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## **ANALYSIS OF QUALITY INDICATORS IN THE PREANALYTICAL PHASE OF LABORATORY DIAGNOSTICS AT THE CLINICAL DIAGNOSTIC LABORATORY OF THE «NATIONAL RESEARCH ONCOLOGY CENTER», ASTANA, KAZAKHSTAN**

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### **Abstract**

**Background.** The primary focus of the clinical diagnostic laboratory is to ensure the attainment of high-quality results for patient laboratory analyses.

**Aim:** This study aims to evaluate the effectiveness of employing quality indicators during the preanalytical phase in the "NROC LLP" laboratory through a comparative analysis of the first and second quarters of 2022. By examining this aspect, valuable insights can be gained to enhance the overall efficiency and reliability of laboratory procedures.

**Results.** The preanalytical phase encompasses a complex set of processes and actions that occur from the moment laboratory tests are prescribed to the initiation of analytical measurements (such as sample loading into analyzers, etc.). This stage involves not only laboratory staff but also the entire medical personnel of the departments. By implementing quality indicators during the preanalytical phase, the functioning of the procedural unit, blood sampling techniques, and proficiency in handling documentation can be assessed. Additionally, this study shed light on the organization of work within the laboratory during this stage. The research methods employed were derived from "Quality Indicators in Laboratory Medicine" proposed by the IFCC Working Group under the guidance of M. Plebani, as well as the current regulations of the Ministry of Health of the Republic of Kazakhstan.

**Conclusions.** Based on our research, quality indicators tend to improve when regular work is conducted with laboratory staff and the average medical personnel of our Center. Quality performance during this stage enables accurate diagnosis and facilitates appropriate patient treatment.

**Keywords:** *laboratory diagnostics, preanalytical stage, quality indicator.*

### **Резюме**

## **АНАЛИЗ ПОКАЗАТЕЛЕЙ КАЧЕСТВА НА ПРЕАНАЛИТИЧЕСКОМ ЭТАПЕ ЛАБОРАТОРНОЙ ДИАГНОСТИКИ В КЛИНИЧЕСКО-ДИАГНОСТИЧЕСКОЙ ЛАБОРАТОРИИ «НАЦИОНАЛЬНОГО НАУЧНОГО ОНКОЛОГИЧЕСКОГО ЦЕНТРА», АСТАНА, КАЗАХСТАН**

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**Актуальность.** В настоящее время основной задачей клинико-диагностической лаборатории является получение качественных результатов лабораторных анализов больного.

**Цель исследования:** Оценить эффективность применения индикаторов качества преаналитического этапа в лаборатории «ТОО ННОЦ» путем сравнительного анализа I-II кварталов 2022 года.

**Результаты:** Преаналитический этап – это комплекс процессов и действий, осуществляемый от момента назначения лабораторных анализов до начала проведения аналитического измерения (загрузки проб в анализаторы

и т. д.). На этом этапе участие принимают не только сотрудники лаборатории, а весь медицинский персонал отделений. Внедряя индикаторы качества преаналитического этапа можно увидеть работу процедурного кабинета, техника забора крови, умение работать с документацией. Также показали, как у нас организована работа в лаборатории на этом этапе. Методы исследования были взяты из «Индикаторы качества лабораторной диагностики» (предложены рабочей группой ИКЛД под руководством М. Плебани, действующих приказов Министерства здравоохранения Республики Казахстан).

**Выводы:** Индикаторы качества по нашему исследованию имеют тенденцию к улучшению, если на регулярной основе проводить работу с сотрудниками лаборатории и среднего медперсонала нашего Центра. Качественная работа на этом этапе дает возможность для постановки правильного диагноза и в дальнейшем лечении пациента.

**Ключевые слова:** лабораторная диагностика, преаналитический этап, индикатор качества

Түйіндеме

## «ҰЛТТЫҚ ҒЫЛЫМИ ОНКОЛОГИЯЛЫҚ ОРТАЛЫҚТЫҢ» КЛИНИКАЛЫҚ- ДИАГНОСТИКАЛЫҚ ЗЕРТХАНАСЫНДА ЗЕРТХАНАЛЫҚ ДИАГНОСТИКАНЫҢ АНАЛИТИКАЛЫҚ КЕЗЕҢІНДЕГІ САПА КӨРСЕТКІШТЕРІН ТАЛДАУ, АСТАНА, ҚАЗАҚСТАН

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**Өзектілігі.** Қазіргі уақытта клиникалық-диагностикалық зертхананың негізгі міндеті пациенттің зертханалық талдауларының сапалы нәтижелерін алу болып табылады.

