Kalorama Information

KALORAMA's FREE IVD MARKET GUIDE AND 300+ COMPANY DIRECTORY

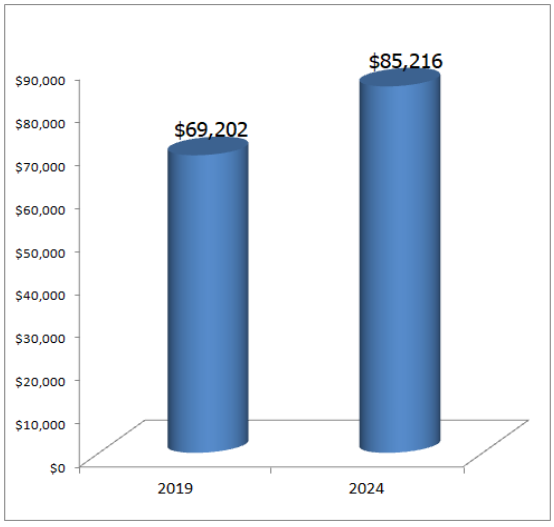
Kalorama Information

THE IVD MARKET

66% of Clinical Decisions Are Based on a Test

In vitro diagnostic testing costs little to the healthcare system and contributes much to clinical practice. For some time this has been stated as educated conjecture; a recent study of U.S and German physicians offers proof. The study found that **66% of clinical decisions made were based on a diagnostic test**, while the costs of those tests were just 2.3% of healthcare expenditure (Rohr U., Binder C, *PLoS One.* 2016).

THE WORLDWIDE IVD MARKET, 2019-2024 ($MILLIONS)

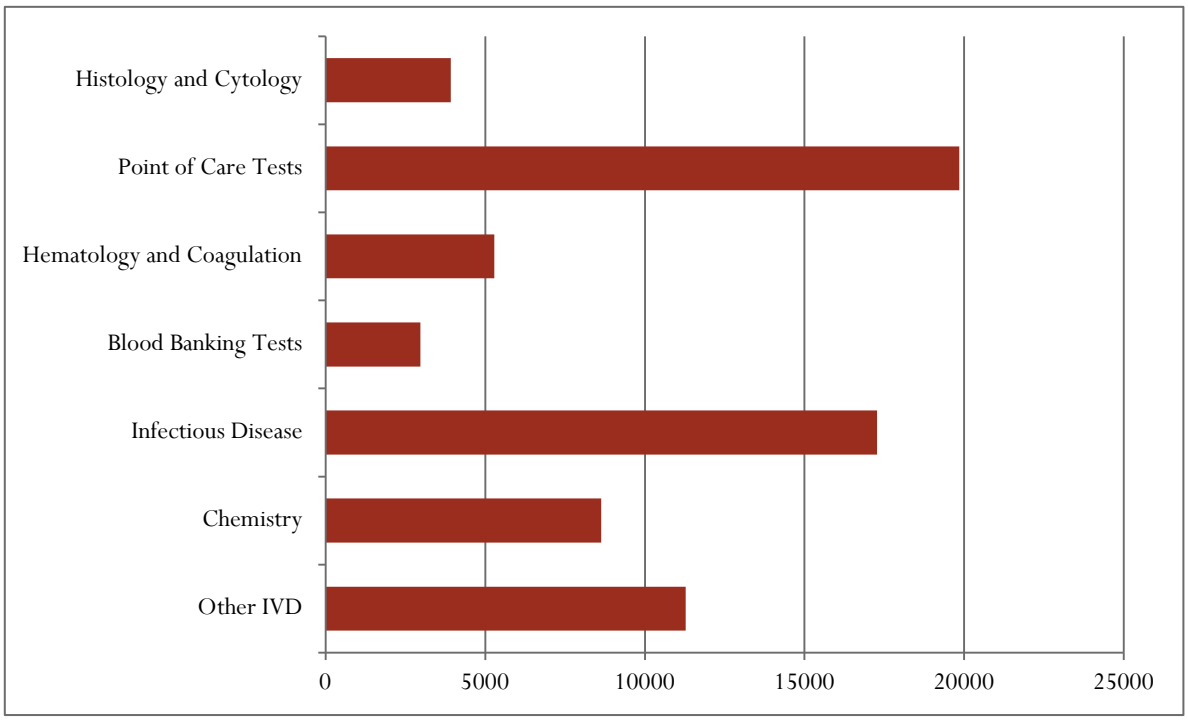


When the cost-effectiveness of in vitro diagnostic testing is then considered along with beneficial effects on treatment outcomes, therapy choices, and hospital management, there should be little surprise about the amount of interest in IVDs and the amount of activity in the market for them. This report, **The Worldwide Market for In Vitro Diagnostics**, now in its 12th Edition, details that activity in a global scope. The report looks at the entirety of

the in vitro diagnostic market and makes forecasts, trend assessments and scrutinizes vendor activities. IVD testing is a 69 billion-dollar market worldwide, as seen in this figure:

The industry continues to push issues and develop solutions for diseases that fall into the paradigm of early testing benefiting outcomes. It can even claim that some known healthcare problems, in some way are the result of a lack of testing. Anti-microbial resistance continues to be an area where IVD shines; there is a growing realization that blind prescribing of antibiotics could be reduced with faster and more targeted testing.

IVD Market by Segment



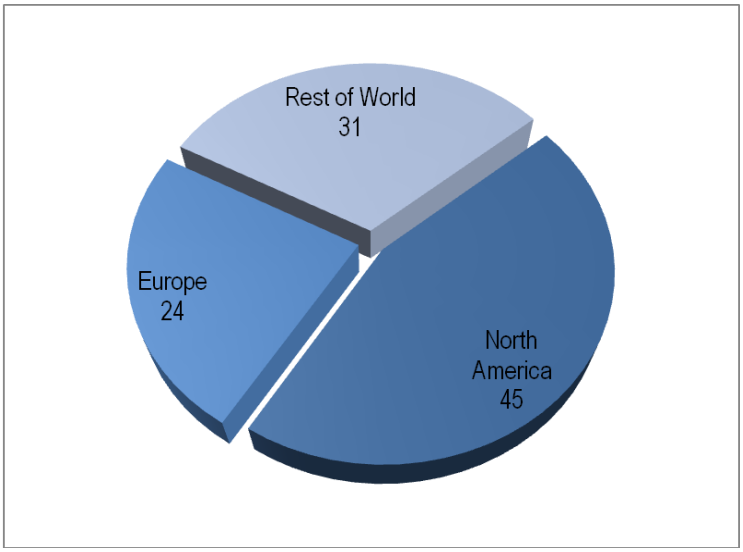
Despite great attention and much action, the opioid crisis continues to plague the United States and countries of the world. 2018 total overdose numbers remained over 70,000, per CDC statistics, indicating that the problem is still severe. The American Association of Clinical Chemistry released a position statement at their 2019 convention, calling for increased collaboration between clinical laboratories and other stakeholders. Early detection of cancer and the popularity of consumer genetic tests are also likely contributors to increased recognition of IVD testing.

