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PROSIGNA® (PAM50) prognostic gene expression test for breast cancer

Assess the risk of recurrence for optimal therapeutic care of your patients

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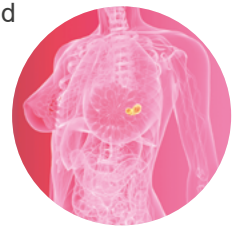
With more than 2,000 000 new cases and nearly 626,000 deaths a year, breast cancer is the most frequently diagnosed cancer and the leading cause of death from cancer in women in the world*.

**Globocan – data 2018*

In recent years, innovative tests in the field of molecular biology have enabled a genuinely theranostic approach to the treatment of cancer patients. The concept of "personalised medicine" is based on the principle that not all patients suffering from the same disease should necessarily receive the same treatment regime.

Prognostic gene expression test in breast cancer

The gene expression tests are based on the identification and quantification of messenger RNAs (mRNAs) of genes primarily involved in tumour proliferation.



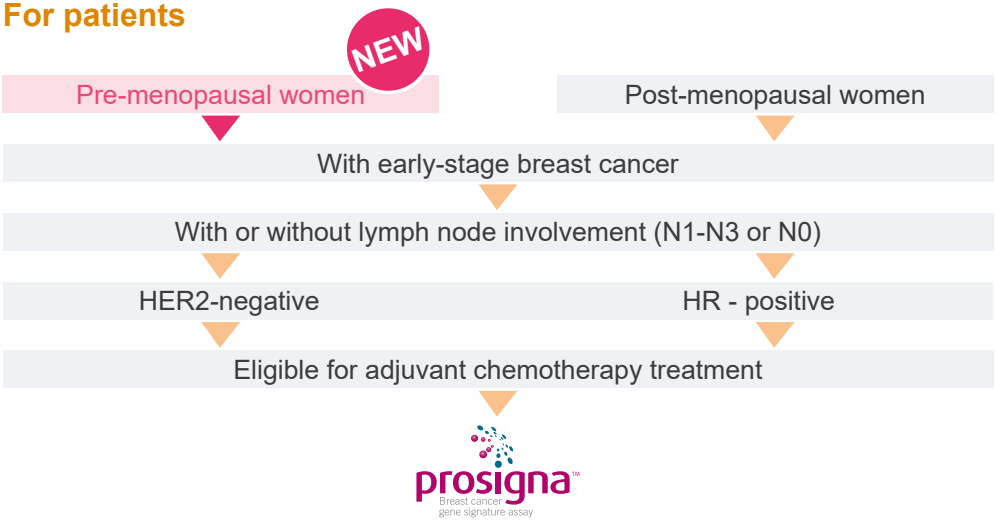
On the basis of expression analyses, breast cancers can be classified into four molecular subtypes. Each of these intrinsic subtypes or classes has its own prognosis and specific recommended treatment regimen:

Luminal A	Luminal B	HER2 enriched	Basal Like (or triple negative)
30 - 40 % of breast cancers	20 % of breast cancers	20 % of breast cancers	20 % of breast cancers
Hormone therapy		Anti-HER2 treatment	Chemotherapy
Combination with chemotherapy should therefore be discussed			

The Prosigna® (PAM50) test

The Prosigna® prognostic gene expression test for breast cancer was developed on the basis of the PAM50 gene signature that measures the expression of 50 genes involved in tumorogenesis.

For patients



A rapid, reliable and individualised assessment of risk

The analysis of these 50 genes associated with the size of the tumour and the number of affected lymph nodes provide, thanks to an algorithm, 4 highly contributive results:

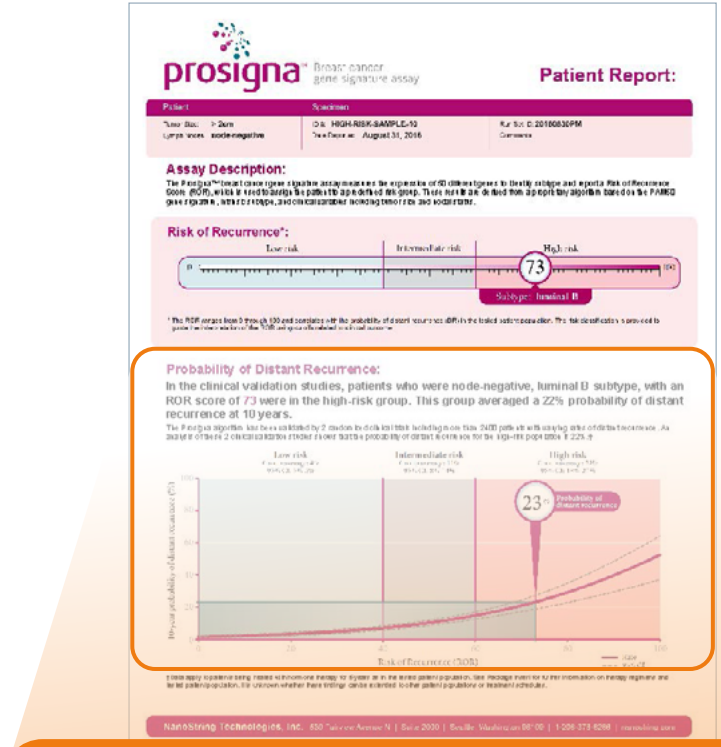
1	Intrinsic tumour subtype	Luminal A Luminal B HER2-enriched Basal-like
2	Individual estimate of the probability of remote recidivism at 10 years	0 - 100 %
3	RDR score: Risk of recidivism	Score on a scale of 0 to 100
4	Risk classification	Low Intermediate Hugh

