TSG

Strategic Opportunities & Directions in Molecular Diagnostics

Sector Review & Analysis by TSG

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2009
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Molecular diagnostics will continue to grow in importance for both the IVD community and personalized medicine, but we expect significant structural changes in the category through 2010

TSG

- ✓ **Sector shakeout will continue as access to capital remains tight and investment needs heighten due to an increased need to develop routes to market**
- ✓ **Established diagnostics and healthcare companies will acquire and tie-up assets of promising pure play companies, especially in the areas of infectious disease and oncology**
- ✓ **There will be an increased focus on novel, portable MDx platforms to enable the next phase of growth, ease of use and clinical value**
- ✓ **Pharma and biotech companies will look to take advantage of the downturn in valuation and the potential tax-credits proposed in** *The Genomics and Personalized Medicine Act of 2008* (HR6498)
- ✓ **Revenue growth will continue to favor MDx companies that also have the ability to deliver test results as a service due to the limited options for in house capabilities or reference labs**

Although it represents a small share of global healthcare spending, the IVD market has accelerated growth to 9% per annum due largely to the importance of molecular diagnostics

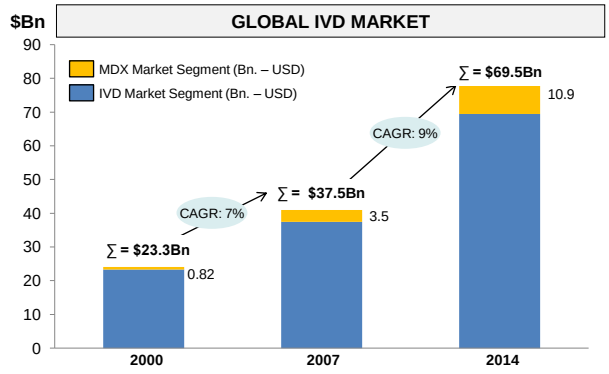
DEFINITION

IVD includes the use of reagents/consumables, instruments, software and systems intended for use in diagnosis of disease or other conditions and/or determination of the state of health in order to cure, mitigate, treat, or prevent disease.

CUSTOMERS

Independent and academic, hospitals, surgical centers, retail clinics and physician office labs.

GLOBAL IVD MARKET



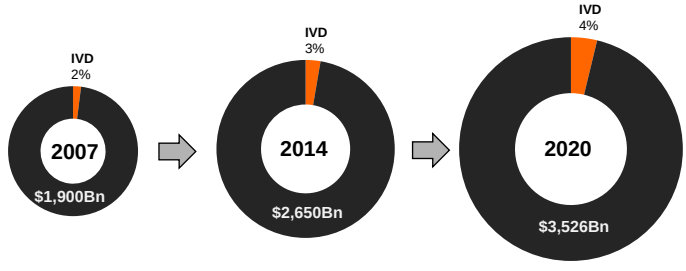
KEY TAKEAWAYS

- IVD is expected to increase to $69.5 Bn. by 2014 and increase its influence over healthcare spending.
- The category's rate of growth is accelerating due to a number of key macro forces, such as demand from emerging economies, aging populations, evolving clinician attitudes, and a push towards theranostics and personalized medicine.
- The molecular diagnostics (MDx)segment has continually outperformed the broader IVD category, and is a key driver of this market's growth.

Source: TSG Analysis, Centers for Medicare and Medicaid Services, Office of the Actuary, National Health Statistics Group., Kaiser Family Foundation Siemens "Pictures of the Future," WHO World Health Statistics 2008.

