Lab-on-Chip Devices - Diagnostics to Witness Growing Adoption in the Future

Reference Code: **GDME0758VPT** Publication Date: **July 2011**

1 Table of Contents

1.1 List of Tables

1.2 List of Figures

2 Summary

Lab-on-chip devices are built on microfluidic technology for integration of typical laboratory processes such as sample preparation, mixing, reaction and analysis on a single miniature chip. These devices have major applications in diagnostics as well as life sciences research. The strongest contender for commercial applications includes clinical diagnostics and point of care testing (POCT). Using lab-on-chip devices, high throughput results can be achieved at a much faster time. Few companies have commercialized lab-on-chip diagnostic devices for diagnostic testing such as Abbott and Abaxis. However, the industry is currently plagued by the high cost of devices and lack of standardization.

3 Lab-on-Chip Devices - Diagnostics to Witness Growing Adoption in the Future

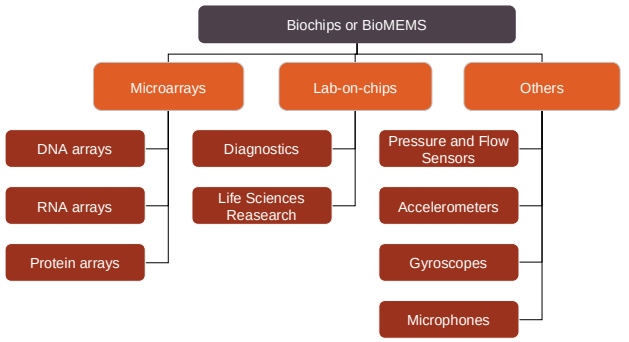
3.1 Introduction

Microfluidics deals with studying and developing industrial applications through the exploitation of the chemical and physical behavior of very small amounts of liquids. Using principles of engineering, physics, chemistry, micro-technology and biotechnology, the flow of liquids can be manipulated through channels the width of a few microns. By reducing the scale of processes to micro proportions, microfluidics is touted to provide many advantages such as better integration with the desired processes. Popular industrial applications of microfluidics include inkjet printheads, DNA chips, lab-on-a-chip technology, micro-propulsion, and micro-thermal technologies.

The first microfluidic based application was commercialized in the early 1990s for inkjet printers wherein the accuracy for spraying ink was vastly improved to within 1/10,000 of an inch.

3.1.1 Lab-on-Chip Devices

Figure 1: Classification of Biochip Devices



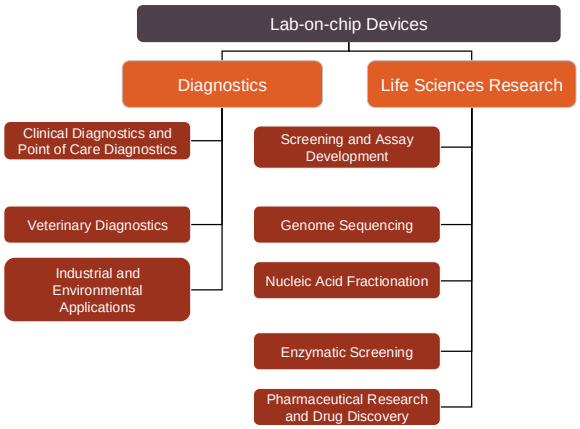
Source: GlobalData, Articles and Publications from Pubmed, Nature, Genome Research, Micro Nano Tech Conference 2011, Publications by Stanford University, University of Minnesota, University of Washington,

Life sciences applications for bioanalysis of microfluidics are generally referred to as “lab-on-a-chip” or µTAS (Micro Total Analysis Systems). Lab-on-chip devices are a subset of biochip devices or BioMEMS (Micro Electromechanical Systems) that include miniature devices built on the principle of MEMS. BioMEMS are MEMS that have biological and/or biomedical functions or applications and often have biological molecules as a component of the system. Microarrays such as DNA arrays are also a type of BioMEMS. Microarrays differ from lab-on-chips in that only reactions can take place in microarrays whereas lab-on-chips are complete systems wherein all processes including sample preparation, reaction as well as analysis takes place. Microarrays typically contain DNA, RNA or proteins transfixed into miniature wells where the reaction takes place. On the other hand, lab-on-chips comprise structures such as valves, pumps and channels which help in directing the flow of liquids in a particular manner which in turn determines the reaction.

The first of its kind lab-on-chip device was developed in 1996 by Caliper Lifesciences for drug discovery. The lab-on-chip device integrates several laboratory processes such as separation, heating, mixing, and detection to be combined on a single chip where they are carried out in micro channels built into a single chip. These micro channels are embedded in chips made of plastic, glass, or other materials. Thus, all essential processes from sample preparation, chemical reaction, analyte separation, analyte purification, analyte detection and data analysis can be performed on the same chip.

3.2 Lab-on-Chip, Market Segmentation

Figure 2: Market Segmentation of Lab-on-Chip Devices



Source: GlobalData, Articles and Publications from Pubmed, Nature, Genome Research, Micro Nano Tech Conference 2011, Publications by Stanford University, University of Minnesota, University of Washington, Primary Interviews with KOLs and Industry Participants

The two major applications of lab-on-chip devices are diagnostics and life sciences research. Lab-on-chip devices have come into focus in clinical and point of care diagnostics due to the relatively high speed, efficiency and sensitivity of the results which can be attained. Novel lab-on-chip devices are also touted to produce low cost solutions for diagnostics of infectious diseases in third world countries. With the growing cost of healthcare, more physicians are looking at point of care solutions for diagnosing patients without the need to send samples to the central laboratory. Similarly, many industrial and environmental diagnostic applications have emerged for lab-on-chips. The devices have also become central to life sciences research because of the potential for providing high throughput systems.

3.3 Lab-on-Chip Market, Technology Trends

3.3.1 Novel Fabrication Technologies and New Fabrication Materials

New fabrication technologies are aimed at making lab-on-chip devices easy and cheaper to manufacture in large quantities.

3.3.1.1 Polydimethylsiloxane (PDMS)

Manufacturers are now experimenting with cheaper materials such as polymers and plastic substrates, such as polyimide, polymethamethylacrylate (PMMA), poly (dimethylsiloxane) (PDMS), polyethylene, or polycarbonate, offer a wide range of physical and chemical material parameters for the applications of biofluidic chips to bring down the total costs. Traditionally, the cost of materials and manufacturing for lab-on-chip devices has been high. Glass and silicone were used earlier for fabrication

of lab-on-chip devices. Polydimethylsiloxane (PDMS) is a type of polymeric organosilicon compound commonly known as silicones. PDMS exhibits unusual rheological (flow) properties. PDMS acts as a viscoelastic at high temperatures or long flow times but acts as an elastic solid at low temperatures and short flow times. Due to these properties PDMS is used for stamping in the soft lithography procedure of fabrication of lab-on-chip devices. Silicon wafers are used to design microchannels in lab-on-chip devices. Liquid PDMS is poured over these wafers and left to harden. When removed, minute details are imprinted in the PDMS slab. To create waterproof channels, hydrophilic surface modification is conducted using RF Plasma techniques on a PDMS stamp. Surface bonds are disrupted to activate PDMS and a piece of glass wafer or a second PDMS slab is placed on top of the imprinted side. Once the bonds relax to their normal state, the glass is permanently sealed to the PDMS, thus creating a waterproof channel. Advantages of PDMS over other materials include:

- Simple and inexpensive fabrication process, which permits rapid prototyping.
- PDMS is optically transparent above y230 nm, making it compatible with a variety of optical detection and microscopy techniques.
- Nontoxic to cells and permeable to gases.
- Flexible and stable over a wide range of temperatures from 250 uC to +200 uC; a property not available in most materials.
- Thermoplastic nature allows for creation of leak-proof sealed systems.
- PDMS surfaces can be modified through absorption of proteins or via plasma processing to obtain specific surface characteristics. Cured PDMS substrates can then easily are bonded to another PDMS slab or glass wafer using a brief O_2 plasma treatment.

