

2024 Diagnostics Research Review

Market Research Report | 2025-03-13 | 458 pages | BCC Research

AVAILABLE LICENSES:

- Single User License \$4650.00
- 2-5 Users License \$5580.00
- Site License \$6696.00
- Enterprise License \$8035.00

Report description:

Description

Research Review Scope

The diagnostics industry has grown despite the challenging economic conditions in recent years. The industry draws much attention and scrutiny from the public and government and is currently undergoing many changes due to increased focus on regulations. These changes can be seen across many countries. The U.S., the largest diagnostics market, is leading the trend with changes intended to make healthcare more affordable. Opportunities for the diagnostics industry are manifold with the appearance of new markets located mainly in emerging economies with varying needs.

Increasing healthcare expenditures and the growth of emerging economies have increased the demand for technologically better diagnostic devices, kits, reagents, and other accessories. Additionally, the introduction of more stringent regulations, specifically in the developed markets of the U.S. and Europe, has forced diagnostics manufacturers to launch advanced products that include new materials, a focus on in-depth indications, and the ability to produce additional new data.

Some of the major driving factors in the market are increasing prevalence of chronic and infectious diseases, technological advancements in the diagnostics, increasing investments in AI in diagnostics market, increased applications in non-oncology areas, growing adoption of personalized medicine, and other driving factors.

Furthermore, technically sophisticated diagnostics are needed for clinical research, as the market is highly competitive, and companies must continuously reinvent their product portfolios to enter new markets and place themselves as significant players in the healthcare system. There is a shift toward a value-based healthcare market where price and purchase decisions are based on outcomes. This has further resulted in increased scrutiny of the technology of devices, and consequently, the degree of competition has risen. Some of the major players in the diagnostics market include Abbott, Medtronic, F. Hoffmann-La Roche Ltd., Siemens Healthineers AG, GE Healthcare, Koninklijke Philips N.V., Agilent Technologies Inc., QIAGEN, Danaher Corp., Sysmex, Thermo Fisher Scientific, Inc., BD, and others.

The diagnostics industry is a multi-billion-dollar market whose outlook is supposed to rise in the coming years. Hospital care is growing, and the diagnostics industry is being looked at to provide low-cost technology for home healthcare. Now, the industry

Scotts International. EU Vat number: PL 6772247784

tel. 0048 603 394 346 e-mail: support@scotts-international.com

www.scotts-international.com

seeks healthcare diagnostic devices, kits, and reagents that individuals with unskilled healthcare experience can use. The need for modern technology, equipment, and devices can be leveraged through diagnostic equipment as manufacturers seek to create better-quality healthcare solutions.

Today's market is worthy of close investigation as it deals with the fallout from COVID-19 and how the global diagnostics market is after the post-COVID-19 pandemic. The global pandemic has impacted the diagnostics industry both positively and negatively. The above reasons are compelling enough to analyze and research the diagnostics market, as the market has tremendous growth potential.

It includes highlights from these reports published in 2024:

- BIO261A AI in Clinical and Molecular Diagnostics Market
- BIO077F Companion Diagnostics: Technologies and Global Markets
- PHM116C Drugs and Diagnostics for Hematological Disorders Global Markets
- BIO233B In Vitro Diagnostics (IVD) Quality Controls: Global Market
- HLC043H Point of Care Diagnostics: Technologies and Global Markets
- BIO157C Polymerase Chain Reaction (PCR) for Point of Care (POC) Diagnostics
- PHM227B Rare Disease Diagnostics: Technologies and Global Markets

After you survey the excerpts in this Research Review, we encourage you to follow up on these topics by checking out the full market research reports associated with each topic. BCC Research looks forward to serving your market intelligence needs in the future.

Executive Summary

Summary:

- The global market for AI in clinical and molecular diagnostics is expected to grow from \$2.6 billion in 2024 and is projected to reach \$8.9 billion by the end of 2029, at a compound annual growth rate (CAGR) of 27.6% during the forecast period of 2024 to 2029.
- The global market for companion diagnostics is estimated to increase from \$7.6 billion in 2023 and is projected to reach \$15.4 billion by 2028, at a CAGR of 15.2% from 2023 through 2028.
- The global market for drugs and diagnostics for hematological disorders is expected to grow from \$131.2 billion in 2024 and is projected to reach \$189.3 billion by the end of 2029, at a CAGR of 7.6% during the forecast period of 2024 to 2029.

