Molecular Diagnostics: Market Segmentation and Opportunities - 4th Edition

Description:

Molecular diagnostics (MDx) are a class of in vitro diagnostic (IVD) tests that identify nucleic acids, such as DNA. MDx tests may identify nucleic acids that are the genetic material of foreign organisms (e.g., HIV genotyping, MRSA screening) or the genetic markers of an individual patient (e.g., Her-2 overexpression for breast cancer, Factor V Leiden for coagulation). MDx tests continue to be the fastest growing segment within the IVD space, driven by high sensitivity, fast turnaround time, easy workflow and relatively low-cost compared to other techniques, such as culture-based or immune-based tests.

MDx involves platforms and assays that leverage multiple technologies to identify genetic variations. Technologies utilized include; PCR (e.g., HBV qualitative screening; Roche) qPCR (e.g., MRSA screening; Cepheid), TMA (CT/GC screening; Gen-Probe), FISH (PathVysion Her-2; Abbott), capillary electrophoresis (CE) sequencing (e.g., BRAC 1/2 testing; Myriad Genetics), next generation sequencing (Trisomy21 test; Sequenom), microarrays (Amplichip, Roche) and a host of other methods (e.g., pyrosequencing, bDNA, hybrid capture, hybridization beads, kPCR, electrochemical detection).
Analysis from this report indicates that the ~$5.9B MDx market (2011E) is expected to grow at >15% p.a. over the next 4 years, reaching $10.9B by 2015. MDx growth is expected to continue to be driven by increased incidence of chronic diseases due to an aging population, increased availability of various tests, and the further adoption of Pharmacogenomics / personalized medicine.

This report reviews the market size, growth, segments and trends of the MDx industry from 2007 through 2015. The market is segmented to provide insights on specific growth opportunities by therapeutic area (infectious diseases, oncology, HPV, others), technology (PCR, qPCR, TMA, hybrid capture, CE Sequencing, NGS, FISH, other), analytes tested (low and high plex level), test rationale (predisposition, screening, diagnosis, therapy selection, monitoring), test location (reference labs, academic hospitals, blood banks, other) and geography (U.S., Europe, Japan, rest of the world). Growth and growth drivers for each segment are quantified and reviewed.

Major competitors shaping the industry include BioPharma (e.g., Abbott, Roche), IVD/MDx pure-play companies (e.g., Myriad Genetics, Cepheid, Gen-probe) or research tool companies (e.g., Illumina, Life Technologies). Major competitors are reviewed along with their key platforms and underlying technologies.

MDx is a highly regulated space. IVD instruments/assays are treated as medical devices and often require 510(k)/IVD clearance to gain full adoption in the marketplace. We briefly review the various level of clearance for MDx tests.

Finally, this report explores opportunities and challenges in the MDx industry. In this fourth edition, we place an emphasis on NGS and its emerging adoption in clinical settings, as well as other emerging technologies (e.g., dPCR, CGH).

Contents:

Market segmentation: Number of analytes tested

Market segmentation: Test rationale

Market segmentation: Test location

Market segmentation: Geography
Major competitors
Large pharmaceutical companies
IVD pure-play and MDx pure-play companies
Life science and research tools companies Other companies

Coverage and reimbursement
Current situation
Impact of the 2010 Healthcare reform

MDx opportunities and challenges
MDx opportunity MDx challenges

Next generation sequencing in the clinic

Other emerging MDx technologies Appendix
LDT regulation HPV and Cervical Cancer
Selected company portfolios
List of key MDx players
Table of exhibits
Key abbreviations Glossary

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