IVD is uniquely poised at the convergence of life science innovation, clinical value and personalized medicine

GLOBAL HEALTHCARE SPENDING & IVD's SHARE



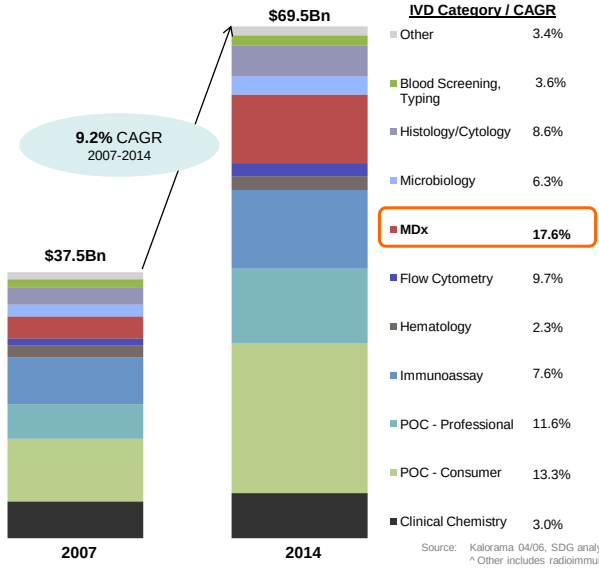
Diagnostics is developing an increasing share of global spend due to higher clinical need, earlier usage and novel technologies

KEY TAKEAWAYS

- IVD is uniquely positioned at the convergence of the life science and healthcare sectors
- Diagnostics provide 60-70% of all the information doctors use worldwide, but make up just 2% of current global healthcare spending
- Molecular diagnostics offer critical, personalized information to inform patient care
- Diagnostics information is driving an increasing proportion of healthcare spend
- This growth has attracted the attention from external players in the medtech community and industry, who are beginning to recognize the high value of Dx testing data
- TSG expects IVD's share of global healthcare will increase to 3% in 2014, and continue to carve out a larger share of global healthcare spend over the next decade

Source: TSG Analysis, Centers for Medicare and Medicaid Services, Office of the Actuary, National Health Statistics Group., Kaiser Family Foundation Siemens "Pictures of the Future," WHO World Health Statistics 2008.

MDx markets are growing faster than the broader IVD categories, and the growth is driven by innovation



IVD Category / CAGR

Other	3.4%
Blood Screening, Typing	3.6%
Histology/Cytology	8.6%
Microbiology	6.3%
MDx	**17.6%**
Flow Cytometry	9.7%
Hematology	2.3%
Immunoassay	7.6%
POC - Professional	11.6%
POC - Consumer	13.3%
Clinical Chemistry	3.0%

DEFINITION

Molecular diagnostics (MDx) evaluates biomarkers or molecular signatures as indicators of normal or diseased biological processes, predisposition to disease, or predictors of clinical outcomes.

KEY TAKEAWAYS

- The MDx market is projected to grow the fastest, with CAGR projected at ~18%.
- Commercial introduction of innovative technologies will be the key driver of growth in these segments.
- Tools enabling earlier, more accurate diagnosis, improved treatment decision and better treatment monitoring will encourage adoption of innovation.
- Automation has been driving growth across almost all segments.

Source: Kalorama 04/06, SDG analysis, Roche & Qiagen presentations, Analyst reports and TSG analysis
^ Other includes radioimmunoassay and coagulation

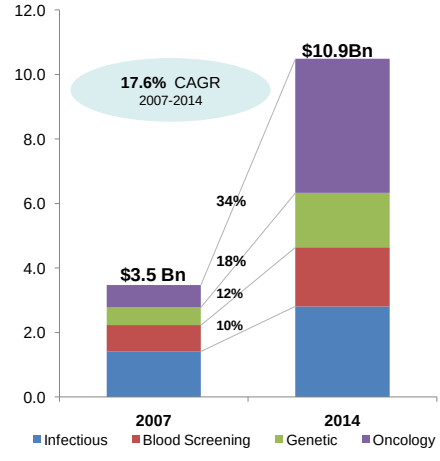
Oncology and genetic testing are growing fastest within the MDx market, but all subsegments show double-digit growth