The diagnostics industry has grown despite the challenging economic conditions in recent years. The industry draws much attention and scrutiny from the public and government and is currently undergoing many changes due to increased focus on regulations. These changes can be seen across many countries. The U.S., the largest diagnostics market, is leading the trend with changes intended to make healthcare more affordable. Opportunities for the diagnostics industry are manifold with the appearance of new markets located mainly in emerging economies with varying needs.

Increasing healthcare expenditures and the growth of emerging economies have increased the demand for technologically better diagnostic devices, kits, reagents, and other accessories. Additionally, the introduction of more stringent regulations, specifically in the developed markets of the U.S. and Europe, has forced diagnostics manufacturers to launch advanced products that include new materials, a focus on in-depth indications, and the ability to produce additional new data.

Some of the major driving factors in the market are increasing prevalence of chronic and infectious diseases, technological advancements in the diagnostics, increasing investments in AI in diagnostics market, increased applications in non-oncology areas, growing adoption of personalized medicine, and other driving factors.

Furthermore, technically sophisticated diagnostics are needed for clinical research, as the market is highly competitive, and

Scotts International. EU Vat number: PL 6772247784

tel. 0048 603 394 346 e-mail: support@scotts-international.com

www.scotts-international.com

companies must continuously reinvent their product portfolios to enter new markets and place themselves as significant players in the healthcare system. There is a shift toward a value-based healthcare market where price and purchase decisions are based on outcomes. This has further resulted in increased scrutiny of the technology of devices, and consequently, the degree of competition has risen. Some of the major players in the diagnostics market include Abbott, Medtronic, F. Hoffmann-La Roche Ltd., Siemens Healthineers AG, GE Healthcare, Koninklijke Philips N.V., Agilent Technologies Inc., QIAGEN, Danaher Corp., Sysmex, Thermo Fisher Scientific, Inc., BD, and others.

The diagnostics industry is a multi-billion-dollar market whose outlook is supposed to rise in the coming years. Hospital care is growing, and the diagnostics industry is being looked at to provide low-cost technology for home healthcare. Now, the industry seeks healthcare diagnostic devices, kits, and reagents that individuals with unskilled healthcare experience can use. The need for modern technology, equipment, and devices can be leveraged through diagnostic equipment as manufacturers seek to create better-quality healthcare solutions.

Table of Contents:

Table of Contents
Chapter 1 Foreword
Research Review Scope
Chapter 2 AI in Clinical and Molecular Diagnostics Market(BIO261A)
AI in Clinical and Molecular Diagnostics
Market Outlook
Scope of Report
Market Summary
Market Overview of AI in Clinical and Molecular Diagnostics
AI in Healthcare
AI in Clinical Diagnostics
AI in Molecular Diagnostics
Market Dynamics of AI in Clinical and Molecular Diagnostics
Market Drivers
Investment in the AI Health Sector
Increasing Prevalence of Chronic and Infectious Diseases
Technological Advances
Demand for Personalized Medicine
Market Restraints
Practitioners Reluctant to Adopt AI-based Technologies
Data Security
Regulatory Challenges
Market Opportunities
Software with AI
Untapped Opportunities in Developing Markets
Regulatory Structure
Emerging Technologies and Developments
Machine Learning Algorithms
Deep Learning
Generative AI
Natural Language Processing (NLP)
Genomic AI
Cloud-Based Solutions

