DEVELOPMENT OF A DIAGNOSTIC TEST SYSTEM FOR CANCER DIAGNOSTICS AND ITS IMPACT ON MEDICINE

Abstract. The development and implementation of innovative diagnostic test systems are becoming a pivotal factor in oncology progress, opening new horizons for the future of medicine and offering hope to millions of people worldwide for an effective fight against cancer. The purpose of this article is to demonstrate the prospects of cancer diagnostic test systems development and their impact on medicine. Research has shown the significant complexity of cancer diseases, characterized by genetic, epigenetic changes, and alterations in gene and protein expression. This underscores the necessity for an individualized approach to cancer diagnosis and treatment, taking into account the genetic and molecular uniqueness of each case. The introduction of innovative methods, such as a universal cancer test capable of identifying eight types of cancer at early stages, is an important step towards improving patient outcomes and reducing mortality rates. However, there are several challenges, including issues related to the accuracy and specificity of the tests, cost, logistics of their implementation, and the selection of treatment strategies following a positive test result. The development and validation of biomarkers for early cancer diagnosis play a critical role in reducing morbidity and mortality. Effective application of biomarkers in clinical practice requires a deep understanding of the molecular mechanisms of cancer and the integration of advanced screening methods, such as mass spectrometry and next-generation sequencing. The use of biochips and biosensors for cancer diagnosis can significantly simplify the diagnostic process, making it more accessible and less invasive. These technologies allow for the detection of minimal quantities of oncological markers in biological fluid samples, facilitating early cancer detection.
and the personalization of treatment approaches. Thus, the integration of cutting-edge technologies into cancer diagnosis and treatment opens new opportunities for improving treatment outcomes and the quality of life for patients, potentially reducing the cost of cancer treatment by 20-30 times.

**Keywords:** test systems, oncology, diagnostics, preclinical research.

**Formulation of the problem.** Cancer remains one of the most significant medical and social issues of our time, being responsible for every seventh death globally. Scientific studies on the cost modeling of cancer from 2020 to 2050 have shown that global expenditures for this period are estimated at 25.2 trillion US dollars. The five types of cancer with the highest economic costs include tracheal, bronchial, and lung cancer (15.4%); colorectal cancer (10.9%); breast cancer (7.7%); liver cancer (6.5%); and leukemia (6.3%). China and the USA face the highest economic costs from cancer in absolute terms, accounting for 24.1% and 20.8% of the total global burden, respectively. Despite this, 75.1% of cancer deaths occur in low- and middle-income countries, although their share of the economic costs of cancer is lower at 49.5% [1].

Advanced research highlights the critical role of early disease detection in increasing the chances of successful treatment and patient survival, which will ultimately have a positive impact on both medicine and the economy. Currently, significant advancements in medical science allow for the treatment of 70% of cancers. However, existing diagnostic and treatment methods often prove to be too expensive, time-consuming, and invasive, which hinders their widespread use among the population.

In light of these challenges, the development of innovative diagnostic systems that meet the criteria of speed, accuracy, affordability, and non-invasiveness is becoming increasingly relevant. It is even more important to find methods for early diagnosis, which would provide information about the predisposition to cancer and its various types. This research direction opens new perspectives for cancer screening and early diagnosis, particularly through the introduction of test systems that can be applied directly at the primary level of medical care. Such an approach is not only capable of ensuring timely detection of diseases but also significantly improving the quality of life for patients, minimizing the psychological and physical discomfort from diagnostic procedures, and contributing to a reduction in global cancer mortality rates [10].

**Analysis of recent research and publication.** The topic of developing diagnostic test systems for cancer diagnosis is well-covered in scientific literature, as evidenced by the wide range of studies presented in the proposed list of sources. Notably, researchers like O. Kallioniemi [3] have made significant contributions to this field with their research on biochip technologies in cancer studies, while H. Schwarzenbach, D.S. Hoon, K. Pantel [8] focused on exploring cell-free nucleic acids as biomarkers in cancer patients.
N.M. Khranovska, O.O. Kovalov, O.V. Hryhoruk [4] have highlighted the latest methods of cancer diagnosis and their importance for choosing treatment options, making an important contribution to the understanding of this topic. I.A. Kryachok [5] discusses the principles of personalized therapy in treating cancer patients, which is critically important for the development of individualized diagnostic approaches.

