



19-050 Report Overview

The Worldwide Market for In Vitro Diagnostics *12th Edition*

August 2019

Overview



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- Now in its 12 editions, this Kalorama Information report, **The Worldwide Market for In Vitro Diagnostic (IVD) Tests**, is the most essential report on the IVD industry. The 1,000+ page report provides in vitro diagnostics market size estimates and projections for the entirety of the in vitro diagnostics testing market.

Objectives

The Worldwide Market for In Vitro Diagnostic (IVD) Tests estimates the current in vitro diagnostics market size and forecasted market size to 2024 for defined segments of the IVD market and various sub-segments, including:

- Molecular Assays (Infectious Disease, Blood Screening, Inherited Diseases, Oncology, Pharmacodiagnosics, Tissue Typing, Prenatal)
- Clinical Chemistry and "Core Lab" Markets (including sub segment revenues for General Chemistries, Workstations, Analyzers, Blood Gases, Urinalysis, Critical Care)
- Point-of-Care Testing (POC), (Professional and Self-Testing, Glucose Testing, Pregnancy Tests, drugs of abuse, HIV, H. pylori, Other, OTC/Self Total, Professional POC, Cardiac Markers, Drugs of Abuse, HbA1c, Pregnancy, Other)
- Microbiology and Virology by Test Type (Immunoassays, ID/AST, Infectious Diseases - DNA; ID/AST: Panels and Reagents, automated; Panels and Reagents, manual; Blood Culture; Chromogenic Media; Rapid Micro; Supplies)
- Blood Banking (Grouping, Immunoassay Screens, NAT Screens)
- Tissue-Based Testing - Histology and Cytology (Pap, ISH, IHC, HPV)
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- Flow Cytometry
- Molecular Tests in Infectious Diseases
- Non-Infectious Disease Immunoassay Sales by Analyte Type (Cardiac markers, Tumor markers, Diabetes/HbA1c, Autoimmune, Allergy, Thyroid, Proteins, Anemia, Fertility, Therapeutic drugs)
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- Clinical Mass Spectrometry
- Clinical Next Generation Sequencing
- Direct-to-Consumer Testing
- Substance Abuse Testing

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- IMMUCOR DX Laboratory Service
- MicroTyping Concepts
- Micronics
- Quotient Limited
 - Recent Revenue History
 - Traditional Blood Grouping
 - MosaiQ Platform
- Reliance Life Sciences

Company Profiles: Coagulation Specialists

- Diagnostica Stago, S.A.S.
 - Instrumentation
 - Test Kits
- Microvisk Technologies
- DIAGON Kft. Hungary

Company Profiles: Blood Bank Specialists

- Bloodsource
- Cerus Corporation
 - Recent Revenue History
- Haemokinesis Pt
- Immucor
 - Recent Revenue History
 - Transfusion Medicine
 - Transplant Diagnostics

Company Profiles: Core Lab and Other Companies

- AB SCIEX Pte Ltd.
- EKF Diagnostics Holdings Plc
 - Lab-based Assays
 - Molecular
- ELITech Group S.A.S.
- ERBA Diagnostics, Inc.
- MedTest DX

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Company Profiles: Core Lab and Other Companies (continued)

- Microsaic Systems plc
- Nova Biomedical
 - Diabetes
- Scienion AG
- Sekisui Diagnostics
- Shimadzu Scientific Instruments
- Snibe Co. Ltd., (Shenzhen New Industries Biomedical Engineering Co. Ltd.)
- Tecan Group
- Tosoh Bioscience
- Trinity Biotech Plc

Company Profiles: CTC & Liquid Biopsy Test Providers

- Angle, plc
- Biocartis
 - Recent Revenue History
 - Connectivity
 - DMAT Instrumentation – MyCartis
 - Idylla News
 - Infectious Diseases
 - Collaborations
- Biocept, Inc.
- Biodesix
- Cynvenio Biosystems