Scotts International. EU Vat number: PL 6772247784

tel. 0048 603 394 346 e-mail: support@scotts-international.com

www.scotts-international.com

Market Segmentation Analysis
AI in Clinical and Molecular Diagnostics: Global Markets
Molecular Diagnostics
Clinical Diagnostics
Market Analysis of AI in Clinical and Molecular Diagnostics by Component
Software
Services
Hardware
Geographic Breakdown
Market Analysis Of AI in Clinical and Molecular Diagnostics by Region
North America
Europe
Asia-Pacific
Rest of the World
Chapter 3 Companion Diagnostics: Technologies and Markets (BIO077F)
Companion Diagnostics
Market Outlook
Scope of Report
Market Summary
Highlights of the Market for Companion Diagnostics (CDx)
Market Introduction
Regulatory Landscape
Companion Diagnostics Regulations in the U.S.
Companion Diagnostics Regulations Outside the U.S.
LDT-CDx Regulation
Market Dynamics of Companion Diagnostics
Market Drivers
Rising Incidence of Cancer
Growing Adoption of Personalized Medicine
Expanded Application in Non-Oncology Areas
Optimization of Drug Development Costs
Market Restraints
High Development Cost of CDx
Reimbursement Challenges
Market Opportunities
Advances in NGS Technologies
Market Challenges
Inefficiencies in Clinical Testing Landscape
Lack of Skilled Labor
Emerging Technologies and Developments
Multiplex Testing
Next-Generation Sequencing (NGS)
Digital PCR
Liquid Biopsy
Artificial Intelligence
Market Segmentation Analysis
Global Market for Companion Diagnostics by Product and Service

Scotts International. EU Vat number: PL 6772247784

tel. 0048 603 394 346 e-mail: support@scotts-international.com

www.scotts-international.com

Market Share and Forecast
Instruments
Consumables
Services
Global Market for Companion Diagnostics by Type of Test
Market Share and Forecast
LDT-CDx
Commercial CDx
Global Market for Companion Diagnostics by Technology
Market Share and Forecast
Polymerase Chain Reaction
Immunohistochemistry
Next-Generation Sequencing
In Situ Hybridization
Genotyping
Immunoassays
Exosomes
Others
Services
Global Market for Companion Diagnostics by Application
Market Share and Forecast
Cancer
Market for the Application of CDx in Cancer by Type
Neurologic Disorders
Cardiovascular Disease
Infectious Diseases
Other Diseases
Market Breakdown of Companion Diagnostics by End User
Market Share and Forecast
Clinical Laboratories
Pharmaceutical Companies
Contract Research Organizations (CROs)
Other End Users
Geographic Breakdown
Global Market for Companion Diagnostics by Region
North America
The U.S.
Canada
Europe
Germany
The U.K.
France
Italy
Rest of Europe
Asia-Pacific
China
Japan

Scotts International. EU Vat number: PL 6772247784

tel. 0048 603 394 346 e-mail: support@scotts-international.com

www.scotts-international.com

India
Rest of Asia-Pacific
Rest of the World
Chapter 4 Drugs and Diagnostics for Hematological Disorders: Global Markets (PHM116C)
Drugs and Diagnostics for Hematological Disorders
Market Outlook
Scope of Report
Market Summary
Market Overview of Drugs and Diagnostics for Hematological Disorders
PESTEL Analysis
Political
Economic
Social
Technological
Environmental
Legal
Porter's Five Forces Analysis
Bargaining Power of Buyers
Bargaining Power of Suppliers
Potential of New Entrants
Threat of Substitutes
Competition in the Industry
Supply Chain and Logistics for Hematological Instruments
Market Dynamics of Drugs and Diagnostics for Hematological Disorders
Market Drivers
Incidence of Blood Disorders
Rising Use of Automation
Diagnosis of Hematology Disorders
Increasing Government and Private Funding for Treatment
Market Restraints
High Cost of Instruments
High Cost of Treatment
Reimbursement Challenges for Physicians
Market Opportunities
Rising Health Awareness
Emerging Economies
Emerging Technologies and Developments
AI-Assisted Diagnosis
Next-Generation Sequencing (NGS)
Microfluidics and Lab-on-a-Chip Devices
Gene Therapies
Immunotherapies
Market Segmentation Analysis
Segmentation by Market
Hematological Disorders Diagnostics Market
Hematological Disorders Diagnostic Market, By Product Type
Hematological Disorders Diagnostic Market, By End User