The study also utilized publications in contemporary online outlets, such as D. Hallaher's [2] work on BBC, examining the development of a universal cancer test. These materials help to understand the latest trends and innovations in the field of cancer diagnostics.

Despite the extensive coverage of the topic in scientific literature, there is a lack of systematized material that would unify the diverse approaches and research outcomes into a single structure. Therefore, using various scientific knowledge methods, the information from available sources was analyzed, grouped, and systematized, allowing for a deeper understanding of the potential and challenges of developing diagnostic systems for cancer detection and their impact on modern medicine.

The purpose of the research. The aim of the article is to demonstrate the development prospects of cancer diagnostic test systems and their impact on medicine.

Research results. Over recent years, dramatic changes have occurred in the diagnosis and treatment approaches for oncological diseases, leading to significant improvements in the treatment outcomes for patients with malignant neoplasms. Today, the assertion "Cancer is not a sentence" is declared as one of the main principles in oncology, primarily due to the widespread adoption of personalized medicine principles.

The approaches to treating patients with malignant neoplasms have evolved with each decade. Nearly 60 years ago, treatment was limited to the prescription of a few drugs in combination with radiation therapy, and the 5-year survival rate was around 1% [6]. Modern theoretical knowledge and the results of fundamental research are rapidly changing the "canonical" understanding of the causes, mechanisms, and characteristics of the malignant process. Changes in the molecular-genetic, epigenetic, and metabolic diversity, considering numerous mutations in malignant cells and their microenvironment system, cause the rapid formation of an individual molecular phenotype of the tumor focus. The disruption of the balance of growth and suppressor factors and the network of signaling cascades of tumor cells creates one of the key problems of clinical oncology – intra- and inter-tumoral heterogeneity. The processes of subordination and reprofiling of normal cells to malignant growth do not have an additive nature, leading to the emergence of unpredictable properties in the biological system.
All of the above and numerous characteristics of the organism as a whole contribute to a reasoned understanding that each patient develops and forms individual parameters and characteristics of the biology of the malignant process, whose diagnosis cannot be limited to traditional methods only.

The search for and emergence of new markers and targets will significantly optimize the current tactics and strategy for treating oncology patients on the basis of fundamentally new methods of personalized biomedicine. Nowadays, precise diagnostics and a differential approach to treatment allow for recovery in approximately 70% of cases on average [5], all thanks to the individualized approach to therapy.

The individualized approach to therapy has been incorporated into the practice of diagnosing and treating cancer in virtually all developed countries. Today, the gold standard of this approach involves making a diagnosis based on morphological and immunophenotypic characteristics [5].

Progressive technologies involve the application of molecular studies. The evolution of molecular diagnostic methods began with immunohistochemistry, which uses antibodies to identify specific proteins in cells, important for determining the type of tumors. Although this method is fast and inexpensive, it requires a lot of material and is prone to subjective interpretation.

– The FISH (Fluorescence in Situ Hybridization) method uses fluorescent probes to identify genetic elements in cells, providing more accurate and objective results than immunohistochemistry, but this method is more expensive and also requires a lot of material.

– Polymerase Chain Reaction (PCR) is capable of amplifying DNA, simplifying analysis. PCR is fast, has high sensitivity and specificity, but requires the selection of specific primers and special conditions for conducting.

– DNA sequencing allows determining the nucleotide sequence, with the Sanger method reading sequences up to 1000 base pairs, and Next-Generation Sequencing (NGS) used for in-depth analysis of genetic material and capable of reading millions of fragments simultaneously, being cheaper and more productive [4].

