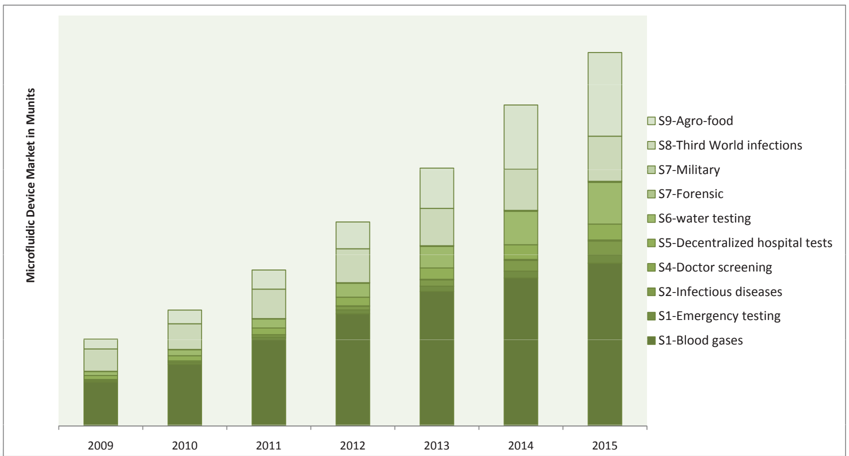
Point of Care Testing Applications of Microfluidics Technologies

Market and technology analysis of microfluidic devices and technologies for point of care diagnostics: Overview of the market drivers, key technical and economic requirements by application segment, advantages of microfluidic technologies...

MARKET OVERVIEW

Point-of-care diagnostics is a field just beginning to hit its stride, according to many in the industry. Advances in microfluidics, lab-on-a-chip methodologies, miniaturization of testing methods and improvements in detection technologies are leading the way. From bedside to battlefield, point-of-care diagnostics also represent one solution to helping solve a major healthcare challenge: how to do more with less.



Today, Point of care diagnostics represents 15% of the In-Vitro-Diagnostics market and has shown tremendous growth over the last 3 years. This market share is expected to exceed 30% by 2014. Key driver for growth will be bringing fast, low cost testing to high volumes of users at the point of care—but only if developers of the technology focus on the right application with real benefit to specific purchasers, and bring together disparate technologies into integrated systems for simple, accurate and low cost tests.

Point-of-care diagnostics has yet to develop into the big market many expected. Testing for infectious diseases and applications in agriculture and environmental screening now look like the most promising markets, as companies develop more sophisticated integrated systems that go beyond simple immunoassays to complex sample preparation and molecular diagnostics at reasonable cost. A focus on wellness testing also is expected to enhance the field. But don't expect point of care to surge overnight. Significant hurdles remain in the technology itself and its fusion into the healthcare system.

Overview of 40 new technologies and technologies in development, with information on:

- Commercial status
- Targeted application
- Technology description
- Sample volume
- Sensitivity level
- Target price

Company name	Picture	Technology Name	Status	Partner	Technology description	Cartridges Materials	Applications	Sample Volume	Sensitivity / accuracy	Analysis time	(Target) price per test
3M		Simplexa Integrated Cycler	commercialy available	Quest Diagnostics, Futura Diagnostics	Microfluidic PCR cycle + Optical detection	Polymer	Flu identification (H1N1, seasonal flu)	10 µl prepared sample	H1N1: 98,3 % Positive and negative agreement	30 to 75 min. Up to 96 samples per run	$50 per cartidge; Cycler $75 000
Abaxis		Piccolo® xpress	commercialy available		monitors the reagent reactions using nine wavelengths, calculates results from the absorbance data	Polymer disc	multi-chemistry blood analysis	100µl of whole blood, serum or plasma	Depend on test. Average 5U/L	12 min	analyser $24000 $13 to $20 per test
Abbott Point of Care		I-Stat	commercialy available		Single use disposable self contained cartridge to introduce in the handheld system	Polymer + Thin film elec	electrolytes and blood gases analyses	2 drops of whole blood	within the 95% confidence interval of conventional tests	2 to 10 min, depending on markers	$4 to $20 per cartridge
Accumetrics		VerifyNow® System	commercialy available		Light transmittance measurement	Polymer	antiplatelet drug patients, cardiovascular diseases	max 2 ml Whole blood, closed-tube samples require no preparation for analysis	Measurements correlate with optical aggregometry	less than 5 min	< $20
Akonni Biosystems		TruDiagnosis System	Only available for research applications today		sample preparation with PCR amplification and detection functions-Test one sample against multiple targets	Glass disposable chip	detection and analysis of both nucleic acid and protein molecular disease indicator - Target Infectious diseases market	Microarray chamber: 25 µl	Not available	15 min to 3 hours, depending on test	Not available

