therascreen PITX2 RGQ PCR Kit

A CE-MARKED CLINICALLY VALIDATED BIOMARKER ASSAY

Therawis
Pharma | Diagnostics

Background

Breast Cancer

One in eight to ten women will get breast cancer during their lifetime. More than 460,000 women in Europe are newly diagnosed with breast cancer each year, with about 50% characterized as high-risk for disease recurrence. Anthracycline-based chemotherapy is considered standard-of-care treatment in the adjuvant setting, but not all patients benefit equally well. A predictive biomarker assay for chemotherapy selection would therefore be highly appreciated.

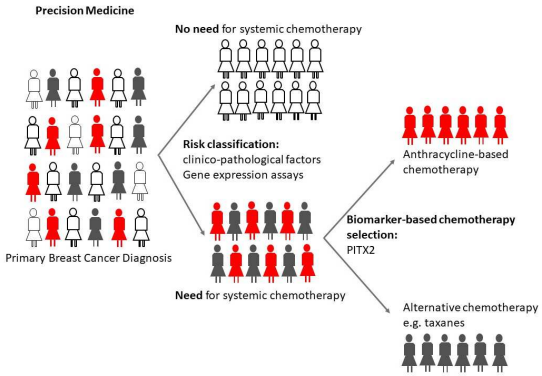

Fig. 1: risk classification & chemotherapy

PITX2

DNA methylation plays a crucial role in the development of cancer, including breast cancer. Hypermethylation of the pituitary homeobox gene 2 (PITX2) promotor region has been shown to be prognostic for disease-free survival and overall survival in several studies in estrogen-receptor positive breast cancer [Nimmrich et al. Breast Cancer Res Treat 2008; Maier et al. Eur J Cancer 2007].

Furthermore, PITX2 DNA methylation has been shown to predict outcome to adjuvant anthracycline-based chemotherapy in estrogen-receptor, lymph node-positive, HER2-negative breast cancer [Hartmann et al. Clin Cancer Res 2009; Aubele et al. Disease Markers 2017].

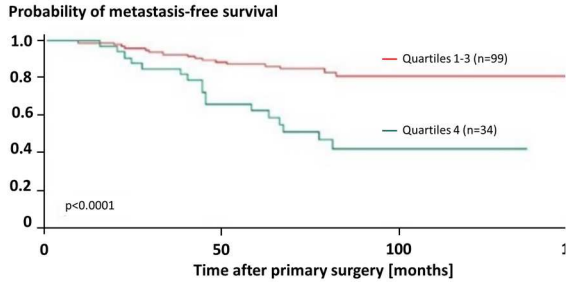

Fig. 2: PITX2 DNA methylation predicts patient outcome [Aubele et al. Disease Markers 2017]

Assay Validation

Earlier studies used fresh-frozen tissue not readily available in clinical routine. The new PITX2 assay format was validated using routinely available formalin-fixed, paraffin-embedded (FFPE) tissue. 205 patients (ER+, LN+, HER2-) were included in a prospective analysis, in which a predefined percent methylation ratio (PMR) cut-off of 12 was used for clinical validation.

Applying 10-year follow-up for disease-free survival (DFS) as primary study endpoint, patients with hypomethylation (PMR ≤12) demonstrated increased DFS (median of 105 months), while patients with hypermethylation (PMR >12) showed a statistically significant shorter DFS (median of 71 months).

therascreen PITX2 Test

The *therascreen* PITX2 RGQ PCR developed by Therawis Diagnostics together with its development partner QIAGEN, has been CE-marked in February 2018.

The assay identifies high-risk, lymph node-positive, estrogen-receptor positive, HER2-negative breast cancer patients, who are more versus less likely to benefit from adjuvant anthracycline-based chemotherapy.

The assay is a unique DNA methylation test that determines the percent methylation ratio (PMR) in promoter 2 of the pituitary homeobox transcription factor 2 (PITX2) gene as a novel biomarker. The kit has been optimized to detect and differentiate between methylated and unmethylated areas within the PITX2 promoter and is characterized by the following properties:

- limit of detection (LOD): PMR 4 to 92
- range of linearity: PMR 5 to 50
- ready-to-use solutions and reaction mixes
- Sample to Insight within 48 hours
- automated software for quick and easy result interpretation

"This novel test is a great step forward for us clinicians to further optimize patient treatment"

Prof. Dr. Marion Kiechle, Department of Obstetrics and Gynecology, Klinikum rechts der Isar, Technical University Munich, Germany

Requirements

For test performance the following sample material is required:

- 5 µm unstained section of formalin-fixed, paraffin-embedded (FFPE) breast cancer tissue
- surface area of at least 100 mm²

Workflow

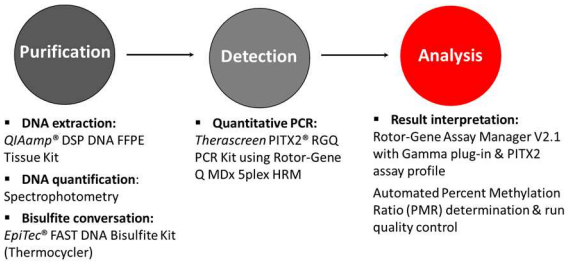

Fig. 3: therascreen PITX2 workflow

The workflow from Sample to Insight is performed using readily available kits within 48 hours.

Summary

The *therascreen* PITX2 RGQ PCR assay is a CE-marked test.

The PMR cut-off of 12 has been validated in high-risk luminal B-patients.

This cut-off is optimized to identify patients with high versus low probability to benefit from adjuvant anthracycline-based chemotherapy.

About Us

Therawis Pharma GmbH and Therawis Diagnostics GmbH are privately held, oncology-specialized companies with offices located in Munich, Germany.

We are an experienced group of clinical research experts with a track record of 20+ years for each team member. As a team we work together in the oncology area for 15+ years.

Contact

If you are interested in the *therascreen* PITX2 RGQ assay, please contact:

Dr. Roman Bartz
Head Clinical & Medical Affairs
Therawis Pharma GmbH
Grillparzerstr. 14, 81675 München

E-mail: roman.bartz@therawis.com
Mobile: +49 (0) 175-7612548
Office: +49 (0) 89 4142 4557 12
Fax: +49 (0) 89 4142 4557 40
Web: **www.therawis.com**

Kit Order Information

Kits can be ordered on the QIAGEN manufacturer's homepage.

https://www.qiagen.com/fi/shop/detection-solutions/personalized-healthcare/therascreen-pitx2-rgq-pcr-kit-ce/

Imprint:
Therawis Pharma GmbH
Therawis Diagnostics GmbH,
Grillparzerstr. 14, D-81675 München
Geschäftsführer: Prof. Dr. Olaf G. Wilhelm,
Sitz der Gesellschaft: München, Amtsgericht München