**Зерттеу мақсаты:** 2022 жылдың I-II тоқсандарын салыстырмалы талдау арқылы "ННОЦ ЖШС" зертханасында аналитикалық кезеңге дейінгі сапа индикаторларын қолданудың тиімділігін бағалау.

**Нәтижелер:** Аналитикаға дейінгі кезең-бұл зертханалық талдаулар тағайындалған сәттен бастап Аналитикалық өлшеу басталғанға дейін (сынамаларды анализаторларға жүктеу және т.б.) жүзеге асырылатын процестер мен әрекеттер жиынтығы. Бұл кезеңге тек зертхана қызметкерлері ғана емес, бөлімшелердің барлық медициналық қызметкерлері қатысады. Аналитикалық кезеңнің сапа индикаторларын енгізе отырып, процедуралық кабинеттің жұмысын, қан алу техникасын, құжаттамамен жұмыс істеу қабілетін көруге болады. Сондай-ақ, осы кезеңде зертханада жұмысты қалай ұйымдастырғанымызды көрсеттік. Зерттеу әдістері "Зертханалық диагностика сапасының индикаторлары" (М.Плебанидің басшылығымен ЗДСИ жұмыс тобы ұсынған, қолданыстағы Бұйрықтар Қазақстан Республикасы Денсаулық сақтау министрлігі).

**Қорытындылар:** Сапа көрсеткіштері. егер біздің орталықтың зертхана қызметкерлерімен және орта медициналық қызметкерлермен тұрақты негізде жұмыс жүргізілсе, біздің зерттеуіміз жақсарады. Осы кезеңдегі сапалы жұмыс дұрыс диагноз қоюға және пациентті одан әрі емдеуге мүмкіндік береді.

**Түйін сөздер:** зертханалық диагностика, аналитикалық кезең, сапа көрсеткіші.

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**Abbreviations:**

**CARIC** - Center for Anesthesiology, Resuscitation, and Intensive Care

**OR** - Oncohematological Resuscitation

**DBMT** - Department of Bone Marrow Transplantation

**CHS** - Center for Hepatopancreatobiliary Surgery, Oncological Hepatology, and Organ Transplantation

**CCC** - Center for Chemotherapy and Chemoreduction

**HEMO** - Hematology

**CVS** - Center for Vascular Surgery

**MPD** - Multi-profile Paid Department

**COO** - Center for Orthopedics and Osteoncology

**CDC** - Consultative Diagnostic Center with Day Hospital

**CMS** - Center for Multi-profile Surgery

**Introduction**

Laboratory medicine is currently one of the most extensive branches of clinical medicine in terms of the number of tests conducted. According to WHO data, laboratory investigations account for 75-90% of the total number of various tests performed on patients in healthcare facilities [1].

The preanalytical (Pre-A) phase is responsible for 46-77% of all errors in the overall testing process, with the following breakdown:

- Patient identification errors: 40.8%
- Blood collection errors: 12.2%
- Sample preparation errors: 30%
- Biological material transportation errors: 17%

Every laboratory should have a policy in place for error detection and prevention. The frequency of errors should be systematically determined using standardized methods [2-4].

In this study, our aim was to establish a system in our laboratory for the collection and assessment of Pre-A errors based on Quality Indicators (QIs) developed by the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) Working Group on Laboratory Errors and Patient Safety (WG-LEPS) [3-5].

Obtaining high-quality results of patient laboratory analyses is a unified process that encompasses various stages, starting from the formulation of test requests, collection of biomaterial, transportation, conducting the investigations, and concluding with the utilization of the results to provide the patient with quality medical care. The quality of this process should be ensured through collaborative efforts between physicians, the average medical personnel, and laboratory specialists [6].

The unified process of laboratory testing is commonly divided into three stages: the preanalytical, analytical, and postanalytical phases.

The preanalytical stage is a complex set of processes and actions that occur from the moment laboratory tests are prescribed to the initiation of analytical measurements (such as sample loading into analyzers, etc.). The preanalytical stage partly takes place outside the laboratory and includes the following steps [7-8]:

- Patient consultation and prescription of necessary laboratory tests by the physician.
- Completion of the test request form.

- Provision of instructions to the patient by the physician or medical nurse regarding the specific requirements for test preparation or collection of biological material.

- Collection of biological samples from the patient in the procedural unit or inpatient department.

- Transportation of the biomaterial to the laboratory.

The following quality indicators for the preanalytical stage have been implemented in the laboratory:

- 1) Errors in patient identification
- 2) Incorrect sample type
- 3) Number of samples unsuitable for testing, including clotted samples
- 4) Hemolyzed samples

All samples that fall into the above-mentioned categories are recorded in a non-conformity log by a registrar or laboratory technician. At the end of each month, the quality manager analyzes these cases and prepares an analytical report, which is then shared with the staff of clinical departments for review and implementation of corrective measures [9-11].