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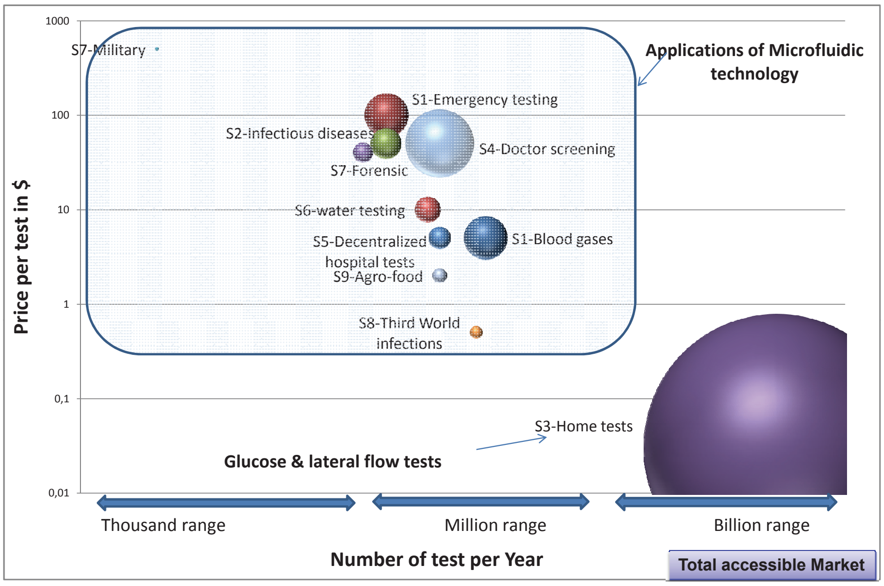
REPORTS HIGHLIGHTS



The first issue is finding the real markets, where a point of care solution really matters enough to some purchaser to drive demand. Obvious as this sounds it has actually proved quite difficult to find the right mix of need, volume and cost to break into the complex established medical infrastructure.

The compelling advantage of true point-of-care diagnostics is of course fast results, right where they're needed, where getting test results in minutes in an emergency can enable immediate critical treatment. There are, however, only a handful of these critical applications, and most turn out not to be huge markets, typically generating demand of under 500,000 units year. Other applications haven't gotten much traction, however, as it is not so clear just how much speed is worth, and just who most benefits. The medical benefit to the patient of a getting a diagnosis in minutes instead of days may be marginal. The operational benefits to the system of increased efficiency and reduced costs may be huge but they are likely to be too diffuse to have a clear champion.

This report provides a segmentation of the Point of Care market and a deep analysis of the different applications for microfluidic technologies. By application, we describe the different requirements such as target price, sample volume, sensitivity…

Over 40 new technologies and technologies in development are reviewed, considering the commercial status, the targeted applications and the addressable segments, the sample volume, the sensitivity level and the target price.

Finally the report addresses the challenges related to the cost and supply chain. Semiconductor and MEMS companies are expert at integrating sophisticated systems on silicon for high volume manufacture at low cost, but the diagnostics market demand simpler systems in volumes notably far below usual silicon MEMS production volumes. Silicon has to compete with low cost glass and polymer at common microfluidics feature sizes.

We explain why disposable microfluidic devices will need production costs under $5, for volumes ranging from 100,000- 1 million units per year, in order to sell commercial tests for $50-$100 including reagents, marketing and distribution. This value chain analysis is illustrated as well by a cost simulation of commercially available microfluidic device.

COMPANIES CITED IN THE REPORT

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BIO

Frédéric Breussin is expert in Microfluidics for diagnostics and life sciences. He has supported many companies in their innovation and product development strategy in making the bridge between micro systems technologies and their applications in Life sciences, diagnostics and medical device industries. He holds an Engineering diploma from INSA Rouen and a DEA in fluid mechanics from University of Rouen.

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KEYWORDS

Point of care applications, market size, market growth, microfluidic devices, sample volume, sample preparation, test sensitivity, test price, value chain, supply chain, key players, existing technologies, POC challenges

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