



Breast Cancer Gene Expression Profile



CONFIDENTIAL

ORDERING PHYSICIAN

Bobby Doctor PhD
The Doctor's Place
123 Street Name
Anywhere, UT 84101

Pathology: Jonny Pathologist PhD

SPECIMEN

Specimen Type: **Resection**
Tissue: **Breast**
Surgery Date: **Mar 13, 2019**
TRF Received: **Sep 23, 2019**
Sample Received: **Sep 23, 2019**
Report Date: **Dec 6, 2019**

PATIENT

Last Name: **Pt Last Name**
First Name: **Pt First Name**
Date of Birth: **Jan 7, 1968**
Patient ID: **Patient id**
Gender: **Female**
Accession #: **08000143-BLD**
Requisition #: **08000143**

Block(s) Analyzed:

12-GENE MOLECULAR SCORE: **11.0**

TUMOR STAGE: **pT3** (>5 cm)

NODAL STATUS: **pN1** (1-3 positive nodes)

EPclin
RISK SCORE

5.8
HIGH RISK

EndoPredict® is a gene expression assay for patients with ER+, HER2- early-stage breast cancer. From this genomic analysis, a 12-Gene Molecular Score is assigned. This score, combined with tumor size and nodal status, contributes to the EPclin Risk Score, from which the risks of distant recurrence (10-year and 5 to 15-years) with 5 years of adjuvant endocrine therapy alone and the estimated absolute benefit of chemotherapy (at 10 years) are determined.

INITIAL Treatment Planning

0-10 YEAR LIKELIHOOD OF DISTANT RECURRENCE
(For patients treated with 5 years of endocrine therapy alone)

69%

**ESTIMATED ABSOLUTE
CHEMOTHERAPY BENEFIT AT 10 YEARS**

32%

LONG-TERM Treatment Planning

LIKELIHOOD OF LATE DISTANT RECURRENCE YEARS 5-15
(For patients with no recurrence after 5 years of endocrine therapy
and no chemotherapy administered)

56%

Note: Recurrence risk and chemotherapy benefit estimates contained within this report are based on analysis of multiple cohorts of women with resected ER+/HER2- invasive female breast cancer who have not been treated prior to resection with neo-adjuvant therapy (e.g. chemotherapy, radiation therapy or endocrine therapy) and who do not have a current or prior diagnosis of an additional cancer. Risks may differ for individuals who do not meet the aforementioned clinical characteristics. Reported recurrence risks assume that this patient will receive endocrine therapy (with or without localized radiation therapy) alone. If adjuvant chemotherapy is administered after resection, the reported 10-year likelihood of distant recurrence and the likelihood of late recurrence (years 5-15) will not reflect actual patient risks. This test result is invalid if the patient has already experienced a distant recurrence.



