Molecular diagnostic tests are now used for a wide range of applications, including:

- Human clinical molecular diagnostic testing
- Identity testing
- Forensic testing
- Histocompatibility testing

Continued on next page
Overview

Within these broad disease areas, molecular diagnostics tests have a wide range of applications, including:

- Identification of individuals who are at increased risk of developing certain disorders
- Screening apparently healthy populations
- Diagnosis
- Determining prognosis, such as with cancer
- Personalized medicine applications, including pharmacogenetic tests such as drug metabolism tests to avoid adverse drug effects and companion diagnostics to identify patients who will respond to a specific drug
- Monitoring response to therapy

Molecular Diagnostics: A Rapidly Shifting Commercial and Technology Landscape focuses on human clinical molecular diagnostics. Even within this field, molecular diagnostics is being applied to a wide range of diseases and applications. The first molecular diagnostics tests to reach the market were for infectious diseases, and this remains the largest segment of the molecular diagnostics market. Molecular oncology tests have been emerging as a second significant—and rapidly growing—market segment. Molecular diagnostics is also starting to emerge as an important tool for inherited disorders, cardiovascular disorders, and other disease areas.

This report provides a thorough discussion of the many companies involved in molecular diagnostics and their commercial products either on the market or in development for these applications. Molecular diagnostics has emerged as a significant segment of the overall clinical diagnostics market. Overall, the molecular diagnostics market is growing rapidly, although some segments are growing more rapidly than others. This report provides an overview of the molecular diagnostics market, and discusses many of the trends in this market—including factors that are driving the growth.

This report also includes results from a Web survey of individuals involved in molecular diagnostics research, development, and use. More than 250 people responded to the survey, pointing out in a question what they think will be the biggest growth areas over the next 5 years:

What do you believe is the most promising major application area for molecular diagnostic testing over the next 5 years?

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<thead>
<tr>
<th>Application Area</th>
<th>Percentage</th>
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<td>Oncology</td>
<td>86%</td>
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<tr>
<td>Pharmacogenomics</td>
<td>67%</td>
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<tr>
<td>Infectious disease</td>
<td>37%</td>
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<tr>
<td>Genetic testing</td>
<td>31%</td>
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<td>Neurological disease</td>
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<tr>
<td>Cardiovascular disease</td>
<td>13%</td>
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<tr>
<td>Other</td>
<td>5%</td>
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Source: CHI Molecular Diagnostics Survey—July 2007

As molecular diagnostics moves into the future, companies in this market will face a number of challenges. Selected examples of the challenges are discussed. The molecular diagnostics market is changing rapidly and is becoming highly competitive. The market shows considerable promise for new tests to improve the diagnosis and treatment of a wide range of diseases and disorders.

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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<td>Selected Companies Developing and/or Marketing Clinical Molecular Diagnostic Products Based on Microarray Technology</td>
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<td>Growth Areas Next 2 Years</td>
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Jorge Leon, PhD, President, Leomics Associates; Former Acting Chief Scientific Officer, Orion Genomics, St. Louis, MO
James White, CEO, Osmetech, Pasadena, CA

Chapter 6: Selected Company Profiles
Abbott Molecular (aka Vysis)
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Appendix: CHI Insight Pharma Reports—Molecular Diagnostics Survey Analysis

References

Company Index with Web Addresses
Combination Drug/Diagnostic Products: Pathways to R&D and Commercial Success

This report assesses the commercial opportunity, and provides the information and guidance, that companies need to steer clear of the pitfalls in combination drug/diagnostic R&D. Specifically, it provides:

- A quantitative survey, rendered in easy-to-scan charts, of the industry’s views, plans, and current actions with regard to combination drug/diagnostic products
- A review of drug/diagnostic combinations in current use, such as Monogram Bioscience’s Trofile Assay, which was codeveloped with Pfizer’s Celsentri (for HIV) as a means to identify responders to the drug
- The outlook for reimbursement of diagnostics, including a case study of Genomic Health’s Oncotype DX gene expression test for predicting the benefits of chemotherapy in newly diagnosed breast cancer patients
- A review of existing safety and status biomarkers that are being used as diagnostics, such as a simple genotyping test to guide warfarin dosing, or molecular markers for identifying responders to Gleevec and Nexavar
- Patenting activity around combination drug/diagnostic products in cancer, neurodegenerative disease, respiratory disease, and viral infection
- A model of the potential expansion of a therapeutic market generated by incremental improvements in biomarker sensitivity
- Implications of FDA’s IVDMIA and ASR draft guidances

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<td>$2,995.00</td>
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