While this is happening, various worldwide payor schemes are pressuring prices. The response is the consolidation of lab operations and facilities, which is the same with IVD vendors. Consolidation remains the rule in the industry among both customers and vendors. Top-tier IVD companies accounted for over 80% of IVD product sales last year. Part of this development is related to organic company growth, but also to strategic acquisitions that add revenue streams and product innovations.

The **world market for diagnostics was estimated at $69.2 billion in 2019** and is expected to grow 4% annually to $85.2 billion by 2024. This includes all laboratory and hospital-based products, and OTC product sales. Several previous editions had growth at 6%. What to make of the recent lower single-digit growth? Faster growth is possible; if the potential of sequencing and personalized medicine testing is fully realized, such rates might return. For the next five years, slowdowns in instrument purchasing decisions, the effects of PAMA legislation in the United States, cold markets in Europe, decreasing reimbursement for glucose and low-cost competition will limit growth somewhat. Also, the migration of previously low volume tests to integrated analyzers (that decreases the cost per test) must be weighed against the positives of an aging population, increasing procedures and test improvements. The consolidation of lab customers is also a concern.

The following chart presents the IVD market worldwide for major regional segments:

Regional Distribution of IVD Market, 2019



Source: Kalorama Information

Top IVD Trends

COVID-19 Boosts Molecular and Antibody Testing: Testing for COVID-19 has not only added millions and perhaps billions to the market for IVD, but it has focused attention worldwide on diagnostics and the need to fund testing. This is particularly true in the United States, where testing was largely rationed under various payment reduction programs. RT-PCR, sequencing and critical care tests have been the most benefited by the unfortunate effects of the disease.

COVID-19 Downside: While COVID-19 has been a plus for relevant tests for either the detection of the virus**,** other categories are down. Kalorama's own tracker surveys of US labs indicated labs down in histology cancer testing as much as 30% in early May, with non-COVID immunoassays down 20%.

Cancer and Infectious Disease Drive IVD Sales: Tissue-based testing for cancer and molecular tests for both cancer and infectious diseases are the growth engine among larger segments; growing at 50% higher than the overall market.

Clear Majority of Market Outside US: 58% of the market is now outside of US. Developed markets (N. America/Europe/Japan) still make up the bulk of IVD sales but growth is dependent on developing nation IVD markets. Among these markets are China, India, Korea, Turkey, and Brazil but IVD vendors are finding new emergent nations, like the Philippines at 9% revenue growth or Malaysia, with 8% growth.

Migration, Customer Protection in the Core Laboratory: Major chemistry vendors are developing improved models selling their existing customers on staying with them – Footprint improvements, IT , automation and expanded menus are expected.

Companies Buy to Grow: No one company owns all the technology to compete in an increasingly complex world. There have been 60 recent mergers and acquisitions related to IVD. Significant recent deals.

Point of Care Driven by Hospitals: It is a mistake to think that point of care is only used by physicians or self-testing. Hospitals are by far the biggest users of rapid IVD tests, and decentralizing certain tests for improved outcomes can boost the right system if the cost case can be made.

Sepsis is a growing problem and early detection is crucial for patients. Approximately 1.7 million individuals in the US develop sepsis each year. Procalcitonin (PCT) and lactate are two established biomarkers for sepsis, but there are limitations.

More Immunoassays Run on Workstations: Traditional specialization barriers, such as microbiology, hematology, blood banking, immunology and even anatomical pathology, are fading. Analytes increasingly are run on large immunoassay workstations.

vitamin D, HbA1c, NGAL, D-dimer, anti-CCP, hsTroponin, hsCRP, cystatin, procalcitonin, HE4 cancer marker and markers for Graves' disease.

Companion Test Progress: Companion testing has expanded since the commercial success of Herceptin (trastuzumab) and Gleevec (imatinib), both of which required testing with companion diagnostics before they could be prescribed. FoundationOne CDx's approval as the first FDA approved companion diagnostic test for solid tumors is a positive signal to

Top IVD Companies

ROCHE DIAGNOSTICS	Roche continues to dominate the industry. Until 2018, Roche's revenues were twice that of its nearest competitors. Roche's growth is linked to its molecular (PCR) IP, chemistries, immunoassays, HPV testing and its diabetes franchise.
ABBOTT DIAGNOSTICS	The point-of-care (near patient) diagnostics leader and no 2 player in the market. Abbott's acquisition of Alere two years ago, its critical care success, and its fast development of COVID-19 related- tests with White House recognition has boosted the company.
SIEMENS HEALTHINEERS	A major player in clinical chemistry, drug testing, hematology, coagulation, immunoassay, infectious diseases, microbiology, molecular diagnostics, plasma proteins, POC testing, blood gases/electrolytes, and urinalysis.
THERMO FISHER SCIENTIFIC	A diagnostics leader by strategic mergers - Phadia: allergy and autoimmunity diagnostics; B.R.A.H.M.S.: novel biomarkers (procalcitonin); TREK Diagnostics: microbiology solutions; Sure-Vue and PathoDx Rapid Serology Tests; One-Lambda: HLA for transplant testing; Soon to also add molecular testing giant Qiagen.
SYSMEX CORPORATION	An integrated manufacturer of laboratory software and diagnostic systems involved in the development, production, marketing, and servicing of clinical laboratory testing devices and reagents. Since its establishment in 1968, Sysmex had concentrated in hematology and urinalysis.
BIOMÉRIEUX	AniInfectious disease-focus company with offices in NC and France. Best known for its microbiology business that includes immunoassays, traditional microbiology and chromogenic media and now its BioFire Diagnostic rapid test system.
ORTHO CLINICAL DIAGNOSTICS	Ortho is a leader in blood typing and reagent systems for clinical chemistry, immunoassays and transfusion medicine, Ortho markets blood virus ELISA screening tests for hepatitis B and C, HIV to blood banks.
WERFEN	Werfen maintains its position in the IVD industry by concentrating on reinforcing its main areas of expertise in coagulation and autoimmune testing and has added to its acute care diagnostics with Instrumentation Laboratory's recent acquisition of Tem and Accriva Diagnostics