Guiding the treatment regimen

Thanks to this risk classification, Prosigna makes it possible to identify patients:

- for whom there is a benefit to adding chemotherapy to hormone therapy,
- in order to avoid other treatments without benefit.

Example of Prosigna® results



Probability of Distant Recurrence:

In the clinical validation studies, patients who were node-negative, luminal B subtype, with an ROR score of 73 were in the high-risk group. This group averaged a 22% probability of distant recurrence at 10 years.

The Prosigna algorithm has been validated by 2 randomized clinical trials including more than 2400 patients with varying rates of distant recurrence. An analysis of these 2 clinical validation studies shows that the probability of distant recurrence for the high-risk population is 22%.†

Low risk
Intermediate risk
High risk
23%
Probability of distant recurrence
10-year probability of distant recurrence (%)
Risk of Recurrence (ROR)
Rate
95% CI

NEW

** FDA approval of the Prosigna test applies for post-menopausal women. However, according to results obtained in recent publications, the test can also be used in pre-menopausal women.*

These publications demonstrate the prognostic and predictive relevance of the molecular subtype and risk of recurrence (as part of neoadjuvant chemotherapy).[1-2]

Prosigna® - PAM50, the choice of Eurofins Biomnis

One of the few tests to identify the intrinsic tumour subtype in breast cancer

CE mark and FDA** authorisation

Included in the new international recommendations (ESMO, ASCO, AGO, SEOM, NICE, …)

“Next generation” test offering one of the best levels of evidence currently available on the market

Test classified with recommendation level HIGH for patients HR+/ HER2-/N0 (ASCO 2016)

Data validated in more than 3,000 post-menopausal women with early stage breast cancer

Model that links the ROR score of the PAM50 test to the probability of distant recurrence in the tested population validated by two studies (TransATAC clinical validation study and ABCSG-8 validation study).

***The FDA authorisation applies to post-menopausal women.*

References

1. *Jensen et al. Breast Cancer Research (2018) 20 :79)*
2. *Liu M. et al, Breast Cancer, Jan 2016*
3. *Lænkholm AV et al. J Clin Oncol. 2018 Mar 10;36(8):735-740.*
4. *Sestak I, Dowsett M, Zabaglo L, et al. Factors predicting late recurrence for estrogen receptor-positive breast cancer. J. Natl. Cancer Inst. 2013;105(19):1504-1511*
5. *Prat A, et al. Prediction of Response to Neoadjuvant Chemotherapy Using Core Needle Biopsy Samples with the Prosigna Assay. Clin. Cancer Research, 2016; 22: 560-566.*
6. *Ivana Sestak, et al. JAMA Oncol. 2018 doi:10.1001/jamaoncol.2017.5524*
7. *Nielsen T et al. (2014), BMC Cancer 14:177*

In practice

Sample	Breast cancer tissue block embedded in paraffin (Biopsy ou tumoral mass)
Controle	The tumour infiltration is controled from the tumour tissue by a anatomopathologist/physician at Eurofins Biomnis. Control of the tumour infiltration on each block by a anatomopathologist / Physician at Eurofins Biomnis
Required document	- "Oncology-Solid tumours" test request form (Ref. B9-INTGB) - Histological report for the diagnosis (including the tumour size and the lymph node envolvement)
TAT	7 - 10 working days
Technique	RT-PCR on nCounter DX Nanostring System
Analysis site	France (Lyon) In partnership with the Curie Institute (Paris)
Price	Contact us
Additional tests available at Eurofins Biomnis	▸ Ki67 ▸ HER2 status (IHC+ FISH) ▸ Hormone receptors status (IHC)
Find the preanalytical conditions for the Prosigna test on **www.eurofins-biomnis.com** > **Test guide** > Analysis code: **PAM50**	

Contact

Dedicated contacts will accompany you in the implementation of the Prosigna® test right through to the interpretation of results:

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