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PROGRAMMABLE BIO NANO CHIP SYSTEM - A REVIEW

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ABSTRACT

Is there a revolution afoot in diagnostic medicine? Could a credit card-sized, disposable cartridge and a toaster-sized analyser 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. The Programmable Bio-Nano-Chip System, p-BNC, currently under development, is a credit card sized disposable device that works in conjunction with a toaster sized imaging platform that analyses biomarkers found in bodily fluids and relays complex test results to consumers through an intuitive smart phone interface. The evolving approach is currently being validated by six major clinical trials in the areas of cardiac heart disease, oral cancer, prostate cancer, ovarian cancer and drug of abuse testing. The technology has the potential to diagnose in minutes what previously took labs, hours or days. Each p-BNC cartridge has etched wells containing one bead per well. The beads, coated with antibody or antigen, serve as immobilized capture reagents. 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.

KEYWORDS: p-BNC, CDSS, score card.

INTRODUCTION

The programmable bio nano chip system (p-BNC) currently under development is a credit card sized disposable device that works in conjunction with a toaster sized imaging platform that analyses biomarkers as found in bodily fluids and the relays complex test result to consumers through a intuitive smartphone interface the evolving approach is currently being in areas on cardiac diseases, oral cancer, prostate cancer, Ovarian cancer and drug abuse testing. The technology has the potential to diagnose in minutes what previously took lab, hours or days.[1]

In diagnosis, lab-on-a chip (LOC) devices has many advantages over standard laboratory methods including faster analysis, reduced cost, lower power consumption and higher levels of integration and automation.

ULTRA-FLEXIBLE PLATFORM FOR BIOSCIENCE

The programmable bio nano chip is a platform to digitalise biology in which small quantities of patient sample generate immunofluorescence signal on agarose bead sensors that is optically extracted and converted to antigen concentration. The platform comprises disposable microfluidic cartridges, a portable analysis, automatic data analysing software and intuitive mobile health interfaces.[2]

The single use cartridges are fully integrated, self contained micro fluidic device containing aqueous buffers conveniently embedded for point of care use. A novel fluid delivery method was developed to provide accurate and repeatable flow rates via actuation of the cartridge's blister packs. A portable analyser instrument was designed to integrate fluid delivery, Optical detection, image analysis and user interface representing a universal system for acquiring, processing and managing clinical data while overcoming many of the challenges facing the wide spread clinical adoption of lab-on-a chip (LOC) technologies.

The programmable bio nano chip flexibility is demonstrated through the completion of multiplex assays within the single use disposable cartridges for 3 clinical applications – prostate cancer, ovarian cancer, acute myocardial infarction.

RELEVANCE OF p-BNC

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 157000 new biomarker publications described in medical literature during the last decade , only about one protein biomarker was approved by the US Food and Drug Administration(FDA) each year. Programmed bio nano chip could change that and could create an era of exponential medicine. Such exponential change may be possible by 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 fluids.[5]

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.

METHOD OF p-BNC ANALYSIS

Each p-BNC cartridge has cartridge has cartridges 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 reagent(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 analyser, which uses pressure to break the blisters and start immunoreaction. The analyser 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 analysis. By varying the biomarker specific beads, the chips are differently programmed.[5]

a) Programmable bio nano chip analyser **b) Disease specific p-BNC catridges**

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 analyse various types of particles. Again versatility in 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 application.

CONVERGENCE OF BIO NANO INFO TECHNOLOGIES

Today, there exist four major barriers to the full development and usage of biomarkers for diagnosis:

1. Integrating lab-on-a-chip (LOC) systems into point-of-care (POC) structures that completely replicate the full functionality provided in remote laboratory settings;
2. Failure of current LOC systems to compete with remote testing, both from cost as well as performance perspectives;
3. LOC systems' need to develop new content that is unavailable at remote labs;
4. Insights into multiple phases of regulatory approval that has traditionally taken decades to complete.[4]

Programmable Bio-Nano-Chip (p-BNC) system overcome these barriers. This platform technology combines unique chem- and biosensing capabilities with powerful machine learning algorithms to provide novel and intuitive single-valued indices across several major diseases. Nano materials and microelectronics have been combined and adapted for the practical implementation of two classes of mini-sensors (bead-based sensors for soluble chemistries and membrane-based chips for cytology) that read out with high-performance yet affordable imaging systems now in development, testing, and clinical validation. Collectively, the two p-BNC sensor ensembles form a modular platform system that demonstrates one of the largest analyte diversity available to date. Micro devices with a demonstrated capacity to learn, the p-BNC system leverages machine learning algorithms and high dimensional data to identify otherwise undetectable patterns underlying various diseases.

These rich data streams are managed with a novel database, and mobile health tools are integrated to help enroll patients, manage and collect their data, and provide precision feedback to healthcare providers and patients alike.

The advantages of high-throughput multiplex testing through high surface-to-volume ratios of solid support porous spheres have allowed for shorter analysis times consistent with the POC using low sample and reagent requirements. Further, the p-BNC assay characteristics now in development adhere to the guidelines for POC tests that have been developed and designated

with the acronym COMMAND QUALS, that is Cheap, Obvious, Miniaturized, Multiplexed, Automated, Non-perishable, Dependable, Quick, Unobtrusive, Adaptable, Limited (volume), and Self-contained.[4]

The programmable bio nano chip employs a size tuneable network of nanometer-scale fibres within agarose microspheres or polymer membrane and a fluorescent signal arising from nanoparticles to isolate and quantify biologically important analytes from complex matrices within a closed miniaturized system(chip).

APPLICATION OF THE SYSTEM

The utility of programmable bio nano chip 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 cancer, ovarian and oral cancers and in detecting multiple drugs of abuse by a single analysis of oral fluid. Thus p-BNC has significant potential for roadside drug testing by law enforcement officers.

Combining multiple such 'score card', 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.

The programmable bio nano chip synergizes components and achievements from nanotechnology, molecular diagnosis, microfluidics and microelectronics to create a new and powerful measurement approach in a small device footprint.

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