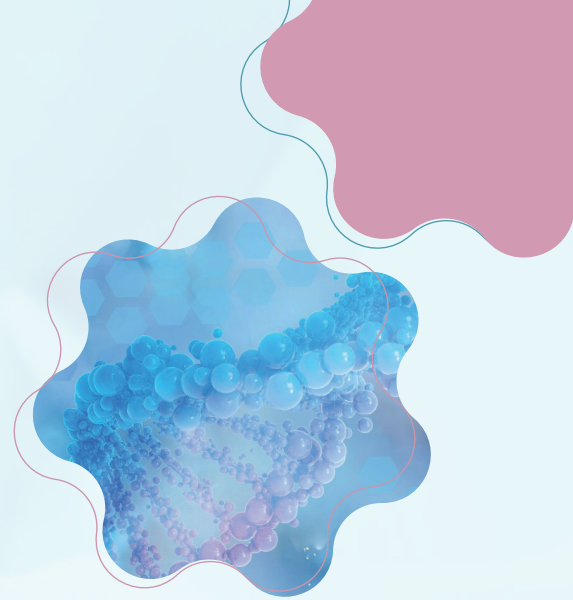


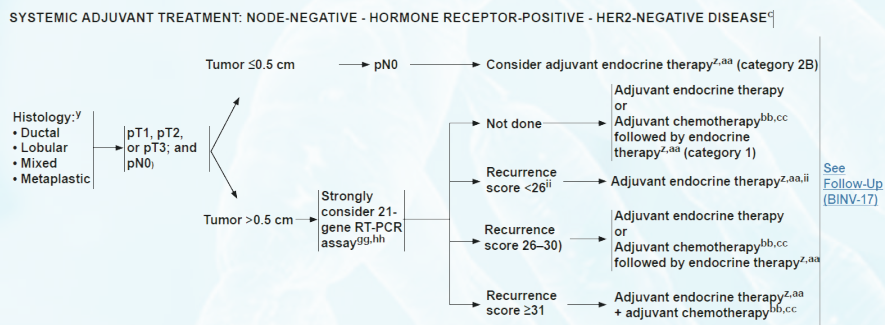
# Human Breast Cancer 21 Genes Expression Detection Kit (Real-Time PCR assay)



## BACKGROUND

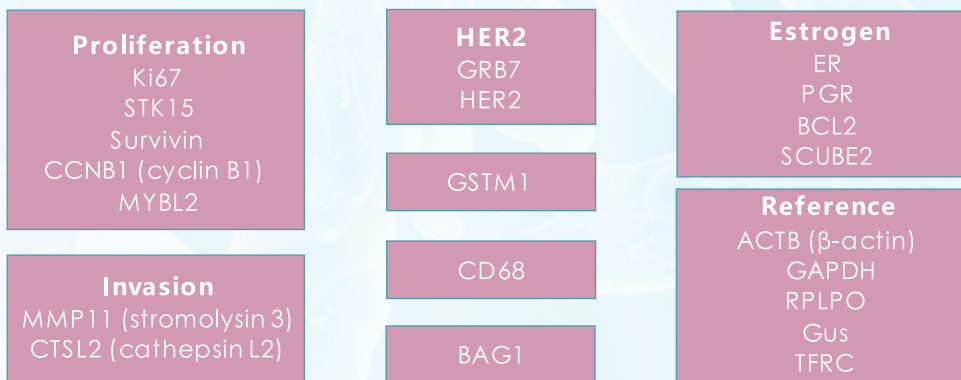
Breast cancer is the most common cancer in women and one of the leading causes of cancer-related deaths among women. The 21-gene test for breast cancer is a quantitative detection of mRNA expression levels of 21 genes associated with breast cancer. Specific algorithms are used to convert gene expression levels into a recurrence score (RS), and the score is used to determine whether breast cancer patients need adjuvant chemotherapy. The results of this test can provide information on prognosis, recurrence, and guide treatment.

In the updated NCCN Clinical Practice Guidelines for Breast Cancer (Version 3, 2018), which references the TAILORx study and previous research, the 21-gene test is now strongly considered for invasive breast cancer. The RS grading system can identify patients with a low risk of recurrence who can be spared from chemotherapy and avoid overtreatment.



