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The Importance of The PCR Method in Clinical Laboratory Diagnostics

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Annotation: This article is devoted to the significance of the polymerase chain reaction (PCR) method in modern clinical laboratory diagnostics. It highlights the molecular-biological foundations of PCR technology, the mechanisms of in vitro amplification of DNA and RNA fragments, as well as the diagnostic capabilities of conventional PCR, real-time PCR (qPCR), and reverse transcription PCR (RT-PCR). In addition, the role of PCR in the detection of infectious, hereditary, and oncological diseases, genetic identification of pathogens, assessment of viral load, and monitoring of treatment effectiveness is analyzed. The article briefly reviews pre-analytical and analytical errors encountered in clinical application of PCR, the risk of contamination, and the limitations of the method. This work has scientific and practical significance for specialists and residents working in the field of laboratory medicine.

Keywords: Polymerase chain reaction (PCR), molecular diagnostics, clinical laboratory diagnostics, DNA and RNA amplification, real-time PCR, RT-PCR, infectious diseases, genetic diagnostics, viral load, high sensitivity and accuracy.

Introduction

An analysis of the activities of clinical diagnostic laboratories (CDLs) in medical institutions shows that laboratory investigations are becoming one of the most important components of modern diagnostics and treatment processes. CDLs are designed to obtain diagnostic information about the state of the body based on medical analyses of samples obtained from biological materials (blood, urine, lymph, cerebrospinal fluid, various secretions, and other substances).
The use of automated systems in processing the large volume of data generated in clinical laboratories provides high efficiency. This article discusses the importance of automated systems in clinical laboratories.

Materials and Methods

Examination of a patient in a hospital largely consists of obtaining a series of systematic medical tests. At the same time, samples from all departments—therapeutic units of various profiles, surgical departments, intensive care units, and others—are submitted to the hospital's CDL for analysis. In some cases, diagnostic data obtained from clinical laboratories allow diseases to be detected long before clinical signs become physiologically apparent. These studies are extremely important for diagnosing infectious diseases, assessing age-related changes in biochemical status, detecting signs of fatigue, and more. Thus, medical laboratory investigations make it possible to obtain early, comprehensive, and objective information about numerous subtle biochemical processes occurring in the human body at the cellular, molecular, and submolecular levels.
The main difficulties in conducting laboratory studies under clinical conditions are associated with the fact that diagnostics and monitoring of the treatment process represent a complex, multilevel information-measurement process that includes a wide range of methodological and instrumental capabilities. To solve such problems, approaches are needed that utilize computer technologies to acquire new medical and biological knowledge, providing not only complete databases but also tools for conducting scientific research in any diagnostic procedure.
In modern medicine, early and accurate diagnosis of diseases is of great importance. In this regard, PCR (polymerase chain reaction), one of the molecular biology methods, is widely used in clinical laboratory

diagnostics. The PCR method allows artificial amplification of DNA or RNA fragments in the body, enabling the detection of even very small amounts of genetic material [1].

The main advantage of PCR is its high sensitivity and accuracy. Traditional laboratory methods require a long time and a large amount of biological material to detect pathogenic microorganisms. With PCR, however, even a very small quantity of a pathogen can be detected in a short time. Therefore, PCR is considered one of the most reliable methods in clinical diagnostics.

In clinical laboratories, PCR is mainly used for the detection of infectious diseases. PCR plays an important role in identifying viral, bacterial, fungal, and parasitic infections. For example, PCR is recognized as the "gold standard" for diagnosing diseases such as hepatitis B and C, HIV, tuberculosis, influenza, and COVID-19. In particular, real-time PCR (RT-PCR) enables rapid and accurate detection of RNA viruses.

PCR also plays an important role in the diagnosis of genetic diseases [2]. This method makes it possible to identify hereditary diseases, gene mutations, and chromosomal abnormalities. PCR is widely used in prenatal diagnostics, that is, in early detection of genetic defects in the fetus during pregnancy, which is of great importance in preventing congenital diseases.

