Molecular diagnostic applications in the areas of oncology, personalized medicine, inherited disorders, prediction of genetic disease risk, and many others, are rapidly increasing in number as this burgeoning field expands beyond infectious disease testing. This report focuses on these newer applications of molecular diagnostics, analyzing:

- Established and up-and-coming technologies
- The activities of more than 35 companies
- More than 300 current and emerging molecular diagnostic tests for disease applications and genetic testing
- Business considerations associated with product development, commercialization, and marketing
- Regulatory issues
- Challenges facing companies developing molecular diagnostics and/or companion diagnostics and targeted therapies
- Major trends in the molecular diagnostics market such as the increasing number of tests that are commercially available.
The molecular diagnostics market is exploding. New genes and biomarkers are continually being identified and clinically validated, increasing the number of different tests available. The requisite technology and instruments are advancing in tandem. While many companies offer tests that detect only one or a few genetic changes, some companies have now developed tests capable of detecting large numbers of these changes. Many companies are taking their tests through the traditional diagnostics market strategy of gaining FDA clearance, while others have chosen a different strategy and are offering tests through their own CLIA-certified laboratories. These and other dynamics are effecting rapid change in this evolving field. Molecular Diagnostics: A Dynamic and Rapidly Broadening Market analyzes the emerging applications and technologies, marketplace trends, and business considerations for companies in this space.

The molecular diagnostics market is already quite large. It is estimated that the worldwide market for in vitro diagnostic kits and reagents sold by diagnostic companies to clinical laboratories may be approximately $3 billion or greater in 2008. It is more difficult to estimate the market size for proprietary clinical tests offered by companies through either their own CLIA-certified laboratories or other clinical laboratories. However, this can be a promising opportunity. For example, Myriad Genetics and Genomic Health saw a jump in molecular diagnostic revenues of 53% and 132%, respectively, over the past two years.

Molecular Diagnostics: A Dynamic and Rapidly Broadening Market considers major trends, including movement toward near-patient testing, growth in the number of new biomarkers, increased effort on clinical validation of tests, increased competition, consolidation in the field, regulatory issues and their impact on laboratories and companies, and the increasing role played by personalized medicine, among others. Technologies discussed include non-amplified probe-based assays, cytogenetics and fluorescent in situ hybridization, amplification technologies, microarrays, and DNA methylation assays.

Current and emerging applications of molecular diagnostics are reviewed and grouped into the following categories: oncology (diagnostic, prognostic, and personalized medicine tests); personalized medicine, pharmacogenomics, and companion diagnostics outside of oncology; genetic testing for inherited disorders and prenatal diagnosis; and predicting genetic risk of disease. The activities of more than 35 companies are discussed. We also consider some of the challenges facing molecular diagnostic and pharmaceutical companies developing pharmacogenomic therapies, such as issues regarding reimbursement, patient and physician education, and the validation of new biomarkers and diagnostic tests. We conclude with 10 exclusive industry expert interviews.

Selected Companies Developing and/or Marketing Molecular Diagnostic Tests for Inherited Disease or Prenatal Diagnosis

<table>
<thead>
<tr>
<th>Company</th>
<th>Product/Technology</th>
<th>Status</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbott Molecular (Abbott</td>
<td>AneaVision</td>
<td>On the market (FDA</td>
<td>• Based on FISH technology&lt;br&gt;• For prenatal diagnosis—for detection of trisomy 13, 18, 21, and sex chromosome aneuploidies</td>
</tr>
<tr>
<td>Laboratories)</td>
<td>Assay</td>
<td>cleared) (CE marked)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Chromosome</td>
<td>On the market as ASRs</td>
<td>• Chromosome-specific FISH probes&lt;br&gt;• Used to evaluate prenatal samples, tumors, hematological malignancies, and other applications</td>
</tr>
<tr>
<td></td>
<td>Enumeration Probes</td>
<td></td>
<td>• Abbott offers numerous CEP probes as ASRs. FDA-cleared/CE-marked probes listed separately.</td>
</tr>
<tr>
<td></td>
<td>Microdeletion</td>
<td>On the market as ASRs</td>
<td>• Based on FISH technology&lt;br&gt;• Multiple probes available to detect microdeletions for genetic disorders, such as Prader-Willi/Angelman syndromes, SRY gene microdeletions, and others</td>
</tr>
<tr>
<td></td>
<td>Probes—TelEnvision</td>
<td></td>
<td>Telomere ASR probes, included in telominal kit.</td>
</tr>
<tr>
<td></td>
<td>ToTelEnvision and</td>
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<tr>
<td></td>
<td>TelEnvision</td>
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Source: Insight Pharma Reports

Selected Recent Corporate Acquisitions in Molecular Diagnostics

Valid Genomic Biomarkers in the Context of Approved Drug Labels

About the Author: Lucy J. Sannes, PhD, MBA, is president of Sannes & Associates, a consulting firm specializing in evaluation and management of the biosciences. Before forming Sannes & Associates, she held management positions at Genetic Systems and Abbott Laboratories in product development, product support, and technical marketing. Dr. Sannes received her PhD in biological chemistry from the University of Michigan and her MBA from Seattle Pacific University.

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Fareed Kureshy, Founder, Chairman, President, and CEO, AutoGenomics
Jeffrey E. Miller, PhD, CSO, CEO, & Chairman, InVivoScribe Board of Directors, InVivoScribe Technologies
Mansoor Mohammed, PhD, President and CEO, CombiMatrix Molecular Diagnostics (CMDX)
Oliver Schacht, PhD, CFO and CEO, Epigenomics Inc., Epigenomics AG
John C. Schafer, President and CEO, DiagnoCure
James White, CEO, Osmotech plc
Matt Winkler, PhD, CEO and CSO, Asuragen

### References

Company Index with Web Addresses
Cancer Biomarkers: Adoption is Driving Growth
Aggressive adoption of cancer biomarkers will accelerate the growth of commercial markets for these products. This report offers in-depth analysis of:

- The current cancer biomarker products, applications, and markets
- Key validation and assessment of cancer biomarker programs integrating established “standards of care” for cancer diagnosis and treatment
- Product opportunities for improved screening and early detection, to provide better guidance on therapy, for understanding cancer staging, response to treatment, and prognosis
- Profile of business models behind cancer biomarker products and a SWOT analysis associated with specific strategies
- Projections for market growth for cancer biomarker product categories

This report includes summaries of interviews with 4 experts from companies engaged in cancer biomarker production commercialization and provides analysis from a recent survey relating to R&D.

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Molecular Diagnostics: A Dynamic and Rapidly Broadening Market

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