Initial Treatment Planning 10 Year Prognostic



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RISK SCORE

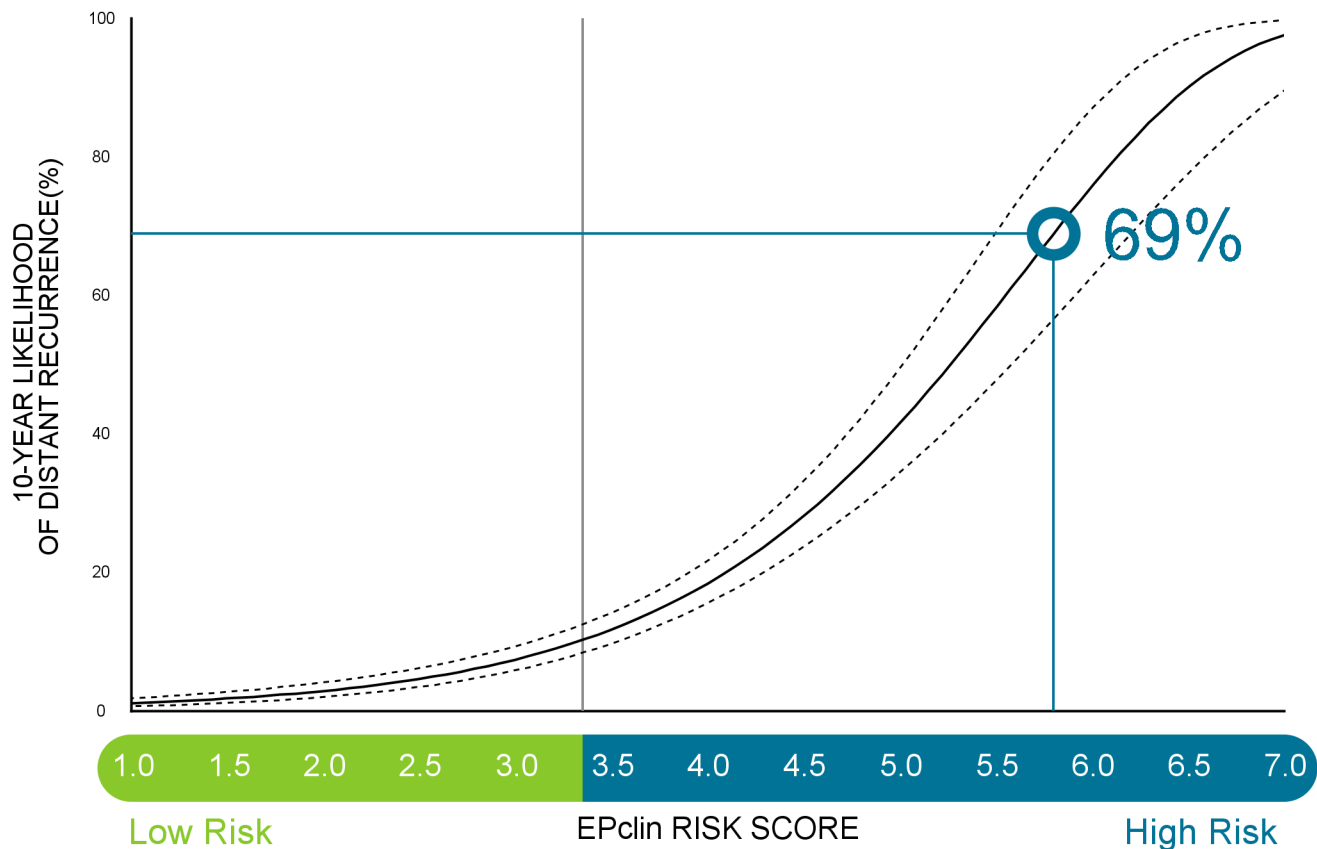
5.8

TREATMENT:

**AFTER 5 YEARS ENDOCRINE
THERAPY ALONE**

Result Interpretation: An EPclin Risk Score of 5.8 is categorized as HIGH RISK and is associated with a 69% (95% CI: 57% - 81%) 10-year likelihood of experiencing a distant recurrence when treated with 5 years of endocrine therapy alone.

LIKELIHOOD OF DISTANT RECURRENCE (YEARS 0-10)





Initial Treatment Planning Adjuvant Chemotherapy Benefit



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TUMOR STAGE: **pT3** (>5 cm)

NODAL STATUS: **pN1** (1-3 positive nodes)