BECTON DICKINSON & CO	Specific products include microorganism identification, rapid immunoassays, microbiology plated media, microbiology laboratory automation and women's health. The company pioneered the use of mass spectrometry in bacterial infection analysis. BD's legacy IVD involvement is in infectious disease testing and flow cytometry, where the company is an industry leader.
QIAGEN N.V.	Soon to be part of Thermo Fisher Scientific, Qiagen is an IVD innovator in automated DNA sample processing, molecular HPV testing, companion test development, liquid biopsy, next generation sequencing automation and digital PCR.
BIO-RAD	The veteran IVD company and IVD quality control leader offers more than 3,000 different products that cover more than 300 clinical diagnostic tests. Bio-Rad's growth comes from its strength in multi-niche markets including infectious disease immunoassays, hbA1c, autoimmune immunoassays, neonatal screening, allergy testing, blood typing, microbiology media and pathogen identification
BECKMAN COULTER	Beckman Coulter, Inc., a subsidiary of Danaher Corporation reports that more than 275,000 Beckman Coulter systems operate in both diagnostics and life science laboratories on six continents. This includes systems for clinical chemistries, immunoassays, hematology, coagulation, urinalysis and microbiology.
HOLOGIC	Hologic, Inc active in several markets: diagnostic products, medical imaging systems, and surgical products. The company operates four core business units focused on diagnostics, breast health, gynecological surgical and skeletal health.
GRIFOLS S.A.	Grifols has transitioned from a blood bank supplies company to a fully integrated blood bank player with the acquisition of Hologic's blood screen, blood bank business, and molecular blood screening products.
RADIOMETER	Radiometer is the world's leading provider of blood gas analyzers. Radiometer is a pioneer in blood gas testing. Radiometer also provides accessories, IT systems and support services for blood gas testing, POC systems and immunoassays.
DIASORIN GROUP	DiaSorin offers a broad range of specialty tests in the immunodiagnostics market and new tests in the molecular diagnostics market. DiaSorin sells its products worldwide directly through 11 subsidiaries and branch offices as well as through an international network of over 80 distributors.

IVD's FUTURE: WHAT TO WATCH

These are exciting times for diagnostics. In expectation that current trends will continue for the next 5-10 years, a number of eventualities are mostly inevitable. Automated, user-friendly molecular systems will bring mainstream molecular tests into the physician office and small hospital labs. This eventuality is driven partly by technological advancements in microfluidics and isothermal amplification techniques and partly by economics.

- The interplay of IT and diagnostic systems will be increasingly important. It's no longer possible to market a successful IVD product without some recognition of the role of IT systems. Increasing demands for cost-effectiveness will prompt laboratories to develop algorithms and IT schemes to limit testing to where it can be most effective, to in effect, increase the changes of a positive result with the use of data.
- Molecular physician office tests have proven success and placements for use in respiratory infections. The driving force was a particularly virulent strain of flu in 2018 and the need of physicians to establish flu typing. The question that remains for these innovative systems is: Will they become a function of respiratory disease only, or will they have the capacity to migrate into sexually transmitted diseases or other infections? Will test development allow for CLIA-waived tests in other areas? Will hospitals continue to purchase systems and decentralize testing?
- IVD continues to attract the attention and involvement of major information technology companies and payers that are tired of paying for drugs that often have limited positive patient outcome.
- Wearable glucose detection devices and now coagulation devices with patient-to-doctor connectivity functions signal a new world and presage the involvement of IVD in the patient-at-home.

- Next-generation sequencing represents a powerful platform that allows for the sequencing of thousands to millions of genes at once. It is believed to revolutionize fields such as personalized medicine, genetic disease and clinical diagnostics.

Furthermore, trends are discussed in the next section that are more specific, but which could also determine how the market grows.

COVID-19

The worldwide COVID-19 crisis has spawned hundreds of diagnostic testing kits and daily announcements. How do you sort out the significant tests with large distribution and market share from promising startups or low volume companies? This Kalorama COVID-19 IVD Test Tracker will update on new EUAs with information and analysis from Kalorama analysts, updated on a regular basis

There's been a steady increase in IVD Test Product EUAs over time. Over a month ago, only the CDC's own test was available. Roche's cobas test approval became the first commercial test, and then many other EUAs followed.

RT-PCR is the gold standard and molecular tests are by their nature slightly faster to develop when a virus has a known genetic signature, as is the case with SARS-CoV-2. Therefore, it's not surprising to see most EUAs consist of PCR tests, though anti-body tests are increasingly netting authorizations:

Significant new EUAs include: Roche's IL-6 Test, Quidel's Direct Test (no RNA extraction kit required), Abbott's Alinity m2000 Test, Everlywell's Home Collection Kit (not a test in the purest sense but regulated by the FDA as one), Quidel's Sofia Antigen Test, Sherlock CRISPR test, Biomerieux's R-GENE 2 triplex PCR test (for covering possible COVID-19 mutations). Bio-Rad's dPCR test, Roche and Abbott high-throughput Serology tests.

Major IVD COVID-19 TESTS

IVD Company	COVID Test Product	Tech	Est. Install Base	Through-put (8hr shift)	Authori-zation
Roche	*cobas SARS-CoV-2*	PCR	827	240-900	FDA
Roche Serology	*Elecsys® Anti-SARS-CoV-2*	Antib.	40000	150-300	FDA
Roche IL-6	*Elecsys® IL-6*	Antib.	40000	150-301	FDA
ThermoFisher	*TaqPath COVID-19 Combo Kit*	PCR	4500	200	FDA
Abbott m2000	*Abbott RealTime m2000 SARS-CoV-2*	PCR	250	150	FDA
Ortho Clinical	*Vitros XT/7600/5600*	Antib.	1000	1200	FDA
Abbott -Rapid Dx	*ID NOW COVID-19*	PCR	4700	32	FDA
Abbott-Serology	*ARCHITECT i1000SR and i2000SR I*	Antib.	2000	200	FDA
Quidel	*Sofia SARS-CoV-2 Antigen Test*	*Antigen*	N/A	N/A	FDA
Abbott Alinity m	*SARS-CoV-2*	PCR	N/A	500	FDA
Siemens Fast Track	*Fast Track Diagnostics*	PCR	N/A	N/A	CE Mark
Siemens Centaur	*Centaur Antibody SARS-CoV-2*	Antib.	N/A	1000	In Dev.
Cepheid	*Gene Xpress SARS-CoV-2 test*	PCR	23000	140*	FDA
BioFire	*BioFire Film Array COVID-19 Test*	PCR	11000	75*	FDA
Sherlock BioSciences	*CRISPR-Based PCR Test*	PCR	N/A	N/A	FDA
Biomerieux	*R-Gene Test Triplex to Cover Mutations*	PCR	N/A	N/A	FDA
Hologic	*Panther Fusion SARS-CoV-2*	PCR	1800	380	FDA
Diasorin	*LIASON Igg*	Antib.	800	N/A	FDA
Bio-Rad	*Platelia SARS-CoV-2 Total Ab assay*	Antib.	N/A	N/A	FDA
Simplexa/DiaSorin	*Simplexa COVID-19 Direct for LIASAON*	PCR	800	64	FDA
Luminex ARIES	*ARIES SARS-CoV-2 Assay*	PCR	320	48	FDA
Qiagen	*QIAstat Respiratory SARS-CoV-2 Panel*	PCR	N/A	50	FDA
Luminex NxTAG	*NxTAG CoV Extended Panel Assay*	PCR	65	192	FDA
GenMark	*ePlex SARS-CoV-2 Test*	PCR	580	96	FDA
BD Max	*BD SARS-CoV-2Reagents for BD MAX*	PCR	150	60	FDA
Quidel	*Lyra SARS-CoV-2 Assay*	PCR	550	200	FDA
bioMérieux	*COVID-19 RT-PCR Test*	PCR	N/A	14000**	FDA
Illumina	*Novaseq*	*Seq.*	N/A	3000/run	FDA
bioMérieux	*SARS-COV-2 R-GENE®*	PCR	N/A	45	CE Mark
Chembio	*DPP COVID-19 IgM/IgG System*	Antib.	N/A	N/A	FDA
Snibe	*MAGLUMI 2019-nCoV IgM/IgG kit*	PCR	N/A	600	China

