



BBDRisk Dx[®] Test Results Report

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Basic Information

Patient Name: Doe, Missie S.

DOB: 5/6/1979

Date of Surgery: 6/6/2017

Medical Record # S2017- 11111

Specimen Type: Breast Atypical Hyperplasia

Order Received: 7/7/2017

Date Reported: 7/21/2017

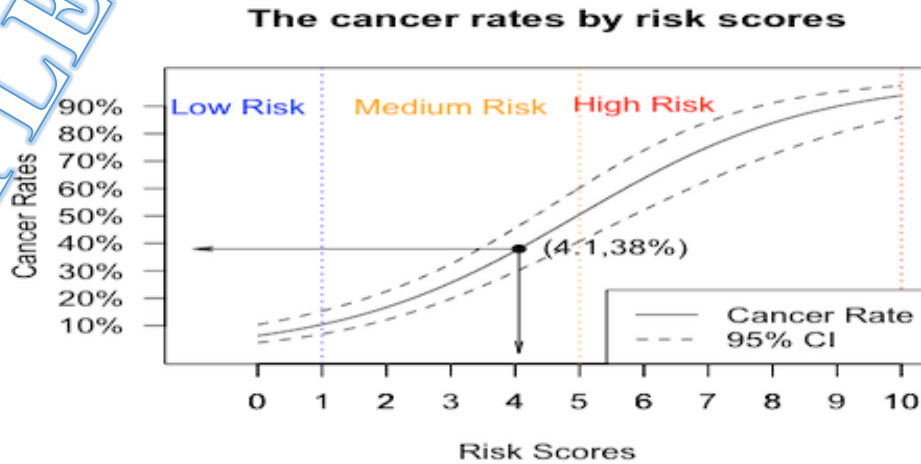
Client: University Hospital

Ordering Physician: Jane Jones, M.D

BBDRisk Dx[®] Assay

BBDRisk Dx[®] assays four cancer markers, CEACAM6, HYAL1, MMP-1 and HEC1 in atypical breast hyperplasia tissues by immunohistochemistry. The Cancer Risk Score is calculated from the expression results of the above four markers. The Cancer Risk Score values range from 0-10, with higher risk scores corresponding to higher risk of subsequent cancer development.

BBDRisk Dx[®] Test Results: Breast Cancer Risk Score = 4.1



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

Clinical Validation Study: Risk Stratifications of Breast Atypical Hyperplasia

The clinical validation study included patients who had atypical hyperplasia that had ADH or ALH or both and clinical surveillance of up to 19 years. Those patients who had a Risk Score of ≤ 0.5 (Low Risk) had an average cancer rate of 0% (CI: 0%, 3 %) for at least five years after atypical diagnosis and 3% (CI: 0%, 8 %) for up to 19 years. Those patients with Risk Scores >0.5 and ≤ 5.5 (Medium Risk) had an average cancer rate of 11 % (CI: 1%, 20 %) for the first 5 years and 18% (CI: 6%, 31%) for up to 19 years. Those patients who had a Risk Score of >5.5 (High Risk) had an average rate of cancer development of 72% (CI: 62%, 83%) within five years and 92% (CI: 85%, 98%) for up to 19 years. It is not known whether the findings apply to the patients outside of the defined criteria.

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

BBDRisk Dx[®] was developed and validated by Silbiotech, Inc. with grant support from NSF and NCI, NIH. The laboratory is regulated 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. BBDRisk Dx[®] test and Risk Scores are registered trademarks of Silbiotech, Inc. All rights reserved.

Disclaimer

The results reported here are based on the tissue sample submitted. 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 the level of tissue cut from the block. As with any IHC, a false negative result is possible. Silbiotech, Inc. does not make any recommendations for treatments based on the BBDRisk Dx[®] test results. Follow up of the patients is strictly based on clinician's judgment.