



## Translational Immunology, Inflammation and Infection

**Representative Case Study — Saving newborns with neonatal sepsis. European researchers developed a sample-to-result automated system for detecting blood pathogens in infants at the point of care.**

**Prof. Orla Sheils**

### Clinical and Market Need

Neonatal sepsis is caused by bacterial pathogens that enter the blood stream, and the disease remains one of the major causes of infant death worldwide, partly due to shortcomings in current diagnostics. This potentially fatal disease is characterised by a whole body inflammatory response coupled with the presence of a known or suspected infection. The clinical signs of neonatal sepsis can be nonspecific, making it hard to distinguish from other conditions such as respiratory distress syndrome or meningitis. This project was driven by the imperative to develop a rapid and reliable mechanism to deliver prompt diagnosis of seriously ill infants.

### Partnership

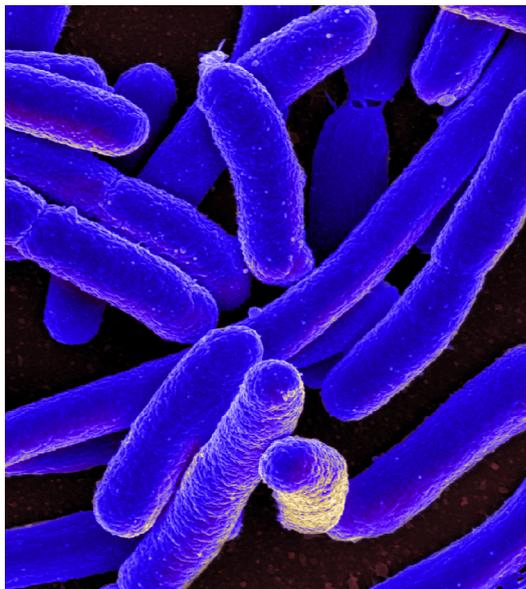
The International Consortium, led by Dr Daniel Mark in Germany was headed by Prof Orla Sheils and Prof John O’Leary at Trinity College Dublin. The other partners included Rohrer AG, Qiagen and Mobidiag Ltd.

### Approach

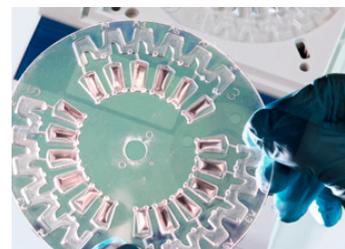
The EU-funded ASCMICROPLAT (Fast automated multiplex analysis of neonatal sepsis markers on a centrifugal microfluidic platform) project addressed this issue through the development of a novel diagnostic platform capable of performing rapid diagnosis of neonatal sepsis. Briefly, the device allows detection of a biologically relevant panel of neonatal sepsis pathogens and sepsis biomarkers from paediatric serum samples within four hours.

The objective of this work was to realise and clinically validate a fully integrated and automated platform for the detection of neonatal sepsis biomarkers and a panel of sepsis-causing bacteria from serum samples. Centrifugal microfluidics were applied to develop an easy-to-use diagnostic test that can be applied at the point-of-care. Biomarker quantification was conducted by a novel magnetic immuno-PCR approach or by automated enzyme-linked immunosorbent assay (ELISA). Pathogen identification was based on an innovative PCR design that included sample preparation (DNA extraction). The tests were integrated on a rotating test carrier, the ‘LabDisk’ that can be processed on a portable processing device using a specific rotational protocol.

The interdisciplinary consortium included a university hospital, a research institute and three SMEs, who have together extensive experience in all relevant fields ranging from neonatal sepsis diagnostics using PCR based assays, to polymer micro fabrication techniques and microfluidics. This project developed an easy-to-use, fast, automated and conclusive test method, with the potential for significant clinical and market impact in the diagnosis and management of neonatal sepsis.



Microfluidic Disc



Collaborator/Funding Agencies

