THE PROGRAMMABLE BIO NANO CHIP: A GAME CHANGER IN DIAGNOSTIC MEDICINE?

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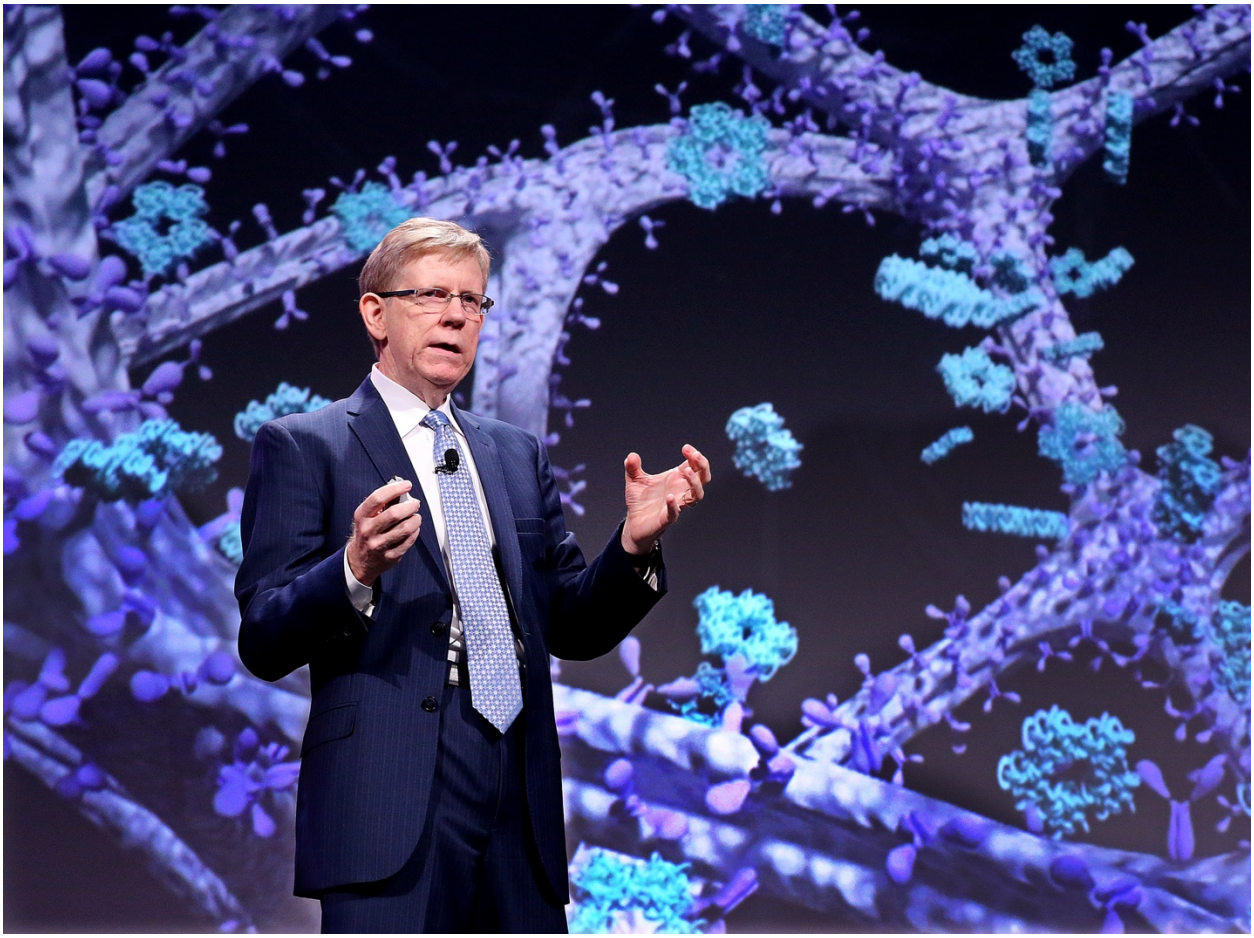

Is there a revolution afoot in diagnostic medicine? Could a credit card-sized, disposable cartridge and a toaster-sized analyzer use artificial intelligence (AI) to digitize biology—detecting and diagnosing sickness instantly even before the patient was aware of it? That is the promise from p-BNC, the programmable bio-nano-chip, unveiled in Sunday's opening plenary presentation by John T. McDevitt, PhD, this year's AACC Wallace H. Coulter Lectureship Award recipient.

McDevitt explained that while a digital revolution is taking place everywhere in exponential fashion, medical diagnosis has remained more linear, depending on a handful of disease-

specific biomarkers. Personalized medicine is only making very slow progress. Of more than 157,000 new biomarker publications described in medical literature during the last decade, only about one protein biomarker was approved by the U.S. Food and Drug Administration (FDA) each year. McDevitt believes that p-BNC technology can change that. His vision foresees the use of AI and digitized biology to map personalized wellness signatures—a deviation from this signature not only detects disease, but diagnoses as well, initiating the era of what he terms exponential medicine.

Such exponential change may be possible from McDevitt's invention, the p-BNC, where multiple porous beads—each of which generates a 3-D fluorescent image for a specific biomarker analysis—create the digital biological image of the patient from specimens like oral fluid. The system is highly flexible. It can be applied for non-invasive analysis in any patient setting, for personalized medicine or new biomarker discovery, and for many kinds of patient samples—oral fluid, a drop of blood, urine, etc.

Each p-BNC cartridge has etched wells containing one bead per well. The beads, coated with antibody or antigen, serve as immobilized capture reagents. The patient sample is applied to the sample well and is taken up into the cartridge passively. Liquid buffers within the blisters in the cartridge draw fluid through reagent pads which contain stabilized reagents (including the fluorescent labels) in the solid-state form and are reconstituted during the assay. After applying the sample, the cartridge is inserted in the analyzer, which uses pressure to break the blisters and start immunoreaction. The analyzer takes high definition fluorescence images of the beads, which are then compared with calibrator and control beads by image analysis, providing quantitative result for the analytes. By varying the biomarker-specific beads the chips are differently "programmed."

The p-BNC comes in a membrane version as well. These chips have a supported polymer membrane instead of beads and can be used to analyze various types of particles. Again, versatility is the key principle—they can be used for cell counting (think flow cytometer on a chip), cytology (high-content, single cell analysis), and cell analysis for environmental applications.

The utility of p-BNC technology combined with clinical decision support systems (CDSS) has already been demonstrated in establishing a "cardiac score-card" that combines results from 14 biomarkers and other cardiovascular risk factor data into a clinical decision support tool; in diagnosis of prostate, ovarian, and oral cancers; and in detecting multiple drugs of abuse by a single analysis of oral fluid. Combining multiple such "score-cards," each person could have easily understandable and interpretable personalized wellness data, accessible to themselves and their care-givers through smartphones or any medium they choose.

According to McDevitt, the combination of the versatile p-BNC technology and CDSS together may be able to finally personalize medicine simply and economically. We certainly shall watch for the fulfillment of that promise.