Double Edge Sword: Non-COVID-19 Testing Declines

Hospital and Reference Labs are feeling the pinch from the drops in elective surgeries, according to a survey conducted by Kalorama information. The results were unveiled at a webinar held by Kalorama and The Science and Medicine Group

Among the results:

- Chemistry testing (BMPs, electrolytes, etc) was reported down 19% in volume.
- Immunoassays down 21%.
- Histology testing is down 32%
- Molecular Testing volumes were up 8%
- PCT testing was the only other positive test category, up 2%.
- Blood Gas testing was down only 5%, cardiac troponin down 10%
- Labs expect to start to use more advanced molecular mass spec and NGS in 2020 and expect to increase chemistry and immunoassay testing as re-openings occur and hospitals reschedule surgeries.
- Layoffs were a factor at over one half of laboratories surveyed.

China and Top Emerging Nations Markets

China is the world's largest and one of the fastest-growing IVD markets. Thus it is a target by all major IVD vendors for replacing some revenue lost to slower growth in developed healthcare markets. The global industry has increased activities here in the past decade, and companies not only sell IVDs but manufacture and distribute here as well. In 2019, the Chinese market for IVD reagents was estimated at approximately $3.8 billion and is expected to show an annual growth of 8% over the next five years.

Expanding beyond the top seven emerging markets is essential for growth in the global IVD industry. Eastern Europe, LATAM (outside of Brazil) and Eastern Europe represent next-tier emerging regions. With a longer-term focus, Africa must be part of 5- and 10-year business plans for companies not already in the region. More than half of global population growth between now and 2050 is expected to occur in Africa, according to the U.N. The American Association for Clinical Chemistry announced an expansion of their Global Lab Quality Initiative (GLQI) to Africa next year. The program circulates testing best practices, providing method verification workshops and other training and education. For 8 years, the GLQI has worked with partner associations in Latin America and the Pacific region. A quality control workshop is slated for Ethiopia in 2020, and a newborn screening workshop is planned in Morocco in the coming year.

Market Drivers

- Aging populations
- Increasing chronic disease
- Government incentives and planning for health markets
- Private hospital growth
- Increasing middle-class

Market Restraints

- Pricing
- Intetellectual property concerns
- Training concerns
- Slow changes in reimbursement

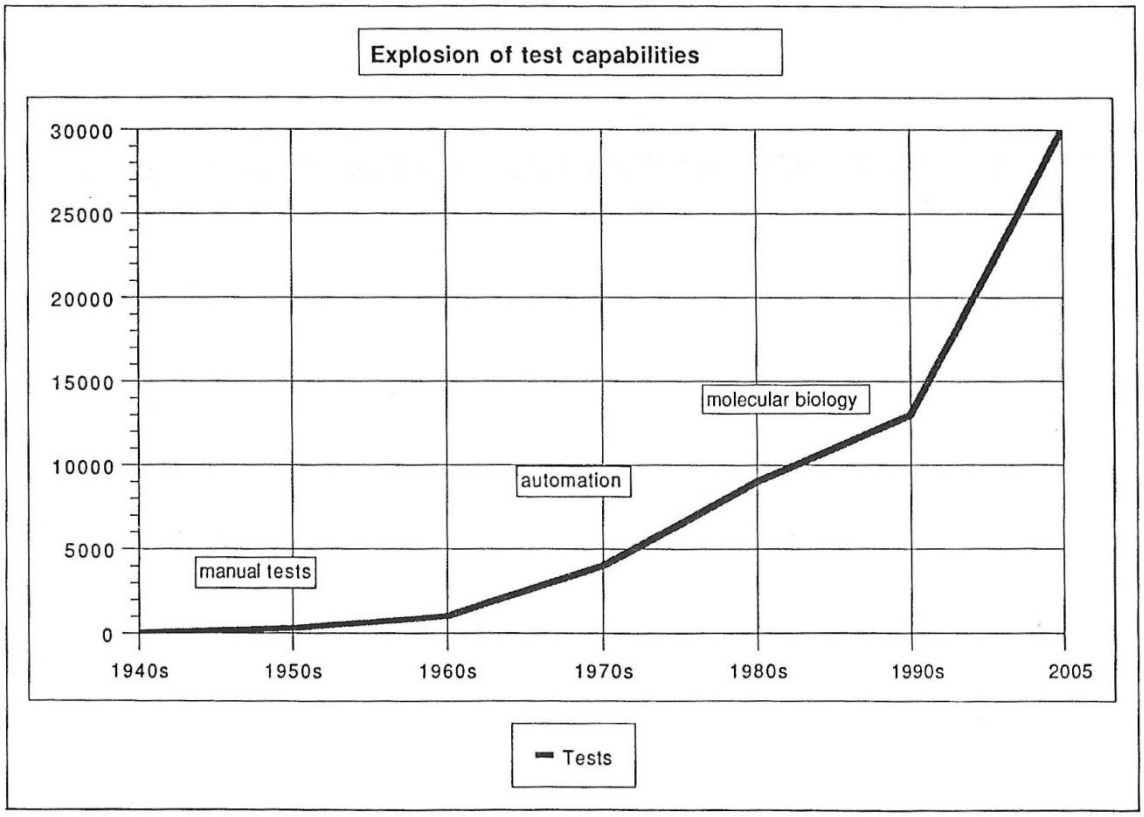
Lab Automation

Clinical lab medicine plays an integral role in healthcare and disease management. It is estimated that some 70% of diagnoses and treatment plans are based on clinical lab test results. Diagnostic laboratory medicine has changed dramatically since the 1970s. Until the 1970s lab medicine was comprised of some 500 to 4000 tests performed manually with the aid of test tubes and a spectrophotometer or microscope. Proteomic research then led to the discovery of important disease markers such as proteins, enzymes and hormones. Enzyme immunoassay techniques provided a tool by which to assay these and other markers.

In the 1980s, the development of enzyme immunoassays and automation led to almost a doubling in the number of tests that could be performed in hospital labs. Then the launch of polymerase chain reaction (PCR), the completion of the Human Genome Project and molecular test modalities added yet another dimension to clinical lab testing. By the 1990s and 2000s developments in molecular biology, proteomics, disease management research and the unraveling of the human genome further expanded the menu of tests available. Thus tests used to analyze biopsied tissue; to measure nucleic acids in blood, sputum, urine, cervical fluid and other samples; and to diagnose infectious diseases, created a rapid expansion in clinical lab medicine. These tests provide physicians information that could be readily applied to therapy selection and patient outcome particularly in cancer diagnosis and disease management, in diabetes and in infectious diseases.