Key Trends and Growth Drivers

- The fastest growing segment of the in vitro diagnostics market, growing at 16% CAGR in 2007 and accelerating
- Clinical validation of molecular tests and associated biomarkers are creating new markets (e.g. HIV) and replacing some existing IVD assays
- Genomics, proteomics, and metabolomics have generated a new source of biomarkers that are increasingly gaining clinical acceptance
- While the Infectious and Blood Screening markets are showing initial signs of maturity, significant growth is occurring in the Oncology and Genetic segments
- TSG expects oncology to comprise roughly 30% of the overall MDx spending in IVD by 2013/14

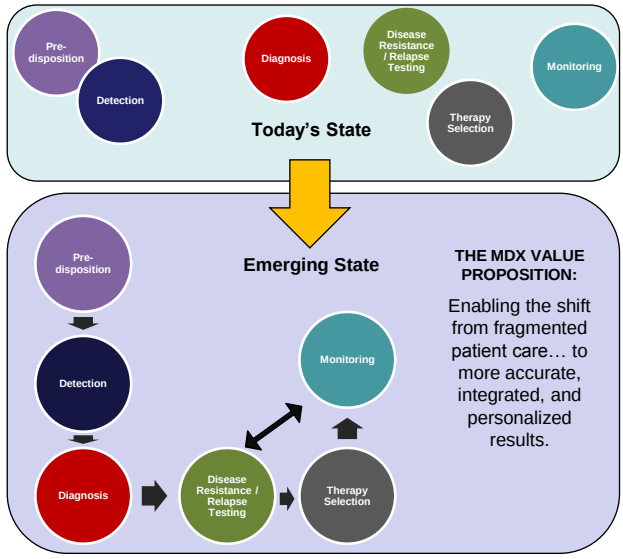
The Global MDx Market* ($Bn)

* Not including Industrial and Research areas



Source: TSG analysis, Qiagen, Roche, Hologic presentations

MDx and personalized medicine are changing the paradigm of disease management



THE MDX VALUE PROPOSITION:

Enabling the shift from fragmented patient care… to more accurate, integrated, and personalized results.

KEY TAKEAWAYS

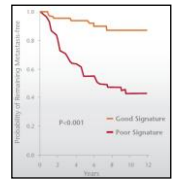
- Current disease management provides inadequate care marked by symptoms-based treatment, lengthy time to diagnosis, and inadequate or non-comparable patient data
- MDx's goal is to predict, diagnose, treat, and monitor disease at an earlier stage, and with greater accuracy
- Growing trend towards multiple biomarker tests to evaluate disease
- Combination drug-diagnostic products will provide critical information for targeted treatment
  - Pharmacogenomics (PGx) and companion Dx offerings represent a shift from "one size fits all" drug development to personalized medicine
  - CYP450 assays: inform physician decisions in warfarin dosing
  - HER2 assays: identify cancer patients who will benefit from Herceptin treatment
- Resistance/relapse tests provide physicians with clinically relevant information on disease pathology, and can predict patients' response to therapy
- Continued adoption of MDx testing will drive healthcare and clinical efficiency, and can improve patient outcomes and quality of life

Reimbursement of MDx tests is changing

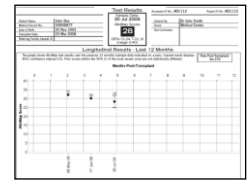
Key Trends

- Historically, diagnostics have been priced in line with Medicare reimbursement codes
- For most low-volume tests, this means cost is determined not by clinical value, but instead on the technical steps (e.g., DNA extraction, sequence amplification) involved in the procedure
- Emerging players seek to redefine MDx's value in line with its growing importance in guiding therapy decisions and changing the costs associated with high quality patient care
- Certain players are dealing directly with private payors and insurance groups to validate and justify the test costs while bypassing the traditional systems

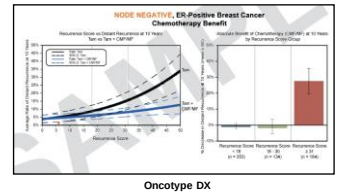
Illustrative Costs of MDx Tests	
Genomic Health's Oncotype DX:	$3,460
Agendia's Mammaprint:	$4,200
xDx's AlloMap HTx:	$2,950
Medicare payout for HER2/neu test:	$89



