



BUSINESS NEWS

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Pronostics set for European expansion with digital multiplexing solution

Despite being the current gold-standard for diagnosing heart disease, angiograms have two major drawbacks. Not only do they cost £700 (\$1,400) per treatment, they also carry a risk of fatality, with three out of every 2,000 patients dying as a result of an angiogram. However, UK-based multiplexed diagnostics manufacturer Pronostics believes it has a solution to this costly technique with its UltraPlex Immunomics disease screening platform.

The company told *Clinica* that not only could its technology help lower the number of patients actually receiving the angiogram, but it could also be used to diagnose other diseases such as cancer, Alzheimer's and osteoporosis with a single blood test. This is something that has not been achieved by existing technologies and Pronostics said its cardiovascular test has been met with "considerable enthusiasm" from senior consultants wanting to cut costs and risks, and improve decision-making.

UltraPlex Immunomics is a combination of two technologies, the UltraPlex assay and the Fingerprint Immunomics molecular profiling platform, both of which are part of Pronostics' technology portfolio. The UltraPlex and Fingerprint technologies were developed by SmartBead Technologies and FingerPrint Diagnostics, respectively. These two firms merged in June 2006 to form Pronostics, bringing together the two technologies in what the firm's chief scientific officer Dr David Gratger described as a "perfect synergistic fit".

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The combined company's portfolio includes three CE-marked products, developed on the back of the UltraPlex technology: the UltraPlex ANA (anti-nuclear antigens), Coeliac, and Thyroid, which are described by the firm as the world's first barcoded immunoassays for simultaneous testing of disease biomarkers.

And it is the barcode technology that Pronostics believes sets it aside from its rivals in the multiplexing sector. The technology utilises microscopic aluminium particles called UltraCodes, each etched with its own unique barcode. The validated assays use analytes tagged by the barcoded microparticles for simultaneous tracking and analysis of multiple tests. The assays are performed in parallel and then are decoded by the company's UltraPlex SmartReader analyser.

Pronostics claims that its digital multiplexing system is more robust and cost-effective, as well as being simple to understand

Dr Gratger explained that Luminex, the market leader in the field of multiplexing with end-user sales of \$170m in 2007, uses a system of colour coding its particles. He said that Luminex's technique, and that of other rival companies, were "in no way superior" - indeed Pronostics claims that its digital multiplexing system is more robust and cost-effective, as well as being simple to understand.

The CSO explained that other methods of tagging particles, such as using magnets or reflective materials, were prone to

errors during the reading process; unlike these techniques, digital multiplexing is error-free. For example, dye-coded beads can bleach or change colour as the temperature changes, whereas the barcode is physically etched into the microparticle, and is therefore permanent. Dr Gratger said that there are around five or six US-based companies currently developing multiplexing techniques, however, unlike Pronostics, none have a system that is commercially available.

Pronostics' first distribution deal was signed with Medipan in March this year, taking the three UltraPlex assays to the German and Austrian market (see *Clinica* No 1299, p 16).



The UltraPlex SmartReader and SmartStation equipment used to perform and analyse assay and profile tests

More recently, the company struck up a partnership with the University of Birmingham for the use of its UltraPlex ANA assay (see this issue, p 16).

However, the company's CEO Robert Booth was cautious about the rate of sales growth. "As with all new and unproven technologies, we do not assume that every laboratory will be using it within 12 months," explained Mr Booth. "But as the advantages of UltraPlex are understood and proven in the marketplace, we expect it to become the gold-standard in multiplexing," he said.

Mr Booth also said the company was working on further deals in the key European markets and had just begun dialogue with the US FDA about a commercial introduction of its autoimmune products to the US market. Approval for the firm's other leading technology, the Fingerprint platform, is also expected during 2009.

He went on to say that Pronostics is always on the lookout for novel content for its platforms, stating that companies developing new biomarkers would be perfect partners for the firm. While expanding its distribution horizons, the company is also working on extending its product portfolio - it currently has two more products in late-stage development, the CADPrint heart diagnostic for coronary artery disease and an unnamed cancer diagnostic assay.

The company claims that medical device giants such as GE Healthcare and Becton Dickinson have gone on record as saying that given the appropriate technological solutions, domination of the biological profiling market would not be far away. Pronostics is confident that its solutions will be the technology that can take assay multiplexing and biological profiling to another level, and told *Clinica* that it is currently in dialogue with "some major companies".

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