3.3.1.2 Soft Lithography or Multi-Layer Lithography

Earlier, principles of the microelectronics industry were used for fabrication which was precise but they were very expensive and inflexible. Soft lithography or multi-layer lithography (MSL) is employed for printing and molding organic material. The technology allows the construction of a three-dimensional (3D) network of channels and components. Each layer of soft elastomer can be imprinted with the desired structure and then bound together to form pumps, valves and channels which are integral to the chip. This helps the manufacturer control the structure of the channel surfaces at molecular level and makes it multi-functional. For instance, MSL is used by Fluidigm Corporation based in San Francisco for the manufacture of integrated fluidic circuits (IFCs).

3.3.1.3 Microfluidic Integrated Circuits

In most microfluidic devices external forces are required for the opening and closing of each individual valve to route fluid through the device during experiments. Each valve on a chip requires its own electromechanical push from an off-chip actuator or pump. This has made it difficult to shrink microfluidic systems to palm- or fingertip-sized diagnostic devices. This also makes the procedure cumbersome and time consuming. A new wave of research by universities and companies is emerging to do away with the external machinery of control for carrying out experiments. Much like the semiconductors of today, where the flow of electricity on computer chips occurs without external controls, researchers are aiming to develop microfluidic circuits to regulate flow of fluid automatically without support. The University of Michigan has developed such a microfluidic integrated circuit on paper which provides a cost effective and efficient way of building lab-on-chip systems. Using a water repellent paper such as parchment paper or wax paper, hydrophobic coatings can be burnt off using a laser in desired patterns creating hydrophilic channels in its place. This modified surface has a highly porous structure, which helps to trap and localize chemical and biological aqueous reagents for analysis. Silica microparticles can also be deposited selectively on patterned areas to allow diffusion from one end of a channel to the other end. The strips can be treated with colorimetric indicators which on exposure to a liquid sample can help in identification of the sample through unique patterns. A single strip can also be used for detecting multiple samples.

Fluidigm has also successfully developed Integrated Fluidic Circuits (IFC) on the basis of its MSL technology. Its trademark Nanoflex valves consist of a membrane that deflects under pressure to pinch off the flow of fluids in a microchannel. The valve is manufactured from two separate layers of elastomeric rubber bonded together to form channels and chambers in a rubber chip. When pressurized gas or liquid is applied to the channels in one layer of the chip, the rubber deflects at precisely the intersection of the channels in the bottom layer. This results in the creation of a valve in the bottom layer and effectively stops the flow of liquid in the deflected state. The company makes use of multiple valves in a single system to create multiple isolated chambers which can be used for analysis of multiple DNA or RNA molecules. Thus, by incorporating such features a single chip can be used for sample preparation, manipulation of live cells, perfusion of reagents, and analyte detection.

3.3.2 Novel Applications for Lab-on-Chip Devices

Advances in microfluidics technology provide a platform for the development of revolutionary products in a myriad of biomedical fields such as molecular biology procedures for enzymatic analysis, DNA analysis, and proteomics. Emerging application areas for lab-on-chips include clinical pathology, especially the immediate point-of-care diagnosis of diseases.

3.3.2.1 Cell Sorting

Holographic Optical Fractionation/Opto-fluidics

A new technique known as holographic optical tweezers has been developed by physicist David Grier of the University of Chicago. The technique is applied to fluid samples for the purpose of cell sorting. A laser beam is sent through a hologram which gets divided into myriad sub-beams. These sub-beams can be used for independently suspending and manipulating many tiny particles for transportation, mixing, or reacting. When applied to fluid samples containing biomolecules, it provides results similar to that obtained by gel electrophoresis. However, this method provides more flexibility by enabling the user to sort objects on the basis of different sizes ranging from 10-nm (e.g. viruses) up to the 100-µm scale by simply adjusting the computer generated hologram or the laser wavelength. Optical fractionation also gives the advantage of performing continuous cell sorting rather than batches and optimization of performance by varying the laser power, laser wavelength, and/or the geometry of the trap arrays. Thus, the same apparatus can sort samples on the basis of size, surface charge, dielectric constant, magnetic permeability, and shape. Chicago based Arryx, Inc. holds exclusive license to all techniques based on holographic optical tweezers. Arryx's BioRyx 2000 system, introduced in March 2002, enables researchers to manipulate hundreds of microscopic objects independently and simultaneously in three dimensions. Its new MatRyx, now in development, is a high-throughput cell sorter initially slated for use in the cattle industry to sort X and Y sperm for breeding.

Another variant of holographic optical tweezers is hybrid optoelectric manipulation developed at Purdue University, Indiana. The technology uses a red laser to position a droplet on a special platform. An infrared laser then heats the droplets, followed by electric fields that cause the heated liquid to circulate in a miniature vortex. This vortex acts like a centrifuge to isolate specific types of particles in the circulating liquid. Particle concentrations replicate the size, location and shape of the infrared laser pattern. The technology can have applications for micro- and nanomanufacturing and lab-on-a-chip sensors.

Dielectrophoresis

Dielectrophoresis can be used for manipulating and separates cells, beads or nanoparticles by means of non-homogeneous electric fields that can be produced with electrodes of specific shapes. The cells can be collected or directed away from the electrodes under the influence of the dielectrophoresis force. Thus, dielectrophoresis can be used for in-vitro separation of cells based on their conductivity characteristics. For instance, separation of white blood cells from erythrocytes can be automated using this approach. The technology can operate directly on native, unlabeled cells and eliminates the expense, labor and time of labeling and tagging, as well as the development and validation of such labels and tags. This can also be applied to the separation of human cancer cells from healthy tissue.

