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AroCell's partnership with Future Diagnostics

The process of assay development is challenging and complex: going from an exploratory phase to testing and developing different types of antibodies to feasibility and optimization, verification, transfer to the manufacturing and validation of the technical and clinical performance of an assay. Quality assurance and control standards must be met throughout these processes.

AroCell's research and development staff members started a valuable collaboration with Future Diagnostics in the Netherlands in 2011, for the development of the TK 210 ELISA test throughout all these different phases. Collaboration between AroCell team members and this extended contract assay development organisation has led to many product milestones along the way.

“Biological materials have a mind of their own”

MIKE MARTENS, co-founder and current Managing Director of Future Diagnostics has experience in development of assays for a large part of the in-vitro diagnostic community since 1997, ranging from large companies, such as Phillips, Abbott and Beckman and smaller niche companies such as AroCell. He recalls some of the challenges and opportunities from the start of the collaboration on TK 210 ELISA in 2011:

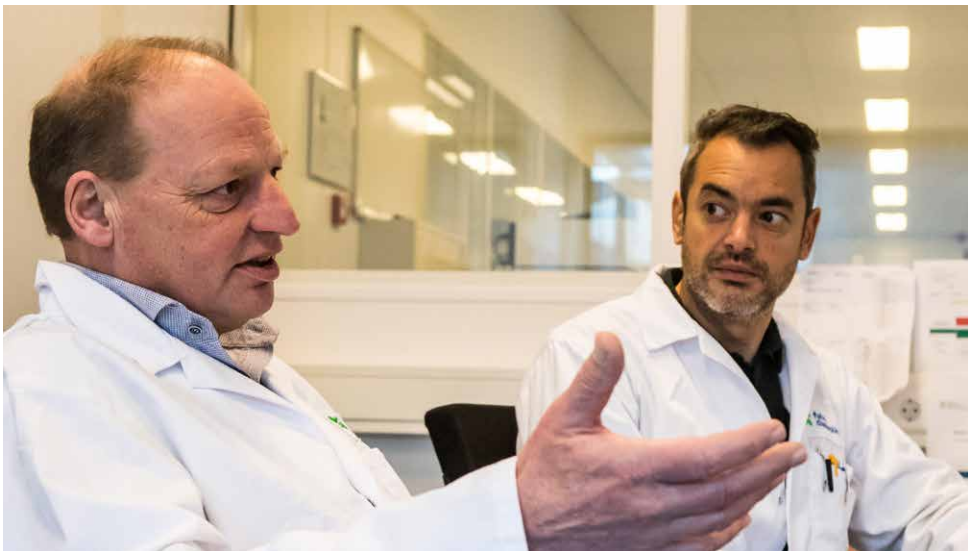
Dr Mike Martens, Managing Director of Future Diagnostics and Jan Stålemark, Chief Executive Officer of AroCell AB have maintained a close dialogue with each other and within their respective organisations for collaboration on the TK 210 ELISA test.

“We had some major challenges along the way, but there will always be challenges and complexities in developing a product like the TK 210 ELISA. There were challenges in respect to the reproducibility of the assay and the use of some critical materials from the very beginning, related to the antibodies, along with changing focus and knowledge on clinical disease areas. But these challenges in the collaborative effort led to the development of several new patents, and new opportunities. A good example is our joint presentation with AroCells’ Product Manager Helena Wensman at the World Biomarker Congress in Philadelphia 2016”.

Future Diagnostics in The Netherlands was established in 1997.

From chinese chicken antibodies to multipatented assay

LEON SWINKELS is Scientist and works as Technical Architect for TK 210 ELISA in Future's R&D department, where he is responsible for development projects, defining objectives and determining solutions and resources to meet them. He has been with Future almost since the very beginning. He shares his insight into some of the development milestones for the TK 210 ELISA test:



Technical Architect Leon Swinkels and Delivery Manager Antwan Maas collaborate closely during the product development process.

"Originally it was intended as a feasibility research project, with a first meeting with AroCell in Uppsala in May 2011. After that the collaboration led to some good leads on how to continue development. In the beginning, we worked with chicken antibodies from China, and a first important project milestone was to develop our own antibodies. That led to work with antibodies from mice and rabbits, until we defined the current two monoclonals in a sandwich ELISA. We started weekly phone conference meetings between project team members in AroCell and Future, which continue to this day, looking at new opportunities for design changes and continued development."

