



### Technology owner

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### IPR status

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### Stage of Development

Proof of Concept

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## Immunosensor for detection of inflammation in amniotic fluid

### Background

Preterm Prelabour Rupture of Membranes (PPROM), during which amniotic sac rupture occurs (3 – 4% of pregnancies, i.e. 3 – 4 thousand pregnancies / year / Czech republic), is up to 1/3 complicated with the presence of bacteria in the amniotic fluid that lead to the development of intra-amniotic inflammation. Although this complication is usually asymptomatic (cannot be detected from standard blood tests of the mother), neonates from these pregnancies are at increased risk of developing neonatal sepsis and impaired psychomotor development. Determining the presence of inflammation is essential for further therapeutic management of the pregnant woman.

Currently, intra-amniotic inflammation can be diagnosed from mother's blood (CRP, leukocytes) which is not very reliable. Determination of inflammatory markers in amniotic fluid (glucose, lactate, IL-6) is also burdened by low sensitivity and specificity. Another method is the examination of microbial invasion, which is very time consuming.

### Description of the Invention

Our solution is point-of-care test (POCT) based on electrochemical immunosensor for simultaneous determination of three significant inflammatory markers in amniotic fluid. This test results in the simultaneous electrochemical detection and quantification of three selected markers in one amniotic fluid sample simultaneously in one analysis. A miniature potentiostat with printed electrode is used for evaluation. The aim of the test is to distinguish between infectious inflammation, when it is necessary to initiate targeted antibiotic treatment, and sterile inflammation, when treatment is indicated to maintain the pregnancy without additional risk for mother and fetus. Clinical relevance of selected markers was determined based on the results of proteomic and antibody studies of amniotic fluid of pregnant women with PPRM.

### Advantages

- POCT detecting multiple inflammatory markers at the same time with high predictive value
- Acceleration of the process of confirmation / elimination of the type of inflammation in amniotic fluid – performance and evaluation of the test in a matter of minutes beside the patient's bed
- Personalized approach to therapeutic intervention of the pregnant woman based on the results of the examination
- The experience of the research team, which has been systematically involved in PPRM problematic since 2008 and is one of the most productive team in this field, not only in the European context

### 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.