Novel Time Resolved Fluorescence Platform for Near Patient Diagnostics

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Abstract

A new universal immunoassay platform for a variety of biomarkers integrating a novel time resolved fluorescence (TRF) label and a low cost portable detection technology is reported. We have previously used this platform to demonstrate a sensitivity improvement of orders of magnitude over gold-label-based assays, with excellent repeatability. The platform has seven benefits, in addition to its high sensitivity, the core components are low-cost and compact, which offers the potential to place the platform at the core of highly commercially attractive low-cost rapid diagnostic systems. Furthermore, the platform can be applied retrospectively to traditional grid-based lateral flow systems to realise significant performance enhancements.

New TRF Label

At the heart of this platform technology is a novel highly sensitive label, developed by XenBio. Because of the time resolved properties this label has a low background signal and exhibits very low non-specific binding due to its proprietary surface. Designed with flexibility in mind, proteins can be covalently bound or physically adsorbed to the surface. This label, when integrated with Cambridge Consultants detection technology, is an ideal label for high sensitivity assays at low cost diagnostic tests, providing the precision, accuracy and sensitivity expected of a clinical laboratory in a near patient setting.

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To determine how mono-dispersed the label was, a serial dilution was run through a Perkin Elmer AlphaScreen. A total of three runs were completed. Results showed that just 40 particles could be detected with a c.v. of 5.9% illustrating firstly the high Quantum efficiency of the label and also effectiveness of the surface properties in ensuring the mono-dispersion is maintained.

New Platform

We have developed a new platform that can be rapidly tailored to a range of analytes and capable of being applied to a range of substrates, arrays, planar surfaces as well as being capable of being reconfigured to a range of lateral flow assays. The current development of the platform uses a scanning feature to increase the sensitivity of the detection but it can be run in a static read format. Based on low cost lateral components, a simple PVS reader is targeted to have a CoGs of <$50 and a disposable OTC device for <$5, where some performance is

Exploring the repeatability of the instrument we repeatable removed and reinserted a 1.1pM NT-proBNP test strip in to the reader five times, Figure 6. From these measurements we found that:

(i) The reader shows good repeatability in signal profile when re-testing a strip.
(ii) Blaming/missing from repeat scanning can be seen, a slight reduction in peak magnitude is observed.

In this configuration the measurements are made using a scanning configuration of the reader. It is possible to further cost reduce the instrument to <$5, for use in an OTC setting or in a disposable format but we would expect to see some degradation in performance.

Results

The results show that the platform is capable of detecting NT-proBNP and Botulinium concentrations of less than 1pM and under certain conditions as low as 0.01pM. The platform can be used for monitoring heart failure and cancer biomarkers and has the potential to achieve a high sensitivity within an optimized system. The low cost of the platform and its suitability for the Point-of-Care and Rapid Diagnostic Test markets make it an attractive candidate for the near patient market.

About XenBio

Xen Biosciences, Inc (XenBio) is an early stage biotechnology company located at the heart of San Diego’s Golden Research Triangle. It was founded in 2005 to develop and commercialize novel in vitro diagnostic (IVD) technologies to allow accurate answers to health questions at the doctor’s office, home, mail, and other point-of-use locations. XenBio’s proven and patented portable detection platform is poised to address the need for real time, low cost, point-of-use solutions for the heart disease and breast cancer diagnostics markets. XenBio presently offers development services on behalf of clients with access to other validated markers. Contact: Victor Manneh, victor.manneh@hotmail.com

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Cambridge Consultants Ltd. (www.cambridgeconsultants.com) is a leading technology and innovation company renowned for its abilities to provide technical products and provide creative innovation services to business needs. CC has offices in the UK and USA and employs some of the world’s leading scientists and engineers. Contact: Simon Burnell, simon.burnell@cambridgeconsultants.com