



# **How to Build a Molecular Testing Laboratory: Key Strategic & Operational Considerations**

***The complete guide to developing or expanding your lab***



**Includes step-by-step plans for basic and full-service MDx labs**

## **How to Build a Molecular Testing Laboratory: Key Strategic & Operational Considerations**

**L. Eleanor J. Herriman, M.D., MBA**, Director of Research and Analysis, G2 Intelligence

*G2 Intelligence estimates that the market for molecular diagnostics laboratory testing (MDx) will reach \$7 billion in 2011—and that it is growing at 15% CAGR. The opportunity is significant—and **How to Build a Molecular Testing Laboratory** provides the intelligence you need to make smart decisions for building, optimizing or expanding your own MDx lab. This comprehensive research, authored by G2 Director of Research and Analysis, Eleanor Herriman, M.D., MBA, gives you valuable, practical insights and step-by-step instructions for your lab—including the five-stage process for developing an MDx strategy, and a real-world execution plan for building basic and full-service MDx labs.*

**The field of molecular diagnostics testing is perhaps unlike any other in the history of laboratory testing.**

Molecular diagnostic testing (MDx), or assaying for nucleic acids, is at the center of a wave that is transforming medicine and the health care industry. This bold assertion is based on the following:

- MDx testing is a key enabler of personalized medicine
- MDx testing is redefining disease states, leading to “precision medicine”
- MDx testing is reconfiguring laboratory medicine’s position in the health care industry
- Some health care industry opinion leaders predict that MDx will usurp pharmaceuticals in terms of investment attractiveness
- PLUS, MDx tests are now used throughout the continuum of care
- AND, MDx has shown that it can advance clinical outcomes and produce health care savings

**Make sure your lab is ready to take the next step with Dr. Herriman’s actionable, practical insights on:**

- The five-stage process for developing your lab’s MDx strategy
- A real-world execution plan for building basic and full-service MDx labs, covering:
  - Testing menus
  - Instrument platforms
  - Facility and supplies
  - Personnel
  - Developing the pro forma financials and business case
  - Laboratory operations
  - Quality, proficiency testing and accreditation
  - Coding and billing
  - Sales and marketing

Figure 1

**Example MDx Lab Requirements According to Primary Strategic Objective**

Strategic MDx Lab Objective	Type of MDx Lab	Client Network	Personnel	Technology
Meet clinicians' service needs	Basic, automated	Start with baseline—if insufficient volume, need to expand	Director and techs, minimal expertise	Automated, easy to operate systems; FDA kits
Reduce send-out expenses	Start with basic, automated lab	Start with baseline—if insufficient volume, need to expand	Director and techs, minimal expertise	Automated, easy to operate systems; FDA kits
Grow lab revenues, profits	Intermediate—move to LDTs	Need to grow client testing share and/or number of clients	Bring in MDx expertise and sales, marketing	Can start with closed and automated, move to open for LDTs
Differentiate lab competitively	Stage—basic to full service	Need to grow client base; network with other labs/start reference business	Bring in MDx expertise and sales, marketing; need IT expertise	Multiple systems—some automated, FDA kits, other open systems for LDTs
Establish institutional leadership	Full service—LDT capabilities	Develop relationships with specialty services and clinical researchers; establish agreements with pharmas, IVD cos. for trial services	Experienced MDx PhD, med techs; clinical research and IT capabilities	Multiple systems—some automated, FDA kits, other open systems for LDTs

Source: G2 Intelligence

**Summary**

In Dr. Herriman's new report, *How to Build a Molecular Testing Laboratory*, you'll also find helpful information on the molecular diagnostics testing market, including:

- The molecular diagnostics testing market, featuring key market trends driving the rapid growth and adoption of MDx testing
- Molecular diagnostics tests and techniques
- Industry trends and best practices
- Evolving regulatory issues and obtaining reimbursement for new MDx tests
- Appendices on FDA-cleared/approved molecular diagnostics tests, and G2's compilation of molecular tests with evidence of health care savings

## **How to Build a Molecular Testing Laboratory: Key Strategic & Operational Considerations is organized as follows:**

- *The Molecular Diagnostics Testing Market*—featuring an overview of key market characteristics, trends and challenges
- *Strategic Planning for the MDx Lab*—the five-stage process for developing your lab's MDx strategy
- *Molecular Diagnostic Tests*—history, test menus and techniques
- *MDx Instrument Platforms*—overview and selecting the right instrumentation for your lab
- *Building a Basic MDx Lab*—a real-world execution plan for building your MDx lab
- *The Full Service MDx Lab*—a comprehensive plan for taking your lab to the next level—one that performs both Food and Drug Administration (FDA)-cleared, In Vitro Diagnostic (IVD) tests, as well as laboratory developed tests (LDTs).
- *MDx Labs—Industry Trends and Best Practices*—results of a G2 Intelligence 2011 survey of 90 laboratories regarding their experiences with MDx testing, as well as a compilation of best practice recommendations from MDx laboratorians.

Order now to receive your copy for just \$995 and your state's sales tax by visiting [www.G2Intelligence.com](http://www.G2Intelligence.com).

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## **About G2 Intelligence**

### **Advancing the Business of Diagnostic Medicine**

G2 Intelligence provides timely, accurate and trusted analysis of industry and market trends, legal and regulatory developments, and technology and innovation that directly affect the operations, financial performance, and competitive position of diagnostic testing laboratories and related medical services providers.

Formerly known as “Washington G-2 Reports”, the company has covered and reported on the diagnostic industry for over 30 years. G2 Intelligence delivers topical and analytical periodicals, proprietary research studies, and custom advisory services, and through live and virtual events, facilitates industry meetings and information exchanges.

Our mission is to deliver relevant, meaningful and actionable findings on diagnostic industry markets, related regulatory change and lab operations. The organization strives to exceed client expectations and develop mutually beneficial relationships with industry leaders and influencers.

G2 Intelligence is a division of Kennedy Information, LLC, a leading provider of professional market analysis.

Information on other G2 Intelligence products and services can be found at [www.G2Intelligence.com](http://www.G2Intelligence.com).



## **About the Analyst**



### **L. Eleanor J. Herriman, M.D., MBA, Director of Research and Analysis G2 Intelligence**

L. Eleanor J. Herriman, M.D., MBA is a pathologist executive with 15+ years experience in the medical technology industry. She has worked across sectors with both small ventures and corporations. Her market experience spans the clinical laboratory, in vitro diagnostics, e-health, biotech, and strategy consulting for Bain & Company. She is the author of two G2 Intelligence reports: *Health Care Market Reforms: Implications and Prescriptions for Laboratories*; and *How to Build a Molecular Testing Laboratory: Key Strategic and Operational Considerations*. Other key accomplishments include growing a venture with a CLIA lab and FDA PMA approved computer-assisted cytology instrument from start-up to publicly traded company (IPO raised \$100M).

She earned an MD at Baylor College of Medicine, did her pathology training at UCSF, and received an MBA from Harvard Business School with highest honors (Baker Scholar).

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