Mammaprint



AlloMap HTx



Oncotype DX

Coding for MDx tests is entering the 21st century

Common Medicare Reimbursement Codes For MDx Tests

Procedure	CPT Code	Reimbursement
DNA/RNA Extraction	83890/83891	$5.60
Enzymatic Digestion	83892	$5.60
DNA/RNA Separation	83894	$5.60
Nucleic Probe	83896	$5.60
Amplification	83898/83901	$23.42
Interpretation	83912	$5.60

KEY TAKEAWAYS

- Many common outpatient molecular tests are reimbursed with a specific CPT code (e.g., 87810 for Chlamydia). However, given the rapid pace of MDx development, the majority of lower-volume tests are reimbursed in stages with generic CPT codes .
- This trend will change as recommendations from the SACGHS report are implemented. The report urged the development of guiding principles to determine coverage protocol for current and future genetic tests.
- A provision in the Deficit Reduction Act (DRA) which called for changes to the coding for patients with hospital-associated infections (HAI) has enabled more vigilant monitoring of patients for signs of HAI.
- HR6761, the Medicare Clinical Diagnostic Laboratory Fee Schedule Modernization Act of 2008, would require HHS to modernize the Medicare part B fee schedule for clinical diagnostics tests.
- Genomic Health and XDx are blazing a path for reimbursement of complex but clinically valuable MDx tests by signing on major third party payers for reimbursement.

Source: TSG analysis, CMS, other industry reports,
Secretary's Advisory Committee on Genetics, Health & Society, company presentations

A comprehensive understanding of regulatory requirements is critical to successful MDx commercialization

US Regulatory Bodies

FDA	CPT/AMA	CLIA
Regulates diagnostic products and related manufacturing practices	Procedural code essential for establishing reimbursement schedule	Extends regulation of devices for performance sites

EU Regulatory Bodies

In vitro Diagnostics Directive	CE Mark	DRG
Guides requirements for clinical diagnostic products and manufacturing practices (device classification)*	Seal of approval to sell clinical product – to be renewed every 5 years	Responsible for reimbursement around diagnostic tests

Analyte Specific Reagent (ASR)

- An ASR can serve as a means for companies with new and emerging technologies to be used in clinical labs and facilitate further preparation for approval.
- ASRs are exempt from FDA's 510(k)/PMA requirements, however the ASR manufacturer has to produce the product according to the quality system regulation.
- ASR manufacturers are not permitted to include any statement regarding analytical or clinical performance of the ASR, or to package ASRs with software for interpretation of results.

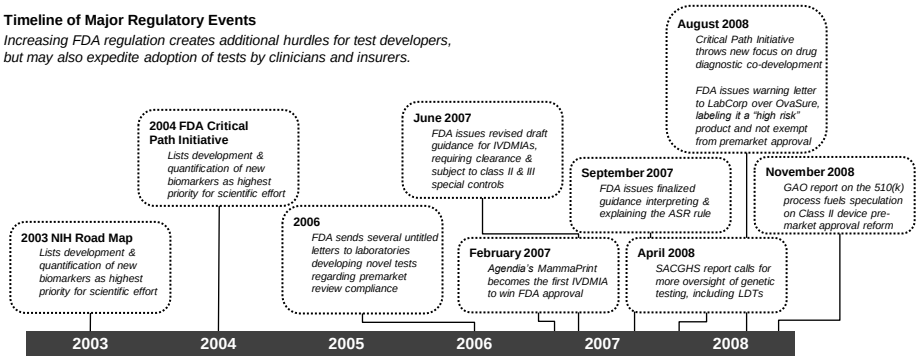
Compliance will require meeting FDA ASR standards, 501k device approvals, internal product design and development documentation, design reviews, internal clinical validation, ISO certification, and adherence to good laboratory practices.