Scotts International. EU Vat number: PL 6772247784

tel. 0048 603 394 346 e-mail: support@scotts-international.com

www.scotts-international.com

Hematology Drug Market
Hematology Drug Market, By Drug Type
Geographic Breakdown
North America
Europe
Asia-Pacific
Rest of the World
Chapter 5 In Vitro Diagnostics (IVD) Quality Controls: Global Market(BIO233B)
In Vitro Diagnostics (IVD) Quality Controls
Market Outlook
Scope of Report
Market Summary
Market and Technology Background
Overview
Classification of In Vitro Diagnostics Elements
Importance of In Vitro Diagnostics Quality Control
Regulations
Regulation of IVD products in Different countries
Market Dynamics of In Vitro Diagnostics (IVD) Quality Controls
Market Drivers
Rise in the Aging Population and Dependency on Frequent Diagnosis Procedures
Rising Demand for Third-Party Quality Control Products
Rising Incidence of Chronic Disease Cases
Strengthening Clinical Laboratories
Improving the Quality of Point-of-Care Testing
Market Restraints
Challenges for Quality Control Product Packaging
Increases in Shipping Costs or Service Issues
Improper Operation and Maintenance of Laboratory Equipment and Consumables
Market Opportunities
Rise in Home Care Testing Devices
Demand for Point-of-Care (POC) Testing Units
Emerging Technologies and Developments
Artificial Intelligence
Prioritizing Old IVD Techniques
Automating In-Vitro Diagnostic Devices
Emerging Trends in In Vitro Diagnostics
FDA Approval
Rise in Demand for Personalized Medicine
Market Segmentation Analysis
Market Breakdown of In Vitro Diagnostics (IVD) Quality Controls by Test Type
Immunodiagnosics
Clinical Chemistry
Hematology
Molecular Diagnostics
Microbiology
Other Test Types

Scotts International. EU Vat number: PL 6772247784

tel. 0048 603 394 346 e-mail: support@scotts-international.com

www.scotts-international.com

Market Breakdown of In Vitro Diagnostics (IVD) Quality Controls by Type of Manufacturer

- Third-party Controls
- ODM Controls

Market Breakdown of In Vitro Diagnostics (IVD) Quality Controls by Products and Services

- Quality Control Products
- Data Management Solutions
- Quality Assurance Services

Market Breakdown of In Vitro Diagnostics (IVD) Quality Controls by End User

- Diagnostic Laboratories
- Hospitals and Clinics
- Point-of-Care Centers
- Research Institutions
- Other End Users

Geographic Breakdown

Market Analysis of In Vitro Diagnostics (IVD) Quality Controls by Region

- North America
 - Market Size and Forecast
 - U.S.
 - Canada
 - Mexico
- Europe
 - Market Size and Forecast
 - Germany
 - France
 - U.K.
 - Italy
 - Spain
 - Rest of Europe
- Asia-Pacific
 - Market Size and Forecast
 - Japan
 - China
 - India
 - Australia and New Zealand
 - Rest of Asia-Pacific
- Rest of the World
 - Market Size and Forecast
 - Brazil
 - GCC Countries
 - Rest of the World Countries

Chapter 6 Point-of-Care Diagnostics: Technologies and Global Markets (HLC043H)

- Point-of-Care Diagnostics
- Market Outlook
- Scope of Report
- Market Summary
- Market Overview of Point-of-Care Diagnostics
- Novel Approaches for POC

