



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.

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.



BreastSentry™
LABORATORY RESULTS

1	Name: STUDY CASE	Phone #: (555) 555-0000	Patient ID #: T15-000-000	Collection Time: T16092200001	Specimen ID: T16092200001	Receiving Provider: TEST PHYSICIAN
	Fasting Status: FASTING	Gender: Female	Birthdate: 01/01/1971	Age: 46	Collection Date: 05/26/2017	Report Type: COMPLETE
	Height:	Weight:	BMI:	Received Date: 05/31/2017	Report Date: 06/12/2017	Client ID: T001

Test Results and Interpretation

The patient has an **Elevated** risk score, 2X greater than a woman at average risk. Increased levels of pro-NT and decreased levels of pro-ENK are predictive of a woman's risk for development of breast cancer.

Test Description

Test results are reported with a 95% CI (Confidence Interval). The BreastSentry™ test measures the levels of pro-NT and pro-ENK biomarkers in fasting plasma to help determine a patient's risk for developing breast cancer relative to the risk in an average risk population.

Clinical Recommendations

If the BreastSentry score is elevated, the patient should discuss with their physician whether advanced imaging is indicated.

Biomarker Levels

Pro-neurotensin pro-NT (pmol/L)	178	< 180pmol/L
Pro-enkephalin pro-ENK (pmol/L)	40	> 44pmol/L

The BreastSentry risk score is determined by interrelating fasting plasma levels of proneurotensin (pro-NT) and proenkephalin (pro-ENK). These neuropeptides have been found to be highly predictive of breast cancer risk.^{1,2,3,4} Published studies suggest that lifestyle changes such as exercise, diet and reduced opioid use may result in a change in pro-NT and/or pro-ENK values over time.⁵ These changes may be associated with a reduction in breast cancer risk. Annual testing with BreastSentry can assist patients in tracking their progress with lifestyle changes and updating their future risk of breast cancer.

Reference

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3. Melander O, 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. Ceilinger KC, Fortnam EH, Elzores R, et al. Breast Cancer Screening for Women at Average Risk: 2015 Guideline Update From the American Cancer Society. *JAMA*. 2015;314(15):1599-1614
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Disclaimer

The BreastSentry Test is intended for use in average risk women. Average risk is defined as women without any of the following: a personal history of breast cancer, a confirmed or suspected genetic mutation known to increase risk of breast cancer (eg. BRCA), or a history of previous radiotherapy to the chest at a young age. Patients with a known history of impaired renal function or heart failure are not candidates for BreastSentry Test.

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 Ref: IDL 2.0 Rev: 4/13/17 Source: 00007259

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 ultrasound, 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 patient's risk of breast cancer.

References

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