**Methods:**

We have identified the most common pre-analytical errors as follows:

- 1) Errors in patient identification
- 2) Incorrect sample type
- 3) Number of samples unsuitable for testing, including clotted samples
- 4) Hemolyzed samples.

We have standardized the terminology and structured the reporting system in our Hospital Information System (HIS) and Laboratory Information System (LIS). Data were collected monthly over a period of 6 months from 2021 to 2022. The collected data were analyzed; quality indicators (QI) were calculated.

The results were evaluated based on desired levels of effectiveness proposed by the WG-LEPS IFCC and regulatory acts of the Republic of Kazakhstan [3-5].

Quality indicators in laboratory diagnostics are evaluated in accordance with the regulatory documents and standards of the Republic of Kazakhstan:

"Approval of the Standard for the Organization of Laboratory Diagnostics." Order of the Minister of Health of the Republic of Kazakhstan No. KR DSM-257/2020, dated December 11, 2020. Registered with the Ministry of Justice of the Republic of Kazakhstan on December 14, 2020, No. 21768.

"Approval of Reporting Documentation Forms in the Healthcare Sector and Instructions for Their Completion." Order of the Acting Minister of Health of the Republic of Kazakhstan No. KR DSM-175/2020, dated October 30, 2020. Registered with the Ministry of Justice of the Republic of Kazakhstan on November 4, 2020, No. 21579.

"Approval of Reporting Documentation Forms in the Healthcare Sector." Order of the Minister of Health of the Republic of Kazakhstan No. KR DSM-313/2020, dated December 22, 2020. Registered with the Ministry of Justice of the Republic of Kazakhstan on December 23, 2020, No. 21879.

**Results:**

The quality indicators (QI) for the 1st and 2nd quarters of 2022 in the clinical diagnostic laboratory revealed that "Quantity of samples unsuitable for testing, clotting" and

"Hemolyzed samples" had the highest deviations from the recommended references. Therefore, these errors should be prioritized in quality improvement efforts.

Table 1. reflects the quality indicators for the Center, highlighting the improving trend in the indicators. The values correspond to the reference standards specified in the Standard.

Table 1.

#### Quality Indicators for the 1st and 2nd Quarter of 2022 in the Clinical Diagnostic Laboratory

№	Indicator	Recommended value	1 <sup>st</sup> quarter	2 <sup>nd</sup> quarter
1	Identification errors	0,1%	0%	0,024%
2	Incorrect sample type	0,03%	0,014%	0,009%
3	Quantity of samples unsuitable for testing, clotting	0,1%	0,06%	0,03%
4	Hemolyzed samples	0.06%	0,03%	0,004 %

Information source: Rejection log and material collection report  
Frequency of information: Monthly

Table 2. shows that over a 6-month period in 2021, a total of 151,955 samples were received at the pre-analytical stage from the departments, out of which 173 samples were categorized as unsuitable, accounting for 0.11%. In the same 6-month period in 2022, a total of 151,723 samples were received at the pre-analytical stage from the departments, out of which 119 samples were categorized

as unsuitable, accounting for 0.078%. There is a trend of improvement in the coefficient. The number of samples categorized as "hemolyzed" decreased by a factor of seven, and the number of samples categorized as "unsuitable for testing, clotting" decreased by 44 samples. The implementation of "identification errors" was initiated in April 2022 based on the recommendation of the Center's auditor.

Table 2.

#### Number of samples rejected during the pre-analytical stage.

	2021 (6 months)	2022 (6 months)
Total samples received during the pre-analytical stage	151955	151723
Incorrect sample type	22	14
Hemolyzed samples	50	7
Identification errors	0	37
Quantity of samples unsuitable for testing, clotting	98	54
Others	3	7
Total	173 (0,11%)	119 (0,078%)

During the investigated period, the number of samples categorized as unsuitable decreased by 54 samples. It is worth noting that no identification errors were addressed in 2021, whereas in 2022 there were 37 samples with identification errors. Taking this into account, the overall

number of samples categorized as unsuitable for testing, clotting, hemolysis, and incorrect sample type decreased by 44 samples. However, there was an increase of 4 units in the number of samples categorized as hemolyzed.

Table 3.

