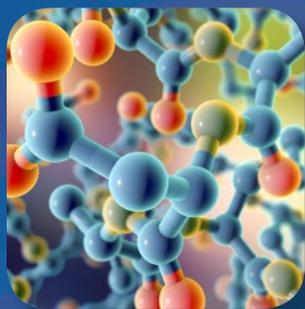


PROSPECTUS



Innovation in Clinical Diagnostic Instruments

PCR, NGS, Mass Spec, and HPLC

NOVEMBER 2017

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OVERVIEW

“With no one brand dominating the Molecular IVD market and a fragmented market in terms of market share by technique, there is an opportunity for both brand growth and expansion with careful planning and investment.”

There are a variety of Molecular Diagnostic (MDx) techniques used in hospitals, research labs, clinics, and commercial reference labs that are used to detect nucleic acids and proteins for diagnostic or monitoring purposes. Most require an analytical instrument, such as a PCR machine, mass spectrometer, or sequencer. While MDx techniques evolve in different ways and not all methods survive, those that do typically transition from basic research to lab developed tests (LDTs) in applied testing and diagnostic markets, where they are able to be used in a more routine and trusted capacity.

In this report, we present a thorough picture of the MDx market – its current situation, trends, recent market-oriented data about analytical solutions being used in this field, as well as future growth projections. This report does not aim to be exhaustive, but it does provide information on those techniques where innovation in established technology platforms is most applicable to clinical diagnostics.

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■ OVERVIEW (continued)

Thus, the scope of this report is not limited to nucleic acid-based techniques (amplification, sequencing, microarrays and in situ hybridization), but also includes mass spectrometry and HPLC for the analysis of proteins, hormones, drugs, and other complex, bioactive molecules.

The MDx market has two major segments: clinical research and molecular in vitro diagnostics (IVD). Clinical research involves the development of assays for molecular diagnostics, biomarker discovery, and pharmacogenomic applications. Molecular IVD embodies the analysis and detection of infectious disease, cancer, genetic disorders, metabolic ailments, and others. It represents about one-tenth of the IVD market and is the fastest growing segment within IVD.

With the data of this report in hand, you can compare your brand's market penetration to your competitors, as well as identify growth segments where you have presence, but no brand leader has yet been established. Confidently steer future marketing efforts and focus resources on segments that make the most sense for your overall (or niche) MDx growth strategy.

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■ STUDY SCOPE

Objectives of this study

The primary objective of this report is to provide a picture of the analytical instrumentation market for molecular diagnostics and related clinical research applications, give insight into projected market trends, and present an analysis of the strategic and competitive landscape for the technologies covered. Detailed definitions and explanations of the included technologies are presented in the Technology Overview section.

The market for each technology is described in terms of various product-oriented segments. Market demand estimates for the techniques are presented for their total associated annual revenues from initial system sales, aftermarket purchases, and service. The following should clarify what is, and is not, included in each category:

- The **initial system** comprises all the hardware, software, supplies, and accessories bought as part of the original order, including data systems.
- The **aftermarket** encompasses any components, accessories, consumables, software, and supplies sold after the original order by instrument manufacturers. This includes data systems sold separately from the initial-system purchase.

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■ STUDY SCOPE (continued)

- **Service** includes all service contracts and replacement parts used in service, whether provided by the manufacturer of the original instrument or through a third party. Other services, such as software support and validation service are also included in this section. However, the value of in-house service is excluded.

All market estimates are at end-user prices and therefore many instrument system and aftermarket sales include distributor or agent commissions or mark-ups. In the market share estimates, distributors are given credit for their commission or markup, but the original vendor is apportioned the remainder of the sale price. Thus, market share estimates are not necessarily indicative of direct end-user funds, but essentially represent the annual sales of a given supplier through various channels. Since some smaller manufacturers provide products and components on an OEM basis to system manufacturers, there could be some double counting. Although this complicates the picture, the overall effect is not significant.

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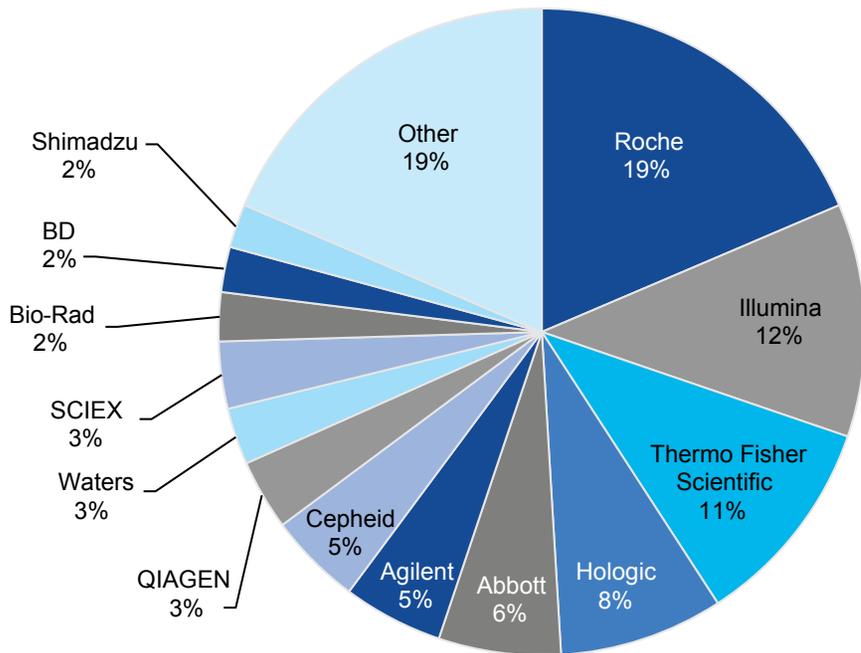
Penetration Strategies & Barriers to Entry

