

The Antibody Lab GmbH

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**The
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Lab**

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profile

Detecting maternal risk before symptoms occur

The Antibody Lab is focused on improving screening for preeclampsia during pregnancy and is seeking strategic partners to change the current risk-assessment paradigm.

According to the World Health Organization, maternal mortality around the world dropped from 532,000 in 1990 to 303,000 in 2015¹. Today, preeclampsia, a condition of hypertension during pregnancy, remains one of the leading causes of maternal and neonatal death, especially in low-income countries with limited health care. Now the team at The Antibody Lab is poised to create a screening test for clinical use to determine a woman's risk of developing preeclampsia so she can take preventative measures and avoid symptoms all together.

Preeclampsia is well known, but not well understood. Roughly 2–8% of all pregnancies are affected by the disease. Doctors currently diagnose preeclampsia on the basis of symptoms such as headaches, protein in urine, blurred vision and high blood pressure. Careful monitoring and other measures can help lessen the impacts of preeclampsia, but only if satisfactory health care is available.

"There is a high medical need for a simple and early test that can determine if a woman is at risk of developing preeclampsia during pregnancy," said Gottfried Himmler, cofounder and CSO of The Antibody Lab. "Our idea is to shift the focus from later diagnosis to earlier risk assessment." Himmler is developing an immunoassay to screen for an elevated level of the biomarker NT-proCNP in serum or plasma, which indicates the synthesis of CNP, a paracrine growth factor in vascular tissue. CNP promotes blood flow through vasodilation and the development of new blood vessels. This is especially important in allowing blood and nutrient exchange between a pregnant woman and a fetus via the placenta. "The biomarker is well known, but the use of this biomarker for screening for potential preeclampsia risk is new."

A recent study by scientists at the University of Otago in Christchurch, New Zealand, showed that

plasma levels of NT-proCNP were elevated in women diagnosed with preeclampsia in data sets from SCOPE (Screening for Pregnancy Endpoints) and bio-bank samples. The marker may be used early in pregnancy in combination with other information to improve the prediction of risk for pregnancy complications. In October 2015, The Antibody Lab signed a worldwide exclusive license agreement with Otago Innovation Ltd. on the diagnostic use of NT-proCNP. Additionally, The Antibody Lab teamed up with Professor Harald Zeisler and colleagues at the Medical University of Vienna to explore the application of its immunoassay to screen for increasing levels of NT-proCNP early in pregnancy. It is undertaking work to validate clinical results of this manual ELISA test as proof of concept with the goal of scaling up to an automated test in the coming years.

"So far, the results are promising, and we have the in-house expertise to develop high-quality assays with the best defined components available," said Wolfgang Woloszczuk, The Antibody Lab's cofounder and CEO. "We have extensive experience in *in vitro* diagnostics both in industry and in the lab."

High-quality people and products

Perhaps the most important part of developing any clinical test is the ability to reproduce results. "There are a number of factors that lead to irreproducible results," said Himmler, explaining a recent study reporting that in the United States, roughly half of all research dollars spent go toward irreproducible results. "A large part of this failure is caused by low-quality reagents and reference materials." The need for high-quality materials was the driving force that brought Himmler and Woloszczuk together in Vienna, Austria, in 2009. The company they started, originally called BDF, built a strong reputation as a

business-to-business supplier of immunoassays for research and diagnostics. In 2015, they renamed the company 'The Antibody Lab'.

Woloszczuk brings nearly 40 years of experience to The Antibody Lab. He was previously a research scientist at the Ludwig Boltzmann Institute for Experimental Endocrinology and currently also serves as the director of Biomedica, a global leader in providing clinical-research-grade immunoassays. "I spent decades in lab and the hospital focusing on diagnosis," he said. "I know what is expected for clinical applications."

Woloszczuk's experience complements that of Himmler, who has 30 years of experience engineering antibodies for clinical research and diagnostics. Rounding out the scientific leadership is The Antibody Lab's COO Anton Bauer, who has a PhD in biochemistry and a global eMBA, as well as deep experience in R&D and antibody technologies.

Partnership opportunities

The Antibody Lab has had a long-term commercial relationship with Biomedica Medizinprodukte GmbH & Co KG. Its task is to support Biomedica in becoming the market leader for high-grade immunoassays in the fields of bone metabolism, cardiovascular disease and kidney disease.

Himmler and Woloszczuk said they are now interested in discussing partnership opportunities with regard to a clinical trial of testing serum or plasma for elevated levels of NT-proCNP to identify early-in-pregnancy women at risk of preeclampsia. "There is potential market value for an automated, high-quality immunoassay for NT-proCNP," said Woloszczuk. "We have the expertise to create a reliable product."

Measuring amounts of NT-proCNP also has promise for detecting severe sepsis in companion animals such as dogs and cats, which has a 50% morbidity rate. The Antibody Lab is currently developing a point-of-care device for veterinary use.

The Antibody Lab will be represented at upcoming conferences in 2016, including in June at BIO 2016 in San Francisco and in November at BIO-Europe in Cologne.

1. World Health Organization. Maternal deaths fell 44% since 1990—UN. <http://www.who.int/mediacentre/news/releases/2015/maternal-mortality/en/> (2015).



Figure 1: A woman reviews ultrasound images of her unborn baby.

contact

Gottfried Himmler, CSO
The Antibody Lab GmbH
Vienna, Austria
Tel: +43 680 3323300
Email:
gottfried.himmler@theantibodylab.com