EPclin
RISK SCORE

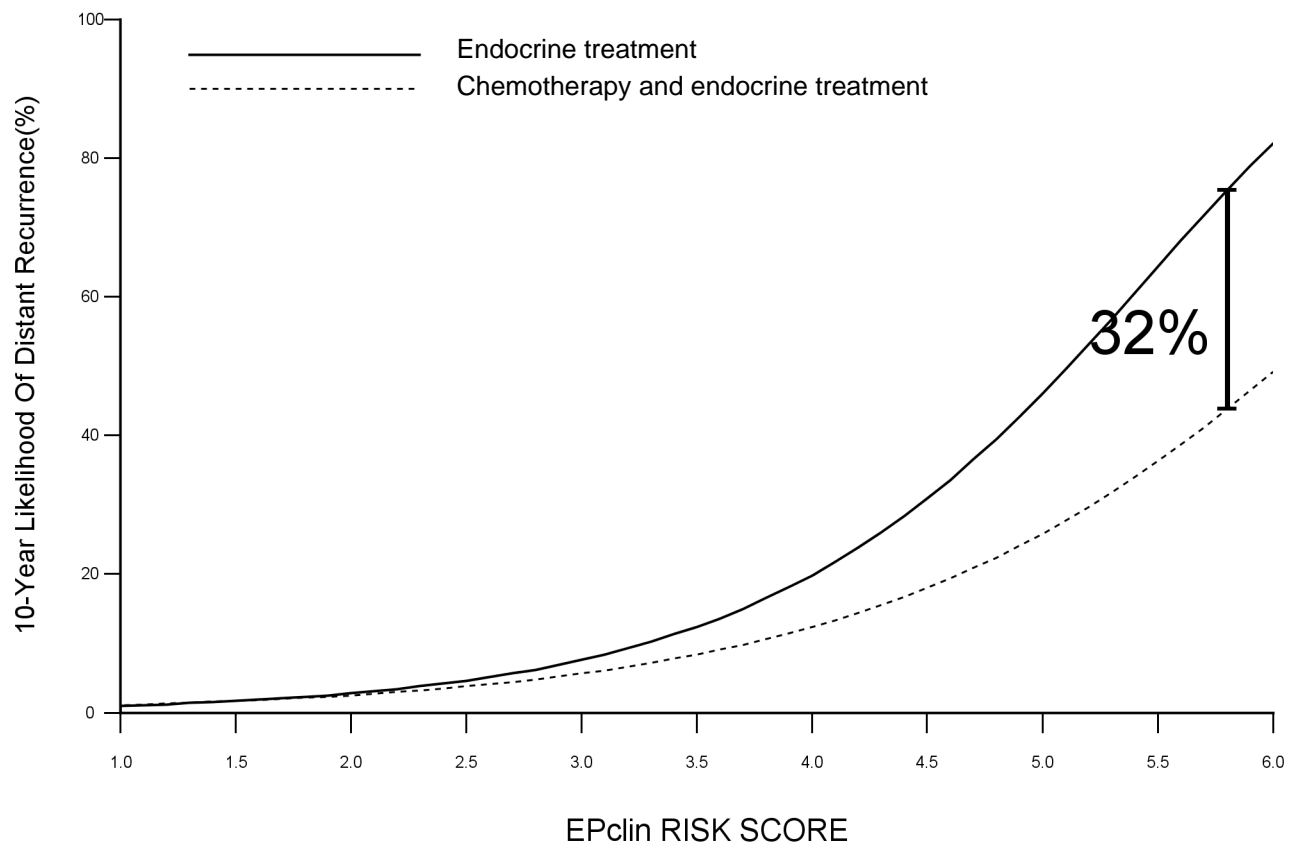
5.8

TREATMENT:

**CHEMOTHERAPY AND/OR
5 YEARS ENDOCRINE THERAPY**

Result Interpretation: At 10 years, an EPclin Risk Score of 5.8 is associated with a 32% (95% CI: 20% - 43%) absolute benefit from chemotherapy, when used in combination with endocrine treatment, compared to endocrine treatment alone.

PREDICTION OF CHEMOTHERAPY BENEFIT AT 10 YEARS



ESTIMATED ABSOLUTE CHEMOTHERAPY BENEFIT AT 10 YEARS

32%



Long-term Treatment Planning 5-15 Year Prognostic



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Accession: **08000143-BLD**

Report Date: **Dec 6, 2019**

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TUMOR STAGE: **pT3** (>5 cm)

NODAL STATUS: **pN1** (1-3 positive nodes)

EPclin
RISK SCORE

5.8

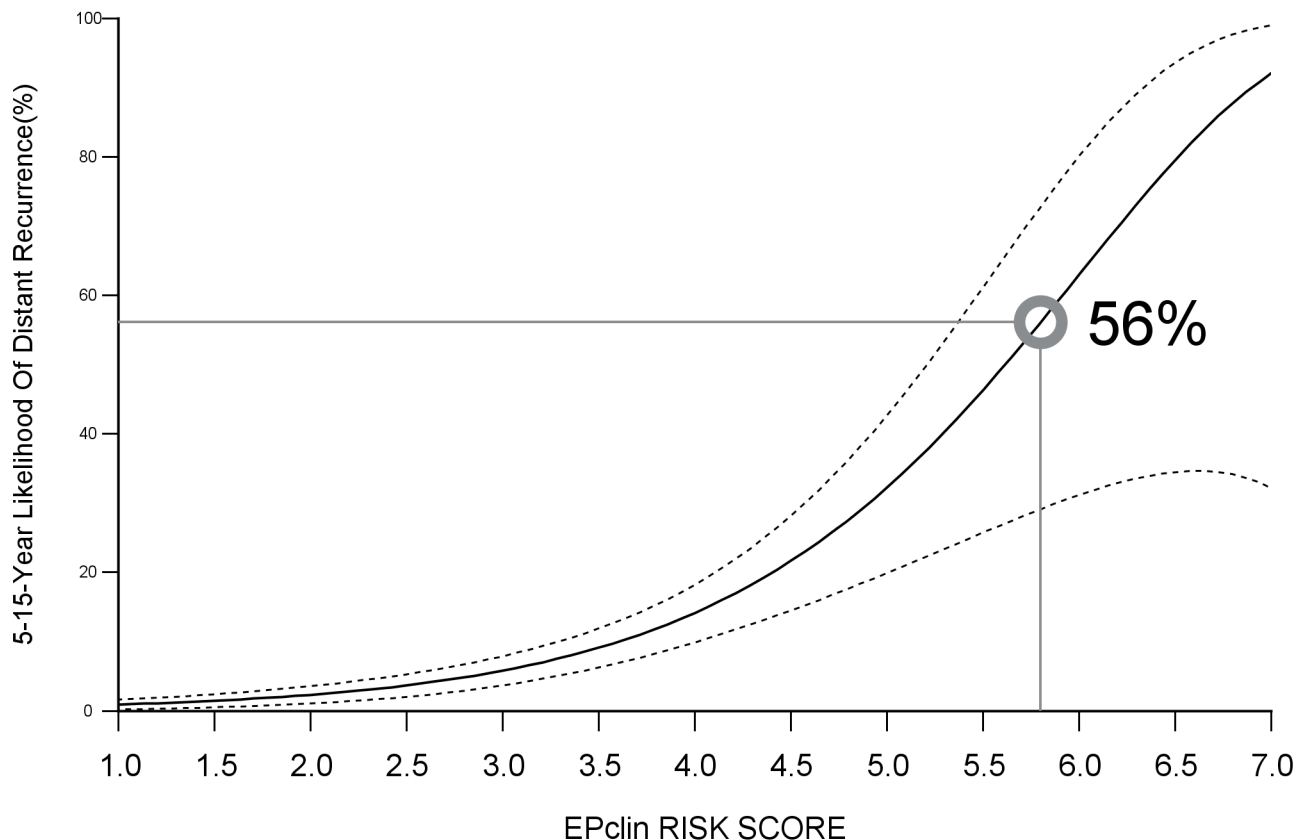
TREATMENT:

