

# Bioinformatics in IVD Testing

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## Abstracts

Computer diagnostics could offer opportunity for clinical laboratory professionals to add value to clinicians in diagnosing diseases. IT companies in collaboration with test vendors are developing computer software that complements the skills of human test interpretation.

This report, Bioinformatics in IVD Testing looks at the various IVD market segments where bioinformatics is expected to have the most impact.

Bioinformatics-based testing has made a huge contribution to cancer diagnosis and therapy management. In infectious disease diagnostics it allows the detection of difficult to culture pathogenic bacteria or viruses and to uncover the epidemiology of infections. The bioinformatic analysis of mutations of known human genes is used to diagnose common disorders, inherited diseases, or different types of cancer and can indicate the prognosis of malignant diseases.

What developments are driving this trend? What are labs and providers doing to incorporate these products into practice? And how are payors and regulators reacting? Who is partnering with who to deliver a solid combination product? This report delves into these issues and provides an excellent round-up of the current status of bioinformatics in the IVD industry.

**As part of its coverage, the report provides information on the following developments:**

Selected Diagnostic Tests That Incorporate Bioinformatics

Selected Multiplexed Tissue-Based Cancer Tests

## Selected Histology Analyses Software Tools

Selected Blood-Based Cancer Biomarker Tests That Use Software Analysis Tools

Selected Chronic Diseases Tests With Integrated Bioinformatics

Selected Innovations in Bioinformatic-Based Tests For Psychiatric Disorders

Selected Systems For Bioinformatics-Based Infectious Disease Testing

Selected Next Generation Sequencing Platforms

The report discusses tests and technologies that are currently available and those that are expected to take their place. Generally, current products and technologies establish the standard of care and its value to payers. Many of the assays and techniques presented in the report are expected to replace the standard of care in 2013, but with healthcare systems' emphasis on cost/benefit analysis for new technologies adoption, the market value and thus penetration capabilities of newer approaches may be limited.

The report looks at the bioinformatics-based product offerings and developments of the following companies, among others:

Abbott

Cannon

RocheAffymetrix Inc.

AssureRx Health, Inc.

Bio-Reference Laboratories, Inc. (BRLI)

Dako A/S

Siemens

Thermo Fisher

Medtronic Inc.

PerkinElmer, Inc.

Prometheus Labs

QIAGEN N.V.

Quest

## Contents

### **CHAPTER ONE: EXECUTIVE SUMMARY**

Introduction  
Scope and Methodology  
Market Trends  
IVD Markets Most Affected by Bioinformatics  
Advances in Lab Medicine

### **CHAPTER TWO: INTRODUCTION**

Background  
Bioinformatics-based Diagnostics  
The Case for Bioinformatics

### **CHAPTER THREE: ENABLING TECHNOLOGIES AND COMMERCIALIZATION ARRANGEMENTS**

Alliances and Collaborations  
Major Partnerships  
Advances in Clinical Bioinformatics  
Reimbursement-Driven Health Data Analytics  
Insurers, PBMs and Providers  
The Interface and Test Technologies  
Bioinformatics for Consumers

### **CHAPTER FOUR: MARKET ANALYSIS – BIOINFORMATICS-BASED DIAGNOSTICS**

Background  
The Commercial Outlook  
Trends In Bioinformatics-Based Tests For Cancer  
Technologies  
Tissue-based Tests  
Blood-Based Tests  
Market-cleared Tests  
Trends in Bioinformatics-based Tests for Diabetes  
Trends in Bioinformatics-based Tests for Cardiovascular Disease

Trends in Bioinformatics-based Tests for Chronic Diseases

Arthritis

Gastrointestinal Conditions

Alzheimer's Disease

Parkinson's Disease

Psychiatric Disorders

Trends In Bioinformatics-Based Tests In Microbiology

Software Applications

Genome Sequencing

Mass Spectrometry

Trends in Bioinformatics-based Diagnostics for Prenatal Studies

The Commercial Outlook

## **CHAPTER FIVE: CONCLUSION**

## **CHAPTER SIX: IVD COMPANIES AND BIOINFORMATIC-BASED OFFERINGS**

23andMe

Affymetrix Inc.

Ameritox Ltd.

Aperio Technologies, Inc.

ArcticDx Inc.

Arrayit Diagnostics Inc.

AssureRx Health, Inc.

Atossa Genetics, Inc.

BG Medicine, Inc.

Biodesix, Inc.

Biolmagene

Bio-Reference Laboratories, Inc. (BRLI)

bioTheranostics

Breath Testing at Home

CardioDx, Inc.

Children's Hospital of Philadelphia:

Chronix Biomedical Inc.

CombiMatrix Molecular Diagnostics, Inc.

Complete Genomics

Crescendo Bioscience, Inc.