- Epic Sciences
- Epigenomics AG
- Foundation Medicine, Inc.
 - Recent Revenue History
 - Collaborations
- Genomic Health
 - Recent Revenue History
 - Market Uptake
 - Liquid Biopsy
 - Service Spin-off
- Guardant Health, Inc.
- Menarini-Silicon Biosystems
- Myriad Genetics, Inc.
- Natera
 - Recent Revenue History
 - Products
- NeoGenomics

Diabetes Specialists

- Animas Corporation
- Ascensia Diabetes Care Holdings AG
- Bigfoot Biomedical Inc.
- Cellnovo Group SA
 - Recent Revenue History

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Diabetes Specialists (continued)

- Debiotech SA
- Dexcom Inc.
 - Recent Revenue History
- Gentag Inc.
- Glooko Inc.
- GlySure Limited
- Glytec LLC
- iHealth Labs Inc.
- Insulet Corporation
 - Recent Revenue History
- Integrity Applications Inc.
- LifeScan Inc.
- Medtronic plc
 - Recent Revenue History
- Nemaura Medical Inc.
- Nightscout Project
- Sanofi
- Trividia Health Inc.
- Verily Life Sciences LLC

Company Profiles: Hematology (Cell Analysis) Specialists

- CellaVision AB
 - Recent Revenue History
- Horiba Medical

- Recent Revenue History
- Chemistry

- Medica Corporation
- Onca Xt Ltd
- West Medica

Company Profiles: Histopathology Specialists

- Advanced Cell Diagnostics (ACD)
- Amoy Diagnostics Co. Ltd.
- Applied Spectral Imaging Inc. (ASI)
- BioGenex Laboratories, Inc.
- BioView Ltd.
- Circulomics Inc.
- Dako A/S
 - Special Stains
 - Immunohistochemistry (ICH)
 - Companion Diagnostics
 - Flow Cytometry
 - Automation
 - Alliances
- Definiens
- HTG Molecular Diagnostics
 - Strategic Partnerships
- Kapa Biosystems Inc.

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Company Profiles: Histopathology Specialists (*continued*)

- Leica Biosystems
 - Collaborations
- MilliporeSigma (formerly EMD Millipore)
- Omnyx LLC
- Visiopharm

Company Profiles: Immunoassay Specialists

- BG Medicine, Inc
 - Recent Revenue History
- Binding Site Group Ltd. (The)
- Biohit Oyj (Biohit Healthcare)
 - Recent Revenue History
 - Market Expansion
- Biomerica Inc.
 - Recent Revenue History
- Bio-Techne Corporation
 - Recent Revenue History
- Corgenix Medical Corporation
- Critical Diagnostic
- Diaxonhit (Eurobio scientific)
 - Recent Revenue History
- EUROIMMUN AG
 - Recent Revenue History
- HOB Biotech
- Immunodiagnostic Systems (IDS)

- Recent Revenue History
- INOVA Diagnostics, Inc.
- Integrated Diagnostics (now Biodesix)
- One Lambda
- Orgentec Diagnostika
- Protagen Diagnostics
- Response Biomedical Corp.
 - Recent Revenue History
- Singulex, Inc.
- Theradig
 - Recent Revenue History
- VolitionRx Limited

Information Technology Specialists in In Vitro Diagnostics

- Advaita Corp.
- Cerner Corp.
- Dell Technologies Inc.
- Desktop Genetics Ltd.
- DNAnexus Inc.
- Edico Genome
- Euformatics Oy
- Genalice
- GenomOncology LLC
- Google LLC

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Information Technology Specialists in In Vitro Diagnostics (*continued*)

- Human Longevity Inc.
- Internation Business Machines Corp. (IBM)
- Intel Corporation
- N-of-One
- PierianDx
- Rennova Health, Inc.
- SOPHiA GENETICS SA
- Sunquest Information Systems Inc.
- WuXi NextCODE

