Molecular Diagnostic Approach In Clinical Laboratory

Khalid Saad Almutairi[1*], Mohammed Yahya Alfaifi[2], Abdullah Ali Hussain Awaji[3]

[1]*LABORATORY SPECIALIST, KS.Almutairi@Psau.Edu.Sa, PRINCE SATTAM BIN ABDULAZIZ UNVERSITY HOSPITAL
[2]LABORATORY Technical, M.alfaifi@psau.edu.sa, PRINCE SATTAM BIN ABDULAZIZ UNVERSITY HOSPITAL
[3]Laboratory technician, A.awaji@psau.edu.sa, PRINCE SATTAM BIN ABDULAZIZ UNVERSITY HOSPITAL

***Corresponding Author:** Khalid Saad Almutairi
*LABORATORY SPECIALIST, KS.Almutairi@Psau.Edu.Sa, PRINCE SATTAM BIN ABDULAZIZ UNVERSITY HOSPITAL

Abstract
Background: A set of modern techniques for molecular diagnostic analysis-genome and proteome within biological markers includes determining an individual's genetic code as well as how their cells express their genes. This technique is used to diagnose and monitor disease, assess risk, and decide which treatments are most effective for specific patients.
Methodology: In vitro" biological analyses used in molecular diagnostics, such as PCR-ELISA or Fluorescence "in situ" hybridization, are critical. The assay determines the structure of the molecule at low concentrations, implying that the marker can predict disease or risk in a patient's sample.
Results: Analysis is performed on any biomaterial that can be sampled for DNA and RNA.
Conclusions: Due to the increasing state support of molecular DNA diagnostics, in the future even the introduction of DNA diagnostics for the detection of cancer will be the foundation for medical development.

Keywords: Clinical laboratory diagnosis, PCR, Molecular diagnostic approach, Molecular diagnosis, DNA detection.

1. Introduction

A set of modern techniques for molecular diagnostic analysis-genome and proteome within biological markers includes determining an individual's genetic code as well as how their cells express their genes. This technique is used to diagnose and monitor disease, assess risk, and decide which treatments are most effective for specific patients[1] The goal of modern diagnostic techniques is to study the genetics of blood coagulation and its pharmacogenomics to determine which drugs work best. They are linked to clinical sciences and theories, specifically clinical chemistry (medical tests on body fluids) and biophysics (the impact of medical tests on the human body).[2]

Microchipping is extremely important in modern medical and technical diagnostics. It can also detect fluorescently labelled DNA sequences. However, these probes are first isolated from patient samples and then compared with microchip samples [3]. A DNA microchip is a base (glass, plastic, or gel) that can support up to several thousand microprobes ranging in length from 25 to 1000 nucleotides [4,5].

Molecular diagnostic methods are commonly used for microorganisms studied using the well-known Koch rules. The quantitative detection of cytomegalovirus in the blood allows for the evaluation of its dynamics after transplantation as well as the efficacy of antiviral treatment. The generally accepted method of assessing viral load in viral hepatitis is quantitative PCR, which allows for the determination of viral levels in plasma before and during treatment. In addition to identifying and quantifying infectious pathogens, clinical molecular biology must also address the genotyping of individual pathogenic microorganisms [6,7]. It's used in the following scenarios:

The study of clinical isolates of bacteria involves identifying specific toxins and genes that determine resistance to therapy.Virus research involves identifying unfavourable genotypes and genes that lead to therapy resistance. Diagnostic kits have been developed to overcome the difficulties of genotyping bacterial resistance genes in clinical isolates.[8]

Currently, in clinical practice, a wide range of laboratory diagnostic methods are available that allow for not only disease diagnosis and therapy monitoring, but also treatment monitoring. Until recently. One common shortcoming of laboratory diagnostic methods used in clinical practice was that they did not account for the patient's susceptibility to various diseases caused by genetic factors. [9] Questions about a patient's susceptibility to various diseases form the foundation of a new field of medicine called personalised medicine, which can be defined as a strategy for disease prevention and treatment based on molecular genetic research findings.[10]

2. Literature review

Scientific research has shown that genetic polymorphisms play an important role in the development of various diseases. Genome changes occur in the human population in at least two variants (alleles) with a frequency of at least 1%. The most common type of genetic polymorphism is a single nucleotide substitution (SNP), which is genetically unique to each individual.[11]

