

Innovative Research Solutions with Industry

Animal Healthcare

CLIENT:
Tridelta

AREA:
Biodiagnostics



Developing an immunoassay to enhance animal healthcare products



Tridelta is an Irish-based diagnostic company specialising in the development of assays specifically for animals. It focuses particularly on Acute Phase Protein Assays for multiple domestic and commercial animals and is regarded as the leading company in this field, exporting over 99% of its production to veterinarians and researchers worldwide.

Tridelta is a world leader in the development of ELISA assay for the detection of acute phase proteins in animals. While ELISA is a universally accepted technology for the highly sensitive and specific detection of antigens in complex sample matrices, it is not readily amenable to automation without significant capital investment. As a result all samples are not tested routinely but only in cases when elevated C-reactive protein (CRP) is suspected.

To address these problems, Tridelta approached the MiCRA centre at ITT Dublin to develop an immunoassay capable of automation using preexisting laboratory equipment such as spectrophotometric clinical chemistry analyzers. The MiCRA centre (www.micra.ie) is an Enterprise Ireland Technology Gateway with an exclusive focus on the delivery of solutions to Irish Industry. The centre is supported by the recently built state of the art facilities and equipment in the Centre for Applied Sciences for Health (CASH) at ITT Dublin.

MiCRA's core expertise is in the area of biosensor development and rapid diagnostic technology development, with a strong track record of company engagement and commercialization



Tridelta animal healthcare products

in this area. To meet Tridelta's needs, it was felt that this expertise could be applied to developing a polystyrene enhanced immunoturbidimetric assay that would deliver the performance characteristics of an ELISA assay while concurrently being suitable for high-throughput sample analysis.

Particle enhanced immunoturbidimetric assays are liquid in format consisting of a two reagent system. Reagent 2 (R2) contains covalently bound anti-CRP antibodies in a stabilization matrix. Reagent 1 (R1) when combined with samples and subsequently R2 initiates a reaction that is measured photometrically. It was of critical importance that the assay was optimized to →

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•> ensure the concentration of CRP in the sample was directly proportional to signal measured. This work was undertaken successfully by the MiCRA centre, which also provided technical transfer support to the company and sourced, installed and validated an appropriate bulk manufacturing system for the assay.

The project produced a fully optimized microparticle enhanced immunoturbidimetric assay for canine CRP. The assay was successfully validated by five independent international sites and was demonstrated to be equivalent in analytical performance to the predicate ELISA test. As a result the assay is now commercially available from Tridelta which in turn has enabled the company to target new markets, generating exports and revenue. The success of the project has further enhanced the company's reputation as a leader in the acute phase protein diagnostic markets. As of release, Tridelta's immunoturbidimetric assay is a world first for specifically detecting canine CRP – a major achievement for an Irish Diagnostics company.

The research and development undertaken by MiCRA was funded through Enterprise Ireland's innovation voucher scheme. Also important to the success of the project was the benefit in kind provided by Tridelta in supplying technicians to complement the research undertaken. Tridelta also invested in the machinery required to manufacture the assay in its Maynooth facility. Indeed Tridelta now retains the core in-house skills to undertake further assay development with the assistance of MiCRA when required.

The major benefit to the company is a new product commercially available for sale and export. With a validated manufacturing facility and an understanding of the reproducible quality manufacture of immunoturbidimetric assays, the transfer of skills and expertise from the Institute to Tridelta will enable the company to develop an in-house product development programme to expand the number of assays in their portfolio. Since the introduction of the CRP assay Tridelta are significantly expanding their facilities and workforce. ■

TESTIMONIAL

Brian Hett
CEO, Tridelta

"Working with MICRA has allowed Tridelta to develop products to both secure its current markets and allow for the expansion of the products into new markets both in terms of customers and market areas. The new technologies that MICRA transferred to Tridelta has strengthened our marketing positions and helped to create jobs"

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