Company Profiles: Microbiology Specialists

- Accelerate Diagnostics, Inc.
 - Recent Revenue History
 - Company Overview
- Advanced Biological Laboratories, S.A. (ABL)
- AdvanDx, Inc.
- altona Diagnostics
- ArcDia International Oy Ltd.
- BioFire Diagnostics, LLC. (Acquired by bioMérieux)
 - Recent Revenue History and Other Financial Information
 - Company Overview
- Bruker BioSciences Corporation

- Recent Revenue History
- Company Overview
- Microbiology
- Tissue Analysis
- COPAN ITALIA S.p.A. and COPAN Diagnostics, Inc.
 - Lab Automation
 - Partnerships
 - Swabs
- Curetis
 - Recent Revenue History
 - Company Overview
- Fast Track Diagnostics (Acquired by Siemens Healthineers)
- Focus Diagnostics, Inc.
- Genetic Analysis AS
- GeneWeave Biosciences, Inc.
 - About Smarticle Technology
- Greiner Bio-One International GmbH
 - Preanalytical Products
- Hain Lifescience GmbH
- Mast Group
- Mobidiag Ltd.
- Nanosphere, Inc. (Luminex)
 - Recent Revenue History
 - Company Overview

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Company Profiles: Microbiology Specialists (continued)

- PositivelD Corporation
 - Recent Revenue History
 - Company Overview
- Q-linea AB
- Seegene, Inc.
 - Recent Revenue History
 - Company Overview
 - Collaborations
 - Molecular Diagnostic Systems
 - Assay Panels
 - Instrumentation
- Specific Technologies
 - Company Overview
 - Developments
- Synbiosis Ltd.
- T2 Biosystems
 - Recent Revenue History
 - Company Overview
 - Financing
 - Collaborations
 - Assays
- ViroCyt, LLC
- Sample Collection
- Sequencing
- AutoGenomics Inc.
- Enzo Biochem Inc.
 - Recent Revenue History
 - IP Situation
- Exosome Diagnostics, Inc.
- Fluidigm Corporation
 - Recent Revenue History
- GenMark Diagnostics, Inc.
 - Recent Revenue History
- Genome Diagnostics BV (GenDx)
- Nanostring Technologies, Inc.
 - Recent Revenue History
 - Immunohistochemistry
 - Alliances
 - LDTs
- Oxford Nanopore Technologies Ltd
- Pacific Biosciences of California, Inc. (PacBio)
 - Recent Revenue History
- QuanDx Inc
- RainDance Technologies, Inc.
 - Recent Revenue History
- Rubicon Genomics, Inc.

Company Profiles: Molecular Test Specialists

- Asuragen Inc.
 - Controls

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Company Profiles: Molecular Test Specialists (continued)

- Takara Bio Inc.
- Trovagene, Inc.
 - Recent Revenue History
- Vela Diagnostics
- WaferGen Bio-systems, Inc.

Company Profiles: Point of Care Test Specialists

- Abaxis, Inc.
 - Recent Revenue History
- Abingdon Health Ltd.
- Atlas Genetics Ltd.
- Biomeme, Inc.
- Chembio Diagnostic Systems, Inc.
 - Recent Revenue History
- DNA Electronics Ltd (DNAe)
- Entopsis
- FABPulous B.V.
- Fio Corporation
- genedrive plc (formerly Epistem Holdings)
 - Recent Revenue History
- Hema Diagnostic Systems (HDS; dba NuGenerex Diagnostics)
- Imec
- InSilixa Inc.