Currently, more than several hundred chemotherapeutic agents, dozens of monoclonal antibodies, and other targeted drugs have been registered. In diagnostics, CTCs (Circulating Tumor Cells) and ctDNA (Circulating Tumor DNA) from cancer patients are analyzed to detect tumor markers such as mutations, microsatellite instability, hypermethylation, and gene expression. It's also possible to detect cancer cells from other body fluids, such as saliva, urine, bronchoalveolar lavage, sputum, and ductal lavage fluid, since epithelial tumors grow, and cancer cells can detach from the tumors into body fluids, allowing for the detection of molecular markers using these samples [8].

Challenges of Individualized Approaches to Cancer Diagnosis and Treatment. Oncology research has demonstrated that cancer diseases can be accompanied by
various genomic changes, such as amplifications, translocations, deletions, and point mutations. Analyzing these changes allows the identification of oncogenes and tumor suppressor genes involved in cancer development [7].

Furthermore, cancer development is not limited to genetic changes; it can also be associated with epigenetic changes and alterations in gene and protein expression levels. Investigating these alterations can help establish diagnostic tumor biomarkers and classify tumors based on complex molecular profiles or unique molecular changes occurring in specific tumor types.

As a result, achieving such goals is highly challenging due to several reasons:
- The interaction of different pathways related to cancer complicates the understanding of cancer biology;
- There is significant heterogeneity within tumors and gene functions among individuals with the same types of cancer;
- Treatment targets are not absolutely specific to cancer cells;
- Treatment efficacy is limited because targets are influenced by other factors, and the functions of these targets can change over time, creating resistance to treatment.

Universal Cancer Test. A team of scientists from Johns Hopkins University (USA) has made a significant breakthrough in medical science, moving closer to creating a universal cancer test – a solution that addresses a range of issues associated with the individual development of this disease. This innovative method allows the identification of eight types of cancer at early stages, which could significantly improve prognoses for patients and reduce mortality rates from this group of diseases. Such an approach could revolutionize modern cancer diagnostic and screening protocols.

The test works on the principle of detecting microscopic traces left by DNA mutations and specific proteins present in patients' blood. In clinical trials involving 1005 individuals with diagnosed cancer (including ovarian, liver, stomach, pancreatic, esophageal, intestinal, lung cancers), the method identified cancer in 70% of cases.

This technology offers hope for the early detection of cancers that are traditionally difficult to diagnose at early stages. Scientists continue to research and test this method, hoping it can complement existing screening techniques such as mammography and colonoscopy.

Despite optimism and significant potential of this discovery, there are still numerous challenges and questions that need to be addressed. These include the test's accuracy, specificity, cost, and logistics of widespread implementation. The question of subsequent actions after a positive test result remains open, especially in the context of choosing the most appropriate treatment strategy [2].

Early Diagnosis through Biomarkers. The implementation of early cancer diagnosis through the detection of biomarkers, which indicate the body's
predisposition to oncological diseases before the manifestation of clinical symptoms, has the potential to significantly reduce morbidity and mortality rates from these diseases. This emphasizes not only the importance of early detection but also the value of personalized medicine, where therapeutic approaches and preventive measures are adapted to the individual risks of a particular patient.

The development and validation of biomarkers require a comprehensive approach, including bioinformatic analysis of large data, a deep understanding of the molecular mechanisms of diseases, and interactions between different risk factors. An important step is conducting clinical studies to assess the effectiveness and specificity of biomarkers in different populations and conditions.

Modern high-throughput screening techniques, such as mass spectrometry, microarrays, and next-generation sequencing, allow the identification of potential biomarkers at various levels, including the genome, transcriptome, proteome, and metabolome. However, as noted in the referenced source, the successful translation of these discoveries into clinical practice requires not only evidence of clinical utility but also consideration of the economic feasibility and accessibility of technologies for widespread application.

Thus, the integration of early diagnosis through biomarkers in oncology can provide a decisive impact on improving cancer treatment outcomes, reducing healthcare costs, and enhancing patients’ quality of life. This, in turn, requires coordinated efforts in scientific research, clinical trials, and healthcare development to ensure rapid and effective implementation of these innovations [12].

