



Enter the Portable DNA Device

A spin-off company resulting from a National Science Foundation EPSCoR grant is positioning itself to revolutionize DNA testing procedures for human identification, medical diagnostics and pathogen detection.

A multibillion dollar business, DNA testing is currently conducted at centralized labs by highly skilled workers. The analyses take anywhere from eight to 20 hours to process a single sample. The turnaround time to receive the results can be two to three days. And currently, there is no compact device for point-of-use DNA testing for paternity and forensics.

BioFluidica Microtechnologies plans to change all that via the introduction of a low-cost, portable device for point-of-use deployment. DNA testing results using this instrument will be attainable in less than 30 minutes.

"Our compact integrated system, about the size of a shoebox, will provide the same capability as that of existing large-scale instruments used for DNA testing. The heart of the system consists of a small plastic chip—like the computer processor chip that is the heart of all computers—except the plastic chip processes liquids instead of electrons," says Yohannes Desta, President and CEO of BioFluidica.

"All processes normally done in the lab for a particular analysis are integrated on that single chip, which has microfluidic channels about the diameter of a human hair. The small size translates into a lower volume of expensive chemicals needed for the process, along with increased rates of heat transfer, diffusion and mixing that result in tremendous reductions in processing time.



BioFluidica Microtechnologies Principals, from left, Yohannes Desta, Mateusz Hupert, Wieslaw Stryjewski, Donald Patterson, David Claypool, Steven Soper. LSU Photo.

Biofluidica will be producing a DNA extraction and purification device based on unique technology developed at the Center for BioModular Multi-Scale Systems, a major interdisciplinary research center funded through Louisiana NSF EPSCoR from 2004-2007.

"Our point-of-use instrument, which is easy to operate and transport, will be especially helpful for speedy crime scene forensics work or to quickly detect pathogens in food and water, which is important to contain supplies that have been contaminated. Paternity testing and medical diagnostics could also be conducted in the privacy of a doctor's office, as opposed to a large centralized laboratory, again, reducing testing time and cost."

It gets better. Dr. Desta predicts that the convenience of use and lower cost of the BioFluidica system will promote earlier detection and more frequent monitoring of diseases that could translate into better survival rates. Additionally, the system could make sophisticated DNA testing available to remote areas without access to costly high-end medical diagnostic equipment requiring operator expertise.

According to David Claypool, BioFluidica's Chairman and CFO, the instrument's chip fabrication has yet another competitive asset. "Using plastic, rather than silicon or glass, results in very low manufacturing costs and the chips are disposable, thus avoiding cross contamination between different samples."

A Compelling Market

BioFluidica is focusing its first product/market development effort on human identification, a point-of-use market that he says is virtually untapped, with growing opportunities for rapid product development and market penetration, says Mr. Claypool.

"Rapid advancement in the use of DNA testing has resulted in enormous opportunities," he notes. "In 2005, the global human identity testing and DNA-based medical diagnostics markets were estimated to be \$1.4 billion and \$5.5 billion, respectively. By 2010, the human identity market is expected to reach \$2.2 billion and medical diagnostics, to double.

"The U.S. paternity testing market is estimated to be approximately one million tests per year plus another 200,000 for the confidential home testing market." If capable of being performed in the privacy

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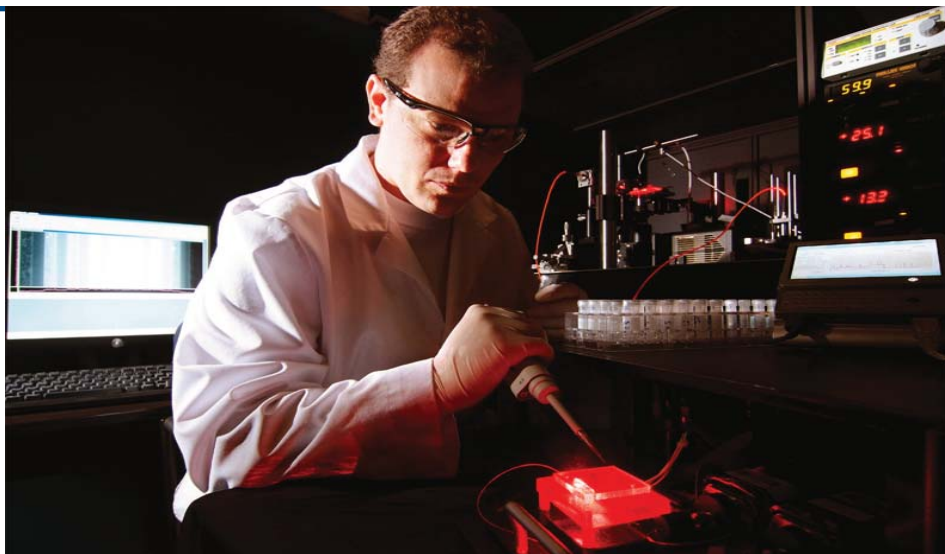
of a doctor's office in a relatively short period of time, he estimates that the market would rapidly increase by 40 per cent. DNA-based pathogen detection for food and water safety and biosecurity is considered small in comparison, but projected to grow with improvements in testing methods and instrumentation.

A complete prototype of BioFluidica's first integrated portable device for human identity point-of-use deployment is scheduled for 2010. In the meantime, to help establish its capabilities in the marketplace, the company is currently commercializing single step instruments in the DNA testing process that they hope can be moved into the marketplace soon.

In the meantime, Biofluidica will be producing a 96-well DNA extraction and purification device based on unique technology developed at the Center for Bio-Modular Multi-Scale Systems (CBM²), a major interdisciplinary research center funded through Louisiana NSF EPSCoR from 2004-2007. The device is expected to significantly reduce the cost and simplify the process of purifying DNA before it is tested.

"A 'proof of concept' of the system has been established and an alpha prototype, the first prototype model that functions like the manufactured product, is currently being developed at BioFluidica. We hope to have it ready in the first quarter of 2009," says Mr. Claypool.

The next priority will most likely be medical diagnostics, followed by pathogen



BioFluidica's technology integrates DNA testing processes normally done in a lab onto a single microchip. Photo by Don Kadair.

detection for food and water safety and biosecurity. These markets are expanding rapidly for a number of reasons, including the need for rapid and low-cost testing capabilities.

In the Beginning

Biofluidica Microtechnologies is a spin-off from CBM², which is housed at LSU's South Campus and composed of a multi-institutional, interdisciplinary research team with expertise in microsystems, engineering, materials, chemistry and biological systems.

Besides LSU, CBM² collaborating institutions are: LSU Center for Advanced Microstructures and Devices (CAMD), LSU Health Science in New Orleans, Tulane University Health Sciences Center, and Xavier University. External partners

include researchers at Cornell Medical College, Memorial Sloan-Kettering Center Research Center, and Baylor College of Medicine.

Many of the BioFluidica participants are, or have been, employed by CBM² or CAMD. Besides Dr. Desta and Mr. Claypool, they include: Dr. Steven Soper, Chief Technology Officer; Dr. Wieslaw Stryjewski, Director, Engineering; Dr. Mateusz Hupert, Director, Microtechnologies; and Dr. Donald Patterson, Chief Electrical Engineer.

"We are learning a lot more about DNA and what it can tell us, especially in disease detection," adds Mr. Claypool. "By having that information in a timelier basis and at a lower cost, we can discover its full benefits."