**AFTER 5 YEARS ENDOCRINE
THERAPY ALONE**

Result Interpretation: An EPclin Risk Score of 5.8 is associated with a 56% (95% CI: 29% - 73%) likelihood of experiencing a distant recurrence within 5-15 years of diagnosis. Estimates of distant recurrence at 15 years apply to patients who are distant recurrence-free after 5 years of endocrine therapy alone.

LIKELIHOOD OF LATE DISTANT RECURRENCE (Years 5-15)

After 5 years of endocrine therapy alone and no chemotherapy administered





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Block(s) Analyzed:

Test Description: EndoPredict is a gene expression test that predicts the risk of late distant recurrence (10-year and 5 to 15-years), with 5 years of adjuvant endocrine therapy alone, and the estimated absolute benefit of chemotherapy (at 10 years) for patients with estrogen receptor-positive and HER2-negative invasive female breast cancer.¹⁻⁵ The test result categorizes patients into "Low" or "High" risk of distant metastasis within 10 years. Analysis is performed on RNA extracted from FFPE blocks of the primary tumor. This test utilizes quantitative RT-PCR to measure the expression of eight target genes, three normalization genes, and one control gene, from which a 12-Gene Molecular Score is calculated.¹ This molecular fingerprint is assessed on a scale of 0-15, with lower risk molecular scores being < 5 and higher risk scores being ≥ 5. The 12-Gene Molecular Score can be combined with clinicopathologic features (tumor size and lymph node status) to generate an EPclin Risk Score, which is a more significant predictor of metastatic disease.¹⁻³ The threshold differentiating "Low" and "High" risk EPclin Risk Scores was established during assay development and is pre-specified during testing of current samples. EPclin Risk Scores from 1.0 through 3.3 are reported as "Low Risk" and are associated with an estimated 10-year risk of recurrence of less than 10%. EPclin Risk Scores from 3.4 through 6.0 are reported as "High Risk" and are associated with an estimated 10-year risk of recurrence equal to or greater than 10%. For patients who are distant recurrence-free at 5 years and have been treated for 5 years with adjuvant endocrine therapy alone, the distant recurrence risk at 15 years without extended endocrine therapy is also provided.⁴

Therapeutic decisions made subsequent to testing should take into account all relevant clinical parameters, including patient's age, overall health, etc.

Please contact Myriad Professional Support at 1-844-887-3636 or email EndoPredict@myriad.com to discuss any questions regarding this result.

References

- 1) Filipits M, et al. Clin Cancer Res. 2011; 17(18):6012-20.
- 2) Buus R, et al. J Natl Cancer Inst. 2016; 108(11). djw149
- 3) Dubsky P, et al. Br J Cancer 2013; 109(12):2959-64.
- 4) Filipits M, et al. Clin Cancer Res. 2019; 25(13):3865-3872.
- 5) Sestak I, et al. Breast Cancer Res Treat. 2019; 176(2):377-386.

Note: Myriad deems information provided on the Test Request Form to be definitive, and to supersede information provided in any other form (e.g., pathology report). Clinicopathologic parameters provided by the healthcare provider(s), in whatever form, have not been verified by Myriad.

Authorized Signature:

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The technical specifications summary (available at myriadpro.com/technical-specifications) describes the analysis, method, performance characteristics, nomenclature, and interpretive criteria of this test. This test may be considered investigational in some states. This test was developed and its performance characteristics determined by Myriad Genetic Laboratories. It has not been reviewed by the US FDA. The FDA has determined that such clearance or approval is not necessary.