NCCN Guidelines Version 3.2018 Breast Cancer

## DETECTED GENES



## PRODUCT INFORMATION

Product Name	Technology	Pack Size	Instruments Validated	Sample Type
Human Breast Cancer 21 Genes Expression Detection Kit	Real-Time PCR assay	6 Tests/Kit	Stratagene Mx3000P™ ABI7500 etc	Tumor tissue

## DETECTION SIGNIFICANCE

Patients with ER+ and HER2- invasive breast cancer can evaluate the risk of recurrence and the benefit of chemotherapy through 21 gene detection, which is helpful for a clinical selection of appropriate treatment options.

Classification	Recurrence risk	Treatment Implications
Postmenopausal patients with pN0 and pN1	<26	Patients with T1b/c-2, pN0, HR-positive, HER2-negative tumors, with risk scores (RS) between 0-10 have a risk of distant recurrence of <4% and those with RS 11-25 derived no benefit from the addition of chemotherapy to endocrine therapy in the prospective TAILORx study. Postmenopausal patients with pT1-3, pN1, HR-positive, HER2-negative, with RS <26 derived no benefit from the addition of chemotherapy to endocrine therapy in the prospective RxPONDER study.
	≥26	In postmenopausal patients with pT1-3, HR-positive, HER2-negative, and pN0 and pN1 (1-3 positive nodes) tumors and an RS ≥26, the addition of chemotherapy to endocrine therapy is recommended.
Premenopausal Patients with pN0	<15	Premenopausal patients with T1b/c -2, pN0, HR-positive, HER2-negative tumors with RS <16 derived no benefit from the addition of chemotherapy to endocrine therapy in the prospective TAILORx study.
	16-25	In premenopausal patients with RS between 16-25, a small benefit from the addition of chemotherapy could not be ruled out, but it is unclear if the benefit was due to the ovarian suppression effect promoted by chemotherapy in premenopausal patients. For this group, consider chemotherapy followed by endocrine therapy or alternatively, ovarian function suppression combined with either tamoxifen or an AI.
	≥26	In premenopausal patients with HR-positive, HER2-negative, and pN0 tumors and an RS ≥26, the addition of chemotherapy to endocrine therapy is recommended.
Premenopausal patients with pN1	< 26	In premenopausal patients with pT1-3 and pN1 (1-3 positive nodes) tumors and an RS <26, the addition of chemotherapy to endocrine therapy was associated with a lower rate of distant recurrence compared with endocrine monotherapy <sup>2</sup> but it is unclear if the benefit was due to the ovarian suppression effects promoted by chemotherapy. For this group of patients, consider chemotherapy followed by endocrine therapy or alternatively, ovarian function suppression combined with either tamoxifen or an AI.
	≥26	In premenopausal patients with HR-positive, HER2-negative, pT1-3 and pN1 (1-3 positive nodes) tumors and an RS ≥26, the addition of chemotherapy to endocrine therapy is recommended.

Breast cancer NCCN.2023.V4

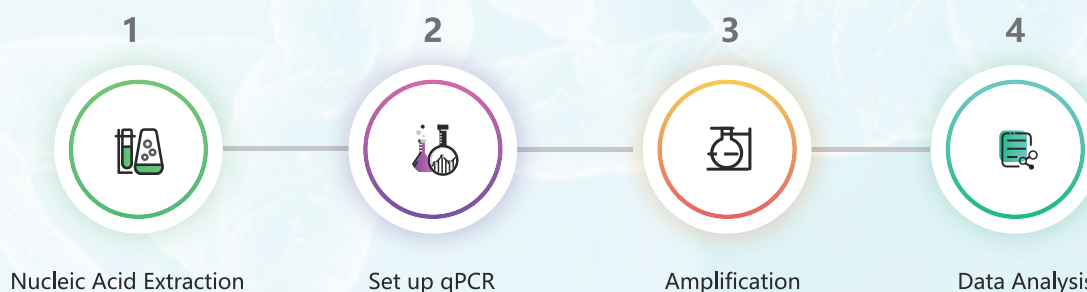
## FEATURES & ADVANTAGES

**Simple and Efficient:** Using high-efficiency reverse transcriptase, the reverse transcription can be completed in 30 minutes.

**Accurate and Reliable:** Based on real-time fluorescence quantitative PCR platform, using Taqman probe method, high specificity and sensitivity.

**Professional and Convenient:** Professional calculation formula, directly calculate the RS value, simple and convenient.

## DETECTION PROCESS



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