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DIAGNOSTIC POTENTIAL OF ENZYME-LINKED IMMUNOSORBENT ASSAY IN CLINICAL PRACTICE

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Abstract. *Enzyme-linked immunosorbent assay (ELISA) is one of the most widely used immunological methods in modern laboratory diagnostics. This method is characterized by high sensitivity and specificity and plays an important role in the diagnosis of various infectious, autoimmune, endocrine, and oncological diseases. The present review article analyzes the theoretical basis of ELISA, its diagnostic potential in clinical practice, major advantages, and existing limitations based on contemporary scientific literature. The comprehensive application of ELISA in clinical laboratory practice enables early disease detection, effective monitoring, and evaluation of therapeutic efficacy.*

Keywords: *enzyme-linked immunosorbent assay, ELISA, laboratory diagnostics, antigen- antibody reaction, clinical practice.*

Introduction. Over the past decades, the implementation of highly sensitive immunological methods in clinical laboratory diagnostics has significantly expanded the possibilities for early disease detection. Among these methods, the enzyme-linked

immunosorbent assay (ELISA) is recognized as one of the most important and widely applied diagnostic tools. ELISA is based on a highly specific antigen–antibody interaction, with the analytical result assessed through an enzyme-mediated colorimetric reaction. This principle ensures the high analytical sensitivity and accuracy of the method [6].

In modern medical practice, early diagnosis, differential assessment, and monitoring of treatment effectiveness are of paramount importance. Within this context, laboratory diagnostics occupies a leading position, and immunological tests serve as key sources of objective clinical information. ELISA allows the detection of clinically relevant biomarkers at very low concentrations, making it particularly valuable for identifying latent or subclinical disease processes [9]. The versatility of ELISA further explains its extensive use across multiple clinical disciplines. The method is widely applied in the diagnosis of infectious diseases through the detection of antigens and specific antibodies, in autoimmune disorders through the identification of disease-specific autoantibodies, in endocrine pathology for quantitative hormone assessment, and in oncology for the determination of tumor markers. As a result, ELISA has become an integral component of routine clinical laboratory investigations [1].

Recent advances in ELISA technology, including automated analytical systems, standardized protocols, and high-affinity monoclonal antibodies, have substantially improved the reliability and reproducibility of test results. At the same time, contemporary scientific literature emphasizes the importance of correct result interpretation, taking into account pre-analytical and analytical factors that may influence diagnostic accuracy [5].

Analysis of scientific publications indicates that ELISA demonstrates high diagnostic sensitivity and specificity, making it a reliable method in clinical laboratory diagnostics. Numerous studies report sensitivity rates ranging from 90% to 98%, particularly for the detection of low concentrations of antigens and antibodies. This high analytical performance allows ELISA to identify pathological processes at early

or clinically inapparent stages [3]. The reliability of ELISA results is closely associated with the quality of reagents, sample preparation procedures, and the level of laboratory automation. The use of standardized commercial test systems significantly reduces analytical variability and minimizes the risk of diagnostic errors [10].

In infectious disease diagnostics, ELISA enables the detection of both antigens and specific immunoglobulins, allowing assessment of disease stage and immune response dynamics. The presence of IgM antibodies typically indicates an acute or recent infection, whereas IgG antibodies reflect past exposure or chronic infection. This distinction is essential for differential diagnosis and the selection of appropriate therapeutic strategies [2,5].

ELISA is widely used in screening programs for viral hepatitis, human immunodeficiency virus (HIV), TORCH infections, and other infectious conditions. Its high throughput and informational value make it particularly suitable for large-scale population screening [4,12].

In autoimmune disorders, ELISA plays a crucial role in the detection of disease-specific autoantibodies that reflect underlying immunopathological mechanisms. Antinuclear antibodies, anti–double-stranded DNA antibodies, anti-thyroid peroxidase antibodies, and other markers detected by ELISA contribute significantly to early diagnosis, assessment of disease activity, and prognostic evaluation. Published data indicate a strong correlation between autoantibody titers and clinical disease activity, highlighting the utility of ELISA for dynamic monitoring of autoimmune conditions and evaluation of therapeutic response [3,8].

ELISA is extensively used for quantitative determination of hormones and tumor markers, providing essential information for clinical decision-making. Measurement of thyroid hormones, insulin, cortisol, and other biologically active substances by ELISA enables comprehensive assessment of endocrine function.

In oncology, ELISA-based detection of tumor markers supports early suspicion of malignancy, monitoring of treatment efficacy, and identification of disease

recurrence. However, tumor marker results should always be interpreted in conjunction with clinical and instrumental findings [7,11].

Despite its advantages, ELISA is subject to certain limitations. False-positive and false-negative results may occur due to pre-analytical factors, cross-reactivity, or improper assay performance. Therefore, ELISA findings should not be interpreted in isolation but rather integrated with clinical data and complementary laboratory investigations. Overall, the reviewed evidence confirms that ELISA represents a powerful diagnostic tool whose clinical value depends on appropriate application and expert interpretation [13].

Conclusion. The enzyme-linked immunosorbent assay is a universal laboratory method with high diagnostic significance in clinical practice. The combined use of ELISA with other laboratory investigations enables early disease detection, effective monitoring of therapeutic outcomes, and improved clinical decision-making. The role of ELISA in modern laboratory medicine is expected to continue expanding with further technological advancements.

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