- Loop Medical (formerly QloudLab SA)
- MedMira, Inc.
 - Recent Revenue History
- OraSure Technologies, Inc.
 - Recent Revenue History
 - The Genotek Business
- PTS Diagnostics
- QuantuMDx Group, Ltd.
- Rheonix, Inc.
- Samsung Healthcare
- Veredus Laboratories Pte Ltd

Company Profiles: Prenatal Test Service Providers

- Affymetrix, Inc.
 - Company Overview
 - Products
- Berry Genomics Co. Ltd.
 - Company Overview
 - Products
- CombiMatrix (Invitae)
 - Company Overview
 - Products
- CooperGenomics (Division of CooperSurgical)
 - Company Overview
 - Products

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Company Profiles: Prenatal Test Service Providers (continued)

- Counsyl
 - Company Overview
 - Products
- GenePeeks, Inc.
 - Company Overview
 - Products
- Genetadi Biotech S.L.
 - Company Overview
 - Products
- Genoma Group
 - Company Overview
 - Products
- Innovations Exchange Pte Ltd (INEX) and iGene Diagnostics Pte Ltd
 - Company Overview
 - Products
- LifeCodexx AG
 - Company Overview
 - Products
- Oxford Gene Technology
 - Company Overview
 - Products
- Premaitha Health
 - Company Overview
 - Products
 - Company Financials

- Ravgen
 - Company Overview
 - Products
- Reproductive Genetics Innovations
 - Company Overview
 - Products
- Sequenom, Inc.
 - Company Overview
 - Products

Company Profiles: Quality Control & Sample Pretreatment Specialists

- 10x Genomics
- Agena Bioscience, Inc.
 - Market Expansion
- Biotype Diagnostic GmbH
 - Samplettype i-sep System
 - Partnership with Qiagen
- DxTertiary Diagnostics Inc.
- Horizon Discovery Group plc
 - Recent Revenue History
 - Company Overview
 - Acquisition of Dharmacon
 - Collaborations
 - Gene Editing
- IncellDx
- Oasis Diagnostics Corporation

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Company Profiles: Quality Control & Sample Pretreatment Specialists (*continued*)

- Precipio, Inc. (formerly Transgenomic)
- PreAnalytiX GmbH
- Quanterix Corporation
 - Recent Revenue History
 - Company Overview
- SeraCare Life Sciences, Inc.
 - Selected Products
 - Collaborations, etc.
- Streck Inc.
 - Selected Products
 - Distribution Deals

Test Service Providers

- 23andMe
 - The Move to Building a Research Company
 - Therapeutics Group
 - Ancestry
 - Outside the U.S.
- Agendia BV
- Ambry Genetics
 - Epilepsy
 - Oncology
 - Cardiac
 - Prenatal
 - Information Technology

- ARUP Laboratories
- Assurex Health
- The BioCollective
- BioReference Laboratories
- Biotheranostics
- BluePrint Genetics Oy
- Boston Heart Diagnostics
- CareDx, Inc.
 - Sequencing
- Cleveland HeartLab Inc.
- Eurofins Genomics
- Exact Sciences Corp.
- Genomic Vision
- Helomics Corporation
- Mayo Medical Laboratories
 - Information Technology
 - Reference Laboratory Services
- MDxHealth SA
- OPKO Diagnostics
- Pathway Genomics Corporation
- Sonic Healthcare
- Veracyte, Inc.
- Vermillion Inc.

■ Sample Data

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Table 1-2: Worldwide In Vitro Diagnostic Reagent Sales by Market Segment, 2017-2022 (\$ million)

	2018	%Market	2023	%Market	CAGR
Clinical Chemistry					
Immunoassays, Infectious Disease					
Immunoassays, Other					
Blood Bank Screening					
Drugs of Abuse					
HbA1c Immunoassays, Lab-Based					
Hematology					
Microbiology (ID/AST)					
Molecular Microbiology					
Radioimmunoassays					
Coagulation					
Histology/Cytology					
HPV, molecular					
Nucleic Acid Assays					
Blood Grouping/Typing					
Blood Bank Molecular					
Circulating Tumor Cells					
POC, OTC diabetes					
Continuous Glucose					
POC, OTC Other					
POC Professional					
Mass Spectrometry					

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