

The Promise of Molecular Diagnostics Innovation

Maria Shepherd • Data Decision Group

One of the most exciting fields, with a tremendous amount of promise for the future of healthcare is the area molecular diagnostics. Molecular diagnostic companies are employing very creative science, creating tests that have potential to cut down on overtreatment, reduce waste in the practice of healthcare, and give physicians a new arsenal in their fight to treat patients.

The diagnostics industry is growing at a rapid pace with projected sales growth between 2012 and 2018 from \$43.6 billion to \$58.8 billion, a compound annual growth rate (CAGR) of 5.1 percent.¹ The molecular diagnostics sector of the market is expanding at a particularly robust clip, estimated to reach \$8 billion by 2018, at a CAGR of 9.7 percent.²

Why It's Important

Diagnostic testing provides critical information that healthcare providers and patients need to make appropriate medical decisions. Diagnostics provide metrics for the continuum of care, from assessing at-risk patients and screening patients, to detec-

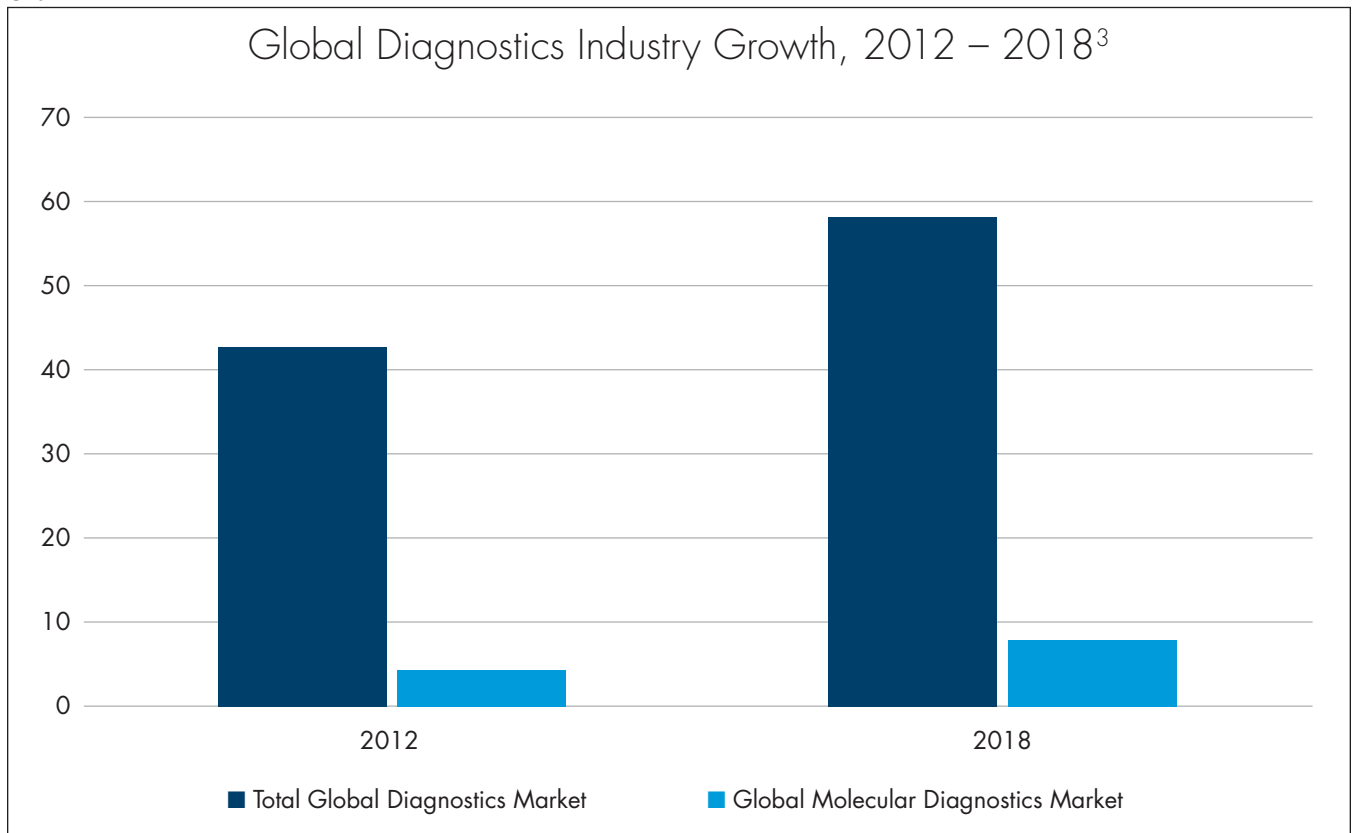
tion and diagnosis, to choices of therapy, cure and surveillance. According to the Advanced Medical Technology Association (AdvaMed), the Washington D.C.-based industry trade group (most often referred to as AdvaMed), the rapidly growing field of molecular diagnostics is one of the most dynamic segments, leading to disease state therapies that can change the course of healthcare.⁴ Molecular diagnostics detect and measure the presence of DNA, RNA or proteins associated with a specific disease state, to discover the fundamental root cause of disease. This is the foundation of personalized medicine, which can enable clinicians to modify care for each individual patient.

Molecular genetic testing is performed for diagnosis of inherited cardiac disease, such as atrial fibrillation, to guide prognosis and treatment, but access is often limited by cost and availability

New molecular diagnostics sequencing tests are faster, less expensive, as compared with current molecular genetic diagnostic tests.⁵

The market for molecular diagnostics is segmented by technique and application. Many techniques are employed to detect

Chart 1



and quantify specific DNA or RNA sequences or proteins. These include polymerase chain reaction (PCR), in-situ hybridization, chips and microarrays and sequencing.