3.3.2.2 Personalized Medicine and Companion Diagnostics

Drug discovery and personalized medicine is witnessing a growing trend in the adoption of more lab-on-chip technology for speeding up the process of biomarkers and drug screening processes. Many pharmaceutical companies are also collaborating with lab-on-chip platform manufacturers to develop novel instrumentation for rapid screening processes. DxS, a diagnostics company, has had particular success in companion diagnostics by partnering with large pharmaceutical companies such as Roche, AstraZeneca and Amgen for their cancer therapies. In 2007, the company launched TheraScreen, a CE marked diagnostic test for determining gene mutations for lung cancer. The test is used for the selection of patients who can be successfully treated by tyrosine kinase inhibitors such as Roche/OSI Pharmaceutical's Tarceva, and AstraZeneca's Iressa. In 2008, the company teamed up with Amgen to develop a companion diagnostic kit for the prediction of responsive patients for Amgen's metastatic colorectal cancer therapy Vectibix. In 2009, GlaxoSmithKline (GSK) and Abbott announced an agreement to co-develop a companion diagnostic kit for GSK's investigational MAGE-A3 immunotherapy. In October 2008, Merck signed a two-year exclusive licensing agreement with Celera that gave Merck access to up to 10 cancer targets for the development of RNAi-based therapeutics. In return, Celera can develop companion diagnostics for any therapeutics that Merck develops out of the licensed targets. In 2007, Merck inked a research collaboration agreement with Asuragen to develop a gene-expression-based companion diagnostic for use in Merck's clinical trials for an investigational cancer treatment.

3.3.2.3 Diagnostics

Lab-on-chip diagnostics are revolutionizing the diagnostics industry by providing a faster, more accurate and efficient way of finding test results.

Clinical Diagnostics and Point of Care Diagnostics

Lab-on-chips or micro Total Analysis Systems (µTAS) facilitate near patient testing or Point of Care Testing (POCT), which can dramatically improve medical management outcomes by providing timely and accurate diagnostic results at the patient's bedside. POCT is rapidly gaining acceptance and is witnessing growing demand. Enhanced patient treatment decision benefits gained from immediate diagnostic findings in settings such as hospital emergency rooms and physicians' offices is driving the need for quick test results. Decentralized testing has also been seen as a means to reduce the burden of growing testing volumes on the central testing laboratories. The technological advances in manufacturing processes and materials for lab-on-chips have made integration of multiple assay steps such as

sampling, sample preparation, separation, mixing, dilution and detection on a single microfluidic system.

- Technologies such as using lyophilized dry reagents, which reconstitute upon contact with a liquid sample, help reduce the overall size of the microfluidic circuit.
- Improvements in manufacturing processes have helped create highly sophisticated lab-on-chips containing a number of sensitive reagents and substrates such as enzymes which denature easily during manufacturing processes.
- The miniaturization of electrochemical sensors into disposable formats and advances in immunological solid-phase technology have resulted in an explosion of qualitative and quantitative POCT systems for a wide range of analytes, including those used in clinical chemistry.

Veterinary Diagnostics

Veterinary lab-on-chip diagnostics are similar to rapid diagnostics for humans. For instance, Abaxis markets several diagnostic solutions such as VetScan VS2 (integrated clinical, immunoassay and blood gas analyzers), VetScan HM5 Hematology (automated 5-part differential cell counter), VetScan HM2 (automated 3-part differential cell counter), and VetScan i-STAT 1 (point of care diagnostics), VetScan VSpro (coagulation and specialty analyzer).

Industrial and Environmental Applications

Microfluidics-based lab-on-chip diagnostics devices for industrial and environment applications include environmental diagnostics, bio-threat diagnostics, agriculture and food diagnostics, and forensics. These diagnostics feature capabilities such as continuous sampling and real-time testing of air/water samples for biochemical toxins and other dangerous pathogens. They can thus serve as an always-on "bio-smoke alarm" for early warning. For instance, scientists at California-based Sandia National Laboratories are developing ChemLab, a portable, handheld chemical-analysis system for homeland security, defense, and environmental and medical applications. ChemLab will be capable of detecting chemical warfare agents and proteins as well as biotoxins such as ricin, staphylococcal enterotoxin B, and botulinum toxin. It can also identify viruses and bacteria using protein fingerprinting. Sandia expects to commercialize the system within the next two years.

3.3.2.4 Nucleic Acid and Protein Fractionation and Purification

Microfluidics or lab-on-chips can also be used for DNA and RNA separation, purification and analysis. Newer devices are integrating the principles of electrophoresis with that of microfluidics to create high throughput systems which can provide results for a large number of samples in a short period of time. For instance, capillary electrophoresis performs electroseparation of the ionic compounds, based on the size-to charge ratio of the ions, which are transported electrokinetically in the carrier liquid. Capillary electrophoresis is used for separating particulate substances like cells, amino acids, proteins, peptides, mitochondria, or bacteria. In microfluidic channels, the surface-to-volume increases significantly due to reduced dimensions, and electrophoresis force becomes more efficient due to the shortening of the distance. Caliper Lifesciences and Agilent Technologies have partnered to develop DNA based arrays and are currently the largest manufacturers of nucleic acid and protein fractionation and purification solutions. Other companies providing microfluidic solutions for protein applications include Biacore (acquired by GE Healthcare), which produces several systems that rely on fundamental flow cell–based fluidics principles to study protein interactions and BioTrove (acquired by Applied Biosciences) with the RapidFire system, an integrated mass spectrometry solution that uses a microfluidic device to clean and purify samples before analysis.

3.3.2.5 Cell and Tissue Based Assays

Lab-on-chip devices applications are also expanding to cell detection, cell cultivation and cell based assays. Cell detection can be performed using the principles of microfluidics using capillary electrophoresis, electroporation, cytometry or electrical impedance. The cells can be cultivated within aqueous microreactors inside the chips. With lab-on-chip devices one can measure accurately chemical stimuli on cells, as cellular signals are weak and not easily detected with conventional analytical methods. For instance, researchers at the University of Washington, Seattle have developed microfluidics-based systems for studying axon guidance and synaptogenesis behaviour for neurobiology studies. With such lab-on-chip systems, the researchers can simulate the microenvironment of cells and enable cell culture. Thus large amounts of data can be gathered about a single cell which can be used to develop a deeper understanding of cell biology.

3.4 Lab-on-Chip, Market Drivers

3.4.1 Advantages of Lab-on-Chip Devices to Drive Lab-on-Chip Market In the Future

Figure 3: Classification of Biochip Devices

Advantages	Description
Smaller Scale of Size	Since lab-on-chip devices require only a small amount (microlitres or nanolitres) of sample and reagent for each process as compared to 100 ml required by existing assays thus saving space and improving portability.
Higher Speed of Achieving Results	Reactions at microscale occur much faster due to short diffusion distances, fast heating, and high surface to volume ratios. – The results for some point of care diagnostic tests based on microfluidics can be achieved in as little as 30 minutes and does not require any sample preparation. Compared to this, traditional methods may provide results after 24-48 hours including time taken for collection of samples, sending samples to central laboratories, testing and analysis of results.
Automation	Microfluidics technologies are easily automated to do routine assay and sample preparation on standardized chips with little human intervention
Lower Cost	Cost can be reduced due to low fluid volumes consumption (lower reagents costs, less waste and smaller sample volumes for diagnostics). However, current devices are much costlier than routine tests.
Ease of Use	Some companies have focused on improving ease of use of lab-on-chip devices which can be used without any special training. – e.g. Daktari's sample preparation technology, known to specialists as microfluidic cell chromatography, isolates cells and other particles in a miniature sensing chamber, without pipetting, labels or reagents of any kind.
High Throughput	Multiplexing is one of the advantages allowing typical chips to perform 10 or more high-throughput sample analysis in 30 to 40 minutes
High Process Control	Better process control because of a faster response of the system (e.g. thermal control for exothermic chemical reactions)

Source: GlobalData, Articles and Publications from Pubmed, Nature, Genome Research, Micro Nano Tech Conference 2011, Publications by Stanford University, University of Minnesota, University of Washington,

The devices can offer numerous advantages over current or traditional systems in the life science industry, including improved performance, speed, reproducibility and throughput, reduced cost and reagents consumption, lower contamination and operator error, and more integrated analysis. These advantages are going to lead to a greater market adoption in the future. The lab-on-chip devices based on microfluidics technology have further improved the throughput of processes such as PCR to provide results in a matter of hours. It has also enabled running multiple tests simultaneously. For instance, Fluidigm's product BioMark 48.48 dynamic array, a microfluidic solution to perform quantitative real-time PCR, is capable of partitioning and combining reagents and samples into 2,304 reactions. Similarly, BioTrove's Open Array allows users 3,072 individual reactions to be run simultaneously.

