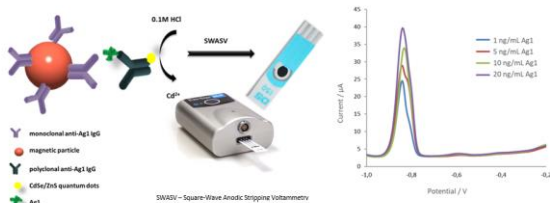




Principle of electrochemical detection of bioconjugate



Technology owner

University Hospital Hradec Králové
University Pardubice

Inventor (s)

Marian Kacerovský, Ctirad Andrýs
Lucie Korecká, Zuzana Bílková

IPR status

CZ patent application PV 2021/401
(priority date 31/8/2021)
PCT application to be filled

Stage of Development

Proof of concept

Contact

Lucie Bartošová, PhD.
lucie.bartosova@fnhk.cz
+420 727 802 314

Immunosensor for Detection of Inflammation in Amniotic Fluid

Background

Preterm Premature Rupture of Membranes (PPROM) is a **pregnancy complication**. In this condition, the sac (amniotic membrane) surrounding the fetus breaks (ruptures) before week 37 of pregnancy. Once the sac breaks, pregnant woman has increased risk for infection. PPROM complicates 3 – 4% of all pregnancies and is up to **1/3 complicated by microbial invasion of the amniotic cavity (MIAC)** leading to infection in amniotic fluid (AF) and development of intra-amniotic inflammation. Although this complication is usually asymptomatic, it is a major cause of preterm birth and neonatal morbidity and mortality worldwide. Neonates from these pregnancies are at **increased risk of developing neonatal sepsis and impaired psychomotor development** and other sometimes lifelong health consequences.

Description of the Invention

Invention is **point-of-care test (POCT)** based on electrochemical immunosensor for **simultaneous detection of three inflammatory protein biomarkers** with high predictive value in AF collected by amniocentesis. The aim of the test is **to confirm intra-amniotic inflammation**. The entire biosensor consists of an immunosorbent - magnetically active microparticles modified with specific antibody. After capturing the protein biomarker by the immunosorbent, the bioconjugate (IgG antibody conjugated with an electroactive indicator, specifically quantum dots or gold nanoparticles) is added. A final measurable signal proportional to the concentration of the inflammatory protein biomarker is provided by metal ions released from the electroactive indicator. Disposable screen-printed three-electrode sensors are used for simultaneous electrochemical analysis. Clinical relevance of selected protein biomarkers was determined based on the results of proteomic and antibody studies of AF of pregnant women with PPROM.

Advantages

POCT enables to **speed up the process of confirmation or elimination inflammation in AF** and can be **easily performed and evaluated in minutes** beside the patient's bed and thus enables personalised approach to therapeutic intervention of the pregnant woman. Currently, determining the MIAC is not specific enough and is very time consuming and technically demanding. It is based on combination of cultivation and molecular methods. Further research is focused on test verification in **cervicovaginal fluid** to avoid amniocentesis.

Potential Applications

IVD test – POCT is intended to be used by medical facilities that take care of pregnant women esp. regional hospitals or perinatology centers.