commercial, specialized EQA programs.

Appendix to the Regulations
on the activities of organizations
and (or) structural units
of healthcare organizations that
carry out laboratory diagnostics

**Nomenclature of clinical laboratory methods**

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| **No.** | **Method name** |
| one. | physical and chemical |
| 2. | colorimetric |
| 3. | microscopic |
| 4. | conductometric |
| five. | flow cytometry |
| 6. | chemical |
| 7. | photometric |
| 8. | turbidimetric |
| nine. | nephelometric |
| 10. | refractometric |
| eleven. | polarimetric |
| eleven. | electrophoresis |
| thirteen. | chromatographic |
| fourteen. | potentiometric |
| 15. | volammetric |
| 16. | polarographic |
| 17. | fluorometric |
| eighteen. | polarographic |
| nineteen. | gravimetric |
| 20. | immunochemiluminescent |
| 21. | electrochemiluminescent |
| 22. | clotting |
| 23. | chromogenic |
| 24. | serological (isoserological) |
| 25. | bacteriological |
| 26. | immunological (immunoenzymatic) |
| 27. | cytological |
| 28. | cytochemical |
| 29. | histological |
| thirty. | polymerase chain reaction |
| 31. | sequencing |
| 32. | multiplex ligase-dependent amplification |
| 33. | mass spectrometry |
| 34. | biological microchip |
| 35. | cytogenetic |
| 36. | fluorescent hybridization |
| 37. | radioimmune |

Annex 2
to the order of the Minister of Health
and Social Development of
the Republic of Kazakhstan
dated September 28, 2015 No. 758

**The scope and types of research conducted by organizations and (or)**
**structural units of healthcare organizations that**
**carry out laboratory diagnostics**

1. The volume of laboratory research is determined by the types of medical laboratories and is carried out in accordance with the standards in the field of healthcare, in accordance with Article 7 of the Code of the Republic of Kazakhstan dated September 18, 2009 "On the health of the people and the healthcare system".
2. Types of laboratory studies:
1) general clinical - chemical and microscopic studies of biological fluids (urine, feces, sputum, duodenal contents, gastric contents, cerebrospinal fluid, transudates and exudates, ejaculate, discharge of female genital organs, and others);
2) hematological - studies aimed at analyzing hemoglobin and its compounds, morphological, physiological and cytochemical characteristics of blood cells and bone marrow;
3) cyto-histological - morphological studies of biological materials obtained by various methods: puncture, exfoliative, endoscopic and others;
4) immunohistochemical studies with monoclonal antibodies, flow cytometry;
5) biochemical - studies at the level of chemical, physico-chemical constituent biological material;
6) coagulological - studies that determine vascular-platelet and coagulation hemostasis, anticoagulant and fibrinolytic systems;
7) immunological and isoserological - laboratory studies characterizing the state of the immune system;
8) chemical-toxicological studies of medicines for therapeutic monitoring;
9) microbiological - studies on the detection of microorganisms in biological materials (virology, bacteriology, molecular biology, mycology, parasitology, immunoserology);
10) cytogenetic - study of the number and structure of chromosomes in the analyzed cells;
11) molecular genetic - detection of changes in the structure of the genome at the level of deoxyribonucleic and ribonucleic acids.

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