3.4.2 Low Cost, Simple Diagnostics Devices to Fuel Demand of Lab-on-Chip Diagnostic Devices in Developing Countries

Research is also underway to reduce the power used for conducting tests using microfluidic principles especially for nucleic acid tests. Low power requirements and low cost of device enable its usage in remote areas which don't have access to electricity. To create low cost devices, researchers are looking at low cost materials that are easily available such as paper and cotton threads.

Paper microfluidics is gaining traction in many research laboratories to develop cheap diagnostics for third world countries. The University of Michigan has provided the proof of concept for integrated circuits based on principles of microfluidics using simple paper. George Whiteside from Harvard University and his research team are also working on developing paper based diagnostics tests. The research group was recently awarded a grant from the Gates Foundation for supporting their research work. A prototype blood test for determining the patient's group has also been developed. The on-the-spot dipstick test is made of paper which is impregnated with antibodies for different blood types. The blood test can be useful for performing instant tests for blood transfusions for road accident victims. The manufacturing cost of such test is estimated for be less than $1.

Diagnostics for All, a non-profit organization, has developed a simplistic paper-based microfluidic immunoassay test for use in emerging countries. Making use of microfluidics and the wicking nature of paper, the company has created a prototype for a viable, universally available, and cheap alternative for IVD testing. The tests make use of paper patterns channels and assay zones (or wells) of water-repellant materials into a piece of paper roughly the size of a postage stamp. Biological and chemical assay reagents are then deposited in the wells. When blood, urine, saliva, sweat or other biological samples are applied to the device, the paper wicks the sample through the channels to the assay zones, without external pumps or power. Upon contact, the assay zone quickly changes color and results are then easily read by comparing the color change with a reference scale printed on the device. After use, the device can be easily disposed of by burning. The device uses paper which is much cheaper than any other material, and can be easily read with minimal training. The company is currently developing a liver function test, which is critical for monitoring adverse side effects of drugs used for tuberculosis, HIV/AIDS and the management of viral hepatitis.

Daktari, another company dedicated to creating solutions for third world applications, is developing a portable and robust CD4 cell counting system which can be used anywhere. The purpose of the device is to provide quick diagnosis in third world countries where people cannot receive adequate treatment because of delayed diagnosis. Daktari uses microfluidic cell chromatography for sample preparation and helps isolate cells and other particles in a miniature sensing chamber, without pipetting, labels or reagents of any kind. The lack of complex manual steps which require sophisticated tools can enable diagnosis by lab clinicians.

3.5 Lab-on-Chip, Market Restraints

3.5.1 High Cost and Lack of Established Cost Efficiency in Central Lab Testing Set-up to Deter Growth of Lab-on-Chip Diagnostics Devices

Current technological innovations such as lab-on-chips, though showing promising results, are sometimes too expensive for mass adoption. For instance, several reasons including high cost components for lab-on-a-chip devices are responsible for making these devices costly. High cost components such as microvalves separate reagents until they are ready for processing within different stages of the testing sequence. Lab-on-a-chip may contain a variety of fluids such as reagents and catalysts which are stored in reservoirs and blocked by valves until testing with the sample is ready. The fluids must be released in a calculated amount because of the sensitivity of chemical reactions. The number of microvalves required for a test increases with its complexity, and consequently its price. Expensive reagents also drive up the costs for lab tests especially for the tests which depend on analysis of nucleic acids.

Most lab-on-chip devices require automated readers or analyzers for analyzing results. These readers can be prohibitively expensive. The table below shows a comparison of cost of leading analyzers used in the diagnostics industry.

Table 1: Cost of Point of Care Diagnostics Analyzers Based on Microfluidics

Product	Company	Cost ($)
ABI Prism 3100 Genetic Analyzer	ABI	300,000
Micralyne Microfluidic Tool Kit	Micralyne	100,000
Agilent 2100 Microfluidic Based Bioanalyzer	Agilent Technologies	12,000
i-STAT Analyzer	Abbott Laboratories	6,000

Source: GlobalData, Trade Journals, Company Press Releases

In developing countries even $6,000 may be unaffordable for government-run laboratories. For private laboratories, automating laboratories requires significant capital and intensive training of staff to make it work. While many laboratories are switching to automated systems in the face of limited supply of laboratory technicians, challenges of high cost remain for non adopters. The problem is especially acute in remote areas where although the number of samples processed may be high, the stand alone laboratories may not have sufficient revenue turnover to switch to automation. Moreover, automation requires moving the current technicians out of their comfort zone and training them on the systems. The existing automation systems are complex and have a significant learning curve associated with them.

Thus many cost related challenges currently deter widespread adoption of lab-on-chip technology.

3.5.2 Lack of Standards in the Industry Prolonging Commercialization of Novel Products

Currently, there are no common standards that are followed across the industry and academia for developing lab-on-chip devices. As a result, manufacturing lab-on-chips is extremely expensive and a cumbersome process. Component manufacturers often build components such as microvalves, pumps, electrodes etc on a custom basis and not on a mass basis. Researchers also repeatedly build the entire lab-on-chip systems from scratch which is time consuming to build and expensive. Thus, the long time needed to build the final product as well as a lack of economies of scale is expected to continue to hinder commercialization of products in the near future.

3.5.3 Lack of Trained Personnel for Diagnostics Laboratories

Across the globe, the lack of skilled labor is becoming a setback in running laboratories. Fewer newly trained professionals are entering the field due to poor wages even in developed countries such as the US and Australia, leading to a shortage of skilled people in the regions. Lab-on-chip devices are complex and sophisticated systems and need skilled clinicians familiar with the principles of the devices to run processes on these devices. For instance, most systems require external controls for manipulating the flow of liquids. Thus, the adoption of these devices may be slow.

3.5.4 Regulatory Changes and Increased Compliance Expected to Adversely Impact Small Laboratories and IVD Product Development Process

In the US, Medical Device Reporting (MDR) for IVD tests, traditionally considered low risk, has increased over the past couple of years. The MDR regulations require manufacturers who have received complaints of device malfunctions, serious injuries or deaths associated with medical devices to notify the Food and Drug Authority (FDA) of the incident. Moreover, the overhaul of the 510(k) process, required for manufacturers to market new medical devices, now requires IVD tests to conduct clinical outcome studies. Earlier, 510(k) for medical devices focused on performance studies demonstrating substantial equivalence studies with marketed devices, rather than outcome.

