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Non-invasive blood tests for early detection and accurate management of cancer

Authorized laboratory:

Bioprognos SL
Benet Mateu, 40 · 08034 Barcelona, SPAIN
www.bioprognos.com · support@bioprognos.com

CE

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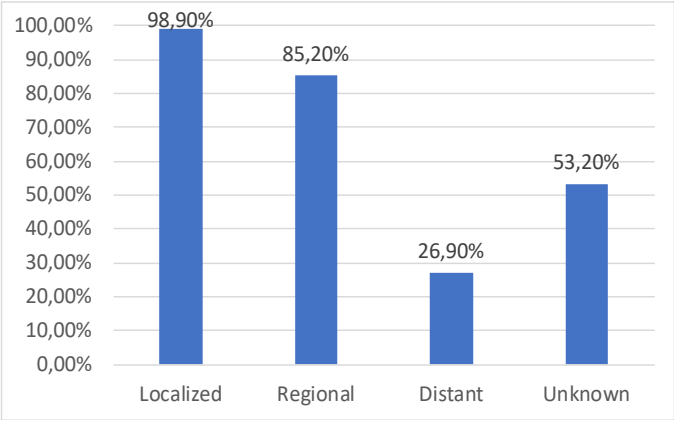
OncoBREAST Dx

Non-invasive blood and urine test to help in differential diagnosis of women with suspected malignancy in the breast, reducing inappropriate diagnostic tests, unnecessary invasive tissue biopsies, days of hospitalization and morbidity.

BREAST CANCER PROGNOSIS

Survival in Breast Cancer is strongly associated with tumor stage: when the cancer is detected at early stages —localized—, the 5-year survival rate (percentage of people who live at least 5 years after being diagnosed) is 98.90%, therefore an early diagnosis saves lives.

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



Survival rate at 5 years according to SEER 18 (Surveillance, Epidemiology and End Results program based on stage distribution between 2007-2013)

Besides, when doctors find an area of concern on a screening test (such as a Mammography), they usually ask for a biopsy to confirm/discard cancer, although only a few of these suspicious masses are malignant (in the United States each year are removed close to 1.7 million of these masses, being cancer only 15% to 20% of the abnormalities found).

Also, several findings are not conclusive (such as BI-RADS 3), meaning imaging procedures must be repeated between 3 to 12 months.

WHAT IS ONCOBREAST DX?

- Innovative: Multiple Biomarkers Disease Activity Algorithm (MBDAA) developed with an Artificial Intelligence (AI) software.
- Non-invasive: First test based on a simple blood and urine test that analyses a panel consisting of several serum tumor markers with other general biochemistry values.
- Accurate: Very high capabilities to confirm or discard previous suspicious imagen findings.
- Effective: Solution to help in Differential Diagnosis for Breast Cancer —as an adjunct to suspicious image findings—, in order to reduce the turnaround time (TAT) for diagnosis confirmation, as well as the number of unnecessary tissue biopsies.
- Already validated: CE Declaration of Conformity reached (According to Annex VII of Medical Device Directive 93/42/EEC).

USES AND PURPOSES

- Confirm or discard Breast Cancer from suspicious images.

FOR WHOM IS IT INTENDED?

- Women with breast image results classified as BI-RADS 3 that should be repeated in a few months for surveillance.
- Women with breast image results classified as BI-RADS 4A or BI-RADS 4B that should be followed by a tissue biopsy.
- Women with other image findings besides BI-RADS, with suspicion of Breast Cancer that should be biopsied to confirm or discard malignancy.

LEARN MORE

- Ask more information to your doctor or visit our website to learn all about OncoBREAST Dx.