In the clinical setting, for a diagnostic device to serve its purpose, it is necessary to identify relevant disease biomarkers and integrate methods of their analysis into the device. Currently, biomarker detection complements imaging or histopathology, providing additional information about prognosis or the best treatment options. However, biomarkers alone cannot yet provide a definitive diagnosis. Despite many biomarkers being identified, they often do not meet the specificity and sensitivity requirements for clinical diagnosis. This may be due to a variety of factors, including the broad intra- and inter-tumoral heterogeneity among patients. Moreover, many "cancer biomarkers" are also elevated in benign diseases or may be below the detection limit at early cancer stages. In such cases, improving diagnostic capabilities in detection and a more thorough characterization of biomarkers through detailed analysis of post-translational modifications and expanding the range of biomarkers can contribute to the development of better biomarker-based technologies [11].

Using Biochips for Cancer Diagnosis. Currently, most tests for diagnosing diseases are performed in specialized laboratories or hospitals using expensive equipment, which requires skilled professionals to operate. To make diagnosis more accessible directly at the point of care (POC), it’s necessary to simplify and reduce these tests, thereby lowering costs for materials, devices, and labor. The introduction
of "lab-on-a-chip" innovations and biosensors makes the transition from laboratory-based diagnostics to portable, patient- or healthcare worker-operable diagnostics possible. Additionally, cost, real-time result provision, ease of use, reliability, and functionality without the need for complex sample preprocessing are important factors. A biosensor that meets these requirements primarily uses a biological component (e.g., an antibody, enzyme, nucleic acid) to detect an analyte, then converts the detection signal into an electrical signal that can be quantitatively measured.

These nanotechnological devices allow the analysis of a large number of parameters simultaneously, making them indispensable for identifying specific oncological markers associated with various types of cancer.

One of the key advantages of biochips is their high sensitivity and specificity, allowing even minimal amounts of markers to be detected in a sample, such as in a patient's blood or urine. This is especially important for early cancer detection when the disease has not yet produced pronounced symptoms but can already be identified through molecular markers.

Biochips also promote personalized medicine, where patient treatment is planned based on the individual characteristics of their disease. By analyzing the genetic and molecular characteristics of a tumor using biochips, doctors can choose the most effective treatment methods, reducing the risk of side effects and increasing the chances of successful recovery.

Another advantage of using biochips is the ability to conduct a large volume of analyses in a short time and with minimal sample use. This reduces the cost of diagnostics and makes the process less invasive for the patient.

In the future, the development of biochip technologies could further expand their capabilities in cancer diagnosis and treatment, offering new methods for detecting early stages of the disease, monitoring treatment effectiveness, and adapting therapeutic approaches to changes in tumor characteristics. The use of biochips contributes to improved cancer treatment outcomes and enhanced patient quality of life [3].

Overall, research shows that patients who undergo testing in the preclinical stage of the disease can reduce treatment costs by 25-30 times. This underscores the importance of early diagnosis, which not only improves survival rates but also reduces the costs of cancer treatment [9].

**Conclusions.** The conducted research highlights the high level of complexity of oncological diseases, emphasizing the importance of genetic and epigenetic variations as well as changes in gene and protein expression. This underlines the necessity of adapting diagnostic and therapeutic strategies to the individual characteristics of each specific case of cancer. The introduction of advanced technologies, including universal cancer tests for the early detection of various types of cancer, has the potential to significantly improve patient prognoses and reduce mortality rates. However, the successful application of these innovations is accompanied by several challenges, particularly in terms of test accuracy,
specificity, economic costs, and implementation logistics. The development and validation of effective biomarkers for early diagnosis play a crucial role in overcoming these challenges, and the integration of modern diagnostic methods, such as mass spectrometry, next-generation sequencing, biochips, and biosensors, can greatly optimize the diagnostic process, making it more accessible and less invasive. In summary, the implementation of cutting-edge technologies in clinical practice promises significant improvements in treatment and quality of life for patients with oncological diseases, while simultaneously reducing the economic burden on the healthcare system.

**References:**