The FDA revised the guidance under which CLIA waivers were granted in 2008, making it more relevant for today's POC testing market. This may complicate the process of product development and approval in the short term as manufacturers adjust to the new changes. Under the revised guidelines, the FDA has placed a greater emphasis on intended users during device testing, stressing the importance of scientific validation associated with a device's risk assessment, and placing extra

emphasis on quality control procedures. Manufacturers will now have to prove that the test system is safe and effective to use and that the test system has an insignificant risk for producing erroneous results. For instance, for the device to be classified as 'simple,' a manufacturer must ensure that the instrument must be automated, use direct unprocessed samples, the specimen is independent of technique or reagent manipulation, the operator cannot intervene with the device during analysis, its operation requires no technical or specialized training, the results must be easy to read, and all labeling must be clearly understood. The manufacturer also must perform risk analysis to test fail-safe and failure-alert mechanisms and conduct valid scientific studies to demonstrate accuracy using labeling and educational materials written at no more than a seventh-grade level. Although this will not impact on the large manufacturers, small manufacturers will have to undertake extensive testing to prove its simplicity and "insignificant risk of an erroneous result". This is likely to drive up the cost of production for small manufacturers. However, in the long run, this is a positive step in the direction of standardization of criteria for POC testing.

In the European Union (EU), new environmental legislation, chemical safety regulations, the batteries directive, and recent updates of the packaging, low-voltage, EMC, and machinery directives are expected to make the new product approval process tougher. The software used for IVDs has also been put under review in the EU and may further add complexity to the product approval process.

These changes are likely to slow down the approval process for the new products, and may increase costs of product development for smaller companies.

3.6 Lab-on-Chip Market, Competitive Landscape

3.6.1 Global Lab-on-Chip Market: Diagnostics

Key companies that have currently commercialized or have developed lab-on-chip platforms for diagnostics are listed in the table below. Only a few companies have currently commercialized diagnostic lab-on-chip devices for end users such as Abaxis, Abott Point of Care and 3M-Focus Diagnostics. Other companies have however commercialized various platforms which can be used to develop specific tests. In terms of product sales, Abaxis and Abbott are the largest diagnostics lab-on-chips companies. The majority of diagnostics applications are in the clinical diagnostics and POCT field.

Table 2: List of Lab-on-Chip Companies, Diagnostics, 2011			
Name of Company	**Website**	**Segment**	**Description**
Abaxis	abaxis.com	Clinical Diagnostics and POCT	Point-of-care blood analyzers
Abbott Point of Care (i-STAT)	abbottpointofcare.com	Clinical Diagnostics and POCT	Point-of-care blood analyzers
Achira	achiralabs.com	Clinical Diagnostics and POCT	Lab-on-chip platform to perform rapid, quantitative and multiplexed immunoassays (protein tests) at a low cost
Adbic	adbic.jp	Clinical Diagnostics and POCT	Diagnostic chips for analysis of blood samples (e.g., detecting BUN, potassium, sodium, glucose levels)
Akonni Biosystems	akonni.com	Clinical Diagnostics and POCT	Develops, manufactures, and markets integrated molecular diagnostic systems such as TruDiagnosis System
Axis-Shield	axis-shield.com/Afinion	Clinical Diagnostics and POCT	Point of care testing on whole blood, plasma or urine samples
Becton Dickinson	bd.com	Clinical Diagnostics and POCT	Develops, manufactures and sells medical supplies, devices, laboratory instruments, antibodies, reagents and diagnostic products
Biodot	biodot.com	Clinical Diagnostics and POCT	Supplier of system tools for the research, development and commercialization of diagnostic tests
Biolithic	biolithic.com	Clinical Diagnostics and POCT	Point of care diagnostics initially focused on infectious disease
Biosite	biosite.com	Clinical Diagnostics and POCT	Rapid diagnostics products and antibody development technologies.
Biosurfit	biosurfit.com	Clinical Diagnostics and POCT	Blood diagnostics enabled by compact-disc format microfluidics, surface plasmon resonance, and an optical visualization sensor
Boston Microfluidics	bostonmicrofluidics.com	Clinical Diagnostics and POCT	Rapid, single use, self-contained sexually transmitted disease in vitro diagnostics
Claros Diagnostics	clarosdx.com	Clinical Diagnostics and POCT	Products to transition in-vitro medical diagnostic tests from the laboratory to the point-of-care, such as a physician's office, bedside, etc.
Daktari Diagnostics	daktaridx.com	Clinical Diagnostics and POCT	Microfluidic point of care diagnostics for global health, including a handheld CD4 counter
Debiotech	debiotech.com	Clinical Diagnostics and POCT	Diagnostic and therapeutic medical devices
Diagnostics for All	dfa.org	Clinical Diagnostics and POCT	Non-profit enterprise creating low-cost, point-of-care microfluidic diagnostics for the developing world
Diagnoswiss	diagnoswiss.com	Clinical Diagnostics and POCT	Automated ELISA
Epocal	epocal.com	Clinical Diagnostics and POCT	Development and commercialization of microfluidic blood analysis systems
Fluidmedix	fluimedix.com	Clinical Diagnostics and POCT	Point-of-care diagnostic system for near-patient DNA based testing
FocusDx	focusdx.com	Clinical Diagnostics and POCT	Infectious disease diagnostic testing services, products, and information
Helicos Bioscences	helicosbio.com	Genome Sequencing, Nucleic Acid and Protein Fractionation and Purification	Genetic analysis technologies for the research, drug discovery, and diagnostic markets
Kumetrix	kumetrix.com	Clinical Diagnostics and POCT	Blood diagnostics based on bioMEMS technology and a single-use disposable silicon microchip
LeukoDx	leukodx.com	Clinical Diagnostics and POCT	Point of care flow cytometry
MicroCHIPS	mchips.com	Pharmaceuticals Research and Drug Discovery	Intelligent implanted medical devices for applications such as glucose monitoring

