THE PRE-ANALYTICAL STAGE OF LABORATORY DIAGNOSTICS AND ITS IMPACT ON THE RELIABILITY OF RESULTS

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Laboratory diagnostics is an integral part of modern clinical medicine and plays a key role in diagnosis, monitoring disease progression, and evaluating the effectiveness of therapy. According to various studies, up to 70–80% of clinical decisions are made based on laboratory test results, which underscores their high diagnostic significance [1]. In this regard, ensuring the reliability and reproducibility of laboratory results is one of the priority tasks of the healthcare system. The laboratory process is traditionally divided into three main stages: pre-analytical, analytical, and post-analytical. Despite the active development of analytical technologies and the automation of laboratory tests, it is the pre-analytical stage that remains the most vulnerable link in laboratory diagnostics [2]. According to the World Health Organization and the International Federation of Clinical Chemistry (IFCC), up to 60–70% of all laboratory errors occur at the pre-analytical stage [3].

The pre-analytical stage covers all processes preceding the actual analysis of the sample, including the appointment of the study, preparation of the patient, collection of biological material, its labeling, transportation, storage, and preparation for analysis [4]. Errors made at any of these stages can lead to distorted laboratory results, false positive or false negative results, and, as a consequence, to erroneous clinical decisions [5]. With the introduction of high-precision automated analyzers, the importance of the preanalytical stage not only remains unchanged but also increases, since analytical systems are unable to compensate for errors made before the start of the test [6]. This determines the relevance of a comprehensive study of the factors of the preanalytical stage and their impact on the reliability of laboratory results.

The pre-analytical stage of laboratory diagnostics is a set of all organizational, clinical, and technical measures performed prior to the actual laboratory analysis of biological material. This stage begins when a clinical decision is made regarding the need for laboratory testing and ends when a correctly prepared sample is received by the analytical system [1]. It is during the pre-analytical stage that the initial conditions

are established, on which the reliability, reproducibility, and clinical interpretation of laboratory results largely depend [2].

In modern laboratory medicine, the pre-analytical stage is considered the most complex and multifactorial part of the laboratory process, as it involves the interaction of medical personnel of various specialties, the patient, and the laboratory service [3]. Unlike the analytical stage, which is largely automated and standardized, the preanalytical stage remains subject to human error and biological variations [4]. According to international studies, preanalytical errors account for 60 to 70% of all laboratory errors, which underscores its critical importance for ensuring the quality of laboratory diagnostics [5].

From a theoretical point of view, the pre-analytical stage covers the entire set of processes preceding the measurement of the analyte, including the clinical justification for the study, patient preparation, collection of biological material, its identification, transportation, storage, and pre-processing [6]. Each of these components is an independent source of possible distortions of laboratory indicators and requires strict compliance with regulatory and methodological requirements [7].

The pre-analytical stage of laboratory diagnostics is conventionally divided into several interrelated sub-stages. The first structural component is the prescription of a laboratory test. The correctness of the clinical prescription of the analysis, the selection of the optimal diagnostic test, and the indication of the clinical context are of fundamental importance for the subsequent interpretation of the results [8]. Incorrect selection of the test or lack of clinical information can lead to diagnostic errors even with technically flawless performance of the analysis [9].

The second important element of the pre-analytical stage is preparing the patient for laboratory testing. The physiological state of the body, dietary characteristics, level of physical activity, medication use, and biological rhythms have a significant impact on the concentration of many laboratory parameters [10]. Failure to follow patient preparation rules is one of the most common causes of preanalytical errors and can lead to false or clinically distorted results [11].

The third structural component is the collection of biological material. This stage includes selecting the optimal type of material, following collection techniques, using appropriate tubes and reagents, and preventing contamination and mechanical damage to the sample [12]. Violations at this stage can cause hemolysis, coagulation, changes in analyte concentration, and a decrease in the diagnostic value of the study [13].

The fourth element of the preanalytical stage is the identification and labeling of biological samples. Correct identification of the patient and sample is a prerequisite for the safety of laboratory diagnostics [14]. Labeling errors, sample substitution, or loss are among the most dangerous preanalytical errors, as they can lead to the erroneous attribution of results to another patient [15].

The fifth component of the preanalytical stage is the transportation and storage of biological material. At this stage, it is particularly important to maintain the correct temperature, delivery times, and biosafety conditions [16]. Violation of these requirements can lead to the degradation of biological molecules, the activation of enzymatic processes, and changes in analytical indicators [17].

The final element of the pre-analytical stage is sample pretreatment, which includes centrifugation, fraction separation, aliquoting, and preparation of the material for analysis [18]. Errors at this stage can be a source of systematic deviations in results and significantly reduce their reproducibility [19]. Patient preparation is one of the most significant factors determining the reliability of laboratory results. The physiological state of the body, diet, physical activity, medication, and psycho-emotional stress can significantly affect the concentration of the parameters being studied [10].

