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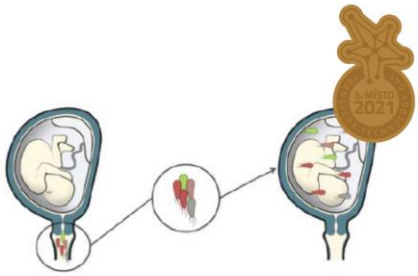
TECHNOLOGY SUMMARY

Bacterial detection in amniotic fluid



Technology owner
University Hospital Hradec Králové

Inventor (s)
Prof. Marian Kacerovský, Ph.D.
and team of inventors

IPR status
Know-how licensing

Stage of Development
Proof of Concept

Contact
Lucie Bartošová, Ph.D.
lucie.bartosova@fnhk.cz
+420 727 802 314

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.
To treat this complication, it is necessary to know the cause of the inflammation so that the chosen antibiotic treatment is correctly targeted at specific bacteria from the beginning. This reduces the fetus exposure to the inflammatory environment of amniotic fluid and the risk of its damage due to infection is minimized.
Currently, determining the presence of bacteria in amniotic fluid in patients with PPROM is very time-consuming and technically demanding. A combination of cultivation and non-cultivation laboratory methods is necessary. On top of that, results are available in days, which is already clinically irrelevant for the initiation of targeted antibiotic treatment.

Description of the Invention
Our solution is the determination of the presence of specific bacteria in amniotic fluid collected by amniocentesis using multiplex RT-PCR test allowing the detection of multiple bacteria from amniotic fluid at the same time. The test consists of 3 panels for detection of DNA of selected bacteria, which are the cause of 88% of all intra-amniotic inflammation. Panels contain specific primer sets, and the test results are interpreted by fluorescence method. Test would determine presence of specific bacteria in amniotic fluid within few hours with sensitivity of 90% and thus allows the timely initiation of targeted therapy leading to a reduction of the risk of possible complications for both mother and fetus.

Advantages
- High sensitivity of the method – 88 % of pathogens
- Time of evaluation – within hours after sampling
- Personalized approach to the therapeutic intervention of the pregnant woman based on the results of the examination
- Suitable for perinatology centers equipped with a PCR cycler – the technology does not require specialized laboratory equipment or specialized personnel
- The experience of the research team, which has been systematically involved in PPROM problematics since 2008 and is one of the most productive team in this field, not only in the European context

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