Micronics	micronics.net	Clinical Diagnostics and POCT	Microfluidic, near-patient, in vitro diagnostic products for disease diagnosis, prognosis and treatment monitoring
Mode Diagnostics	modedx.com	Clinical Diagnostics and POCT	Diagnostics integrating biosensing and electronics for the home-based point-of-care markets
Molecular Vision	molecularvision.co.uk	Clinical Diagnostics and POCT	Diagnostic devices combine microfluidic chips with organic-semiconductor light-sources and photodetectors
Mycrolab	mycrolab.com	Clinical Diagnostics and POCT	Hand-held, point of care diagnostics using lab-on-a-chip consumables
Nanobiosym	nanobiosym.com	Clinical Diagnostics and POCT	Lab-on-a-chip diagnostics such as Gene-RADAR, a device resembling a mobile phone that has the ability to analyze biofluids such as a drop of blood or saliva and identifies DNA and RNA signatures
NanoEnTek	nanoentek.com	Clinical Diagnostics and POCT	Lab-on-a-chip technologies for life sciences research and diagnostics, including automatic cell counters, gene transfection electroporators, and point-of-care diagnostics
Nanomix	nano.com	Clinical Diagnostics and POCT	Lab-on-chip point of care diagnostics of multiple analytes on a single platform based on carbon nanotube technology.
Nanosphere	nanosphere.us	Clinical Diagnostics and POCT	Nanotechnology-based healthcare company that manufactures Verigene, a microfluidics product capable of analyzing DNA directly from a blood sample
On-Q-ity	on-q-ity.com	Clinical Diagnostics and POCT	Microfluidic cancer diagnostics
Pathogenetix	pathogenetix.com	Clinical Diagnostics and POCT	Commercial applications of single molecule DNA, RNA and protein analysis
Rheonix	rheonix.com	Clinical Diagnostics and POCT	Microfluidic solutions for automated molecular diagnostic assays
Samsung	samsung.com	Clinical Diagnostics and POCT	Microfluidic point-of-care diagnostics
Sensivida	sensividamedical.com	Clinical Diagnostics and POCT	Developing a digital allergy test and portable glucose monitor
Siloam Biosciences	siloambio.com	Clinical Diagnostics and POCT	Point-of-care clinical diagnostic systems using microfluidic and microsensor technology
Smart holograms	smartholograms.com	Clinical Diagnostics and POCT	Commercializing "sensor hologram" technology from the University of Cambridge to develop non-invasive and multi-analytic diagnostics
TearLab	tearlab.com	Clinical Diagnostics and POCT	Lab-on-a-chip diagnostics testing for disease markers in tears at the point-of-care
TECAN	tecan.com	All	Laboratory instruments for pharmaceuticals, forensics, and clinical diagnostics
Veridex	veridex.com	Clinical Diagnostics and POCT	Commercializing microfluidic circulating tumor cell diagnostics
3M collaboration with Quest Diagnostics and Futura Diagnostics	integratedcycler.com	Clinical Diagnostics and POCT	Microfluidic device such as Simplexa integrated cycler which can run a microfluidic PCR cycle and uses optical detection for Flu detection (H1N1 and seasonal flu)

Source: GlobalData, Company Websites, Investor Presentations, News Releases, Trade Journals, Blogs, PubMed and Other Scientific Publications
Note: The list of companies given above is not an exhaustive list of companies involved in lab-on-chip diagnostics

3.6.2 Global Lab-on-Chip Market: Life Sciences Research

Key companies that have currently commercialized or have developed lab-on-chip platforms for life sciences research are listed in the table below. Market leader in life sciences research is Caliper Lifesciences. The company pioneered lab-on-chip technology for research purposes. Most IVD companies currently manufacture or are involved in the development of lab-on-chip or biochip instrumentation for life science research purposes.

Table 3: List of Lab-on-Chip Life Sciences Research Companies

Name of Company	Website	Segment	Description
ACEA Bioscience	ACEAbio.com	Screening and Assay Development	Microelectronic systems for cell-based assays
Advalytics (Beckman Coulter)	advalytix.com	Screening and Assay Development	Product group of Beckman Coulter developing single-cell analysis platforms
Advanced Liquid Logic	liquid-logic.com	Screening and Assay Development, Genome Sequencing	Lab-on-a-chip microfluidic devices using electronic fluid control for immunoassays, PCR, clinical chemistry, sample preparation and more
Advanced Microlabs	advancedmicrolabs.com	Nucleic Acid and Protein Fractionation	Instrumentation for microchip capillary electrophoresis
Affymetrix	affymetrix.com	Genome Sequencing, Genotyping and Gene and Protein Expression Studies	Highly parallel genetic assays (DNA microarrays)
Agilent	chem.agilent.com	Nucleic Acid and Protein Fractionation and Purification	Commercial microfluidic Lab-on-a-Chip technology enabling sample handling, mixing, dilution, electrophoresis and chromatographic separation, staining and detection on single integrated systems
Applied Biosystems (BioTrove)	Appliedbiosystems.com	All	Lab-on-chip based technologies such as OpenArray Real-Time PCR System and TaqMan OpenArray Genotyping Plates.
Applied BioPhysics	biophysics.com	Pharmaceuticals Research and Drug Discovery	Tools for cell research and drug discovery
ArrayJet	arrayjet.co.uk	Genome Sequencing, Genotyping and Gene and Protein Expression Studies	Production of high quality microarrays with inkjet technology for life sciences R&D
Bellbrook Laboratories	bellbrooklabs.com	Screening and Assay Development	Drug discovery technologies for the pharmaceutical industry, including microfluidic cell culture systems and high throughput biochemical assays
Biocius	biocius.com	Pharmaceuticals Research and Drug Discovery	High-throughput screening for drug discovery
BiofluidiX	biofluidix.com	Genome Sequencing, Genotyping and Gene and Protein Expression Studies	Non-contact, nanoliter to microliter liquid handling devices mainly for life science applications, with a strong focus on micro arrays and well plate technology
BioForce Nanosciences	bioforcenano.coms	All	Develops and commercializes nanotech instruments, consumables, and applications for the life sciences
BioMicro Systems	biomicro.com	All	Biological research products based on microfluidic handling technologies
Bionas	bionas.de	All	Microfluidic systems for live cell analysis
Bioscale	bioscale.com	All	Ultra-sensitive biological measurements for protein research.
BioTray	biotray.fr	All	Microtechnology for Life Science & Chemistry Applications

Boehringer Ingelheim	boehringer-ingelheim.de	Clinical Diagnostics and POCT	Works with international diagnostics companies to develop microfluidic applications in fields such as hematology, microbiology, DNA assays, high-throughput screening, biochemistry and immunology
Caliper Life Sciences	caliperls.com	All	Microfluidics, lab automation and liquid handling, optical imaging technologies, and discovery and development outsourcing solutions
Cambridge Biomagnetics	cambridge-biomagnetics.com	All	Magnetic lab-on-a-chip devices combining microfluidic channels with advanced magnetic sensors
Capilix	capilix.com	All	Modular sensor solutions based on lab-on-glass-chip technology, with a focus on microchip capillary electrophoresis
CapitalBio Corporation	capitalbio.com	Clinical Diagnostics and POCT	Develops and commercializes biochip-related products for genomic, proteomic and cellomic research, bio-safety testing, and clinical applications
CEA Laboratory of Electronics and Information Technologies (LETI)	cea.fr	All	Nanobiotechnologies and biochips devoted to analyzing the genome; lab-on-a-chip devices for rapid, miniaturized in vitro diagnosis and microsystems used to analyze living cells and handle them individually
Cellasic	cellasic.com	All	Microfluidic platforms for cell and tissue based applications
Cellectricon	cellectricon.com	All	Real-time cell-based screening devices for applications in biotechnology, biomedical research and drug discovery
Cellix	cellixltd.com	Pharmaceuticals Research and Drug Discovery	Microfluidic drug screening tools
Celula	celula-inc.com	Screening and Assay Development	Instruments for clinical diagnostics and biomedical research using microfluidics and other technologies, including primary cell sorting via on-chip flow cytometry
Cepheid	cepheid.com	Clinical Diagnostics and POCT	Molecular diagnostics for genetic analysis in the clinical, industrial and biothreat markets
Cleveland Biosensors	clevelandbiosensors.com	All	Portable high-precision biosensor instrument
Cyclofluidic	cyclofluidic.co.uk	Pharmaceuticals Research and Drug Discovery	Integrated microfluidic platform combining both chemical synthesis and biological assay to rapidly deliver high quality molecules and data to feed the drug development pipeline
Cynvenio	cynvenio.com	Pharmaceuticals Research and Drug Discovery	Development and commercialization of high performance instruments and assays for the life sciences market (especially cancer, stem cells, and drug discovery)
Cytoo	cytoo.com	All	Chips for micropatterned cell culture
Deltadot	deltadot.com	Nucleic Acid and Protein Fractionation and Purification	Biomolecular separation instruments based around High Performance Capillary Electrophoresis (HPCE) and microfluidic separation systems
DEOS Labs	deoslabs.com	Clinical Diagnostics and POCT	Technology transfer, diagnostic kits (biochip) and electronic instruments
Digilab Global	digilabglobal.com	Genome Sequencing, Genotyping and Gene and Protein Expression Studies	Manufactures technologies for generating microarrays, picoliter droplet, live-cell and bio-compatible material printing instruments, hybridization systems, as well as imaging and analysis systems
DNA Electronics	dnae.co.uk	Genome Sequencing, Genotyping and Gene and Protein Expression Studies	Electronic microchip-based solutions for DNA analysis

