BreastSentry™

Help Predict a Woman's Risk for Developing Breast Cancer

The Problem:

- An estimated 20% of breast cancers are missed at least once by mammography, especially if the patient has dense breasts or has mucinous, lobular or rapidly growing cancers.[1]
- 50% of women have dense breasts and cannot benefit from mammography alone.[1]

Why Should I Use This Test In My Practice?

- BreastSentry can help you to determine if a female patient should be referred for advanced breast diagnostic procedures.
- BreastSentry provides women with additional information about breast health beyond mammography.
- Empowers women to identify breast cancers early, when they are most treatable.

The BreastSentry Solution:

- BreastSentry measures the levels of two bio-markers, proneurotensin (pro-NT) and proenkephalin (pro-ENK), which are highly predictive of a woman's risk for developing breast cancer.
- Elevated levels of pro-NT and decreased levels of pro-ENK are strong, independent risk factors for the development of breast cancer.

The Science Behind the Test:

- Two large Swedish general population longitudinal studies were used to validate the BreastSentry test.[2-11]
    - The Malmo Diet and Cancer study (MDC) and the Malmo Preventive Project (MPP) found a significant predictive relationship between individual pro-NT (neurotensin) and pro-ENK (enkephalin) biomarkers and the development of breast cancer (Participants 28,098)
    - Results from the MDC study in 2012 showed a highly significant relationship between the concentration of pro-NT in the blood and the risk of developing breast cancer; the MPP study confirmed these results.

BreastSentry Patient Profile:

- The test is for any woman who needs further evaluation of breast cancer risk.
- The test should not be used on women with:
    - a personal history of breast cancer
    - a confirmed or suspected genetic mutation known to increase risk of breast cancer (e.g., BRCA)
    - a history of previous radiotherapy to the chest at a young age
    - a history of kidney disease

The Patient Benefit:

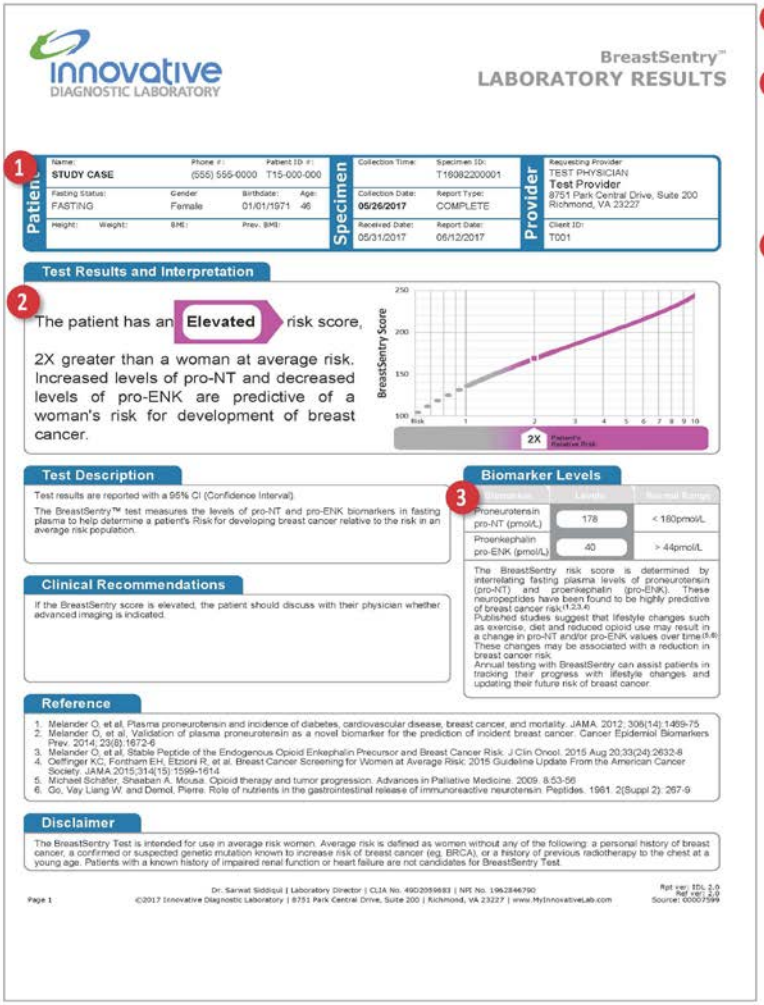
- Finding Breast Cancer early saves lives.
  - When Breast Cancer is found early, the five-year survival rate is 98%. [12]
  - When Breast Cancer is found late, the five-year survival rate drops to 22%.[12]

How Do I Get Started?