A brochure summarizing lab test activities at Baylor University Medical Center (Wako, TX) during 1951–1952 reported that 245,296 laboratory tests were completed, for a daily average of 672 tests. Since that time, the article states "the number of tests processed has tended to increase at a rate of about 10% per year" and therefore by our calculation the Baylor labs would have processed at least 100 million tests in 2019 (or some 285,000 tests per day). The figure shown below illustrates the expansion of tests available for inclusion in a laboratory's test menu.

Explosion of Test Capabilities



Source: Kalorama Information

It is obvious that the manual test methods used in most labs until the mid 1960s and 1970s could not cope with the increased expansion of the test menu. Automated instrumentation was a solution that allowed test results to be generated in a fraction of the time that they used to take. For the purposes of this report; laboratory automation is defined as the use of technology to streamline or substitute manual manipulation of test processes including: simple capping and decapping of sample tubes and bottles, creating test lists, high throughput screening of test samples, the storage of patient samples and the communication of test results to a laboratory information system.

The use of automation in labs progressed step by step. Barcoding and scanners replaced hand-written test lists and have sped up the specimen tracking process. This was

accompanied by automated clinical chemistry, immunoassay and hematology/coagulation instrumentation. Next came what are termed independent "islands of automation" used to conduct pre-analytical sample manipulation, automated testing and sample storage modules. The final and most sophisticated phase resulted in "total lab automation" whereby these independent modules are linked by a track that is powered by advanced robotic solutions with multiple connectivity options. These track-based automation solutions are scalable and flexible to meet the demands of any size laboratory.

Total automation solutions can be open or closed. Closed automation track solutions are provided by instrument manufacturers and typically connect only to instruments from that vendor or assigned partners. All of the major diagnostic companies including Abbott Diagnostics, Beckman Coulter/Danaher Diagnostics, Ortho Clinical Diagnostics, Roche Diagnostics and Siemens Healthineers offer total lab automation solutions. Open automation solutions are designed and acquired by labs independently and can interface with any instrument, regardless of the vendor. They are built by independent companies and interface to the instruments and the lab information system to automate the pre- and post-analytical work flow.

Tecan Group, Copan, Kiestra, Hitachi High Technologies, and others are among the major automation companies that partner with IVD companies to provide customized automation solutions.

One of the most popular automation solutions for any size lab has been the pre-analytical sample preparation station. This is because the pre-analytical phase is associated with more than half of all laboratory costs and has been shown to be the source of laboratory errors due to specimen mislabeling, misidentification, missorting, and improper routing, and decanting. While Beckman Coulter/Danaher has been a pioneer in this area, other major IVD vendors now offer a variety of automated pre-analytical solutions including Bio-Rad Laboratories, Abbott Diagnostics, Siemens Healthineers, Roche Diagnostics and others.

The ultimate goal of these various automated systems is to minimize labor intensive manual work previously performed by medical technicians (sorting tubes, decapping, centrifuging, loading analyzers, prepping and sorting materials for storage, etc.) while optimizing workflow, improving productivity, and increasing patient safety.

Gene Editing

Until recently gene editing floated under the radar as a research tool with rumors of efforts to create designer babies. Then, gene editing using CRISPR (clustered regularly interspaced short palindromic repeats) burst onto the scene with potential applications in disease diagnosis, personalized medicine, animal and plant manipulations and more. Scientists have known for years that bacteria have the ability to fight off invading viruses. Bacteria have sophisticated immune systems, called CRISPRs, that allow them to fight off invading viruses. Understanding how CRISPRs work in bacteria has led to human gene editing, a transformative technology that has profound implications in biotechnology and in medicine. The use of CRISPR systems in human cells can be used to program these systems to cut out and repair defective DNA in human cells.

CRISPR pioneer Jennifer Doudna and Trevor Martin have co-founded Mammoth Biosciences (San Francisco, CA) to develop a device that uses CRISPR to detect infectious diseases, including malaria, tuberculosis and Zika. The company is working on a **credit-card-sized paper test** and smartphone app combo for disease detection. Mammoth reported: "These CRISPR-based diagnostic tools have the potential to revolutionize how we test for diseases in the hospital, or even at home."

Mammoth Biosciences is not alone in this endeavor. Researchers around the world are finding innovative ways to employ the technology of CRISPR to detect disease in some of the most remote, challenging areas where are found diseases such as Lassa fever, Zika, and dengue fever, among others. Genomic DNA amplified or sequenced from circulating tumor cells (CTCs), circulating tumor cell DNA (ctDNA) and circulating cell-free DNA (cfDNA) harbor complementary information on mutations relevant for the treatment of individual cancer patients. These applications promise to impact clinical protocols and treatment regimens and will likely determine the future standard of care in oncology.

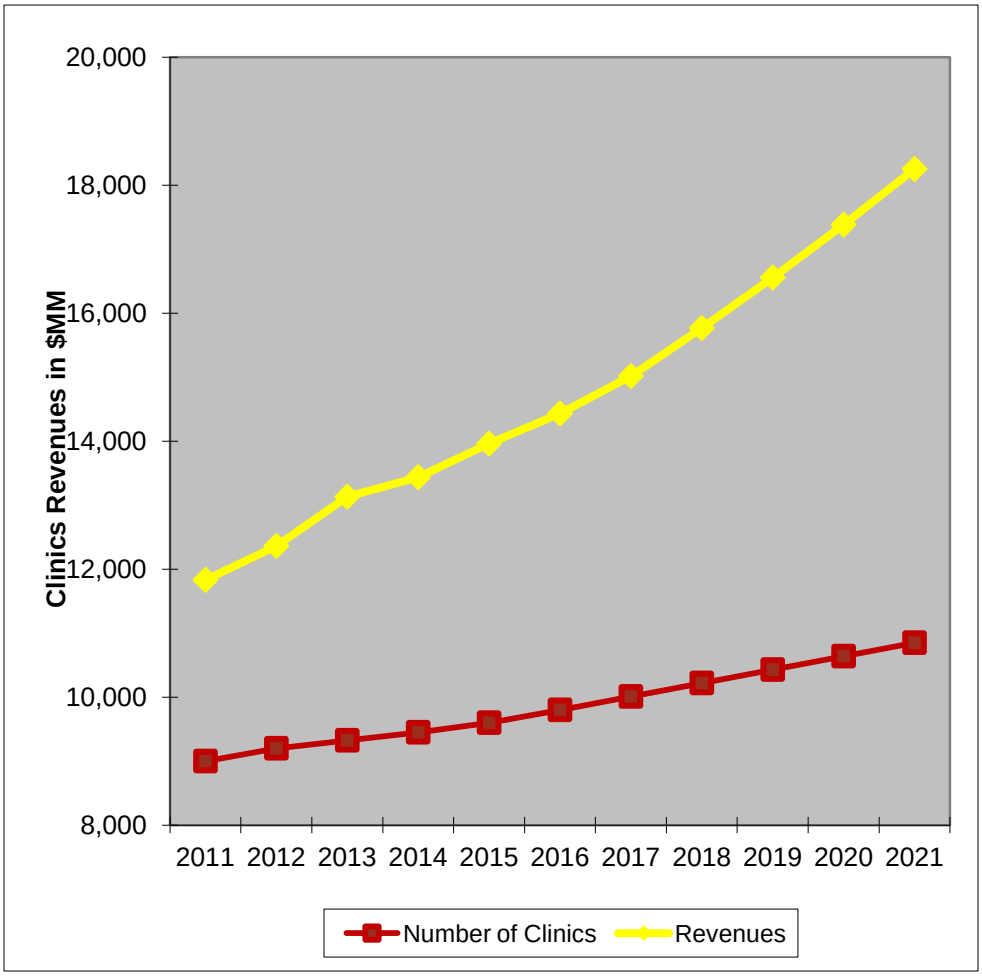
New Venues – Urgent & Retail Care, "Microhospitals"