Source: TSG Analysis, FDA

The FDA is pushing personalized medicine, and has adopted increased vigilance towards molecular tests

Timeline of Major Regulatory Events

Increasing FDA regulation creates additional hurdles for test developers, but may also expedite adoption of tests by clinicians and insurers.

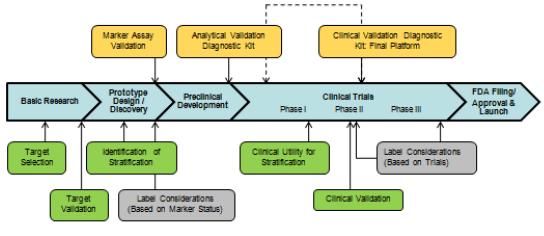


The incoming administration's focus on health reform is expected to expedite greater industry and FDA oversight of genetic testing, as well as payment reforms. How these reforms are implemented will significantly impact MDx test developers in 2009.

Source: FDA, Nature, HHS, TSG analysis

Both industry trends and public policy are driving companion diagnostics development

Proposed Drug Device Co-Development Process (FDA)



KEY TAKEAWAYS

Pharma perspective:

"Pharmacogenomics, you either do it, or it is done to you." – Drug Industry Leader^

- In the short term, personalized medicine may seem unappealing to drug companies, as it will reduce the market for individual drug therapies.
- However, disease-related biomarkers have the potential to save resources and time by guiding drug-development decision making, and may provide additional evidence for obtaining FDA approval for new drugs.

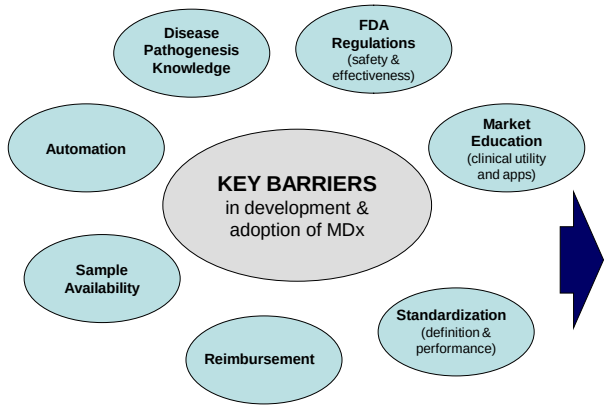
Dx perspective:

"Being part of the clinical trials and just being part of the FDA filing is as important as having exclusive license to the biomarker." – Patrik Dahen, Dako CEO^

- Working with drug companies can give Dx companies access to additional income and hard-to-obtain clinical samples.
- However, companion Dx development carries additional risk. If a partner's drug fails to make it to market, the diagnostic test might not either.

Source: ^"Enabling Personalized Medicine Through Analysis of Gene Expresssion." van 't Veer, L.J. and René Bernards. *Nature*. Vol 452, 3 April 2008.

