

Shuwen Biotech Announce CE Mark of qPCR Assay for ERBB2 Expression

CercaTest ERBB2 Assay and MammaTyper® may serve as novel companion diagnostics for anti-HER2 therapies targeting HER2-low cancer.

BERLIN, GERMANY, April 27, 2022 /EINPresswire.com/ -- Shuwen Biotech, an integrated in vitro



CercaTest™ ERBB2 Assay provides simple, fast, reproducible and accurate assessment of ERBB2 mRNA levels in tissue samples including HER2-low breast cancer samples.”

Barclay Li

diagnostic company with focuses on women’s health, today announces that it has obtained a CE mark for its quantitative qPCR kit for measuring ERBB2 gene expression in breast cancer tissue (CercaTest™ ERBB2 Assay).

Immunohistochemistry (IHC) analysis of HER2 protein expression and fluorescent in situ hybridization (FISH) have been used to characterize HER2 status in breast cancer to guide anti-HER2 therapies. However, studies have shown that current standard qualitative HER2 IHC assay is

insufficient especially in the low range (0 and 1+) of HER2 expression. In particular, a recent study showed the use of HER2 IHC assays as a companion diagnostic test for the new drug trastuzumab deruxtecan may result in misassignment of patients for treatment.¹ In view of the direct link between gene amplification, RNA transcription, and protein expression, experts have suggested measures of messenger RNA as potentially a more reproducible quantitative assay.²

CercaTest™ ERBB2 Assay is a quantitative real-time PCR assay for accurate measurement of ERBB2 gene expression in breast cancer tissue slices. Contiguous quantitative PCR cycle numbers may be generated from different FFPE tissue samples with the same IHC scores (such as HER2 0 or 1+), allowing delineation of different ERBB2 mRNA expression levels in full spectrum. The assay is run on commonly available PCR platforms, thus obviating the need for pathology readings and scorings and avoiding human subjectivity and errors.

“With CercaTest™ ERBB2 Assay and [MammaTyper®](#), we have shown that qPCR analysis of ERBB2 mRNA in our assays exhibits high inter- and intra-laboratory reproducibility and good concordance with HER2 IHC scores by experienced pathologists, even in HER2 low expression samples.^{3, 4} Coupled with our RNXtract® Nucleic Acid Extraction Kit and RNXtract® Automated Purification System, CercaTest™ ERBB2 Assay provides simple, fast, reproducible and accurate assessment of ERBB2 mRNA levels in tissue samples including HER2-low breast cancer samples.

We believe our CercaTest™ ERBB2 Assay and MammaTyper® potentially offer superior companion diagnostics for anti-HER2 therapies especially the newer generation of anti-Her2 ADC drugs,” commented Barclay Li, Chief Scientific Officer of Shuwen Biotech. Both CercaTest™ ERBB2 Assay and MammaTyper® are commercially available worldwide through [Cerca Biotech GmbH](#), a European subsidiary of Shuwen Biotech.

1. Fernandez et al., Examination of Low ERBB2 Protein Expression in Breast Cancer Tissue, JAMA Oncol. 2022 Apr 1; 8(4):1-4. doi: 10.1001/jamaoncol.2021.7239.
2. Allison et al., ERBB2-Low Breast Cancer-Is It a Fact or Fiction, and Do We Have the Right Assay? JAMA Oncol. 2022 Apr 1; 8(4):610-611. doi: 10.1001/jamaoncol.2021.7082.
3. [Wirtz](#) et al., Biological Subtyping of Early Breast Cancer: A Study Comparing RT-qPCR with Immunohistochemistry. Breast Cancer Res Treat. 2016 May 24; 157:437–446. Doi: 10.1007/s10549-016-3835-7
4. Varga et al., An International Reproducibility Study Validating Quantitative Determination of ERBB2, ESR1, PGR, and MKI67 mRNA in Breast Cancer Using MammaTyper®, Breast Cancer Res. 2017 May 11; 19(1):55. doi: 10.1186/s13058-017-0848-z.

About Shuwen Biotech

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 provided 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), Shuwen’s European subsidiary in Berlin.

For more information, please contact
Jay Z. Zhang, info@shuwendx.com
Richard Hughes, rich@cercabiotech.com

Jay Z. Zhang
Cerca Biotech GmbH
[email us here](#)

Visit us on social media:
[LinkedIn](#)

EIN Presswire's priority is source transparency. We do not allow opaque clients, and our editors try to be careful about weeding out false and misleading content. As a user, if you see something we have missed, please do bring it to our attention. Your help is welcome. EIN Presswire, Everyone's Internet News Presswire™, tries to define some of the boundaries that are reasonable in today's world. Please see our Editorial Guidelines for more information.

© 1995-2022 IPD Group, Inc. All Right Reserved.