IVD marketers cannot ignore the trend of healthcare following the patient. Urgent care centers are not new but have taken on new importance as convenient healthcare options. Kalorama Information's recent report, **The Market for Urgent Care Centers**, projects that there will be 1,000 new urgent care centers in the next five years. Some of these will compete for patients with existing locations and all may not survive, but they will add an estimated $3 billion extra into that market, and create millions of dollars in new sales to these new centers of equipment, including point-of-care IVDs. Retail clinics within CVS and Walgreens chains in the U.S. are venues for respiratory disease testing and some POCs. These new venues will drive some test business to reference labs as well. Watch urgent cares openup near retail pharmacies in the same location rather than an inside clinic.

There is a new opportunity opening for clinical laboratories: micro-hospitals. Micro-hospitals feature 8 to 10 inpatient beds (but can have as many as 50 beds), and range from 15,000 to 50,000 square feet, whereas full-service hospitals are 100,000 square feet or more. At a cost of $7 million to $30 million, micro-hospitals are significantly less expensive than large hospitals to bring to market. For patients, micro-hospitals offer the 24-hour care that cannot be found at healthcare clinics located inside drugstores or urgent care clinics.

The chart on the next page describes the growth of retail clinics, that is clinics within a hospital or grocery store with dedicated space and a closed exam room. The concept was new two decades ago. Now it is a functional part of U.S. healthcare. Diagnostics, such as point of care tests for respiratory conditions are an important part of the services offered at retail clinics.

Figure 5-1: Growth of U.S. Retail Clinic Services, 2011–2021



Source: Kalorama Information

DIRECTORY OF IVD COMPANIES

IVD COMPANY, LOCATION AND WEBSITE

10x Genomics	Pleasanton, CA	www.10xgenomics.com
Opko Health	Woburn, MA	www.opko.com
23andMe	Sunnyvale, CA	www.23andme.com
Abaxis, Inc.	Union City, CA	www.abaxis.com
Altona Diagnostics	Germany	www.altona-diagnostics.com
Asuragen Inc.	Austin, TX	www.asuragen.com
Binx Health	Boston, MA	www.binxhealth.com
Bruker BioSciences Corporation	Billerica, MA	www.bruker.com
Exact Sciences Corp.	Madison, WI	www.exactsciences.com
Fluidigm Corporation	South San Francisco	www.fluidigm.com
Genedrive plc	UK	www.genedriveplc.com
Greiner Bio-One	Austria	www.gbo.com
Helomics Corporation	Pittsburgh, PA	www.helomics.com
IncellDx	SanCarlos, CA	www.incelldx.com/
Response Biomedical Corp.	Vancouver, CA	www.responsebio.com
T2 Biosystems	Lexington, MA	www.t2biosystems.com
Theradig	France	www.theradig.com
Tosoh Bioscience	South San Francisco, CA	www.tosohbiosicence.com
Vela Diagnostics	Singapore	www.veladx.com
A. Menarini Diagnostics	Italy	www.menarinidiagnostics.com/en-us/
Abbott	Abbott Park, IL	www.abbott.com
Able Diagnostics, Inc.	San Diego, CA	www.ablediagnostics.com
ACM Global Labs	Rochester, NY	www.acmgloballab.com

Adaptive Biotechnologies	Seattle	www.adaptivebiotech.com
Adian	Finland	www.aidian.edu
Advanced Cell Diagnostics (ACD)\	Newark, CA	www.acdbio.com
Agena Bioscience, Inc.	SanDiego,CA	www.agenabioscience.com
Agendia BV	Irvine, CA	www.agendia.com
Agilent Technologies	Santa Clara, CA	www.agilent.com/
Ambry Genetics	Aliso Viejo, CA	www.ambrygen.com
Amedica SA	Norway	www.amedica.no
America DX	San Diego, CA	www.americadx.com
Amoy Diagnostics Co. Ltd.	China	www.amoydx.com
ANGLE, plc	UK	www.angleplc.com
Animas Corporation	West Chester, PA	www.animas.com/
AnyGenes	France	www.anygenes.com
Applied Spectral Imaging Inc. (ASI)	Carlsbad, CA	www.spectral-imaging.com
ArcDia International Ltd	Finland	www.arcdia.com
Arkray	Japan	www.arkray.co.jp/english/
ARUP Laboratories	Salt Lake City, UT	www.aruplab.com
Assay Genie	UK	www.assaygenie.com
Atila BioSystems, Inc.	Mountain View, CA	www.atliabiosystems.com
Atlas Medical	UK	www.atlas-medical.com
Atomo Diagnostics	Australia	www.atomodiagnostics.com/
Autobio Diagnostics Co. Ltd.	China	www.autobiodiagnostics.com
AutoGenomics Inc.	Carlsbad, CA	www.autogenomics.com
Banyan Biomarkers	San Diego, CA	www.banyanbiomarkers.com

Beckman Coulter	Brea, CA	www.beckman.com
Beckton Dickinson	Franklin Lakes, NJ	www.bd.com
Berry Genomics Co. ltd.	China	www.berrygenomics.com
BG Medicine, Inc	Waltham, MA	www.bg-medicine.com
BGI	China	www.bgi.com
Bigfoot Biomedical Inc.	Milpitas, CA	www.bigfootbiomedical.com/
Binding Site Group Ltd. (The)	Birmingham, UK	www.bindingsite.co
Biocan Diagnostics Inc.	Canada	www.biocan.com
Biocartis Group NV	Belgium	www.biocartis.com
Biocept, Inc.	San Diego	www.biocept.co
BioGenex Laboratories, Inc.	Fremont, CA	www.biogenex.com
Biohit Oyj (Biohit Healthcare)	Helsinki, Finland	www.biohithealthcare.com
Biolidics	Singapore	www.biolidics.com
BioMaxima SA	Poland	www.biomaxima.com
Biomerica Inc.	Irvine, CA	www.biomerica.com
Biomerieux	France	www.biomerieux.com
Bioneer	Korea	www.bioneer.com
Bioperfectus Tech.	China	www.bioperfectus.com
Bio-Rad Laboratories, Inc.	Hercules, CA	www.bio-rad.com
Biosynex International	France	www.biosynex.com
BIOSYNEX S.A.	France	www.biosynex.com
Bio-Techne Corporation	Minneapolis, MN	www.bio-techne.com
Biotime Biotechnology Co., Ltd	Canada	www.biotime.cn
BioView Ltd.	Rehovot, Israel	www.bioview.co.il