Sustaining MDx's growth requires overcoming key barriers

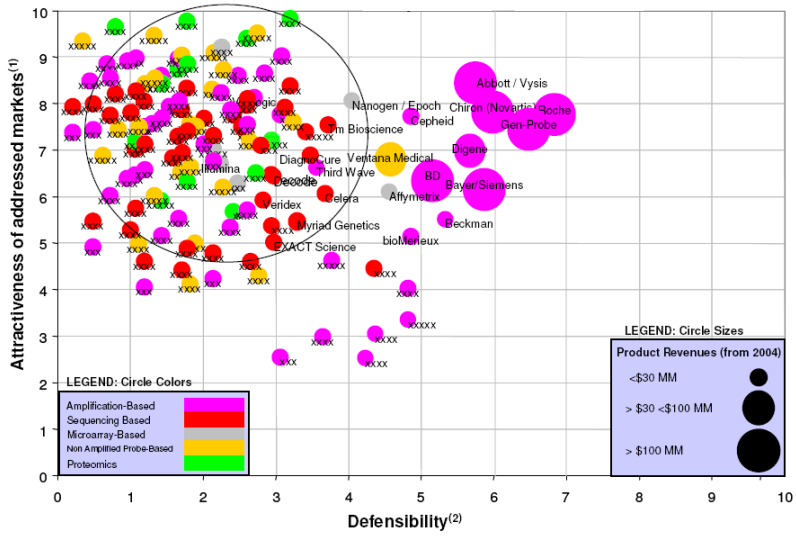


KEY TAKEAWAYS

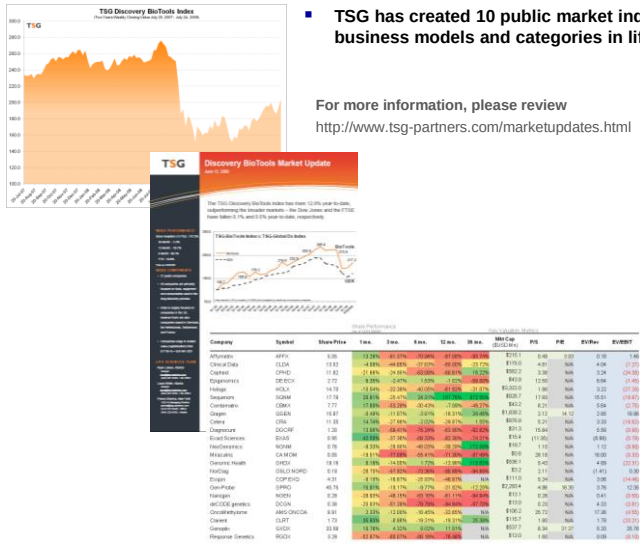
- CDC's recommendation for HIV testing to be done as part of routine medical tests and changes in DRA* coding for hospital acquired infections will greatly boost MDx test volume.
- FDA's push towards personalized medicine will lead to the proliferation of PGx tests and may lead to mandating of companion Dx to therapies.
- Although the FDA permits selling tests as ASRs, future degree of enforcement and oversight by the FDA may change.
- Physician education is an important component of adoption of MDx. For instance, an increase in CF testing was driven by ACOG's endorsement to test all pregnant Caucasian females.
- Recommendations from the recent SACGHS^ report could lead to positive reimbursement changes for MDx tests,
- Even though many of today's MDx tests are esoteric, as test volumes increase and automation improves, MDx will eventually be more routinely performed by all clinical labs .

* Deficit Reduction Act (DRA)
^ Secretary's Advisory Committee on Genetics, Health and Society (SACGHS)
Source: TSG Analysis

MDx is positioned in a fragmented, competitive landscape with segments demonstrating high growth and crowded by emerging companies



TSG has developed 10 Life Science Indices that track the public companies and market sentiment in a variety of specific life science sectors



- **TSG has created 10 public market indices that cover a range of business models and categories in life sciences**

For more information, please review
http://www.tsg-partners.com/marketupdates.html

- **Bioscience Indices**
  - Global Discovery BioTools
  - Global Diaganostics
  - Molecular Diagnostics
  - Point of Care Diagnostics
  - Global Lab Services
- **Regional Innovation Center Indices**
  - Israeli Life Sciences Index
  - Scandinavian Life Sciences Index
- **Nutrasciences Indices**
  - Global AgBio Index
  - B2B Nutrascience Index
  - B2C Nutrascience Index

Trends and directions to expect in molecular diagnostics TSG's perspective for 2009-2010

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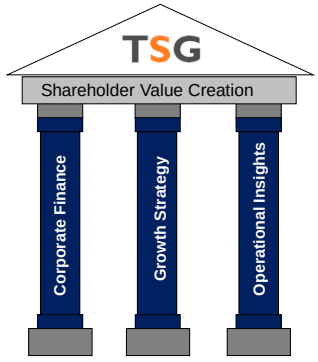

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