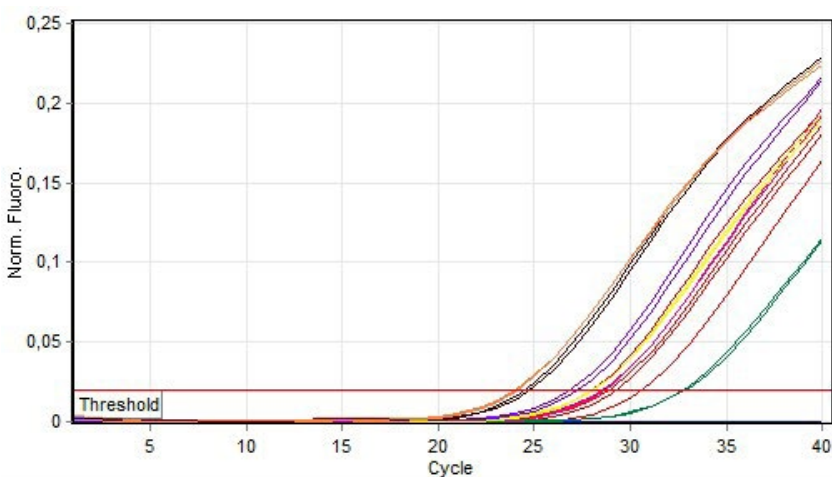




Method of HER2 gene copy number quantification in samples with indeterminate ISH

Introduction:

Current oncology is focused towards the search and use of predictive biomarkers that could determine suitable patients for targeted therapy. One of the well-known predictive biomarker is HER2 gene, localized on 17q, which is amplified in 15-20% breast cancer patients. HER2 amplification is poor prognostic factor but predictor of good response to anti-HER2 therapy (trastuzumab, pertuzumab and lapatinib) which significantly increases survival rates in both palliative and adjuvant settings. Anti-HER2 agents are approved for treatment of HER2- positive breast cancer patients usually determined by immunohistochemistry and in situ hybridization (ISH). The proper determination of HER2 status is therefore fundamentally important.



Technology description:

The HER2 DNA quantification kit was developed as a complementary test method for the quantification of HER2 gene in breast cancer patient samples which cannot be reliably evaluated by ISH. The kit works on the basis of the three duplex quantitative real-time polymerase chain reactions (qPCR) and is applicable for DNA from formalin-fixed, paraffin-embedded (FFPE) tissue samples. The HER2 gene copy number status is compared with three reference genes – GCS1 (chromosome 2), DCK (chromosome 4) and EPN2 (chromosome 17). The kit reliably detects HER2 gene amplification in samples containing at least 5% of strongly positive cells (approximately 20

HER2 gene copies per cell). High sensitivity and specificity levels were validated using 223 breast cancer patient samples.

Advantages:

Presented product is able to determine HER2 gene status in breast cancer FFPE samples with indeterminate ISH result. This kit allows quick and reliable identification of patients who could benefit from targeted anti-HER2 therapy and is useful in clinical practice as an alternative DNA-based method when ISH fails.

Publications:

Koudelakova, V., J. Berkovcova, R. Trojanec, J. Vrbkova, L. Radova, J. Ehrmann, Z. Kolar, B. Melichar, M. Hajduch. Evaluation of HER2 Gene Status in Breast Cancer Samples with Indeterminate Fluorescence in Situ Hybridization by Quantitative Real-Time PCR Method. *Journal of Molecular Diagnostic*. 2015, 17(4), 446-455. ISSN 1525-1578. IF: 5.201. PMID: 25956448

IP protection:

CZ 28596

Commercial offer:

Laboratory scale, validation study on patient samples.

Ownership:

Institute of Molecular and Translational Medicine, Faculty of Medicine and Dentistry, Palacky University, Olomouc.

Contact:

More information is available upon signing a CDA/NDA. Please contact IMTM's director (director@imtm.upol.cz) or the technology transfer office (tto@imtm.upol.cz)