Evotec	evotec.com	Pharmaceuticals Research and Drug Discovery	Discovery and development of novel small-molecule drugs
GE Healthcare (Biacore)	Gehealthcare.com	All	Develops systems to evaluate molecules in terms of specificity of interaction, kinetics and affinity.
Fluidigm (Qaigen)	fluidigm.com	Pharmaceuticals Research and Drug Discovery	Microfluidic systems based on integrated fluidic circuits (IFCs) for life science applications such as molecular diagnostics and personalized medicine
Fluigent	fluigent.com	Genome Sequencing, Genotyping and Gene and Protein Expression Studies	Tools for flow control in micro-channels and genetic testing in capillaries and chips
Fluxion Biosciences	fluxionbio.com	All	Live cell assays and automated patch clamp
FutureChemistry	futurechemistry.com	Screening and Assay Development	Develop, implement and sell microreactor hardware and procedures for optimising and screening chemical reactions and processes
GeneFluidics	genefluidics.com	Screening and Assay Development	Platform integrating bionano and microfluidic technologies for complex assays on samples such as whole blood, urine, saliva or water
GeneWave	genewave.com	Screening and Assay Development	Microarray instrumentation for diagnostic, clinical and life science research
GeSiM	gesim.de	All	Microsystems and instrumentation specializing in low-volume liquid handling for the life sciences
GnuBio	Mass High Tech Article	Genome Sequencing, Genotyping and Gene and Protein Expression Studies	Microfluidic gene sequencing
Gyros	gyros.com	Screening and Assay Development	Automated micro-immunoassays for therapeutic protein development
Habsel	habsel.com	Pharmaceuticals Research and Drug Discovery	Water-droplet-in-oil emulsion based microfluidics technology to develop ultra high throughput screening for antibodies/proteins/peptide agents against human pathogens
Ibidi	http://www.ibidi.com	All	Supplier for functional cell based assays and products for cellular microscopy
IBM Zurich Research Labs	zurich.ibm.com	Screening and Assay Development	Design, fabrication and use of simple microfluidic networks for the simultaneous delivery of functionally distinct molecules onto targeted regions of a surface.
Ingeneron	ingeneron.com	Screening and Assay Development	Development and commercialization of products for cell identification, separation, and delivery
IonTorrent (Life Technologies)	iontorrent.com	Genome Sequencing, Genotyping and Gene and Protein Expression Studies	DNA sequencing
Labcyte	labcyte.com	Screening and Assay Development	Assay miniaturization and automation, low-volume liquid handling for the life sciences
Micro2Gen	micro2gen.com	Genome Sequencing, Genotyping and Gene and Protein Expression Studies, Nucleic Acid and Protein Fractionation and Purification	Integrated micro system with modules for nucleic acid extraction, mixing steps, purification, PCR amplification, biochemical reactions, and DNA micro array detection in real time
Microchip Biotechnologies	microchipbiotech.com	All	Integrated systems enabling microsample preparation and analysis for the life sciences
Microfluidic Systems	microfluidicsystems.com	All	Automated instruments for the detection and processing of biological samples
Microlytic	microlytic.com	All	Consumable laboratory products for the structural biology marketplace
Micropointbio	micropointbio.com	All	Research, development, manufacturing, and marketing of the "Lab-On-Chip"products based on the MEMS (Micro-Electro-Mechanical System) technology

Micrux Technologies	micruxfluidic.com	All	Develops a variety of microfluidic devices, either standard or customized (e.g., microchips for capillary electrophoresis)
Millipore	millipore.com	All	Technologies, tools, and services for bioscience research and biopharmaceutical manufacturing
Molecular Cytomics	http://www.molecular-cytomics.com	All	Array platform enables scientists to perform live cell imaging and time lapse imaging of thousands of individual living cells
Nanion Technologies	nanion.de	Pharmaceuticals Research and Drug Discovery	Bio- and microtechnology for increasing the speed and efficiency of drug discovery, in particular High Throughput Screening systems for ion channel active drugs
Nanopoint Imaging	nanopointimaging.com	All	Microfluidics platform integrated with live cell imaging capabilities, used for applications such as assisted reproductive technology, drug discovery, cell culturing, and other life science research
NextAdvance	nextadvance.com	All	Laboratory instruments for life sciences research, also technical consulting for microfluidics and fluid mechanics, biotech instrumentation, and mechanical and electrical engineering design
QuantaLife	quantalife.com	Nucleic Acid and Protein Fractionation and Purification	Microdroplet-based digital PCR
Raindance Technologies	raindancetechnologies.com	Pharmaceuticals Research and Drug Discovery	Microdroplet-based solutions for human health and disease research
RheoSense	rheosense.com	Others	Fast, small-footprint microfluidic viscometers/rheometers
Roche Applied Science	roche-applied-science.com	Genome Sequencing, Genotyping and Gene and Protein Expression Studies, Nucleic Acid and Protein Fractionation and Purification, Others	Instruments and reagents for the life sciences research market, including genome sequencing, microarray analysis, nucleic acid purification, real-time PCR, and cell analysis
Scienion	scienion.de	Genome Sequencing, Genotyping and Gene and Protein Expression Studies, Nucleic Acid and Protein Fractionation and Purification, Others	Ultra-low volume liquid handling systems and microarray technologies for multiparallel bioanalytics, high throughput screening and high throughput production of microarrays in the genomics and proteomics fields
Seahorse Bioscience	seahorsebio.com	Pharmaceuticals Research and Drug Discovery	Analytical instruments, biomanufacturing systems and consumable labware products for biological research and drug discovery
Shimadzu Biotech	shimadzu-biotech.net	Pharmaceuticals Research and Drug Discovery	Technologies to aid the protein research work flow and drug discovery
Shrink Nanotechnologies	shrinknano.com	Industrial and Environmental Application, Other	Nanotechnology company developing products and licensing opportunities in the alternative energy industry, medical diagnostics and sensors and biotechnology research and development tools businesses
Siemens	siemens.com	All	Instrumentation for life sciences, medical diagnostics
Silicon Biosystems	siliconbiosystems.com	All	Lab-on-a-chip cell biology testing
Sphere Fluidics	spherefluidics.com	All	Commercializing lab-on-a-chip and picodroplet technology from Cambridge University high-throughput reactions on single cells and molecules contained within aqueous droplets; this platform enables diverse applications including: miniaturised profiling of diagnostics
SpinX Technologies	spinx-technologies.com	All	Programmable microfluidics platform, with applications ranging from drug discovery to consumer diagnostics
Stokes Bio	stokesbio.com	All	Microfluidics-based systems for genetic analysis, particularly for the measurement of gene expression