Scotts International. EU Vat number: PL 6772247784

tel. 0048 603 394 346 e-mail: support@scotts-international.com

www.scotts-international.com

Significance of CLIA in the United States
Regulatory Guidelines
Good Manufacturing Practice
The FDA's Role in POC Testing
Conclusion
Market Dynamics of Point-of-Care Diagnostics
Market Drivers
High Incidences of Infectious Diseases
Growing Prevalence of Chronic Diseases
Increasing Demand for Self-Testing
Aging Population
Market Restraints
Challenges Faced by POC Manufacturers Due to Pricing Pressure
Technical Complexity
Lack of Specialized Training
Market Challenges
Challenges in Deploying Point-of-Care (POC) Diagnostics in Remote Settings
Environmental and Contamination Challenges in Point-of-Care Diagnostics
Market Opportunities
Increasing R&D Budget
Excellent Market Potential for POCT with AI and ML Integration
Emerging Economies
Emerging and Upcoming Technologies in the Market
AI in Point-of-Care Diagnostics
CRISPR-Cas Systems
3D Rapid Prototyping
Quantum Dots
RFID (Radio-Frequency Identification) and NFC (Near Field Communication)
Smartphone-Based Medical Imaging
Nanomaterials in POC Devices for Pathogen Detection
Microfluidics-Based Sensing Technologies
Cloud-Integrated AI
D3 Array-UTI
EVIK DxSpheres: A Solid Assay Solution
UNIQO 160 Automated IIFT System
Recent Developments
Market Segmentation Analysis
Market Breakdown of Point-of-Care Diagnostics by Test Type
Drug and Alcohol Screening
Blood Gas Electrolyte and Metabolite (BGEM)
Cardiac Markers
Cholesterol Testing/Monitoring
Glucose Testing and Monitoring
Infectious Disease Testing
Pregnancy and Fertility Testing
Hemoglobin and Hemostasis
Tumor Marker

Scotts International. EU Vat number: PL 6772247784

tel. 0048 603 394 346 e-mail: support@scotts-international.com

www.scotts-international.com

Urinalysis/Urine Chemistry
Others
Market Breakdown of Point-of-Care Diagnostics Market by Product
Hardware
Software
Market Breakdown of Point-of-Care Diagnostics Market by End User
Hospitals and Critical Care Settings
Home Care Settings
Geographic Breakdown
Market Breakdown of Point-of-Care Diagnostics Market by Region
North America
Europe
Asia-Pacific
Rest of the World (RoW)
Chapter 7 Polymerase Chain Reaction (PCR) for Point-of-Care (POC) Diagnostics (BIO157C)
Polymerase Chain Reaction (PCR) for Point-of-Care (POC) Diagnostics
Market Outlook
Scope of Report
Market Summary
Market Overview of Polymerase Chain Reaction (PCR) for Point-of-Care (POC) Diagnostics
Polymerase Chain Reaction Technology
Point of Care PCR Systems and Assays
Market Dynamics of Polymerase Chain Reaction (PCR) for Point-of-Care (POC) Diagnostics
Market Drivers
Increasing Incidence of Infectious Diseases
Decentralization of Testing
Increasing Adoption of Point-of-Care Testing and Expansion
Multiplexing Testing
Response to the Pandemics
Market Opportunities
Integration of PCR POC Technology in Primary Care and Low-Income Countries
Market Restraints
High Initial Cost
Market Competition
Market Challenges
Operational Challenges
Supply Shortages
Emerging Technologies and Developments
Instrument-Free PCR Tests
Five-Minute Point-of-Care Testing
Smartphone Enabled PCR System
Global Market for PCR POC Diagnostics
Market Breakdown of Polymerase Chain Reaction (PCR) for Point-of-Care (POC) Diagnostics by Product Type
Market Breakdown of Polymerase Chain Reaction (PCR) for Point-of-Care (POC) Diagnostics by Analyte
PCR POC Analyzers by Analyte
PCR POC Consumables by Analyte
Market Breakdown of Polymerase Chain Reaction (PCR) for Point-of-Care (POC) Diagnostics by Application

