Global Genetic Testing
Market Analysis

November 2018

Strategic assessment of a high growth market

Growing incidence of genetic disorders and genetically predisposed
diseases will drive the future market growth.
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23ANDME, INC.
24GENETICS
AB SCIEX PTE., LTD.
ABACUS DIAGNOSTICA OY
ABBOTT LABORATORIES (ALERE, INC.)
ABBVIE, INC.
ABCAM PLC
ACCESS GENETICS
ACCURAGEN HOLDINGS
AC-GEN READING LIFE S.L.
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ALERE, INC.
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ALLELE DIAGNOSTICS
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ALMAC GROUP
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ALTA GENETICS, INC.
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AMGEN, INC. (DECODE GENETICS)
AMOY DIAGNOSTICS CO., LTD.
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ANALYTIK JENA AG
ANCESTRY
ANDROLOGY SOLUTIONS
ANGLE PLC (AXELA, INC.)
ANIMAL GENETICS, INC.
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ARCHERDX, INC.
ARKRAY, INC.
ARRAYIT CORP.
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ASSUREX HEALTH, INC.
ASTELLAS PHARMA, INC.
CARDINAL HEALTH
CARE FERTILITY
CAREDX, INC.
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CELLNETIX PATHOLOGY & LABORATORIES LLC
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CYTOGENX
CYTOGNOMIX, INC.
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DANAHER CORP. (CEPHEID)
DANONE NUTRICIA
DANTE LABS
DECODE GENETICS
DEEP GENOMICS
DEFINIENS
DELCATH SYSTEMS, INC.
DEPIXUS
DIACARTA, INC.
DIAGNOMICS, INC.
DIAN DIAGNOSTICS
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HALOZYME, INC.
HEARTGENETICS
HELIX OPCO LLC
HELSINN HEALTHCARE SA
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<td>NEXT BIOSCIENCES</td>
<td>PARSEQ LAB CO., LTD.</td>
</tr>
<tr>
<td>N-OF-ONE, INC.</td>
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PATHWAY GENOMICS
PAXMAN
PERKINELMER, INC. (VANADIS DIAGNOSTICS)
PERSONAL GENOME DIAGNOSTICS, INC.
PERSONALIS, INC.
PERTEN INSTRUMENTS
PFIZER, INC.
PHARMAMAR
PHARMANOVIA
PHOSPHORUS, INC.
PIC NORTH AMERICA
PIERIANDX
PIERRE FABRE
PLUSVITAL
POLYPLUS TRANSFECTION
PORTABLE GENOMICS
POSITIVE BIOSCIENCES, LTD.
PRECISION ONCOLOGY
PRECISION SYSTEM SCIENCE CO., LTD.
PREMAITHA HEALTH
PRENETICS, LTD.
PREVENTIONGENETICS
PROGENESIS
PROMEGA CORP.
PROOVE BIOSCIENCES, INC.
QIAGEN (EXIQON)
QUANTUMDX GROUP, LTD.
QUEST DIAGNOSTICS, INC. (ATHENA DIAGNOSTICS, INC.)
RAINDANCE TECHNOLOGIES, INC.
RANDOX LABORATORIES, LTD.
RARECELLS
RENNOVA (GENOMAS, INC.)
REPROCCELL, INC.
REPRODUCTIVE BIOLOGY ASSOCIATES
REPRODUCTIVE HEALTH GROUP
RESOLUTION BIOSCIENCE, INC.
SAMSUNG BIOEPIS
SAMSUNG BIOLOGICS (SAMSUNG BIOEPIS)
SANOFI GENZYME
SANTA CRUZ BIOTECHNOLOGY, INC.
SAVYON DIAGNOSTICS
SCIENCEON AG
SCIGENE CORP.
SCIGENOM LABS PVT., LTD. (MEDGENOME)
SCREENCELL
SEATTLE GENETICS, INC.
SEATTLE REPRODUCTIVE MEDICINE
SEEGENE, INC.
SEQUENOM
SERVIER
SEVEN BRIDGES GENOMICS
VETGEN
VETNOSTIC LABORATORIES
VIRTUS HEALTH
VITROLIFE
WAFTERGEN BIO, INC.
WALK-IN LAB LLC
WELLTK
WUXI APPTEC
XCELL BIOSCIENCES
XYTEX, CORP.
YIKON GENOMICS
YX GENOMICS HOLDING CORP. (TRANSNETYX, INC.)
ZOETIS
ZYMO RESEARCH
Global Genetic Testing Market Analysis

