

**Raymond D. Aller, MD, and Hal Weiner**

### **Microchip at core of Silicon BioDevices' prototype product to test for troponin**

At Silicon BioDevices, concepts for microchip-based products are entering the research-and-development pipeline at a rapid pace. The first product to exit? A point-of-care testing device, roughly the size of a thumb drive, for measuring cardiac troponin.

The aptly named Lab-in-Your-Hand, a prototype developed by the Berkeley, Calif.-based company, is a single-use handheld blood analyzer that can measure the concentration of cardiac troponin in a single drop of whole blood within 15 minutes. A filter in the device blocks red blood cells, delivering plasma to a microchip for analysis. An array of sensors on the surface of the chip, potentially numbering up to 100,000, count the molecules of troponin, one at a time. Next to the sensors is a microprocessor that sends the information to an integrated display.

Although the initial applications will be single-analyte assays, says Octavian Florescu, PhD, founder and president of Silicon BioDevices, the chip ultimately will have the ability to target as many as 10 markers simultaneously.

A number of innovations distinguish Lab-in-Your-Hand from other POC testing devices, such as strip tests, continues Dr. Florescu. "The filtration protocol is relatively aggressive and new, in that you can take just one drop of blood for processing and apply it to the device and run it," he says. The chip also integrates all analytical functions, which eliminates the need for an external reader and could keep the cost of manufacturing the device to an estimated \$2 per unit, depending on the volume produced. Finally, Dr. Florescu points out, the ability to count single molecules is a "leapfrog technology; standard diagnostic tests do not perform single-molecule counting."

Beyond the microprocessor, "we can also include all the other standard features of digital microchips, such as a wireless radio, so we can transmit the information," says Dr. Florescu. "The nice thing about having a digital microchip at the core is that you can build in all the usability features that you have with an iPhone or iPad. You could deactivate it if it's improperly used, [and] it could display messages that give information about how to run it."

The idea for the device grew from Dr. Florescu's research doctorate thesis at Berkeley and his experience designing microchips for cell phones. "The microchip is absolutely primed right now to transform the point-of-care diagnostics industry," he insists. Not that investors always saw it that way: "There's a lot of distrust of new technology and skepticism about new devices, specifically point-of-care devices, so that's been difficult."

Silicon BioDevices will continue developing Lab-in-Your-Hand for about 18 months before submitting its data for FDA review, a process that Dr. Florescu anticipates will take an additional 18 months.

The company is initially focusing on testing for troponin, Dr. Florescu says, because "it is a billion dollar market worldwide, and it demonstrates the potential of our platform technology. Our development pipeline is brimming with ideas, but we can't explore those by ourselves until we put a first product on the market."

While the first target market for Lab-in-Your-Hand will be hospital emergency rooms, company CEO Gary Stroy points out that a POC test for troponin could be useful in a variety of care settings. "People who are suspected of having a heart attack could be tested in an ambulance," he notes. "Another possibility is pharmacies like Walgreens and CVS that are open 24/7; those are rapidly becoming care sites. A troponin test could be done there and instantly transmitted to a local hospital that can treat AMI." Self-testing at home—say, by a patient known to be at high risk for a heart attack—is also conceivable, but the regulatory hurdles are much higher for home-based tests, Stroy adds.

And what comes after troponin? Most likely a multiplex test for troponin and brain natriuretic peptide, Dr. Florescu says. “We’re also looking at quantitative whole blood hCG in hospitals to quickly determine if a woman is pregnant. Thyroid-stimulating hormone is another good application for physician office labs looking to screen for the 20 to 30 million patients with thyroid disorders who are undiagnosed.” Other applications could include drug monitoring of targeted therapies. “We think the paradigm of taking a drug based on body weight has run its course, and the next-generation drugs will be tailored to your natural response,” Dr. Florescu explains.

The only markers that Lab-in-Your-Hand is not equipped to measure, he says, are those “that need a lot of sample pretreatment, those that are present at extremely low concentrations in the blood, and cells.”

## **FDA releases guide on wireless medical devices**

The Food and Drug Administration recently published a guide for the use of wireless medical devices in the health care setting to promote the safe and optimal use of such devices.

The document, “Radio Frequency Wireless Technology in Medical Devices—Guidance for Industry and Food and Drug Administration Staff,” contains recommendations for a broad assortment of radio-frequency devices, including “those that are implanted, worn on the body, or other external wireless medical devices intended for use in hospitals, homes, clinics, clinical laboratories and blood establishments.” These include wireless induction-based devices and radiated radio-frequency technology device systems.

The guide is intended for health care providers and the marketers of such devices. It breaks down the various aspects of what to consider when designing, testing, and using wireless medical devices, as well as how to handle premarket submissions for devices that incorporate radio-frequency wireless technology.

The document also offers a glossary of terms pertaining to wireless medical devices and systems and a list of standards, documents, and organizations that address electromagnetic capability and telecommunications.

The guide is available on the FDA Web site at [www.fda.gov](http://www.fda.gov).

## **Ventana and EMC partner on digital pathology endeavor**

Ventana Medical Systems has entered into an agreement with EMC Corp. under which EMC will offer a line of products to store and archive medical images as part of the Ventana digital pathology solution for anatomic pathology labs.

“By embedding EMC’s industry-leading VNX unified storage and information-management products within the Ventana Virtuoso software, Ventana ... is providing their customers with a more advanced, scalable, and integrated digital imaging solution,” says Tony Wood, general manager of OEM solutions for EMC.

EMC is providing Ventana, a member of the Roche Group, with the EMC VNXe unified storage platform, EMC Unisphere unified storage-management system, and EMC DiskXtender solution for strategic placement and retrieval of images. The products allow Ventana’s Virtuoso Web-based image- and workflow-management software to support data-storage capacities of up to 43 terabytes.

[Ventana Medical Systems](http://www.ventanamedicalsystems.com), 520-887-2155

[EMC Corp.](http://www.emc.com), 630-505-3273

## **HIMSS launches Web site focused on health IT value**

The Healthcare Information and Management Systems Society has released the HIMSS Health IT Value Suite, a Web-based collection of quantitative and qualitative data designed to help health care providers, lawmakers, and others research the value of health information technology.

The suite is intended to be a comprehensive knowledge repository that offers a common vocabulary to classify, quantify, and discuss real-world examples of health IT value.

Using user input in the form of narratives about how health care organizations have realized the value of health IT, the Web site is developing a library of patient care-focused data. The suite offers answers to such questions as: How does health IT improve patient care? How do we know health IT works? Can others achieve the same type or degree of value?

As the library grows, HIMSS plans to aggregate and analyze the data for patterns of success.

The value suite is available on the HIMSS Web site at [www.himss.org](http://www.himss.org).

## **Pathologist group joins Xifin's digital pathology network**

Xifin, which recently purchased PathCentral, has reported that Affiliated Pathologists Medical Group will participate in Xifin Pro.net, formerly the PathCentral Professional Network, an online information exchange and digital consultation forum.

Affiliated Pathologists has service locations in California, Arizona, and Oregon.

[Xifin](#), 858-793-5700

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