

Intravacc announces publication of *In Vitro* alternative to replace animal pyrogen test for vaccines

- Intravacc and Sanquin Diagnostic Services optimized the *in vitro* Monocyte Activation Test (MAT) for OMV vaccines
- MAT test potential replacement for the traditional rabbit pyrogen testing (RPT) for vaccines
- The implementation of the MAT reduces the use of animals for vaccine safety testing
- Article published in the peer reviewed journal Scientific Reports

Bilthoven, The Netherlands, 19 September 2023 – [Intravacc](#), a Leading Contract Development and manufacturing Organisation for translational research and development of preventive and therapeutic vaccines together with MAT services at Sanquin Diagnostic Services, today announced the publication of a scientific article of an *in vitro* alternative assay to the replace rabbit pyrogen test for vaccines.

Vaccines play a crucial role in public health by providing immunity against various diseases. However, vaccine safety is of paramount importance, and researchers are continually exploring innovative methods to ensure that new vaccines are both effective and safe. All parenteral vaccine products must be tested for pyrogen/endotoxins to ensure an acceptable safety profile. Currently, often the RPT is used to demonstrate the safety profile. The MAT is an *in vitro* assay that can replace the rabbit pyrogen test. This study showed that the MAT assay is a robust assay that can be used to determine the reactogenicity of OMV based vaccines, even those which are still in the developmental phase. An OMV based vaccine candidate for Bordetella Pertussis, Avacc® 3 demonstrated to have a desired safety profile in terms of systemic reactogenicity, as determined with both MAT and RPT. The article entitled “*In vitro* alternative for reactogenicity assessment of outer membrane vesicle based vaccines” is published in the peer reviewed [journal of Scientific Reports, volume 13, 2023](#).

Dr. Bernard Metz, Director Product Characterization & Formulation at Intravacc, stated:

“The study showcases a significant step forward in vaccine safety testing, offering the potential to enhance the efficiency and ethical standards of vaccine development. By optimizing the MAT for early-stage testing and demonstrating its comparability with RPT results, this research contributes to our ongoing efforts to create vaccines with optimal safety and efficacy profiles.”

This joint development project for advancing vaccine safety evaluation marks a pivotal advancement in vaccine safety assessment. The MAT also proved its applicability to assess reactogenicity levels of pyrogen containing vaccines at multiple stages of vaccine development and could eventually replace RPT. The use of this test may contribute to a significant reduction in the use of animals, currently the standard for vaccine safety profiles.

Dr. Marijke Molenaar, senior scientist MAT services at Sanquin Diagnostic Services

“With our broad knowledge on the MAT we were able to optimise the MAT so that it can be used to determine the reactogenicity of OMV based vaccines from Intravacc. This paper shows that the MAT is a valuable assay to assess reactogenicity levels of OMV based vaccines at multiple stages of vaccine development and the data presented could help to substantiate the switch from small animal testing to cellular assays at several stages of vaccine development.”



About Intravacc's OMV platform technology

For the development of vaccines, Intravacc has designed and developed a platform based on outer membrane vesicles (OMVs) - spherical particles with intrinsic immune-stimulating properties. The OMVs can be designed with immunogenic peptides and/or proteins that stimulate effective adaptive immunity. The OMV carrier has been optimized to induce a more effective immune response against these newly introduced antigens. Intravacc has also developed genetic tools to increase the yield of the OMVs, reduce the toxicity and achieve the desired antigenic composition. Intravacc's OMV platform is scalable and allows rapid and efficient modification of the antigen composition, either through genetic modification of the bacterial host or by associating antigens with stored OMVs.

About Intravacc

Intravacc, located at Utrecht Science Park Bilthoven in the Netherlands, is a leading global CDMO for infectious diseases and therapeutic vaccines. As an established independent CDMO with many years of experience in the development and optimization of vaccines and vaccine technologies, Intravacc has transferred its technology world-wide for many vaccines including polio, measles, DPT, Hib and influenza. Approximately 30% of childhood disease vaccines are based on Intravacc's know-how and proprietary technology. Intravacc offers a wide range of expertise for independent vaccine development, from concept to Phase I/II clinical studies for partners around the world, including biotech and pharmaceutical companies, governmental agencies and NGOs. With its innovative vaccine platforms OMV-VaccT, Cell-VaccT, Con-VaccT, E.co-VaccT and good manufacturing procedures (GMP) facilities the company is well positioned to address the unmet needs in the vaccine and immune therapy market.

About Sanquin Diagnostic Services

Sanquin Diagnostic Services, part of the Sanquin Foundation, collaborates with Sanquin Research to offer diagnostic and bioanalytical CRO services to the healthcare, biotech and pharma community.

Sanquin Diagnostic Services is specialized in Antibody structure and function, disease Biomarkers and Cellular immune responses. These are used to monitor biotherapeutic safety and mode of action and for developing difficult tests on demand. Analysing intricate interactions among cells, drugs, and blood components, considering both innate and adaptive immune responses. Together this offering is known as 'the ABC of blood'. Sanquin Diagnostic Services applies this expertise in immune disorders, hematology, oncology, immunomodulation therapies, and vaccines. They offer specialized services including assay development, immune response analysis, and toxicity testing. They provide comprehensive support through their decades of experience, specialized solutions, tailored approaches, and access to an extensive network of experts.

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