Executive Summary

Global genetic testing market has shown steady growth and is expected to exceed $9 billion by 2023

- The global market for Genetic Testing is projected to reach $9.2 billion by 2023, driven by aging population, rising incidence of genetically predisposed and hereditary diseases, growing awareness, technological advances and increasing success of direct-to-consumer (DTC) genetic testing.

- Genetic testing broadly refers to the analysis of genes by examining genetic material taken from cells in a person’s blood sample, or a sample of other body fluids. It constitutes the most rapidly expanding segment of the molecular diagnostics market worldwide. The genetic testing market is boosted by higher incidence of genetic diseases, such as Huntington’s disease and cystic fibrosis, coupled with aging population, increased demand for personalized medicine, growing application in oncology, and increasing awareness of early disease detection and prevention among people. With the advent of advanced DNA analysis, the scope of genetic testing expanded widely into new application areas, driving the market further. Non-Invasive Prenatal Diagnosis (NIPD), for instance, has revolutionized the prenatal testing area, and is garnering significant attention due to its potential to wipe out procedural issues in invasive diagnostic techniques.

- Technological advances such as development of chromosomal microarray analysis and next generation sequencing are revolutionizing identification of structural and numerical abnormalities in chromosomes, and in turn leading to detection of various rare genomic and genetic disorders. The technologies are also contributing to the developing of carrier screens that allow simultaneous detection of various genetic disorders. Further, these technologies contributed to the development of non-invasive cffDNA (cell-free fetal DNA) for identifying subchromosomal abnormalities, single-gen disorders, and chromosomal aneuploidy.
Executive Summary

Strong growth curves for the emerging markets

- Another notable technological advancement is the development of liquid biopsy that depends on a blood draw for isolating DNA of tumor shed into the blood stream called the cfDNA for further genetic analysis. Advancements in technologies that allow analysis of even small quantities of cfDNA for identifying mutations related to specific diseases is advancing the area of liquid biopsy, which is slated to transform the area of cancer genetic testing of the future. However, growth in the market will be challenged by higher costs of genetic testing in most applications and associated reimbursement issues. While prenatal & newborn genetic testing dominates the market, pharmacogenomics is garnering growing interest. Advances in gene sequencing in terms of efficiency, speed and cost-reduction are driving interest among pharmaceutical companies to develop personalized medicines and shelve the one-size-fits-all approach in therapeutics.

- The United States represents the largest market worldwide supported by robust investments in biomedical and life sciences research, launch of several advanced tests, higher awareness over unmet therapeutic needs and better reimbursement scenario. Asia-Pacific ranks as the fastest growing market with a CAGR of 18.2% through the analysis period, led by growing population and healthcare burden; developing healthcare system especially clinical diagnostic infrastructure; and growing incidence of cancer and other genetic disorders due to demographic/lifestyle changes, modern living conditions and complex interplay of environment factors and susceptible genes. Especially poised to benefit growth is the deteriorating genetic health of the human population as evidenced by the growing load of defective genes in the gene pool due to medical interventions that have improved the survival rate and reproductive success of individuals with undesirable genetic traits and thereby a higher risk of inherited genetic conditions among the population.