Dako A/S

deCode genetics ehf

Diaxonhit Group  
DiaGenic ASA  
DiaTech Oncology  
Duke University Medical Center  
Everist Genomics, Inc. (EGI)  
Foundation Medicine. Inc  
Genelex Corporation  
Genomic Health, Inc.  
Health Discovery Corporation (HDC)  
Inform Genomics  
Lab21 Limited  
Life Technologies  
Massachusetts Institute of Technology  
Mayo Medical Laboratories  
Medtronic Inc.  
Metabolon Inc.  
Omnyx, LLC  
One Lambda, Inc.  
Oregon Health & Science University (OHSU)  
Pathogenica  
Pathway Genomics  
PerkinElmer, Inc.  
PGXL Laboratories  
Prometheus Laboratories Inc.  
Qiagen N.V  
Ridom GmbH  
Selventa  
Signal Genetics  
Tethys Bioscience Inc.  
Stanford University  
University of Houston  
XDx Inc. – Expression Diagnostics

## **CHAPTER SEVEN: COMPANY PROFILES: INFORMATION TECHNOLOGY SPECIALISTS**

Access Genetics  
BioDiscovery, Inc.  
CLC bio

CollabRx, Inc. (formerly Tegal Corp)  
Definiens  
eGenomics  
GeneInsight LLC  
GenomeQuest Inc.  
IBM Corporation  
Ingenuity Systems  
Knome Inc.  
NSilico  
Personalis  
Signature Mapping Medical Sciences, Inc.  
Silicon Valley Biosystems (SV Bio)

## List Of Exhibits

### LIST OF EXHIBITS

#### CHAPTER ONE: EXECUTIVE SUMMARY

Table 1-1: Selected Salient Developments For Now And The Future

Table 1-1: IVD Segments Potentially Most Affected By Bioinformatics-Based Tests

#### CHAPTER TWO: ENABLING TECHNOLOGIES AND COMMERCIALIZATION ARRANGEMENTS

Table 3-1: Selected Collaborations For Bioinformatics-Based Diagnostics

Table 3-2: Selected Open-Source Variant Annotation Software

Table 3-3: Selected Information Technology Innovations In Clinical Diagnostics

#### CHAPTER THREE: MARKET ANALYSIS – BIOINFORMATICS-BASED DIAGNOSTICS

Table 4-1: Selected Diagnostic Tests That Incorporate Bioinformatics

Table 4-2: Selected Multiplexed Tissue-Based Cancer Tests

Table 4-3: Selected Histology Analyses Software Tools

Table 4-4: Selected Blood-Based Cancer Biomarker Tests That Use Software Analysis Tools

Table 4-5: Selected Innovations In Bioinformatic-Based Tests For CVD

Table 4-6: Selected Chronic Diseases Tests With Integrated Bioinformatics

Table 4-7: Selected Innovations In Bioinformatic-Based Tests For Psychiatric Disorders

Table 4-8: Selected Systems For Bioinformatics-Based Infectious Disease Testing

Table 4-9: Selected Next Generation Sequencing Platforms

Table 4-10: Ivd Segments Potentially Most Affected By Bioinformatics-Based Tests



## About

IDBS (Guilford, UK) has developed the Biomolecular Hub that enables all relevant data and annotations for a particular gene or protein to be quickly and easily found regardless of data format. The Biomolecular Hub provides bioinformatics organizations with a unique data and result management capability that can easily integrate with existing tools and analysis environments. It indexes metadata from all types of molecular output files, including NGS, gene expression, arrayCGH, GenomeWide Association Study (GWAS) and proteomics, to provide a managed file store with unique security, audit and search capabilities. Genomic variant and analysis results are stored and associated with their source files to ensure traceability and reproducibility of results.

January 2013, Weill Cornell Medical College and New York-Presbyterian Hospital have created the Institute for Precision Medicine at Weill Cornell and New York-Presbyterian/Weill Cornell Medical Center. This new translational medicine research hub will explore the new frontier of precision medicine, offering optimal targeted, individualized treatment based on each patient's genetic profile. The institute's new genomic research discoveries will help develop novel, personalized medical therapies to be tested in innovative clinical trials, while also building a comprehensive biobank to improve research and patient care.

Physician-scientists at the Institute aim to identify the genetic influencers of a patient's specific illness such as cancer, cardiovascular disease, neurodegenerative disease and others and use this genetic information to design a more-effective course of treatment that targets those specific contributing factors.

The Diagnostic Algorithms Subgroup will publish diagnostic algorithms for challenging clinical scenarios to demonstrate the complexity of choosing the most appropriate test(s) to support an accurate diagnosis and treatment. It will also develop information technology tools using decision support algorithms to help clinicians choose appropriate tests and improve patient outcomes.

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