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HandyLab is developing nano-based diagnostics tool with wide-ranging applications

By Rosemary Clandos

HandyLab, Inc. is developing ways to move nanoliters of liquids in devices that will make diagnosing some diseases as easy as taking a pregnancy test or testing blood sugar.

The trend for developing in-home and point-of-care diagnostic products is fueling HandyLab's determination to advance in the race to move nanofluids in DNA analysis devices. The nanofluids are a combination of cells, DNA, reagents, and other components. And as technology becomes smaller, the need for effective ways to move nanoliters will become more important.

Sanjeeb Das, business development associate of the Ann Arbor, MI-based company, says HandyLab's technology could be a convenience in the U.S. and an essential diagnostic tool in developing countries.

"In the third world, testing is done in masses, and announcements are made by the government, usually weeks later. It's unlikely that all the patients return," Das says. "We want to drive down testing times and costs." Patients could receive test results within minutes and treatment programs could begin immediately.

The company is working on a real-time device in preclinical studies that can identify Group B strep, a bacterial pathogen that causes life threatening infections in pregnant women. In the future, a disposable device for women's gynecological health could contain approximately six pathogens. And for other applications, it could tote up to 25 pathogens. The device also could be used to test for gonorrhea and chlamydia, hepatitis C, tuberculosis, HIV and other diseases prevalent in developing countries.

A raw biological sample is gathered by a collection tool and injected into the cartridge of the device, which is placed in a portable docking unit. The sample preparation and testing steps are done in the cartridge. After 30 minutes, the test results can be read on the device's screen, stored, or transmitted to a central database.

To develop the portable device, researchers at HandyLab had to address the problem of nanofluid movement. At the nano and micron level, fluids require tremendous force to move them.

Plastic channels with hydrophobic and hydrophilic patches help to move the liquid. The repelling and attracting action of the patches jostles the liquid through the channels of the device.

To allow fluid to move from one chamber to the next, and open and close the micron-sized gates, wax valves are heated and cooled. The maximum temperature goes up to approximately 102°F and does not affect the DNA sample material. Also, the wax is not effected by atmospheric temperature changes, says Das.

"It's a closed system and we have unique ways of controlling temperatures in localized regions on the microchip -- between 5 and 200 microns," says Das.

The core technology also has applications in pharmacogenetics, where drug treatments are tailored to an individual's genetic requirements, and in proteomics.

HandyLab holds U.S. patent No. 6,575,188 for the technology.¹ They have three exclusive licenses from the University of Michigan for the microfluidic technology, which was developed by Sundaresh Brahmasandra and Kalyan Handique, former doctoral students at that university, and co-founders of HandyLabs.

The tissue-box sized technology would replace diagnostic systems that are the size of a small desktop and cost up to \$60,000. Das says the disposable portion of the device would cost between \$25 and \$100, and the permanent unit would cost between \$500 and \$2,000. "We believe prices for the permanent unit will go down substantially so that it will be affordable for consumers in their homes," says Das.

While those numbers may look good one day to potential buyers, investors are looking harder now at other numbers.

"There's a trend of tight fistiness," says Das. "They are wanting more milestones and results. They've always wanted the wow factor, but now they want to go beyond that. They all have their own hurdle rates. We want investors to see we're in it for the long haul."

Funded by EDF Ventures, Ardesta, SBV Partners, Hewlett-Packard and XR Ventures, HandyLab has also received \$400,000 from the National Institutes of Health. In July, the company was awarded a \$2 million grant from the National Institute of Standards and Technology's Advanced Technology Program to develop a DNA analysis device using electrochemical detection.

HandyLab is in the process of developing a partnership and is looking for other strategic partners.

"It's one way to reduce the level of risk for our investors," says Das. It may also move the nanofluidic technology into the U.S. marketplace and developing countries a lot faster.

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