North American genetic testing market, by application

Aggregate demand in $ Billion for the period 2017 to 2023 & Demand growth %, CAGR

<table>
<thead>
<tr>
<th>Country</th>
<th>2017-2023 Demand</th>
<th>2017-2023 Demand Growth</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Canada</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mexico</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rest of North America</td>
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Market Analysis

Convenience, privacy, and cost benefits drive the proliferation of DTC genetic testing

- The global market for DTC Genetic Testing is projected to reach $410 million by 2023, driven by declining costs of tests, ease of ordering a test, and growing prominence of personalized medicine.
- A relatively new and growing concept, Direct-to-Consumer Genetic Testing is a form of genetic testing service which makes possible for an individual to obtain personal genetic information without needing to go through a healthcare provider. Genome sequencing time and costs have come down from billions of dollars at the turn of the century to the current level of few thousand dollars. Various benefits of DTC testing that are driving its adoption include convenience of tests, privacy of genetic data and promotion of proactive healthcare. Advancements in technology over the years not only reduced time taken for genomic sequencing, but also reduced costs involved in conducting tests, leading to the surging popularity of DTC genetic testing.
- Future growth in the market will be driven by the growing prominence of personalized medicine, an umbrella term which includes vital healthcare as well as therapeutic goals. Personalized medicine has the potential of transforming how medicine is practiced. Utilization of genetic information, in the context of healthcare might enable medical practitioners to better manage diseases, which not only benefits an individual, but also the economy and society at large. Another important growth driver is the emergence of the modern proactive patient with increased awareness about various health issues, for whom the ability to order tests from within the confines of one’s home (without requiring a doctor visit) offers savings, both in terms of time as well as healthcare costs. Despite the strong growth expected for the DTC genetic testing market, key growth impeding factors includes lack of governmental regulation, possibility of misinterpreting genetic information, misuse of data and ethical issues, among others.
Global molecular diagnostics market for genetic testing poised for strong growth

- Molecular diagnostics for genetic testing brings advanced analytical techniques to the diagnosis and treatment of genetic disorders. The confluence of breakthroughs in genomics and proteomics and the development of microarray devices to measure analytes in the blood and various body tissues are driving significant growth in the segment.
- Major developments include the integration of specialty labs and gene expression profiling into clinical practice, the introduction and rapid growth of cell-free fetal DNA prenatal testing, the development of companion diagnostics for drug development, the widespread installed base of automated instruments for molecular testing and the development of personalized medicine. The genetic testing space is one of the most profitable sectors of molecular diagnostics and is expected to be an area of high growth and corporate change throughout the forecast period.
- Genetic disease management, which includes screening, diagnosis and monitoring, continues to be a market with strong clinical need. One of the most frequently performed screening assays for genetic disorders is the detection of mutations in the CFTR (Cystic Fibrosis Trans-Membrane Conductance Regulator) gene. The molecular market is expected to expand for newborn screening as more advanced technology becomes integrated into recommended protocols for screening. In addition, advances in genetic testing procedures will promote testing for the early detection of Alzheimer disease, hemochromatosis, breast cancer, colorectal cancer, diabetes in young people and rare forms of amyotrophic lateral sclerosis. Moreover, the market will thrive with the personalization of diagnosis and therapy by identifying genes associated with complex diseases, optimizing the drug response and reducing side effects and failure rates.

![Steep growth curve ahead for the market](chart1.png)
![Market share breakdown, 2017](chart2.png)
Global Genetic Testing Market Analysis

Regional Analysis

Global Genetic Testing Market by Region the total addressable market worldwide was $ xx billion in 2017.

Total Annual Addressable Market by Region

<table>
<thead>
<tr>
<th>Region</th>
<th>2017</th>
<th>2023</th>
<th>CAGR: xx%</th>
</tr>
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<tbody>
<tr>
<td>NAFTA</td>
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<tr>
<td>Western Europe</td>
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<td></td>
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<tr>
<td>Eastern Europe</td>
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<tr>
<td>CIS</td>
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<td></td>
<td></td>
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<tr>
<td>World market</td>
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<tr>
<td>Rest of Americas</td>
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<td>Africa &amp; Middle East</td>
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<td>Asia &amp; Pacific</td>
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Addressable market: 2017-23
Country Analysis

Transitioning to NGS-based workflows from microarray will create new growth opportunities in the U.S. prenatal genetic testing market

- Prenatal genetic tests, which are predominantly used to test disorders such as aneuploidies in chromosomes 21, 18, and 13, and carrier screens, are gaining momentum in the United States due to enhanced assay outcomes through non-invasive methodologies, increased popularity through social media channels, and the growing number of women choosing to undergo pregnancy at an advanced maternal age. The growth in demand has led to a high level of merger and acquisition activity, apart from numerous collaborations, which in turn has bolstered the product portfolio of several companies in the women’s healthcare segment.