References

1. *EvaluateMedtech, World Preview 2013, Outlook to 2018: The Future of Medtech, September 2013*

2. *Molecular Diagnostics Market by Application Global*

Forecasts to 2018, www.market-sandmarkets.com/Market-Reports/molecular-diagnostic-market-m33.html?gclid=Cj161YrHs78CFW4Q7Aod-BcAwA

3. <http://aje.oxfordjournals.org/content/157/11/1015.full.pdf+html>

4. *Introduction to Molecular Diagnostics, http://advameddx.org/download/files/AdvaMedDx_DxInsights_FINAL(2).pdf*

5. Li X, Buckton AJ, Wilkinson SL, John S, Walsh R, et al. (2013) *Towards Clinical Molecular Diagnosis of Inherited Cardiac Conditions: A Comparison of Bench-Top Genome DNA Sequencers.* PLoS ONE 8(7): e67744. doi:10.1371/journal.pone.0067744

6. <http://pitchengine.com/pitches/39afc905-b545-4255-9700-68eea57780c1>

7. *Ibid*

Editor's note: Readers are invited to submit market data and trend questions to Maria Shepherd. Periodically, selected questions will be presented in this column, with answers from Maria. Send your questions to her email address (below).

Maria Shepherd has 20 years of leadership experience in medical device/life-science marketing in small start-ups and top-tier companies. After her industry career, including her role as vice president of marketing for Oridion Medical, where she boosted the company valuation prior to its acquisition by Covidien plc, director of marketing

for Philips Medical and senior management roles at Boston Scientific Inc., she founded Data Decision Group. Data Decision Group provides whitespace research and critical data to support medical device decision-making. The firm quantitatively and qualitatively sizes opportunities, evaluates new technologies, provides marketing services and assesses prospective acquisitions. Shepherd has taught marketing and product development courses, and is on the board of the MSBiV Medtech Investment Committee. She can be reached at (617) 548-9892 or at mshepherd@dddecisiongroup.com.

Chart 2

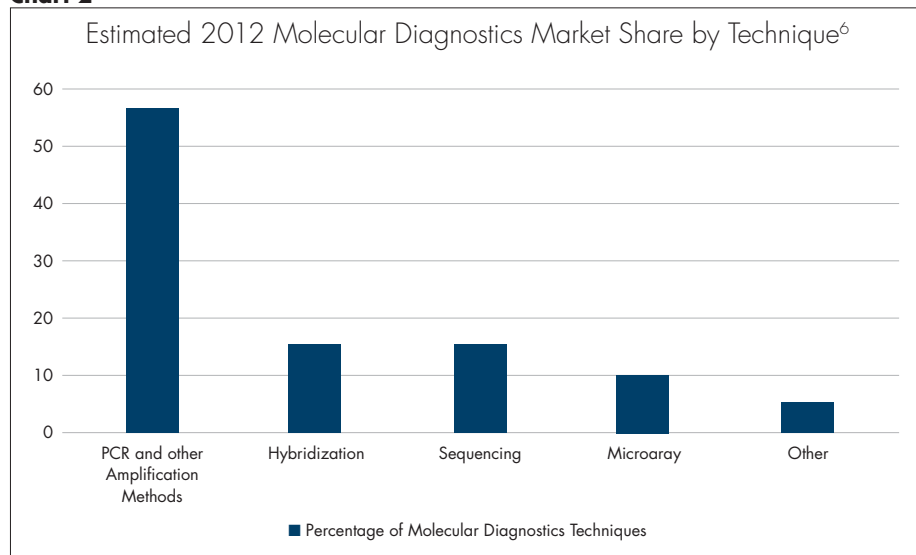
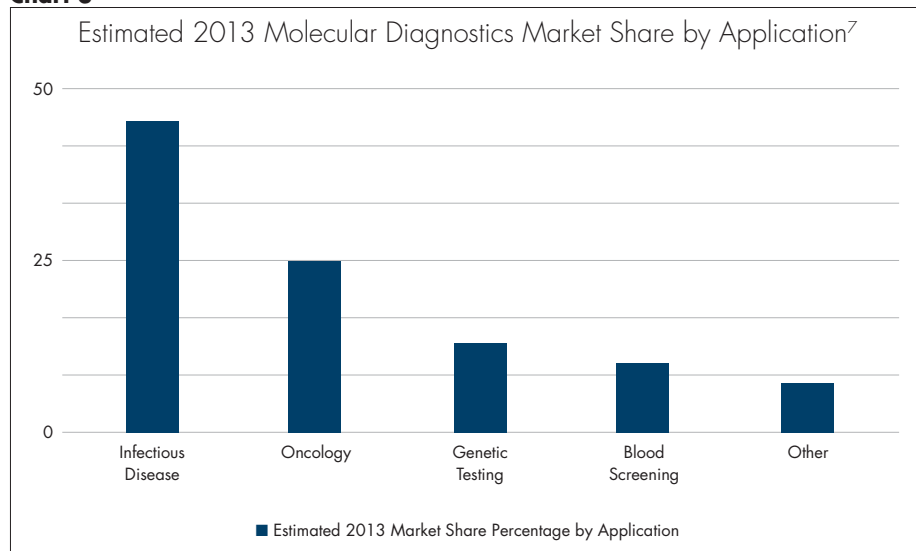


Chart 3



How Will This Drive Innovation in Medtech?

A higher level of accuracy will drive decreased cost for the health-care system, benefiting us all. Entrepreneurs on the cutting edge of the market will make new molecular diagnostics a reality by improving outcomes and reducing healthcare costs, which along with safety and efficacy are becoming part of the true value proposition for savvy medtech firms. There is profit in providing improved financial outcomes in healthcare. How will you identify those opportunities? ❖