			and gene target detection. Applications include basic life science research and in the molecular diagnosis of cancers, pathogen detection and pharma-geno
Superior NanoBioSystems	superiornanobiosystems.com	All	Platform development to support medical and bio-defense initiatives, including handheld diagnostics, therapeutics, and cell capture
Xona Microfluidics	http://www.xonamicrofluidics.com/	Others	PDMS-based microfluidic platform for neuroscience research
YMC	keyboardchemistry.com	Others	Specializes in microreactors
Source: GlobalData			

4 Appendix

The data and analysis within this report is driven by Medical eTrack

Medical eTrack gives you key information to drive sales, investment and deal making activity in your business. It includes the following information:

- 14,000+ Market size data tables across 400 medical equipment segments and 37 countries with historic data from 2000 forecast to 2016
- 3,000+ Primary expert interviews conducted for ensuring data and report quality
- 1,000+ Conferences on medical equipment covered
- 1,000+ Industry leading reports covering growing sectors, market trends, investment opportunities and competitive landscape
- 450+ Analysis reports covering market and pipeline product analysis reports by indication, medical equipment trends and issue reports and investment and M&A trend reports worth over $3 Million
- 20,000+ Medical equipment companies profiled
- 1,500+ Private, emerging and technology start-up company profiles
- 1,000+ Medical equipment manufacturers in China and India
- 1,500+ Medical equipment companies in Japan
- 450+ Companies with revenue splits and market shares by category
- 500+ Quarterly and annual medical equipment company financials
- 400+ Medical equipment company SWOT's
- 7,000+ Pipeline product profiles
- 4,000+ Marketed product profiles
- 1,500+ Pipeline technologies
- 10,500+ Clinical trials
- 12,000+ Trial investigators
- 9,000+ New product patents
- 2,500+ Companies with products in development
- 12,000+ Deals in the medical equipment industry
- 1,100+ Surgical and diagnostic procedures by therapy area
- 40+ Key healthcare indicators by country

For more information or to receive a free demo of the service visit http://www.medicaletrack.com/contactus.aspx?RD=Demo

4.1 Research Methodology

GlobalData's dedicated Research and Analysis Teams consists of qualified professionals with experience in marketing, market research, consulting background in the medical devices industry and advanced statistical expertise.

GlobalData adheres to the Codes of Practice of the Market Research Society (www.mrs.org.uk) and the Society of Competitive Intelligence Professionals (www.scip.org).

All GlobalData databases are continuously updated and revised.

4.2 Secondary Research

The research process begins with exhaustive secondary research on internal and external sources being carried out to source qualitative and quantitative information relating to each market.

The secondary research sources that are typically referred to include, but are not limited to:

- Company websites, annual reports, financial reports, broker reports, investor presentations and SEC Filings;
- Industry trade journals, scientific journals and other technical literature;
- Internal and external proprietary databases;
- Relevant patent and regulatory databases;
- National government documents, statistical databases and market reports;
- Procedure registries; and
- News articles, press releases and web-casts specific to the companies operating in the market.

4.3 Primary Research

GlobalData conducts hundreds of primary interviews a year with industry participants and commentators in order to validate its data and analysis. A typical research interview fulfills the following functions:

- It provides first-hand information on the market size, market trends, growth trends, competitive landscape, future outlook etc;
- Helps in validating and strengthening the secondary research findings; and
- Further develops the Analysis Team's expertise and market understanding.

Primary research involves e-mail interactions, telephonic interviews as well as face-to-face interviews for each market, category, segment and sub-segment across geographies.

The participants who typically take part in such a process include, but are not limited to:

- Industry participants: CEOs, VPs, marketing/product managers, market intelligence managers and national sales managers;
- Hospital stores, laboratories, pharmacies, distributors and paramedics;
- Outside experts: Investment Bankers, Valuation Experts, Research Analysts specializing in specific medical equipment markets; and
- Key Opinion Leaders: Physicians and surgeons specializing in different therapeutic areas corresponding to different kinds of medical equipment.

4.4 Models

Where no hard data is available, GlobalData uses modeling and estimates in order to produce comprehensive data sets. The following rigorous methodology is adopted:

Available hard data is cross referenced with the following data types to produce estimates:

- Demographic data: Population, split by segment;
- Macro-economic Indicators: GDP, Inflation Rate etc;
- Healthcare Indicators: Health expenditure, physicians base, healthcare infrastructure and facilities; and
- Selected epidemiological and procedure statistics.

Data is then cross checked by the expert panel. All data and assumptions related to modeling are stored and are available to clients on request.

4.5 Forecasts

GlobalData uses proprietary forecast models. The following four factors are utilized in the forecast models:

- Historic growth rates;
- Macro indicators such as population trends and healthcare spending;
- Forecast epidemiological data; and
- Qualitative trend information and assumptions.

Data is then cross checked by the Expert Panel.

4.6 Expert Panels

GlobalData uses a panel of experts to cross verify its databases and forecasts.

GlobalData's expert panel comprises marketing managers, product specialists, international sales managers from medical device companies; academics from research universities, KOLs from hospitals, consultants from venture capital funds and distributors/suppliers of medical equipment and supplies etc.

Historic data and forecasts are relayed to GlobalData's Expert Panel for feedback and adjusted in accordance with their feedback.

Details of the make up of the expert panel can be viewed through GlobalData.com, and are available to clients on request.

4.7 GlobalData Consulting

We hope that the data and analysis in this brief will help you make informed and imaginative business decisions. If you have further requirements, GlobalData's consulting team may be able to help you. GlobalData offers Tailor made analytical and advisory services to drive your key strategic decisions. For more information about GlobalData's Consulting capabilities, please contact us directly at info@globaldata.com

4.8 Contact Us

If you have any queries about this report or would like further information, please contact at the below given telephone numbers or email address.

- North America: +1 646 395 5460
- Europe: +44 207 406 6653 (or) +44 1204 543 523
- Asia Pacific: +91 40 66166700
- Email: info@globaldata.com

4.9 Disclaimer

The facts of this report are believed to be correct at the time of publication but cannot be guaranteed. Please note that the findings, conclusions and recommendations that GlobalData delivers will be based on information gathered in good faith from both primary and secondary sources, whose accuracy we are not always in a position to guarantee. As such GlobalData can accept no liability whatever for actions taken based on any information that may subsequently prove to be incorrect.