Under certain adverse conditions, some polymorphic variants of genes ("susceptibility genes") contribute to the development of multifactorial diseases. Unfavourable allelic variants in these genes can cause common diseases such as atherosclerosis, cardiovascular disease (CVD), osteoporosis, diabetes, bronchial asthma, and tumours. [12]
Gene networks are normal metabolic processes that combine allelic variants from different genes to ride or participate in the development of a specific pathology. Predictive (prognostic) medicine is founded on determining the components of each multifactorial disease's gene network and developing a set of preventive measures for a specific patient on this basis [13,14].
Molecular diagnostic technologies are currently being developed, improved, and implemented in clinical practice. As a result, clinical laboratory diagnostics now includes a wide range of methods for detecting and diagnosing nucleic acid analysis, such as polymerase chain reaction (PCR), genotyping, biochips, and sequencing.[15]
PCR is one of the few laboratory diagnostic methods currently used in clinical practice, and it has the highest specificity and sensitivity for detecting diseases like bacterial vaginosis, trichomoniasis, syphilis, viral hepatitis, HIV infection, tuberculosis, and so on [16]. The PSR method is especially effective at detecting difficult-to-cultivate and non-cultivable viruses and bacteria that are common in latent and chronic infections. This should be noted. Unlike bacteriological and virological diagnostic methods, PCR diagnostics are not limited by the ability of microorganisms and viruses to grow in an artificial environment or in cell culture. The primary advantage of PCR over bacteriological and virological diagnostic methods is its ability to identify, characterise, and work with a wide range of microorganisms that cannot be replicated in laboratory conditions for various reasons.[17]
The advancement of research tools, as well as the development and industrialization of molecular biology analysis tools, has made their use in clinics feasible. A clinical laboratory must meet high reliability standards, which means diagnostics may require accreditation or compliance with medical device regulations. Laboratory data management systems help to systematise these processes by tracking them. In laboratories, automation and sample barcoding via medical equipment maximise efficiency while lowering the risk of error or morbidity during manual processing. Reporting of results.[18]

3. Methodology

“In vitro" biological analyses used in molecular diagnostics, such as PCR-ELISA or Fluorescence "in situ" hybridization, are critical. The assay determines the structure of the molecule at low concentrations, implying that the marker can predict disease or risk in a patient's sample. It is critical to preserve the sample before analysis. It is beneficial to develop these techniques to reduce manual labour. Because molecular diagnostic methods detect sensitive markers, they take less time than conventional tests. [19]
Cell-free nucleic acids exist in human plasma, a simple blood sample may be sufficient to obtain genetic information from a tumour, transplant, or unborn foetus.

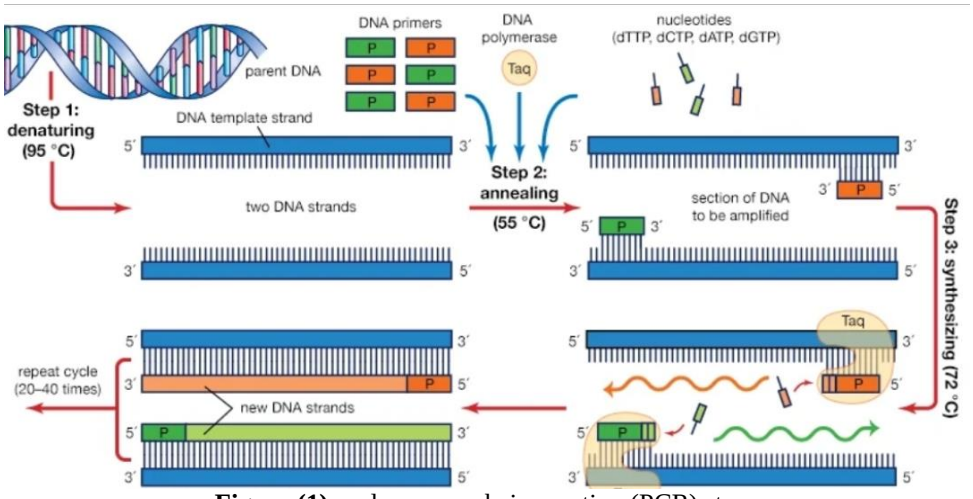

Figure (1): polymerase chain reaction (PCR) steps

In most cases, molecular diagnostic methods employ nucleic acid detection, i.e., polymerase chain reaction (PCR), which significantly increases the number of nucleic acid molecules and thus the number of clinical analyses of target sequences in a patient's sample. Modern medical technology and molecules enter the field of medicine.[20]

4. **Results**

The samples (probes) obtained after cleaning the biomaterial are combined with the microtests on the chip, and the marker reactions are observed. The results will be ready within 4-6 days of the material being collected. Analysis is performed on any biomaterial that can be sampled for DNA and RNA.
This method is used in oncology and cardiology (including genetic predisposition for learning) and is both precise and sensitive. DNA Printing 3D is another important technique for molecular diagnostics and new technologies in modern examinations.

Printing technologies will generate a distinct new industry for printing and selling DNA. Millions of pieces of DNA are placed on tiny metal substrates and scanned by a computer, which finally selects the strands that make up the The entire sequence of the DNA chain. The most common targets of DNA diagnostics in the clinic are infectious pathogens and microflora, DNA and RNA viruses, slow-growing flora, and slow-growing organisms (microorganisms, fungi).

5. **Discussion**

Several pathogens within taxonomically related Lated groups may be screened using broad-range PCR. and detected using a nucleic acid sequence or probe. Analysis Primer are selected on the basis of Comparing nucleic acid sequences to identify pathogenic agents and, if possible, to exclude any potential environmental contaminants. For instance, the application of broad-range PCR primers and sequence analysis has successfully identified Diseases caused by members of the Rickettsiaceae. This technique is quite useful in instances. the differential diagnosis can be limited to a A particular group of organisms. The type of assays performed by a molecular diagnostic laboratory can be influenced by sample volume, and the required equipment investment.[21]

6. **Conclusions**

To summarise, it can be said that due to the increasing state support of molecular DNA diagnostics, in the future even the introduction of DNA diagnostics for the detection of cancer will be the foundation for medical development, as well as the organisation of reliable, low-cost patient examinations.[22]

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