OncoBREAST Dx

Non-invasive blood and urine test useful to suggest a possible diagnosis in women with suspected malignancy in the breast, reduce inappropriate diagnostic tests, unnecessary tissue biopsies, days of hospitalization, as well as morbidity.
BREAST CANCER STATISTICS

Global
Breast Cancer ranks first in cancer incidence worldwide, representing 15.0% of all new cancer cases in the United States. A woman’s risk of getting Breast Cancer during her lifetime is about 1 in 8. Her lifetime chance of dying from Breast Cancer is about 1 in 37 (according to the American Cancer Society).

This cancer mainly develops in older women. About half of the women who are diagnosed with Breast Cancer are 62 years or older, although 29.50% of cases occur in case of women between 35 and 54 years.

The age at which women are diagnosed with Breast Cancer has been slowly falling over the past 20 years.

Number of New Cases and Deaths per 100,000
The number of new cases of Breast Cancer was 124.9 per 100,000 women per year. The number of deaths was 21.2 per 100,000 women per year. These rates are age-adjusted and based on 2010-2014 cases and deaths.

Percent Surviving 5 Years
Based on data from SEER 18 2007-2013, only the 89.7% of women being diagnosed with Breast Cancer will survive 5 years or more. Gray figures represent those who have died from Breast Cancer. Green figures represent those who have survived 5 years or more.

Lifetime Risk of Developing Cancer
Approximately 12.4 percent of women will be diagnosed with Breast Cancer at some point during their lifetime, based on 2012-2014 data.

Prevalence of this Cancer
In 2014, there were an estimated 3,327,552 women living with Breast cancer in the United States.
RISK FACTORS

- Aging
- Genetic risk factors
- Family history of breast cancer
- Personal history of breast cancer
- Race and ethnicity
- Dense breast tissue
- Certain benign breast conditions
- Lobular carcinoma in situ
- Menstrual periods
- Previous chest radiation
- Diethylstilbestrol exposure
- Birth control
- Hormone therapy after menopause
- Drinking alcohol
- Being overweight or obese
- Physical activity

SYMPTOMS & SIGNS

- Breast lump or mass
- Swelling of all or part of a breast (even if no distinct lump is felt)
- Skin irritation or dimpling
- Breast or nipple pain
- Nipple retraction (turning inward)
- Redness, scaliness, or thickening of the nipple or breast skin
- A nipple discharge other than breast milk
PROGNOSIS

Prognosis refers to the likely outcome, or forecast, of a disease. For cancer, it refers to the chance of recovery or recurrence. The prognosis for Breast Cancer is an estimate based on the course of the disease taken from studying hundreds or thousands of people who have been diagnosed.

Survival in Breast Cancer is strongly associated with tumor stage: when the cancer is detected at early stages—localized—, the survival rate at 5 years is 98.90%.

However, despite all screening programs (recommending annual mammograms beginning at age 40), 39% of patients arrive at an advanced stages—distant—, without having had previous symptoms, where survival rates are low (26.90%).

In a similar way to what happens in Lung Cancer, it is necessary to remove those suspicious Breast masses, which in most cases are not cancerous (in the United States each year are removed close to 1.7 million of these suspicious breast masses, being cancer only 15% to 20% of abnormalities).

STATE OF THE ART IN BREAST CANCER DIAGNOSIS

Breast Cancer is sometimes found after symptoms appear (mainly breast lump or mass, among others), but many women with Breast Cancer have no symptoms. This is why the American Cancer Society recommends women undergo regular screening mammography for the early detection of Breast Cancer.

Besides, if doctors find an area of concern on a screening test (such as a mammography), they use to ask for a breast biopsy to know for sure if it’s cancer (a biopsy is done when mammograms, other imaging tests, or a physical exam show a breast change that may be cancer).

Unfortunately biopsies cause permanent scar that may make future mammograms difficult to read, possible breast disfigurement and often require stitches and longer recovery. Besides, biopsies do not always obtain suspicious tissue to analyze, so they must be repeated.
OncoBREAST is based on a simple blood and urine test that can detect Breast Cancer with 91.7% of sensibility and 93.6% of specificity.

OncoBREAST reduces —in a very significant way—, the number of false positives (FP) and false negatives (FN) typical of other diagnosis procedures.

OncoBREAST can reduce up to 90% of unnecessary tissue biopsies that patients have to undergo when suspicious finding.

OncoBREAST has been performed with data from 3,655 patients, then fine-tuned by other research.
WHY CHOOSE BIOPROGNOS’ TEST?

✅ Innovative
Based on the combined count of a panel consisting of 6 Serum Tumor Markers (CA 15.3, CEA, EGFR, NGAL, NSE and 8-OHdG).

✅ Non-invasive
First test based on a simple blood test.

✅ Accurate
Very high diagnostic capabilities: 91.7% Sensitivity and 93.6% Specificity.

✅ Cost-effective
Solution to help in Breast Cancer diagnosis as well as confirmatory diagnostic —as an adjunct to suspicious image procedures findings, in order to reduce the number of unnecessary tissue biopsies that women have to undergo—.

✅ Already validated

FOR WHOM IS IT INTENDED?

✅ High-risk patients (both women with family history of Breast Cancer older than 40 years —for which risk is doubled if one first-degree relatives have been diagnosed, or risk is 5 times higher than average if two first-degree relatives have been diagnosed—; women having an abnormal gene, such as the BRCA1 or BRCA2 gene as well as abnormal CHEK2 gene).

✅ Women with previous image findings suspicious of Breast Cancer that should be biopsied to verify malignancy (as a complementary method for those with a level of BI-RADS 3 and 4A).
USES AND PURPOSES

- Aid in diagnostic assessments for high-risk patients.
- Confirm or discard malignancy from results obtained previously with other tests —such as Ultrasound (US) or Computed Tomography (CT) Scan—, to avoid invasive, costly and unnecessary biopsies —as well as days of hospitalization—, to low-risk patients.
- Therapy monitoring (how the cancer is responding to treatment) and predict or monitor for recurrence (detecting a recurrence sooner than other methods).

INTERPRETATION OF RESULTS

Once the blood is analyzed and the Tumor Marker values are calculated, a final report with the probability of finding Breast Cancer is generated.

This report includes all the patient information, results, comments —if available—, as well as conclusions. It also includes a comprehensive 3 level color score bar to facilitate test interpretation in an easy way, which can result in Negative, Low Positive and High Positive as follows:

- **Low**: There is a low risk of Breast Cancer.
- **Moderate**: There is a certain chance of Breast Cancer that does not allow to exclude malignancy, so it is recommended to repeat the test in 4 weeks to obtain a serial determination and determine the final risk. One woman will present Breast Cancer out of every two with “Moderate” result.
- **High**: There is a high risk of Breast Cancer.

The meaning of these segments of the score bar is:

- High: There is a high risk of Breast Cancer.
- Moderate: There is a certain chance of Breast Cancer that does not allow to exclude malignancy, so it is recommended to repeat the test in 4 weeks to obtain a serial determination and determine the final risk. One woman will present Breast Cancer out of every two with “Moderate” result.
- Low: There is a low risk of Breast Cancer and it is recommended to repeat the test in one year due to low risk of malignancy.
Improving clinical outcomes and quality of life