



Global Molecular Diagnostics Market Expands Rapidly with Enormous Potentials in Infectious Diseases and Cancer

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DOI: 10.31080/ASMI.2020.03.0502

Received: January 20, 2020

Published: January 31, 2020

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Abstract

Molecular diagnostics are the novel technologies used to commission the faster results and provide more personalized diagnosis on the basis of DNA and RNA. Genetic testing can detect the mutated genes even before the development of specific disorder and disease. Molecular diagnostics are the types of genetic tests used to diagnose, monitor and detect risks. Also help in decision making to take further steps in the prevention of disease. There are many opportunities in the growth of molecular diagnostics to watch the infectious diseases especially STIs around the globe. Market segmentation will be based on techniques, applications, end users and regions. Market definitions of analysis is evidently based on the current infectious diseases like HIV, HBV, HCV, HPV, Influenza, Tuberculosis, MRSA *Staphylococcus aureus*, vancomycin-resistant *Enterococcus* etc. Clinical laboratories, traditional market, industry structure, hospital testing share, economies of scale and POCT defined the market segmentation based on end users.

America holds the largest regional market of POC because of the prevalence of cardio vascular disease and diabetes along with rising geriatric population. By end user, hospital and clinics are accounted for 85% of share. PCR, real-time PCR, fluorescent in-situ hybridization, microarray, and NGS are expected to grow at a CAGR of 9.6% by 2023. Market is established in the region wise in America, Europe, Asia Pacific region, Pacific/Middle Eastern region and India, Australia, and Japan will hold country specific market.

Keywords: Molecular Diagnostics; Genetic Testing; Infectious Diseases; Gene; Market Segment

Abbreviations

STI: Sexually Transmitted Diseases; POCT/ POC: Point Of Care Testing; HIV: Human Immunodeficiency Virus; HBV: Hepatitis -B Virus; HCV: Hepatitis-C Virus; HPV: Human Papilloma Virus; MRSA-Methicillin Resistant *Staphylococcus Aureus*; VRE: Vancomycin Resistant *Enterococcus*; PCR: Polymerase Chain Reaction; IVD: *In-vitro* Diagnostics; DNA: Deoxyribonucleic Acid; RNA: Ribonucleic Acid; CAGR: Compound Annual Growth Rate; WG: Working Group, European Accreditation; CLIA: Clinical Laboratory Improvements Amendments| FDA; CAP: Laboratory Accreditation Program; NABL: National Accreditation Board For Testing And Calibration Laboratories; NAB: National Association For Long Term Care Administrator Boards; NGS: Next Generation Sequencing; IANZ: International Accreditation New Zealand; QC: Quality Control; ISO: International Organization For Standardization.

Introduction

The classical period of Molecular biology began in 1953, with James Watson and Francis Crick's discovery of double helical structure of DNA. Molecular diagnostics are used to analyze the biological markers in the genome and proteome. This field is very

important in cancer care, to analyze the changes in genes and proteins and how they are interacting in the cells. These changes can reveal the cause the specific disorder/ disease development. Molecular diagnostics is one of the developments of novel technologies enabling the faster and more personalized diagnosis using DNA and RNA based approaches.

Genetic testing is used to find out the gene mutations before even the disease has to develop, and also known as pre-symptomatic and predictive testing. Main challenge in the molecular testing is the number of mutations occurred in the same gene, sometimes it is difficult to make correct decisions of results obtained.

The techniques in the molecular biology are: Molecular Cloning, Polymerase Chain Reaction, Gel Electrophoresis, Macromolecule Blotting and Probing, Microarrays and Allele-Specific Oligonucleotide.

Genetic tests are of different types such as Molecular Genetic Tests, Biochemical Tests, Chromosomal Genetic Tests, New Borne Screening, Diagnostic Testing, Carrier Testing, Prenatal Testing and Pre-Implantation Testing.

Market overview

Molecular diagnostics are the recent developments in diagnostics, the smarter and better testing tools in infectious diseases. Molecular Diagnostics Market segmentation would be based on:

- **Techniques:** PCR, Real Time PCR, Fluorescent in-situ Hybridization, Microarray, Transcription Mediated Amplification, and NGS are in the global market set to grow at CAGR of 9.6% by 2023 [5].
- **Applications:** The market caters largely to Infectious Diseases, Oncology, Blood Screening, Genetic Testing, Pharmacogenomics, Human Leukocyte Antigen Typing etc.
- **End Users:** Hospitals, Diagnostic Laboratories, Academics and Research Institutions.
- **Regions:** America, Europe. Asia pacific region, Pacific/Middle Eastern region, and other country specific market is India, Australia and Japan.

Genetics in diagnostics is one of the key drivers in the industry. The main market definitions are molecular diagnostics and its revolution. Analysis is based on the current prevalent diseases like HIV, HBV, HCV, HPV, Influenza A, B and C, *Chlamydia/ Gonorrhoea*, Tuberculosis, MRSA methicillin-resistant *Staphylococcus aureus*, VRE -vancomycin-resistant *Enterococcus*, Blood screening and market opportunity analysis [5]. Industry has recommended the industry participants, IVD supplier, independent labs, hospital labs, physician lab and audit body. Clinical laboratory market segment has covered the traditional market with laboratory focus segmentation, industry structure, hospital testing share, economies of scale, physicians and POCT. Factors driving growth and market trends are the new genotypes, aging population, developing world driving ID dx growth, point of care, self-testing, the need for rapid diagnosis.

