Dorie Vier

I was diagnosed with atypical lobular hyperplasia in 2013. My doctor told me that I could take tamoxifen as a preventative treatment. However, I

read that many women with my diagnosis never go on to develop cancer. I worried about the known side effects of the drug. Additionally, I was concerned that if I took the drug, I might develop a resistance to it and it might not be as effective at the point that I would really need it. I decided not to take the drug with the information that I had to go on. Unfortunately, in 2017 I was diagnosed with invasive ductal carcinoma. Of course, I second guessed my decision to refuse tamoxifen four years earlier. If the BBDRisk Dx® test had been available to me I would have had a way of knowing that my risk for developing cancer was high, and the decision to take a preventive course would have been an easy one for me. This test, no doubt, will help women make the best decisions when faced with hyperplasia.

Lori Baran

I am an 8-year survivor of metastatic breast cancer. I believe that knowledge is power, and that being able to assess your cancer risk is a "must" when weighing out your treatment options. I would highly recommend the BBDRisk Dx® test for anyone with pre-cancerous breast tumors.



Valerie Fraser, Research Advocate Women diagnosed with precancerous breast conditions such as hyperplasias and papillomas from biopsies are often confused and concerned about their

risk of progression to invasive breast cancer. The BBDRisk Dx® test provides a personal 5 year risk assessment with a low, intermediate or high risk score to identify those who are at greater risk of developing breast cancer. BBDRisk Dx® is an exciting new tool in the breast cancer assessment toolbox that will enable women and their doctors to make more personalized breast cancer risk prevention decisions.

When and How Is the BBDRisk Dx® Test Ordered?



BBDRisk Dx® Test ordered by Surgeon, or Oncologist or Primary Care Physician or Gynecologist and tissue sample mailed to Silbiotech by Pathologist

- The BBDRisk Dx® test can be ordered at any time after the hyperplasia diagnosis.
- However, it is recommended that the test is ordered to understand personalized risk level before the patient and healthcare provider discuss and consider all the options in medical management.
- No need to undergo any additional procedures to have the BBDRisk Dx® test. It is performed on a small amount of tissue that was previously removed during the biopsy.
- The test can be ordered by a primary care physician, the surgeon who performed the biopsy, a clinical oncologist, or a gynecologist.
- The test results report will be sent to the ordering physician within 2-3 weeks of receiving the tissue.
- Details for ordering the testcan be found on our website below.

PUBLICATIONS ON BBDRISK DX TEST DEVELOPMENT

- 1. Poola et al., 2019, Cancer Prevention Research, Vol. 12, pp. 471-480
- 2. Poola et al., 2008, Clinical Cancer Research, Vol. 14, pp. 1274-1280
- 3. Poola et al., 2006, Clinical Cancer Research, Vol. 12, pp. 4773-4783
- 4. Poola et al., 2005, Nature Medicine, Vol. 11, pp. 481-483 For more info email: info@bbdrisk.com

Website: www.BBDRisk.com



For an Informed Treatment Decision to Prevent Breast Cancer Among Women with Hyperplasias

Diagnosed with Breast Atypia, or other Hyperplasia? Decision Dilemma About Preventative Therapy?



The information provided here shows how the BBDRisk Dx® test can help you to understand your risk and may help you and your doctor make a more informed treatment decision.



High Risk Breast Hyperplasias and Preventative Treatment Dilemma:

Clinical studies have shown that $\sim\!20\%$ of women diagnosed with atypical-, and $\sim\!10\%$ of women diagnosed with non-atypical hyperplasias and papillomas subsequently develop breast cancer. The challenge has been how to precisely identify a subclass of elevated risk patients who will benefit from preventative therapies.

What is the BBDRisk Dx® Test and How Can It Help?

The BBDRisk Dx® is a unique genomic test developed to help women diagnosed with high risk precancerous breast tumors which have one or more of the following: Atypical Ductal Hyperplasia (ADH), Atypical Lobular Hyperplasia (ALH), Usual Ductal Hyperplasia (UDH) or Papilloma. The BBDRisk Dx® test assays multiple oncogenic proteins in hyperplastic tissue from which a Risk Score is calculated to predict the likelihood of developing breast cancer in the next 5-10 years.

Is the BBDRisk Dx® Test Covered by Insurance?

BBDRisk Dx Test coverage is approved by Medicare Medicaid (CMS) and Major private Insurance agencies. A patient's insurance company will be billed directly. If the insurance carrier does not cover some or all of the cost of the test, we will work with patients to set up an alternate payment plan.









Integration of BBDRisk DX® Test in Clinical Oncology Practice to Prevent Breast Cancers

Radiologist identifies a suspected mass by Mammography/MRI and reports to primary care physician. The patient referred to a Surgeon for biopsy.

Risk Score ≤ 0.5

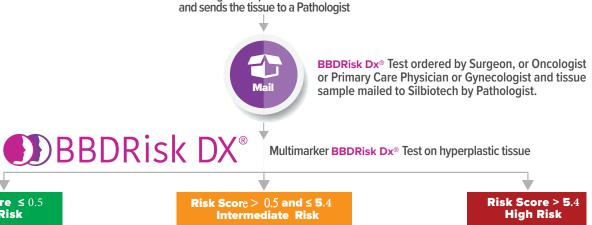
Low Risk







Pathologist reviews histology of the mass and diagnoses as Atypical Hyperplasia or Usual Hyperplasia or Papilloma or any combination.







Stop $^20\% - 25\%$ of overall sporadic breast cancers/year





How Can the BBDRisk Dx® Test Results Help to Understand the Cancer Risk Level?

The results of the BBDRisk Dx® assay will be reported as a Cancer Risk Score from 0-10, with higher scores corresponding to higher risk of subsequent cancer development.

In addition, an overview of the clinical validation study will be provided which correlates the Risk Score to cancer rate. The BBDRisk Dx® results will indicate whether the patient falls under a Low Risk, Intermediate Risk or Elevated Risk category – important information when deciding on undertaking treatments or surgery to prevent cancer.

A Low Risk result does not guarantee a patient will not develop breast cancer. A High Risk or Intermediate Risk result does not guarantee that a patient will develop cancer. These results, in addition to all other factors, will help the patients and physicians make the most appropriate breast cancer prevention treatment decisions.

SILBIOTECH, INC.

7858 Beechcraft Ave, Gaithersburg, MD 20879 Email: info@BBDRisk.com

CLIA # 21D2137469

Clinical Director: John Gillespie, M.D.

www.BBDRisk.com