#### Comparative analysis of pre-analytical stage errors by departments for the 1st and 2nd quarters.

	Quantity of samples unsuitable for testing, clotting		Hemolyzed samples		Incorrect sample type		Identification errors
	0,1 1 кв.	0,1 2 кв.	0,06 1 кв.	0,06 2 кв.	0,03 1 кв.	0,03 2 кв.	
Acceptable indicator range							
Center	0,06	0,04	0,03	0,004	0,014	0,009	0,024
CARIC	0	0,01	0	0,015	0,02	0,024	0,02
OR	0,029	0	0	0	0	0	0,012
CMS			0	0,004	0,004	0,012	0,015
HEMO	0,012	0,01	0,01	0,006	0,002	0,024	0,012
DBMT	0,09	0	0	0,003	0,021	0,024	0,024
CVS	0,22	0,23	0	0	0,003	0	0,021
CHS	0,1	0,04	0,13	0,002	0	0	0,050
CCC	0,17	0,28	0,068	0,003	0,011	0,012	0,027
COO	0,12	0,07	0,016	0	0,023	0	0,041
CDC	0,22	0	0	0	0	0,003	0,029
MPD	0,027	0	0,173	0,011	0,07	0,0	0,013

The recommended value for the "Quantity of samples unsuitable for testing, clotting" according to the Standard is 0.1%. However, in the CDL of "NROC" LLP, the values are

0.04% for the 1st quarter and 0.06% for the 2nd quarter. The highest indicators were observed in the CVS department with 0.22% and 0.23%, respectively. In the

CCC department, the values were 0.17% and 0.28%, while in the COO department, they were 0.12% and 0.07%, respectively. These findings demonstrate a notable enhancement in the respective indicator.

Over the course of 6 months, the indicator "Hemolyzed samples" at the Center was 0.01%, 0.03% for the first quarter, and 0.004% for the second quarter, falling within the recommended range according to the Standard of 0.06%. The table shows that the departments with the highest percentage of samples categorized as hemolyzed are MPD with 0.17% and 0.11%, CHS with 0.13% and 0.02%, and HEMO with 0.01% for the first quarter and 0.006% for the second quarter.

Regarding the indicator "Incorrect sample type," the recommended range according to the Standard is 0.03%. At the Center, the values were 0.014% for the first quarter and 0.009% for the second quarter. There were no violations observed for this indicator.

For the indicator "Identification errors," with recommended values of 0.1% according to the Standard, the Center had a value of 0.024%. The departments with the most identification errors were CHS with 0.05%, COO with 0.041%, and CDC with 0.029%.

#### Discussion:

Our findings demonstrate that quality indicators can be valuable for evaluating the Pre-A process, particularly in identifying frequently occurring errors. However, it is essential for the Hospital Information System (HIS) and Laboratory Information System (LIS) to be structured to collect error data, and the competence of laboratory staff in data management and utilization of quality control tools should be improved.

#### Summary by departments and recommendations for corrective actions:

Overall, there is an improvement in the indicators across all departments. The number of samples rejected has decreased. In the CVS, MPD, CHS, and HEMO 1, 2 departments, it is recommended to focus on refining blood collection techniques. Additionally, for identification purposes, it is advised that the average healthcare personnel diligently fill out the paper requisitions and cross-verify them with the Comprehensive Medical Information System (CMIS).

#### Conclusions:

The analysis of quality indicators demonstrates an observable improvement when comparing the first and second quarters. It is noteworthy that efforts should persist in addressing indicators that deviate from the established standards.

The pre-analytical stage plays a pivotal role in the overall process of laboratory testing, consuming a considerable amount of time. Even minor errors encountered during the pre-analytical stage inevitably led to the distortion of the quality of final laboratory test results. Thus, regardless of the laboratory's proficiency in subsequent analyses, the presence of errors during the pre-analytical stage impedes the attainment of reliable results.

All samples that have been rejected undergo thorough analysis, accompanied by collaborative efforts with the procedural unit's staff. At the conclusion of each quarter, departments are duly informed of any pre-analytical stage violations through the dissemination of an analytical report.

In the year 2022, a seminar was conducted involving the participation of the average healthcare personnel from the center after the analysis of the first-quarter performance. To enhance the quality indicators, it is imperative to engage in regular endeavors aimed at capacitating departmental healthcare personnel through ongoing professional development initiatives and refining their techniques for biomaterial collection. The implementation of seminars and workshops targeting the average healthcare personnel has yielded positive outcomes in the improvement of quality indicators. Moreover, it is crucial to emphasize the significance of patient preparation for sample collection, elucidating the pivotal role it plays in ensuring accurate test results.

Consequently, it is evident that the pre-analytical stage encompasses paramount importance in laboratory diagnostics, acting as a primary determinant in mitigating the occurrence of erroneous results and, subsequently, avoiding inappropriate treatment approaches.

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**Conflict of Interest.** The authors declare that they have no competing interests.

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