Blusense Dx Ap	Denmark	www.blusense-diagnostics.com
Bruker Diagnostics business	Billerica, MA	www.bruker.com
Calbioreagents	San Mateo, CA	www.calbioreagents.com
Camtech Diagnostics Pte Ltd	Singapore	www.camtechdiagnostics.com
Canvax Biotech	Spain	www.canvaxbiotech.com
CareDx,	Brisbane, CA	www.caredx.com
CellaVision AB	Sweden	www.cellavision.com
Cellex	Durham, NC	www.cellex.com
CellMax Life	Sunnyvale, CA	www.cellmaxlife.com
CellSafe	Malaysia	www.cellsafe.au
Cepheid	Sunnyvale, CA	www.cepheid.com
CerTest Biotec	Spain	www.certest.es
Chembio Diagnostic Systems, Inc.	Medford, NY	www.chembio.com
Circulogene	Birmingham, AL	www.circulogene.com
Circulomics Inc.	Baltimore, MD	www.circulomics.com
Co-Diagnostics	Salt Lake City, UT	www.codiagnostics.com
Combinati	Paul Alto, CA	www.combinati.com
COPAN Diagnoostics	Italy	www.copanusa.com
Corgenix Medical Corporation	Bloomfield, CO	www.corgenix.com
Coris BioConcept	Belgium	https://www.corisbio.com/
Credo Dx BioMed	Singapore	www.credodxbiomed.com
Critical Diagnostics	San Diego, CA	www.criticaldiagnostics.com
CTK Biotech, Inc.	San Diego, CA	www.ctkbiotech.com
Curetis	Netherlands	www.curetis.com

Curiosity Diagnostics	Poland	www.curiositydiagnostics.com
Dako A/S	Denmark	www.dako.com
Debiotech SA	Switzerland	www.debiotech.com
Definiens	Germany	www.definiens.com
Dexcom Inc.	San Diego, CA	www.dexcom.com
Diacarta	Richmond, CA	www.diacarta.com
Diagnostica Stago, S.A.S.	Italy	www.stago.com
DIAGON Kft. Hungary	Hungary	www.diagnon.com
DiaSorin S.p.A	Italy	www.diasorin.com
Diazyme	La Jolla, CA	www.diazyme.com
DxGen	Korea	www.dxgenco.com
DxTerity Diagnostics Inc.	Rancho Dominguez, CA	www.dxterity.com
Dynamiker Biotechnology (Tianjin) Co., Ltd.,	China	www.dynamiker.com
Eagle Biosciences Inc.	Germany	www.eaglebio.com
Eiken Chemical Co.	Japan	www.eiken.co.jp/en/
EKF Diagnostics Holdings Plc	UK	www.ekfdiagnostics.com
ELITech Group S.A.S.	Lincoln, RI	www.elitetechgroup.com
Enzo Biochem Inc.	Farmingdale, NY	www.enzo.com
Epic Sciences	San Diego, CA	www.epicsciences.com
Epigenomics AG	Germany	www.epigenomics.com
Epitope Diagnostics, Inc.	Canada	www.epitopediagnostics.com
ERBA Diagnostics, Inc.	Germany	www.erbadiagnostics.com
Eurobio Scientific	France	www.diaxonhit.com
Eurofins Technologies	Hungary	www.eurofins.com

EUROIMMUN AG	Germany	www.euroimmun.com
Euroimmune (Perkin Elmer sub)	Germany	www.rapidtest.ca
Everlywell, Inc.	Austin, TX	www.everlywell.com
Exalenz	Israel	www.exalenz.com
Fio	Canada	www.fio.com
Fortune Bioscience Co., Ltd.	China	www.fortunebio.alibaba.com
Fujirebio Diagnostics	Japan	www.fujirebio.com
Fulgent Therapeutics, LLC	Temple City, CA	www.fulgentgentics.com
GA Generic Assays GmbH	Germany	www.biocartis.com
Gene Biosystems	Egypt	www.gene-biosystems.com
GeneMatrix Inc.	Korea	www.genematrixllc.com
GeneMe	Poland	www.geneme.eu
Generi Biotech s.r.o.	Czech Republic	www.generi-biotech.com
GenMark Diagnostics, Inc	Carlsbad, CA	www.genmark.com
Genomica	Spain	www.genomica.com
Gensure Biotech, Inc	India	www.gensurebiotech.com
GILUPI GmbH	Germany	www.gilupi.com
Gnomegen LLC	San Diego, CA	www.gnomegendx.com
Gravity Diagnostics	Covington, KY	www.gravitydiagnostics.com
Grifols S.A.	Spain	www.grifols.com
Healgen Scientific	Houston, TX	www.healgen.com
Helena	Beaumont, TX	www.helena.com
HemoSonics	Charlottesville, VA	www.hemosonics.com
Hipro Biotechnology	China	www.hipro.us

HOB Biotech	Beijing, China	www.hob-biotech.com
Hologic	Marlborough, MA	www.hologic.com
Horiba Medical	France	www.horiba.com
Hotgen Biotech Co., Ltd	China	www.hotgenbiotech.com
HTG Molecular Diagnostics	Tucson, AZ	www.htgmolecular.com
Humanwell Biocell Biotechnology Co., Ltd	China	www.humanwellco.com
Humasis,	Korea	www.humasis.com
Ideal Tashkhis Atieh Co.	Iran	www.idealdiag.com
Illumina	San Diego, CA	www.illumina.com
Immunodiagnostic Systems (IDS)	UK	www.idsplc.com
Inivata	UK	www.inivata.com
INOVA Diagnostics, Inc.	San Diego, CA	www.inovadx.com
J Mitra	India	www.jmitra.co.in
JAL Innovation	Singapore	www.jalinnovation.com
Kapa Biosystems Inc.	Wilmington, MA	www.kapabiosystems.com
Kewei Clinical Diagnostic Reagent Inc.	China	www.keweidiagnostic.com
KRISHGEN BioSystems	India	www.krishgen.com
LabCorp, Laboratory Corporation of America	Burlington, NC	www.labcorp.com
Lifeassay Diagnostics Pty. Ltd.,	South Africa	www.lifeassay.com
Liquid Biotech USA	Philadelphia, PA	www.liquidbiotechusa.com
LOMINA AG.,	Czech Republic	www.lomina.ch
Loop Medical	Switzerland	www.loop-medical.com
Luminex	Austin, TX	www.luminex.com