PCR is also diagnostically significant in oncology. The method is used to detect genetic changes, oncogenes, and tumor markers associated with cancer. This helps detect disease at an early stage and develop an individualized treatment plan.

In addition, PCR is effective in determining microbial resistance to antibiotics [3]. By identifying antibiotic resistance genes, physicians can select the most effective medication for a patient, thereby preventing incorrect treatment and increasing therapeutic effectiveness.

PCR, or polymerase chain reaction, is a laboratory procedure in which millions of copies of a specific DNA fragment are produced. Essentially, it is an amplification method in which even the smallest amount of DNA present in blood, hair, or tissue can be copied into sufficient quantities for analysis.

The name of this technique comes from its main component, DNA polymerase, which performs DNA replication. This enzyme exists naturally. The most commonly used polymerase is Taq polymerase, derived from the bacterium Thermus aquaticus [3]. This enzyme works optimally at around 70°C. Using a DNA template and DNA oligonucleotides (also called primers), it synthesizes a new DNA strand. Primers used in PCR are synthesized short DNA sequences that correspond to the ends of the DNA region to be copied.

PCR has replaced earlier DNA replication methods used by bacteria, which could take several weeks. PCR, however, can be completed rapidly—within a few hours. This speed is especially important in diagnostic settings where quick results are required. PCR was developed by Kary Mullis, who received the Nobel Prize in Chemistry in 1983 for this invention. Since then, PCR has been widely used as both a diagnostic and research tool. Its applications have expanded across many scientific fields, including molecular biology, microbiology, genetics, clinical diagnostics, forensic medicine, ecology, heredity studies, and paternity testing.

Application of PCR in Detecting Infectious Agents

PCR is widely used in analyzing clinical samples for infectious diseases such as HIV, hepatitis, human papillomavirus (which causes genital warts and cervical cancer), Epstein–Barr virus (infectious mononucleosis), malaria, and anthrax.

PCR is particularly invaluable in early detection of HIV because it can identify viral DNA in human cells, unlike antibodies that appear weeks or months after infection. Additionally, PCR can be used to measure viral load (i.e., the amount of virus circulating in the body).

Traditionally, malaria is diagnosed by microscopic examination of blood samples to detect malaria parasites (Plasmodium falciparum). However, PCR technology is useful because it can rapidly identify malaria species. This is especially important in cases of mixed infections and in selecting appropriate drug therapy. Currently, PCR is used as a complementary method to microscopic examination.

PCR can also detect the anthrax pathogen Bacillus anthracis. Due to the urgent need for rapid diagnosis of such infections, PCR has become an important tool for identifying anthrax in clinical samples. It replaces traditional methods that require at least 24 hours to culture bacteria in the laboratory. PCR offers a rapid, sensitive, and specific alternative [9].

Results.

PCR is an invaluable tool because it provides information about patient prognosis and predicts response or resistance to therapy. Many cancers are characterized by small mutations in specific genes, which can be detected using PCR.

For example, in acute myeloid leukemia (AML), the presence of a mutation known as t(8;21) may indicate a favorable prognosis, as patients with this mutation often respond well to certain treatments. The presence of mutations in the FLT3 gene can identify patients who are less responsive to chemotherapy and have a higher risk of relapse after treatment.

PCR can also be used to monitor leukemia patients after treatment by quantifying the number of residual cancer cells still circulating in the body.

Conclusion

In conclusion, it can be stated that the use of modern information technologies and automated systems in clinical diagnostic laboratories—which play a crucial role in maintaining human health—significantly increases efficiency [4]. Such systems not only improve the productivity of laboratory staff but also ensure fast and high-quality services for patients.

The polymerase chain reaction (PCR) method is a modern and reliable tool in clinical laboratory diagnostics. PCR enables genetic identification, assessment of viral load, and monitoring of treatment processes. At the same time, PCR technology requires careful handling at pre-analytical and analytical stages, as contamination and methodological limitations can affect results. Overall, PCR is an indispensable method in laboratory diagnostics and plays an important role in the development of modern medicine.

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