Countless growth opportunities will be arising in the molecular diagnostics, especially in the wake of STIs (Sexually Transmitted diseases). The companies are collaborating with research institutes in order to advance their products in the field. The molecular techniques used are to analyse the biological markers in genes /or proteins. They detect, diagnose and monitor the risk even before the development of disease. These tests are useful in a range of medical specialities e.g. Infectious Diseases, Oncology, Human Leukocyte Antigen Typing, Coagulation and Pharmacogenomics.

Aging thoroughly increase the risk of chronic conditions and infectious diseases. Which can be taken care of better by diagnosis at the early stage of development, resulting in demand of molecular diagnostics for early detection of diseases, will be a great tool for their growth in near future. UN forecast the global geriatric population is set to increase to 2.1 Billion by the year 2050 [5].

POC diagnostics segmentation market research offers the detection and monitoring of diabetes, infectious diseases, urinalysis, faecal occult, coagulation, cardio-metabolic, drug of abuse, tumor and pregnancy/ fertility.

POC market is expected to grow at CAGR of 8% during 2017 - 2021 and 14% during 2019 - 2023 [7]. The driving growth factors are:

- Prevalence of infectious disease in the developing countries.
- Awareness of POC diagnostics in the rising incidence of target diseases.
- Adoption of next generation technology and increasing preference to home health care

Continuous introduction of new biotechnological products to cater healthcare entities that are involved in diagnosis, prognosis and biopharmaceutical development is estimated to propel the market. Decreasing costs and rise in number of services in this segment will drive the growth.

The test speed is taking centre stage in molecular diagnostics, and multiplex testing actually, threatens existing assays. However, the multiplex assays have the potential to limit the threat of antimicrobial resistance. In spite of thorough declining of the disease ubiquity, the diagnostic sector keeps on growing. It takes a lead to eradicate the infectious diseases [1,2]. The following dynamic trends to push the market growth are as

- Pathogen evolution and climate change
- Rising rapid testing market
- Multiplex testing
- Biotechnology advances in genetics
- Globalization, emerging economies and global prosperity.

America holds the largest regional market of POC due to high incidence of cardio vascular disease, diabetes and also the increasing geriatric population. Technavio identifies an increasing geriatric population. POC is the major emerging trend expected to impact the POC diagnostic market due to next generation technologies, data management and connectivity to Electronic Health Record. By end user, hospitals and clinics are two major segments accounts for 85% of share [7]. Demands for coagulation testing devices are increasing in the developed countries.

Discussion

There are some limitations in the molecular / and genetic testing field, as the positive testing result doesn't necessarily mean that one will develop cancer, but can increase the stress level heavily in person's mind. However, the negative testing doesn't guarantee that you won't develop cancer [3]. Some advantages/ and disadvantages of genetic testing are as:

- Early detection would increase the chances of successful outcome.
- Opportunities to reduce cancer developments by making certain changes in the life style, if one has the positive results.
- A sense of comfort from uncertainty.
- One can make life style decisions at the time of information.
- Awareness and Education of other friends and relatives about the potential risks.
- Too many mutations in a gene creates a big challenge for testing.
- Testing can increase anxiety and stress level for other individuals.
- Testing doesn't erase the risk.
- Uncertainty and inconclusiveness in results.

Genetic/ molecular diagnostics are used to confirm a diagnosis when a particular condition is suspected on the basis of physical signs and symptoms. Diagnostic testing can be performed at any time during person's life time, even before birth, but still not available for all types of genes and genetic disorders. The results influence the person's choice about the health care and management of disorders.

Accuracy of the genetic test is measured by analytical and clinical validity and utility [3].

- Analytical validity refers to detect specific genetic variations accurately.
- Clinical validity refers to the presence, absence, or risk of a specific diseases.
- Clinical utility refers to the information about diagnosis, treatment, management, or prevention of a disease will be helpful to the consumers.

Both federal and state laws exist to protect patients from health insurance discrimination based on genetic test results.

Some of the recognized accredited bodies are as WG, CLIA, CAP, NABL, NAB (per European country), IANZ etc., they comply with ISO15189, ISO17025, ISO15195 and ISO17011 on the basis of requirements. These standards cover the test performance, qualification of laboratory personnel, QC and testing procedures for each lab. These are designed to ensure the analytic validity of genetic tests. ISO/TS 17822 is used to address the clinical validity and utility of genetic tests. Consumers and healthcare providers always determine the clinical utility of a genetic test. Direct-to-consumer tests offer the easy to understand the scientific basis of their tests to help the consumers making informed decisions. However, the quality of these genetic tests is still difficult to determine. It is prudent to discuss any concern with health professionals before ordering a direct-to-consumer genetic test.

Conclusion

Molecular diagnostics are evolved to provide rapid results in order to make the supportive decisions in the wellbeing of patients. They can also be taken as a threat to the current microbiological and clinical practices of diagnosis. Due to decline in the disease prevalence pattern, molecular diagnostics are still reserved for continued growth. They are taking a lead to eradicate the infectious diseases. The market growth is mostly impacted by multiplex testing, pledging to reduce the anti-microbial resistance threats. Globalization, climate change and pathogen evolutions have reinforced the demand for rapid testing will undoubtedly boost the market size in future.

Despite the limitations in genetic testing like number of mutations at a gene, doesn't necessarily point out the development of disease but it can increase the anxiety. On the other hand, the negative testing doesn't ensure that the patient will not develop the disease. The outcome of the results obtained would be based on the scientific conclusions, physical signs and other related symptoms.

Molecular diagnostic testing can be performed at any stage in the life. The results influence the person's choice about the health-care and management of disorders. This field is the fastest growing area, with the ability to achieve highest diagnostic accuracy enabling early diagnosis in the prevention of chronic and infectious diseases. It has the great potential to replace the present microbiological and clinical methods of diagnosis.

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