Mayo Medical Laboratories	Rochester, MN	www.mayocliniclabs.com
MBio Diagnostics, Inc.	Boulder, CO	www.mbiodx.com
MDxHealth SA	Irvine, CA	www.mdxhealth.com
Medica Corporation	Bedford, MA	www.medicacorp.com
MedMira, Inc.	Canada	www.medmira.com
Medtronic plc	Ireland	www.medtronic.com
Menarini-Silicon Biosystems	Italy	www.siliconbiosystems.com
Meridian Bioscience, Inc.	Cincinnati, OH	www.meridianbioscience.com
Meril Diagnostics Pvt Ltd	India	www.merillife.com
Mesa Biotech Inc.	San Diego, CA	www.mesabiotech.com
Microvisk Technologies	UK	www.microvisk.com
MilliporeSigma (formerly EMD Millipore)	Burlington, MA	www.emdmillipore.com
Mindray Medical International	China	www.mindraymedical.com
Miraca	Japan	www.miraca.com
Mobidiag Ltd.	Finland	www.mobidiag.com
Mokobio Biotechnology	Rockville, MD	www.mokobio.com
Na Gene Diagnostics Reagents	China	www.dlongwood.com
NanoEnTek	Korea	www.nanoentek.com
NanoString Technologies, Inc.	Seattle, WA	www.nanostring.com
NeuMoDx Molecular, Inc.	Ann Arbor, MI	www.neumodx.com
Newomics	Berkeley, CA	www.newomics.com
NG Biotech	France	www.ngbiotechl.com
NovaBiomedical	Waltham, MA	www.novabiomedical.com

NovaTec Immundiagnostica GmbH	Germany	www.novatech-id.com
NTBio Diagnostics Inc.	Canada	www.assuretech.com
Nvigen	Sunnyvale, CA	www.nvigen.com
Omnyx LLC	Pittsburgh, PA	www.omnyx.com
Onca Xt Ltd	Abingdon, UK	www.oncascan.com/
One Lambda, Inc	Canoga Park, CA	www.onelambda.com
Operon	Spain	www.operon.es
OPTI medical	Roswell, GA	www.optimedical.com
Optolane	China	www.optolane.com
OraSure Technologies, Inc.	Bethleham, PA	www.orasure.com
Orgentec Diagnostika	Germany	www.orgentec.com
Ortho Clinical	Raritan, NJ	www.orthoclinicaldiagnsotics.com
Oxford Nanopore Technologies Ltd	UK	www.oxfordnanopore.com
P23 Labs, LLC.	Little Rock, AR	www.p23labs.com
Pacific Biosciences (PacBio)	Menlo Park, CA	www.pacb.com
Pathway Genomics Corporation	San Diego, CA	www.pathway.com
Perkin Elmer	Waltham, MA	www.perkinelmer.com
Pictor	New Zealand	www.pictordx.com
Pishtaz Teb Diagnostics	Iran	www.pishtazteb.com
Polymed Therapeutics	Houston, TX	www.polymedt.com
Prantae Solutions	India	www.pranteae.solutions
Primerdesign Ltd.	UK	www.primerdesign.com
Princeton Biomedical	Monmouth, NY	www.pbmc.com

Prognosis Biotech	Greece	www.prognosis-biotech.com
Promega	Madison, WI	www.promega.com
Protagen Diagnostics	Germany	www.protagen.com
PTS Diagnostics	Whitestown, IN	www.ptsdiagnostics.com
Qiagen	Germany	www.qiagen.com
QuanDx Inc	San Jose, CA	www.quandx.com
QuantuMDX	UK	www.quantumdx.com
Quest	Secaucus, NJ	www.questlabs.com
Quidel	San Diego, CA	www.quide.com
QuikPath	India	www.quickpath.com
Randox Laboratories	UK	www.randox.com
Rapid Bio LLC	Russia	www.rapidbiosystems.com
Renesa	Germany	www.renesa.de
Resolution Biosciences	Kirkland, WA	www.resolutionbio.com
Response Biomedical Corp.	Canada	www.responsebio.com
Reszonics	Malaysia	www.reszonics.com
Rheonix, Inc	Ithica, NY	www.rheonix.com
Roche	Switzerland	www.roche.com
RPC Dx systems	Russia	www.npods.ru.en/about
Sartstedt	Newton, NC	www.sarstedt.com
Savyon Diagnostics	Israel	www.savyondiagnostics.com
ScienCell Research Laboratories	Carlsbad, CA	www.sciencell.com
SD Biosensor, Inc.	Korea	www.sdbiosensor.com
Seasun	China	www.seasunbio.com

Seegene, Inc.	Korea	www.seegene.com
Sekisui Diagnostics LLC	Burlington, MA	www.sekisuidiagnostics.com
Sherlock BioSciences, Inc	Cambridge, MA	www.sherlock.bio
Shimadzu Scientific Instruments	Japan	www.shimadzu.com
Siemens Centaur	Germany	www.biohit.com
Singulex, Inc.	Alameda, CA	www.singulex.com
Snibe Co. Ltd.,	China	www.snibe.com
SolGent	China	www.solgent.com
Spectrum for Diagnostic Industries (SDI)	Egypt	www.sdidiagnostics.com
Spring Healthcare Services AG	Switzerland	www.mdeasydiagnosis.com
Streck Inc.	LaVista, NE	www.streck.com
Sugentech, Inc.	Korea	www.sugentech.com
Takara Bio Inc.	Mountain View, CA	www.takarabio.com
Tezted Oy	Finland	www.tezted.com
ThermoFisher	Waltham, MA	www.thermofisher.com
Trovagene, Inc.	San Diego, CA	www.trovagene.com
U2USystems (India) Pvt. Ltd	India	www.u2usystems.com
Veracyte, Inc.	South San Francisco, CA	www.veracyte.com
Vermillion Inc.	Austin, TX	www.vermillion.com
Viet A Technology Corporation	Vietnam	www.vietatech.com
Vircell S.L.	Spain	www.vircell.com
ViroResearch	Snellville, GA	www.viroresearch.com
Visiopharm	Denmark	www.visiopharm.com
VolitionRx Limited	Belgium	www.volitionrx.com

WAMA Diagnostics	Brazil	http://www.wamadiagnostics.ch/
Waters Corporation	Milford, MA	www.waters.com
Werfen	Spain	http://www.werfen.com/en
West Medica	Austria	www.westmedica.com
West Medica	Austria	www.westmedica.com
Wiener Lab	Argentina	www.wiener-lab.com.ar/
Xincheng Biological Co., Ltd	China	www.xincheng.com
Yhlo Biotech Co. Ltd Contact	China	www.szyhlo.com
Zymo Research	Tustin, CA	www.zymo.com