Violation of patient preparation rules, such as failure to fast before biochemical tests, can lead to changes in glucose, lipid, hormone, and enzyme levels [11]. Physical activity before blood sampling can cause transient changes in creatine kinase, lactate dehydrogenase, and electrolyte levels [12]. Of particular importance is the use of medications that can affect laboratory test results either directly or indirectly [13]. In this regard, patient education and standardization of preparation procedures are prerequisites for ensuring the reliability of laboratory diagnostics.

The collection of biological material is a key stage in the pre-analytical process of laboratory diagnostics, directly affecting the reliability and reproducibility of results. This process includes selecting the type of material, complying with collection rules, using specialized containers and protective equipment, and ensuring conditions of minimal contamination and damage to the sample [1]. Errors at this stage can lead to distorted analytical indicators and, as a result, to incorrect interpretation of data, which is particularly critical in clinical practice [2].

The choice of biological material type is one of the most important decisions. Depending on the purpose of the study, blood, urine, saliva, cerebrospinal fluid, tissue samples, or cells may be used. Each type of material has its own characteristics that affect the stability of analytes and the interpretation of results. For example, venous blood serum is preferred for assessing metabolic disorders, while smears or cultures of specific tissues are preferred for detecting infectious agents [3]. Mismatching the type of material to the research objectives can lead to false positive or false negative results [4].

The technique of collecting biological material plays a crucial role. In the case of blood, errors in the collection procedure can cause hemolysis, which leads to the destruction of cellular components and the release of intracellular enzymes, affecting biochemical parameters [5]. Incorrect use of needles, excessive pressure during

collection, and multiple punctures in one place are all sources of preanalytical errors [6]. Similarly, when collecting urine or saliva, it is important to avoid contamination by foreign microorganisms, which can distort the results of microbiological and molecular analysis [7].

The use of specialized containers and equipment is also critical. Tubes with anticoagulants, preservatives, and stabilizers help keep biological material intact and prevent it from breaking down before analysis [8]. Picking the wrong tube, not labeling it, or not storing it right can mess up the analytes, make the test less sensitive, and mess up the quantitative results [9]. The impact of time and temperature factors on material quality cannot be underestimated. Prolonged storage of biological material at an inappropriate temperature leads to protein destruction, nucleic acid degradation, and changes in metabolite concentration [10]. Rapid transportation and adherence to temperature conditions are essential for maintaining data reliability [11].

Finally, the training and qualification of personnel performing material collection is of key importance. Studies show that human error accounts for up to 50% of all pre-analytical errors [12]. Standardized collection protocols and regular staff certification minimize the risk of such errors and improve the quality of laboratory diagnostics [13].

Thus, the correct collection of biological material is a critical condition for obtaining reliable laboratory results. This process combines several key aspects: the choice of material, the collection technique, the use of specialized containers and protective equipment, compliance with transportation and storage conditions, and the professionalism of medical personnel. Any violation at this stage can lead to systematic and random errors, which emphasizes the need for strict adherence to standards and protocols in modern laboratory practice [14].

Correct identification of samples is a prerequisite for the reliability of laboratory tests. Labeling errors, sample substitution, or loss are among the most dangerous preanalytical errors, as they directly affect patient safety [18]. Biological material must be transported and stored in compliance with temperature requirements, time intervals, and biosafety conditions [19]. Failure to comply with these requirements may lead to analyte degradation, activation of enzymatic processes, and changes in the concentration of the substances being studied [20].

Errors in the preanalytical phase have a direct impact on the clinical interpretation of laboratory data. Distorted results can lead to incorrect diagnoses, the prescription of inappropriate treatment, or delays in treatment [21]. Pre-analytical errors are particularly critical in emergency diagnostics, intensive care, and oncology, where laboratory indicators play a decisive role in the choice of treatment tactics [22]. In this regard, minimizing pre-analytical errors is a key task of the laboratory testing quality management system.

Modern approaches to improving the quality of the preanalytical stage include

standardization of procedures, development and implementation of standard operating protocols, staff training, and use of automated sample identification systems [23]. The implementation of laboratory information systems that ensure sample route control and reduce the risk of human error plays an important role [24]. A comprehensive approach to managing the preanalytical stage can significantly improve the reliability of laboratory results and the clinical effectiveness of diagnostics.

The pre-analytical stage of laboratory diagnostics is a key factor determining the reliability and clinical significance of laboratory tests. Most errors in laboratory diagnostics occur at this stage, which emphasizes the need for strict control and standardization. Improving preanalytical processes, training staff, and introducing modern technologies are the main areas for improving the quality of laboratory diagnostics and patient safety.

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