PROSPECTUS

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

NOVEMBER 2017
## TABLE OF CONTENTS

- **OVERVIEW** ........................................................................................................................................................... 3
- **STUDY SCOPE** ...................................................................................................................................................... 5
- **REPORT TABLE OF CONTENTS** .......................................................................................................................... 7
- **REPORT HIGHLIGHTS** ........................................................................................................................................... 8
- **METHODOLOGY** .................................................................................................................................................... 9
- **PRICING** ............................................................................................................................................................ 10
- **CURRENT REPORT TITLES** ............................................................................................................................... 12
- **ABOUT BIOINFORMATICS LLC & SDI** ............................................................................................................... 13
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.
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.
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.
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.
TABLE OF CONTENTS

Section 1. Overview
   Introduction
   Scope
   Executive Summary

Section 2. Technology Overview

Section 3. Recent Business Events

Section 4. Market Demand (2016-2021)
   Overall
   Nucleic Acid Amplification
   DNA Sequencing
   Mass Spectrometry
   Liquid Chromatography
   In Situ Hybridization
   Microarrays

Section 5. Strategic Perspectives
   Opportunities and Threats
   Penetration Strategies & Barriers to Entry

Section 6. About Us
REPORT HIGHLIGHTS

OVERALL MOLECULAR DIAGNOSTICS VENDOR SHARE, 2016

- Roche: 19%
- Illumina: 12%
- Thermo Fisher Scientific: 11%
- Hologic: 8%
- Agilent: 5%
- Cepheid: 5%
- QIAGEN: 3%
- Waters: 3%
- SCIEX: 3%
- Bio-Rad: 2%
- BD: 2%
- Shimadzu: 2%
- Other: 19%

OVERALL VENDOR SHARE BY TECHNIQUE, 2016

- Market Demand ($M)
  - Total = 7,523
  - Amplification: 3,651
  - Sequencing: 1,391
  - LC: 773
  - Mass Spec: 728
  - Microrna: 654
Innovation in Clinical Diagnostic Instruments: PCR, NGS, Mass Spec and HPLC

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.
Pricing

Why Buy Our Reports

Developed by a Team of Experts

Our reports are developed by a multidisciplinary team of scientists, industry veterans and market research experts with years of experience. These professionals thoroughly understand the material covered and the scientific and business implications of the results based on sophisticated statistical analysis.

Proprietary Market Forecasting Methodology

BioInformatics’ SDi division maintains a database spanning decades of the corporate financial performance of scientific suppliers that is updated continuously. Proprietary algorithms, adjusted by market knowledge and client feedback, allocate revenues across dozens of product categories to create reliable models of market size, share, segmentation and growth. SDi 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. Secondary research is also conducted to provide background perspective, to derive and substantiate market estimates, and to supplement those insights gleaned from primary research activities.
Complimentary Consulting Provided

With your purchase, we offer one free consultation with our talented team of scientific and business analysts who created the reports. During this consultation, we can answer any questions you may have about the methodology, survey results, and what we believe to be the significant trends affecting the market.

Custom Analysis & Research Available

If you’d like to delve deeper into the data from a study, we can always perform custom cross-tabulations or other analysis on your behalf. We can even pose followup questions to respondents who answered in a particular way or conduct a custom qualitative or quantitative study to extend your knowledge.

Pricing

- Single Site License PDF – $6,500
- Company-Wide License - $8,500

All orders received by December 16, 2017 will receive a 10% discount.

For more information about BioInformatics’ product and service offerings, please visit our website at www.gene2drug.com, call 703.778.3080 x19, or email reports@gene2drug.com
CURRENT REPORT TITLES

Lab Budgets and Sources of Funding in 2017:
The Market Outlook for the United States, Europe and Asia
March 2017....................................................................................................................... $4,000 - $5,000
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
The 2017 Market for Single Cell Analysis Products: Convergence of
Microfluidics and Omics Platforms - August 2017.......................................................... $4.00 - $6,500
The 2017 Market for CRISPR/Cas9 Genome Editing
Products – September 2017.............................................................................................. $4,000 - $6,500
The 2018 Global Security Market for Analytical
Instrumentation – September 2017.................................................................................. $8,995 - $10,995
2018 Trends in Marketing to Life Scientists – Connecting,
Influencing, and Sharing – October 2017.......................................................................... $4,000 - $6,500

Upcoming Reports

The 2018 Market for Confocal and Advanced Microscopy: End-User Perspectives (November 2017)

ABOUT BIOINFORMATICS LLC & SDI

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.

By leveraging our online professional network of tens of thousands of biomedical researchers, we have supported more than 500 companies and provided insights that lead to better decisions. Our expertise includes assessing the size and attractiveness of markets, optimizing product configurations and pricing, validating corporate acquisitions, measuring customers’ brand loyalty, and evaluating brand strength and positioning.

For more information about BioInformatics’ product and service offerings, please visit our website at www.gene2drug.com, call 703.778.3080 x19, or email reports@gene2drug.com