

## Applications

- Recurrence of atypical hyperplasias of the breast
- Recurrence of *in situ* carcinomas of the breast
- Diagnostic and prognostic

## Advantages

- Simple testing – using IHC technology
- Long term risk prediction independent of pathological diagnosis

## Inventors

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## Market Need

Breast cancer can recur at any time, but most recurrences occur in the first three to five years after initial treatment. Breast cancer can come back as a local recurrence (in the treated breast or near the mastectomy scar) or somewhere else in the body. Currently, the pathological diagnosis and characteristics of the biopsied tumor is used to predict a possible recurrence of breast cancer. There are no specific molecular biomarkers that could predict the recurrence of different types of breast cancer, including atypical hyperplasia and *in situ* carcinomas, independently of pathological diagnosis. Early risk assessment of possible recurrence is critical in designing treatment for these patients.

## Technology Summary

Dr. Marz and colleagues from Virginia Commonwealth University have identified a family of molecular biomarkers that can be used to assess the 5-year recurrence of atypical hyperplasias and *in situ* carcinomas of the breast. Using biopsy tissues from patients initially diagnosed with atypical ductal hyperplasia (ADH), atypical lobular hyperplasia (ALH), ductal carcinoma in situ (DCIS), or lobular carcinoma *in situ* (LCIS), researchers identified 6 biomarkers that are critical for predicting the cancer recurrence rate within 5 years from the initial diagnosis. Using a simple immunohistochemistry methodology, percentage of positive cells for each biomarker, as well as staining intensity was determined and the average values were evaluated separately for their ability to predict recurrence. Thanks to this evaluation patients can be categorized as low and high risk of recurrence and a proper treatment can be designed to meet the individual needs.

## Technology Status

*In vitro* data from patients available.

Patent pending: U.S. and foreign rights available.

This technology is available for licensing to industry for further development and commercialization.