

Clinical Study Results on CercaTest RED™ Presented in 18th APCMFM

DEQING, CHINA, November 3, 2025 /EINPresswire.com/ -- [Shuwen Biotech](#), an integrated in vitro diagnostic (IVD) company today announced that results from a prospective clinical study on CercaTest RED™ was presented in the Asia Pacific Congress in Maternal Fetal Medicine 2025 (APCMFM) held from November 1 to 3 in Osaka, Japan.

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Our study suggests that CercaTest® RED could offer significant value in early detection in clinical settings and at home for early intervention, thereby improving maternal and fetal outcomes.”

*Dr. Xiaoxia Bai, Zhejiang
University Women's Hospital*

The Asia-Pacific Congress of Maternal-Fetal Medicine (APCMFM) is one of the most influential academic conferences in the field of maternal fetal medicine in the Asia-Pacific region.

CercaTest RED™ is a patent-protected point-of-care test for detection of misfolded proteins in urine samples to aid in the diagnosis and screening of preeclampsia after the 20th week of pregnancy. Preeclampsia is a hypertensive syndrome that complicates 2 to 8% of all pregnancies and accounts for about 70,000 maternal deaths and 500,000 fetal or newborn deaths each year worldwide. CercaTest

RED™ is non-invasive and easy to use, providing results within 10 minutes. It is a CE marked product, and has been approved in China for both professional and home testing.

During the first day of the Conference, Dr. Xiaoxia Bai from Women's Hospital of Zhejiang University School of Medicine presented a multicenter prospective longitudinal study using CercaTest RED™ involving 365 women suspected of having preeclampsia. When the CercaTest RED™ test results were combined with clinical parameters into a prediction model, a high accuracy was demonstrated in predicting preeclampsia within one week of clinical diagnosis, with an AUC 0.937 (95 % CI 0.911–0.964), PPV 54.4 % (95 % CI 44.3–63.7 %) and NPV 97.7 % (95 % CI 95.3–99.1 %). For severe preeclampsia the AUC rose to 0.955.

“CercaTest RED™ is a urine-based one-step test that can be performed by pregnant women or professionals with almost instant result,” said Dr. Xiaoxia Bai, “Our study suggests that it could offer significant value in early detection in clinical settings and at home for early intervention, thereby improving maternal and fetal outcomes.”

Shuwen Biotech is an integrated diagnostic company with offices in China and Germany. 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 a range of novel diagnostics in the fields of cancer and women's health. Shuwen has also developed quality companion diagnostics and provides central lab biomarker testing services to leading pharmaceutical developers and hospitals. Shuwen houses an in-house development team, CAP-accredited central labs, and GMP/ISO13485-certified IVD manufacturing facilities, 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. Innovative products are offered on the international market through [Cerca Biotech GmbH \(www.cercabiotech.com\)](https://www.cercabiotech.com), Shuwen's European subsidiary in Berlin.

Jay Z. Zhang

Shuwen Biotech Co. Ltd.

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