Scotts International. EU Vat number: PL 6772247784

tel. 0048 603 394 346 e-mail: support@scotts-international.com

www.scotts-international.com

Infectious Diseases
STIs
Geographic Breakdown
Market Breakdown of Polymerase Chain Reaction (PCR) for Point-of-Care (POC) Diagnostics by Region
North America
Latin America
Europe
Asia-Pacific
Rest of the World
Chapter 8 Rare Disease Diagnostics: Technologies and Global Markets (PHM227B)
Rare Disease Diagnostics
Market Outlook
Scope of Report
Market Summary
Market Overview of Rare Disease Diagnostics
Diagnostic Odyssey
What Is Genomic Testing?
Rare Disease Clinical Assays Development and Marketing
Rare Disease Treatment
Bioinformatic Resources for Rare Disease Research and Genetic Information
Large-Scale Initiatives and Consortia
Population Sequencing Programs
Market Dynamics of Rare Disease Diagnostics
Market Drivers
Significant Unmet Need in Rare Disease Diagnostics
Orphan Drug Act
Advances In Gene Therapy
Rare Disease Initiatives
Advances in Genomic Technologies and Analytical Tools
Decreasing Cost of Next-Generation Sequencing (NGS)
Market Driving Forces and Their Impact on Market Growth
Market Restraints
Lack of Commercially Available IVDs for Rare Disease Diagnosis
Stringent Regulatory Landscape
Ethical and Legal Concerns
Shortage of Genetic and Rare Disease Specialists
Emerging Technologies and Developments
Shift Towards a Multi-omics Approach
Artificial Intelligence (AI) and Machine Learning
Collaboration Between Rare Disease Diagnostics and Pharma Companies
Market Segmentation Analysis
Market Breakdown of Rare Disease Diagnostics by Analysis Platform
Next-Generation Sequencing (NGS)
Polymerase Chain Reaction (PCR)
Sanger Sequencing
Microarrays
Karyotyping and Fluorescent in Situ Hybridization (FISH)

Scotts International. EU Vat number: PL 6772247784

tel. 0048 603 394 346 e-mail: support@scotts-international.com

www.scotts-international.com

Biochemical Testing
Market Breakdown of Rare Disease Diagnostics by Analysis Target Type
Single Genes
Multiple Genes
Whole Exome
Whole Genome
Other Genomic Variants
Protein and Other Biochemical Markers
Market Breakdown of Rare Disease Diagnostics by Disease Class
Rare Cancers
Neurological Diseases
Metabolic and Endocrine Disorders
Hematology
Respiratory
Immune System and Inflammation-Related Disorders
Dermatology
Musculoskeletal
Others
Market Breakdown of Rare Disease Diagnostics by Test Purpose
Diagnosis
Screening and Early Detection
Therapy Guidance
Monitoring
Geographic Breakdown
Market Breakdown of Rare Disease Diagnostics by Region
North America
Europe
Asia-Pacific
Rest of the World
Chapter 9 Appendix
Methodology
Analyst's Credentials

Scotts International. EU Vat number: PL 6772247784

tel. 0048 603 394 346 e-mail: support@scotts-international.com

www.scotts-international.com

2024 Diagnostics Research Review

Market Research Report | 2025-03-13 | 458 pages | BCC Research

To place an Order with Scotts International:

- ☐ - Print this form
- ☐ - Complete the relevant blank fields and sign
- ☐ - Send as a scanned email to support@scotts-international.com

ORDER FORM:

Select license	License	Price
	Single User License	\$4650.00
	2-5 Users License	\$5580.00
	Site License	\$6696.00
	Enterprise License	\$8035.00
		VAT
		Total

*Please circle the relevant license option. For any questions please contact support@scotts-international.com or 0048 603 394 346.

** VAT will be added at 23% for Polish based companies, individuals and EU based companies who are unable to provide a valid EU Vat Numbers.

Email*	<input type="text"/>	Phone*	<input type="text"/>
First Name*	<input type="text"/>	Last Name*	<input type="text"/>
Job title*	<input type="text"/>		
Company Name*	<input type="text"/>	EU Vat / Tax ID / NIP number*	<input type="text"/>
Address*	<input type="text"/>	City*	<input type="text"/>
Zip Code*	<input type="text"/>	Country*	<input type="text"/>
		Date	<input type="text" value="2026-02-11"/>
		Signature	

Scotts International. EU Vat number: PL 6772247784

tel. 0048 603 394 346 e-mail: support@scotts-international.com

www.scotts-international.com



Scotts International. EU Vat number: PL 6772247784

tel. 0048 603 394 346 e-mail: support@scotts-international.com
www.scotts-international.com