1. Fill out a new account form and submit it to client relations clientrelations@myinnovativelab.com.
2. Upon completion of new account form, a starter kit(s) will be shipped based upon your testing needs.
3. Schedule training of staff through onboarding call with Innovative Diagnostic Laboratory.

How To Read A Lab Report

BreastSentry™



1. All patient demographics appear at the top of each page.
2. Women with an elevated BreastSentry risk score Should discuss with their doctor whether screening such as breast ultra-sound, digital breast tomosynthesis (DBT), and/or a breast MRI examination is indicated
3. The patient's pro-NT and pro-ENK values are reported individually. Patients should discuss with their physician lifestyle changes,such as diet and exercise, which may affect these biomarker levels and reduce the patients risk of breast cancer.

BreastSentry was developed in, and is performed in, IDL's CLIA-certified laboratory.

What Do I do With the Results?

- Women with elevated BreastSentry scores may need to be referred for advanced imaging tests, such as breast MRI, in addition to a screening mammogram.

References

1. https://www.cancer.gov/types/breast/mammograms-fact-sheet/#q3. Accessed 2018
2. Melander O, Belting M, Manjer J, et al. Validation of plasma proneurotensin as a novel biomarker for the prediction of incident breast cancer. Cancer Epidemiol Biomarkers Prev. 2014 Aug;23(8):1672-6.
3. Melander O, Orho-Melander M, Manjer J, et al. Stable Peptide of the Endogenous Opioid Enkephalin Precursor and Breast Cancer Risk. J Clin Oncol. 2015 Aug 20;33(24):2632-8
4. Dupouy S, Mourra N, Doan VK, et al. The potential use of the neurotensin high affinity receptor 1 as a biomarker for cancer progression and as a component of personalized medicine in selective cancers. Biochimie 2011;93:1369–78
5. Melander O, Maisel AS, Almgren P, et al. Plasma proneurotensin and incidence of diabetes, cardiovascular disease, breast cancer, and mortality. JAMA 2012;308:1469
6. Dupouy S, Viardot-Foucault V, Alifano M, et al. The Neurotensin Receptor-1 Pathway Contributes to Human Ductal Breast Cancer Progression. PLoS ONE 2009; 4(1): e4223. https://doi.org/10.1371/journal.pone.0004223
7. Hoff SR, Abrahamsen A-L, Samset JH, et al. Breast Cancer: Missed Interval and Screening-detected Cancer at Full-Field Digital Mammography and Screen-Film Mammography— Results from a Retrospective Review. Radiology 2012 264:2, 378-386
8. Gartlehner G, Thaler K, Chapman A, et al. Mammography in combination with breast ultrasonography versus mammography for breast cancer screening in women at average risk. Cochrane Database of Systematic Reviews 2013, Issue 4. Art. No.: CD009632.
9. Ho JM, Jafferjee N, Covarrubias GM, et al. Dense breasts: a review of reporting legislation and available supplemental screening options. AJR Am J Roentgenol. 203(2):449-56, 2014.
10. Sprague BL, Gangnon RE, Burt V, et al. Prevalence of mammographically dense breasts in the United States. J Natl Cancer Inst. 106(10), 2014.
11. Yaghjyan L, Colditz GA, Collins LC, et al. Mammographic breast density and subsequent risk of breast cancer in postmenopausal women according to tumor characteristics. J Natl Cancer Inst. 103(15):1179-89, 2011.
12. https://www.cancer.org/cancer/breast-cancer/understanding-a-breast-cancer-diagnosis/breast-cancer-survival-rates.html. Accessed 11/1/2017