

Shuwen Launches Multicentre Study on Pre-eclampsia Self-Testing with CercaTest RED

The prospective PreShield Study evaluates CercaTest RED in self-testing by pregnant women for pre-eclampsia screening and early detection

DEQING, ZHEJIANG PROVINCE, CHINA, January 20, 2025 /EINPresswire.com/ -- [Cerca Biotech](#) GmbH ("Cerca Biotech") and [Shuwen Biotech](#) ("Shuwen") announce that Shuwen has embarked on a multicentre prospective study in China evaluating [CercaTest RED](#) for self-testing by pregnant women for pre-eclampsia screening (the "PreShield Study").



PreShield is one of the largest studies for self-testing in pre-eclampsia, and we hope to further validate, through this study, the value of the device in at-home and resource-limited settings."

*Ada Yuan, MD, Shuwen's
Medical Director*

CercaTest RED is a proprietary point-of-care device to aid in the diagnosis and short term prediction of pre-eclampsia based on the presence of misfolded proteins in the urine of pregnant women. The association of misfolded proteins in urine with pre-eclampsia was originally discovered by Professor Irina Buhimschi at Yale University, and Shuwen has exclusive patent license to the technology in certain

territories including China.

The CercaTest RED device developed by Shuwen has previously been CE marked in Europe for professional use and recently approved in China for both professional use and self-testing at home. The device employs a one-step process using urine samples and requires no extra lab equipment. The test generates an easy to read visual test result in less than 10 minutes. The device has previously demonstrated good performance in several clinical studies at leading hospitals in China and the UK.

The PreShield Study is a large multicentre study organized and led by "China Healthy Birth Science Association" and sponsored by Shuwen. Twelve leading hospitals in Northwest China will participate in the study enrolling a total of 1500 pregnant women who are between 18 and 20 weeks of gestation age and are identified to be at high risk for pre-eclampsia. The enrolled women will conduct serial self-testing with CercaTest RED during their pregnancy. Shuwen expects the study to be completed by the end of 2025.

Commenting on the PreShield Study Ada Yuan, MD, Shuwen's Medical Director stated, "In

previous studies, CercaTest RED has shown promising clinical value in pre-eclampsia screening, triage and aid-in-diagnosis in second and third trimesters. PreShield is one of the largest studies for self-testing in pre-eclampsia, and we hope to further validate, through this study, the value of the device in at-home or resource-limited settings. We believe close monitoring at home of women with high risk factors, or suspected, of pre-eclampsia improves health and saves lives.”

About Cerca Biotech:

Cerca Biotech is a diagnostic company based in Germany focused on bringing novel and innovative diagnostic products to the oncology and women’s health market. We strive to introduce the best tests to meet the unmet clinical needs at an affordable cost, with clinical accuracy and rapid results as our focus. Utilising a combination of experienced distributors and direct sales Cerca Biotech has a commercial reach from Germany through the Nordics and Eastern Europe to the Middle East, Africa, India and beyond. Our team comprises of highly experienced commercial, technical and clinical experts in the field of IVD, allowing rapid deployment of novel technologies with a ‘get it right first time’ strategy. Cerca Biotech is an affiliated subsidiary of Shuwen Biotech. For more information, please visit:

www.cercabiotech.com.

About Shuwen Biotech

Shuwen Biotech is an integrated women’s health diagnostic company with offices in China and Germany. Shuwen houses an experienced development and regulatory team, GMP/ISO13485-certified IVD manufacturing facilities, and CAP-accredited central labs, all in line with global standards to continue to deliver transformational products and services to its customers globally and open new possibilities in the advancement of health. Founded on the principles of innovation, patent protection, and international collaboration, Shuwen established strategic partnerships with leading academic and commercial institutions to commercialize first-in-class diagnostic technologies and patents, and has developed and commercialized a range of novel diagnostics in the fields of cancer and women’s health. Shuwen has also developed quality companion diagnostics and provided central lab biomarker testing services to leading pharmaceutical developers and hospitals. Innovative diagnostic products in women’s health are marketed throughout China and internationally in more than 50 countries. For more information, please visit <https://www.shuwendx.com/en/home/>.

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