- With this accelerated growth, companies are exploring new avenues to market their products, thereby strategically tying up with IVF clinics, physicians, and OBGYNs. New business models like DTC are seeing increased uptake due to ease of use and hassle-free processing. Partnerships with Big Data companies will be the next big leap in the prenatal genetic testing market, thereby providing interpretation of vast volumes of data to increase specificity and sensitivity.

- Companies are shifting toward online and retail-like business models such as DTC to promote the use of tests. Such DTC companies can stifle the growth of expensive, physician-prescribed LDT tests as there will be a higher preference toward low-cost options. In addition, approximately 60 to 65% of the prenatal genetic tests are now switching to next-generation sequencing (NGS) methodologies. Transitioning to NGS-based workflows from microarray will open up opportunities to create tests with better specificity, sensitivity and cost.

- Investing in research and development to reduce test failure rates and improve company differentiator rates and strategizing about test prices to avoid revenue loss following the standardization of prenatal test prices in January 2018 are some of the key imperatives for prenatal genetic test providers.
Country Analysis

Government support for improved genetic disease management fuels the Indonesian genetic testing market

- The market for molecular diagnostics in genetic testing is one of the largest segments of the in-vitro diagnostics (IVD) market in Indonesia. Increased incidence of genetic diseases such as thalassemia have spurred the government to invest strongly in primary healthcare system, public hospital reforms, promotion of IVD-related technology innovation among local participants, and improved reimbursement policy, thus creating a favorable climate for market participants.

- Despite the strong government backing, Indonesia’s genetic disease testing market is battling a shortage of skilled healthcare workers and laboratory facilities. This issue hampers the accurate identification, diagnosis and reporting of genetic diseases in the country. The market is further pegged back by the long turnaround times of tests and high level of investments needed. These challenges, however, are opportunities for companies in the opposite ends of the spectrum.

- The domestic participants in the low-end market will have an edge due to their competitive pricing and faster turnaround time. Meanwhile, multinational companies (MNCs) in the high-end market can meet various end-user demands by offering improved localized service.

- This scenario is ideal to foster partnerships between multinational companies and local participants. Collaborations between the two will create a symbiotic ecosystem, wherein local companies will gain access to capital, technology and intellectual property, and MNCs will benefit from the market reach of the domestic companies. Furthermore, the rise in private funding has paved the way for innovations in the Indonesia’s infectious disease IVD market. Manufacturers are already developing analyzers to meet end-user budgets, test volumes, desired breadth of test panels, and levels of automation.
Global Genetic Testing Market Analysis

Competition Analysis

Fourteen players identified as candidates for benchmarking as 'Large Competition' given industry spread

Significant shift in market shares in the last 5 years

Top xx players contribute to yy% of the market

Break-up of revenue share

Market Volatility

- Movement of market shares among top 3-4 players in industry in last 10 years with reason
- Merger/Acquisition
- Disruptive product
- Aggressive expansion program etc.

- Cyclical vs Consistent (details of current cycle)
- Dependency on Macro factors

Key market trends

- Amenable to tech disruptions
- Risk assessment
- Is there consolidation in industry?
- Competition is organized by particular segment or domain (design, manufacturing etc.)
- Potential new entrants
- Geographical split of contribution to market

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About us

GMR Analytics is a global market research and business consulting firm which provides global enterprises as well as medium and small businesses with unmatched quality of business intelligence solutions. Our team of experts guides our clients toward transformational growth strategies by focusing on innovation opportunities driven by disruptive technologies, mega trends, emerging markets and new business models. Our mission is to provide business in-depth market research analysis reports that assist our clients to take success-oriented strategic business decisions in their respective domains.

Thank you

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