As Technical Architect for TK 210 ELISA, Leon works closely in product development with project Delivery Manager ANTWAN MAAS, who focuses on project budgets, timelines and quality assurance planning. He states that one of the development milestones in his opinion was transfer of the design phase of the product into contract manufacturing.

Leon Swinkels and Antwan Maas together with key R&D project members working on the development of TK 210 ELISA at Future Diagnostics.

Producing a totally new novel biomarker

Manufacturing Expert CARLO FRUNT started at Future Diagnostics with AroCell's product in 2015, a critical year for the TK 210 ELISA when the product achieved CE mark status. He shares: "There have been different milestones in the process of the TK 210 ELISA test, from the verification to the validation batches, and on to the step pilot batches. In each step, we have learned more and become more familiar with producing the assay".

Carlo works on the team of CATHELIJNE VAN DUREN, Head of the Production Department. She started as an R&D scientist with Future in 2004. She oversees 12 staff members in production, and has worked closely with the product from the earliest manufacturing stage:

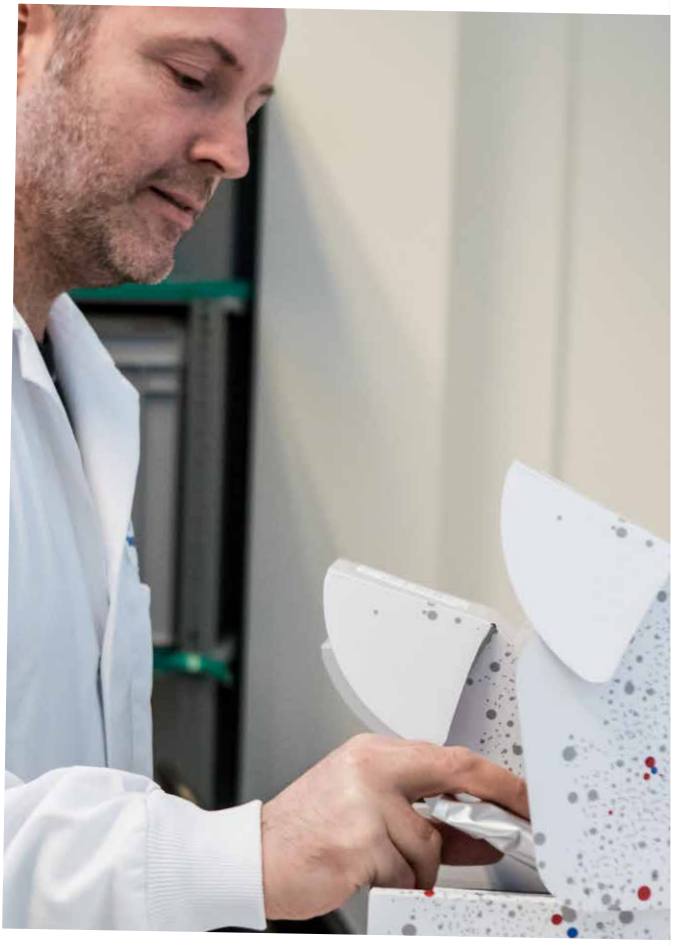
"Basically, the entire manufacturing department was involved at some stage of the production process. There is a good team effort, and we work closely together with the R&D department and key individuals at AroCell. We have now done several manufacturing batches, the most recent one with the new AroCell packaging. The production team felt the new box was like a holiday gift in producing the latest batch."

Cathelijne van Duren, Head of Production at Future.

Cathelijne summarizes: "There is always a challenge in developing and producing a totally new novel biomarker. There are parallel processes in development and manufacturing, and in clinical validation to determine which disease areas the product might best be used, as well as diagnosis and prognosis. With TK 210 ELISA we are in the midst of this exciting process in every way, for the product itself and to see how it functions with existing biomarker panels, such as CA 15-3. This is all part of the product journey".

Carlo Frunt, Manufacturing Expert at Future for TK 210 ELISA.

Cathelijne van Duren, Carlo Frunt and some of the manufacturing team members working on the production of TK 210 ELISA.



Some scenes from production of the latest batch of the TK 210 ELISA, with new product packaging.