Molecular Diagnostics: Double-Digit Growth Anticipated

Ken Rubenstein, PhD

Industry-leading growth rates, expanding applications, and innovation characterize the molecular diagnostics sector. This report presents a synthesis of these developments including the increased diversity of assay targets, emergence of new and proposed point-of-care (POC) products, the appearance of sequencing-based assays that could fundamentally alter the field, and automated low-density microarray-based assays.

Discussed in this report:
- The technological landscape underlying molecular diagnostics today
- Products and systems currently on the market
- Products and platforms in development
- Market dynamics of competition, regulation, and reimbursement
- Applications beyond infectious agents, cancer, and genetic disease
- Promising multiplex assays in development
- Novel Point-of-Care (POC) formats
- Likely impact of regulatory reform
- Coverage of over 100 companies
OVERVIEW

Molecular Diagnostics: Double-Digit Growth Anticipated

Molecular diagnostics (MDx) is a vital and dynamic field in which yesterday’s new technologies and platforms are today becoming populated with novel, diverse, and useful content. One might conclude that the MDx market is approaching maturity as advances in automation have shifted the market toward the higher-volume end of the spectrum, and platform offerings are now largely stabilized, enabling manufacturers to focus on adding platform-specific content.

However, as this report reveals, the MDx market remains dynamic in the sense that small companies are continually developing useful new assays to meet unmet needs in MDx sectors. Also, significant technological contributions in the areas of signal amplification, multiplex assays, and DNA sequencing are contributing to the continuing expansion of applications. Tests for Alzheimer’s disease and autism are in development as well as additional companion diagnostics, prognostic/prediction tests, genetic disease screens, and pharmacogenetic assays.

This report found that companies are pursuing sample-to-answer automation for single assays. These point-of-care (POC) approaches appear likely to result in sophisticated test strips, disposable plastic rotors, and other formats for this purpose.

The MDx market is currently growing at nearly double the rate of the overall IVD market; we conclude that this growth is likely to continue for several more years. Oncology and critical care infectious disease testing sectors are likely growth leaders. In the current environment, regulatory reform, with reference to LDTs, is likely to advance slowly; however, the pace could quicken should political leadership shift back toward the left in 2012. Despite this chance, this report finds that the previously modest pace of MDx deal-making actually accelerated in late 2010.

Furthermore, if and when significant regulatory reform does adversely affect MDx, it is likely to do so in a phased manner—starting with the highest-risk assays and including significant levels of “grandfathering.” Limited funding for small companies and difficulty in achieving adequate reimbursement are issues that the public and private sector must address if personalized medicine and related entities are to continue advancing at healthy growth rates. In any event, point-of-care applications and next-generation sequencing-based assays are quite likely to provide significant sector growth over the next decade.

New technologies promise to open an extensive point-of-care market, with next-generation sequencing awaiting further refinement before quite possibly having a major impact on the character of the MDx market. Multiplex assays have achieved only modest success in the market to date, but products now in development show great promise. Regulatory reforms now under consideration could slow market growth, although recent political shifts are likely to slow or even prevent much of an impact for 2011.

Even if regulatory reform stalls, the industry still needs improved reimbursement for esoteric and expensive personalized medicine products. The entire reimbursement infrastructure drastically needs updating in order to accommodate advances in MDx. Companies are also faced with growing costs for assay validation. Limited automation capability caused by intrinsic protocol complexity of MDx assays relative to other IVD sectors provides another limitation to market growth in high-volume test sites. As test menus grow, manufacturers will likely accelerate efforts to advance automation capabilities.

Table 5.1 Molecular Diagnostics Licensing Deals

<table>
<thead>
<tr>
<th>Company</th>
<th>Partner</th>
<th>License Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Roche</td>
<td>QSI Pharmaceuticals</td>
<td>9-10; Roche licenses rights to EUR mutations from Genzyme and will collaborate with QSI to develop a CBA</td>
</tr>
<tr>
<td>Precision Diagnostics</td>
<td>MD Bioscience</td>
<td>11-18; Precision licenses DNA methylation markers for atherocclerosis diagnostics</td>
</tr>
<tr>
<td>Precision Diagnostics</td>
<td>Enzo Genetics AG</td>
<td>11-12; Precision licenses early agreement option to license McPherson gunshot markers for prostate cancer diagnostics</td>
</tr>
<tr>
<td>Michael Genetics</td>
<td>Molecular Diagnostics</td>
<td>12-18; Michael Genetics acquires rights to commercialize markers to detect gastric and esophageal cancer</td>
</tr>
<tr>
<td>BD Diagnostics</td>
<td>Lonza Group</td>
<td>10-10; licensing and collaboration; BD gets rights to develop assays, large-scale market opportunities</td>
</tr>
</tbody>
</table>

Source: Insight Pharma Reports

About the Author

Ken Rubenstein, PhD, a biochemist and molecular biologist, received his PhD at the University of Wisconsin and postdoctoral training at the University of Pennsylvania School of Medicine. He was a key innovator and research manager for Syva Company, the diagnostics branch of Syntex Corporation. During his 13 years with Syva, Dr. Rubenstein became vice president, scientific affairs, a function that included strategic planning. Since 1983, he has served as a technology and marketing consultant to biomedical companies and an industry analyst, with more than 40 published studies to his credit.
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