



BBDRisk Dx™ Test Results Report

7858 Beechcraft Ave
Gaithersburg, MD 20879
Phone: 301-787-1216
Fax: 301-987-9724
<http://www.breasthyperplasiacancerrisk.com>

Patient Information

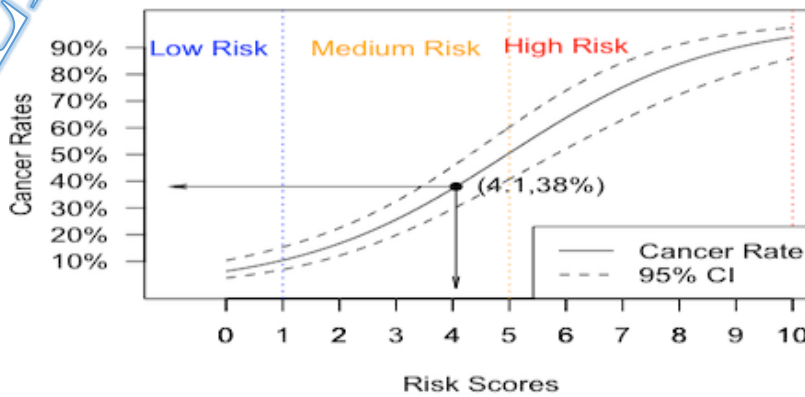
Patient Name: Doe, Missie S. **Order Received:** 7/7/2017
DOB: 5/6/1979 **Date Reported:** 7/21/2017
Date of Surgery: 6/6/2017 **Client:** University Hospital
Medical Record # S2017- 11111 **Ordering Physician:** Jane Jones, M.D.
Specimen Type: Atypical Ductal Hyperplasia and Atypical Lobular Hyperplasia

BBDRisk Dx™ Test Description

The BBDRisk Dx™ test assays 3-4 markers, CEACAM6, HYAL1, MMP-1 and HEC1, in hyperplastic breast tumor tissues by immunohistochemistry. A Cancer Risk Score is calculated from the expression results of the assayed markers using Silbiotech, Inc’s proprietary algorithms. The Cancer Risk Score values range from 0-10. The higher the risk score, the higher one’s risk of developing breast cancer. The risk level, Low-, Intermediate- or High, is predicted by comparing the patient’s risk score to a plurality of risk scores in Silbiotech’s database.

BBDRisk Dx™ Test RESULTS: Breast Cancer Risk Score = 4.1

The cancer rates by risk scores



Scoring is based upon the findings summarized in the Clinical Validation section of this Report and are applicable to patients defined in that section. It is not known whether the findings apply to patients outside of the defined criteria.

Clinical Validation Study: Risk Stratifications of Precancerous Breast Tumors

The clinical validation study included patients who had precancerous tumors that had one or more of the following histologies: ADH, ALH, UDH, ULH, Papillomas and Sclerosing adenosis and clinical surveillance of up to 19 years. Those patients who had a Risk Score of ≤ 1 had an average cancer free rate of 95% (95% CI: 5%-10%) for at least five years after precancerous diagnosis. Those patients who had a Risk Score of ≤ 5 had an average cancer free rate of about 85% for the first 5 years (95% CI: 7%-10%). Those patients who had a Risk Score of ≥ 5 had an average rate of cancer development of 60% (95% CI: 6%-10%) within 5 years. These results are from a NCI grant supported clinical study conducted with tumor tissue samples from over 500 patients with up to 19 years of clinical follow up information.

Laboratory Clinical Director: John Gillespie, M.D; CLIA Number: 21D2137469

The BBDRisk Dx™ test was developed and validated by Silbiotech, Inc. with grant support from the National Science Foundation and National Cancer Institute. The laboratory is approved under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high-complexity clinical testing. This test is intended for clinical purpose and should not be regarded as investigational or for research. The BBDRisk Dx™ test and Risk Scores are registered trademarks of Silbiotech, Inc. All rights reserved.

Disclaimer

The results of the test can be altered/affected by variables beyond our laboratory control. For example, non-standard fixatives, fixing duration, time lapse between biopsy and fixation and depth of the tissue block from which slides are cut. As with any IHC, a false negative result is possible. Silbiotech, Inc. does not recommend any treatments based on the BBDRisk™ Dx test results. While BBDRisk Dx™ test results provide useful information, medical management decisions should be made based on consultation between each patient and his or her healthcare professional. The patient and his or her doctor are solely responsible for making any medical management decisions.