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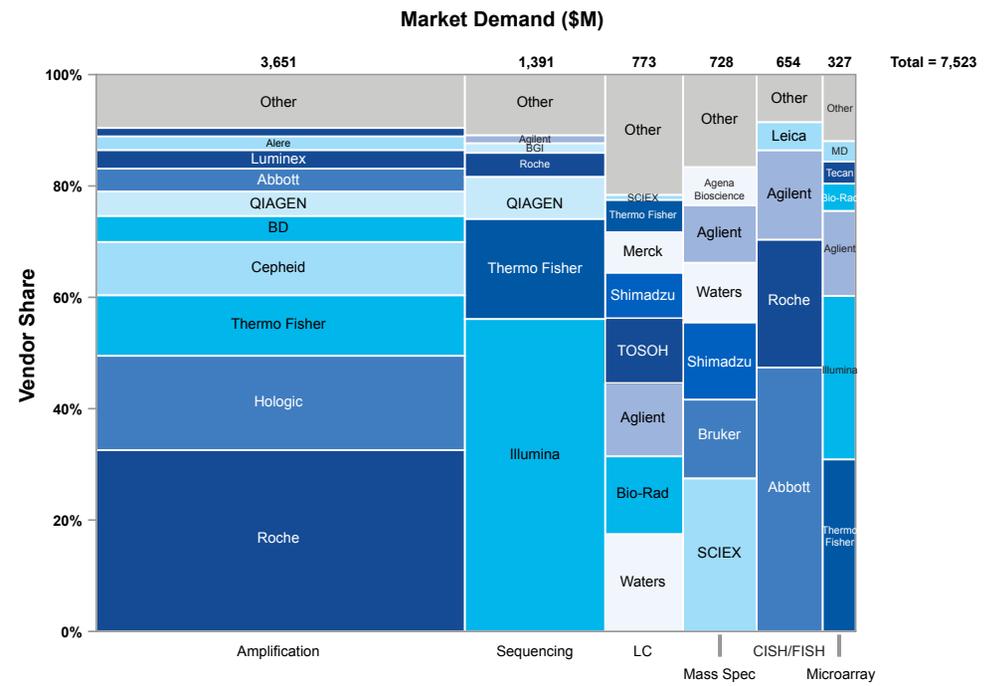
Innovation in Clinical Diagnostic Instruments PCR, NGS, Mass Spec and HPLC

REPORT HIGHLIGHTS

OVERALL MOLECULAR DIAGNOSTICS VENDOR SHARE, 2016



OVERALL VENDOR SHARE BY TECHNIQUE, 2016



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■ METHODOLOGY

Innovation in Clinical Diagnostic Instruments: PCR, NGS, Mass Spec and HPLC

is based on company financial statements, publications by industry observers and market participants, general and industry publications, and other information. Proprietary algorithms, adjusted by decades of market knowledge and client feedback, create reliable models of market size, share, segmentation and growth. Our analysts also employ primary research that involves substantial interactions with knowledgeable sources, including end-users, individuals within regulatory agencies, marketing and technical personnel of participating vendors, and other informed observers.

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■ PRICING (continued)

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■ CURRENT REPORT TITLES

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The 2017 Market for Research Antibodies: Keys to Success for Commercial Suppliers	\$4,000 - \$6,500
The 2017 Market for Laboratory Plasticware: Cell Culture & Liquid Handling/Storage June 2017	\$6,500 - \$8,500
The Analytical & Life Science Instrument Market in China: Dispatch from the Middle Kingdom - July 2017	\$8,995 - \$10,995
The 2017 Market for NGS Informatics: Probing the Commercial Landscape - August 2017	\$4,000 - \$6,500
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2018 Trends in Marketing to Life Scientists - Connecting, Influencing, and Sharing - October 2017	\$4,000 - \$6,500

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BioInformatics LLC, along with our SDi division, is the premier research and advisory firm serving the life science and analytical instrument industry. Since 1994, we have been providing off-the-shelf reports, custom-designed studies and market analysis that enable companies to understand their market and competitors through the eyes of the most important information source of all – *the people who buy their products*.

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