



Breast Cancer Gene Expression Profile



CONFIDENTIAL

ORDERING PHYSICIAN Bob Doctor MD 123 Grand Ave Anywhere, NV 89109 Pathologist: Jonathan Pathologist MD	SPECIMEN Specimen Type: Resection Tissue: Breast Surgery Date: Oct 13, 2017 TRF Received: Jan 2, 2018 Sample Received: Jan 2, 2018 Report Date: Jan 5, 2018	PATIENT Last Name: Pt Last Name First Name: Pt First Name Date of Birth: Jan 7, 1968 Patient ID: Patient id Gender: Female Accession #: 07001035-BLD Requisition #: 07001035
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Block(s) Analyzed:

12-GENE MOLECULAR SCORE:	3.7	EPclin RISK SCORE 2.0 LOW RISK
TUMOR STAGE:	pT1b (>0.5 cm but ≤1 cm)	
NODAL STATUS:	pN0 (zero positive nodes)	

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 <i>(For patients treated with 5 years of endocrine therapy alone)</i>	2.9%
	ESTIMATED ABSOLUTE CHEMOTHERAPY BENEFIT AT 10 YEARS	0.3%

LONG-TERM Treatment Planning	LIKELIHOOD OF LATE DISTANT RECURRENCE YEARS 5-15 <i>(For patients with no recurrence after 5 years of endocrine therapy and no chemotherapy administered)</i>	2.3%
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Note: Recurrence risk and chemotherapy benefit estimates contained within this report are based on a analysis of multiple cohorts of post-menopausal 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.¹⁻³ 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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Name: Last Name, First Name

DOB: Jan 7, 1968

Accession #: 07001035-BLD

Report Date: Jan 5, 2018

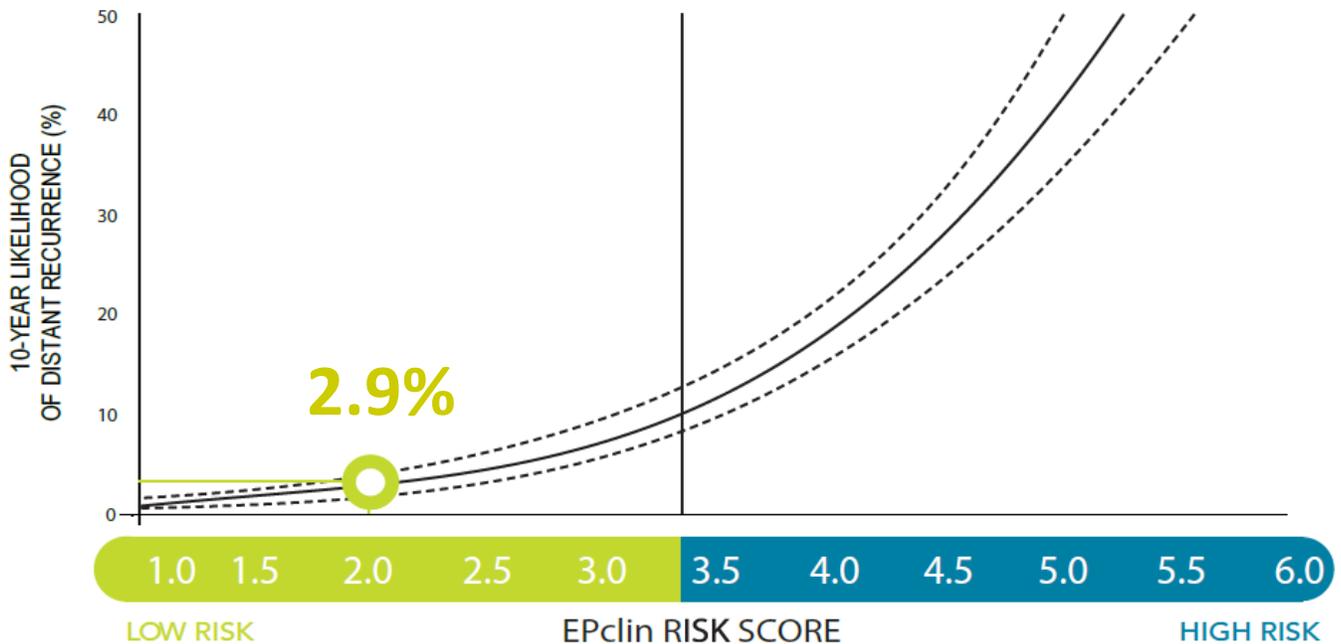
12-GENE MOLECULAR SCORE:	3.7
TUMOR STAGE:	pT1b (>0.5 cm but ≤1 cm)
NODALSTATUS:	pN0 (zero positive nodes)

EPclin
RISK SCORE **2.0**

TREATMENT:
**AFTER 5 YEARS ENDOCRINE
THERAPY ALONE**

Result Interpretation: An EPclin Score of 2.0 is categorized as LOW RISK and is associated with a 2.9% (95% CI: 2.0% - 4.1%) 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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Accession #: 07001035-BLD

Report Date: Jan 5, 2018

12-GENE MOLECULAR SCORE: **3.7**

TUMOR STAGE: **pT1b** (>0.5 cm but ≤1 cm)

NODALSTATUS: **pN0** (zero positive nodes)

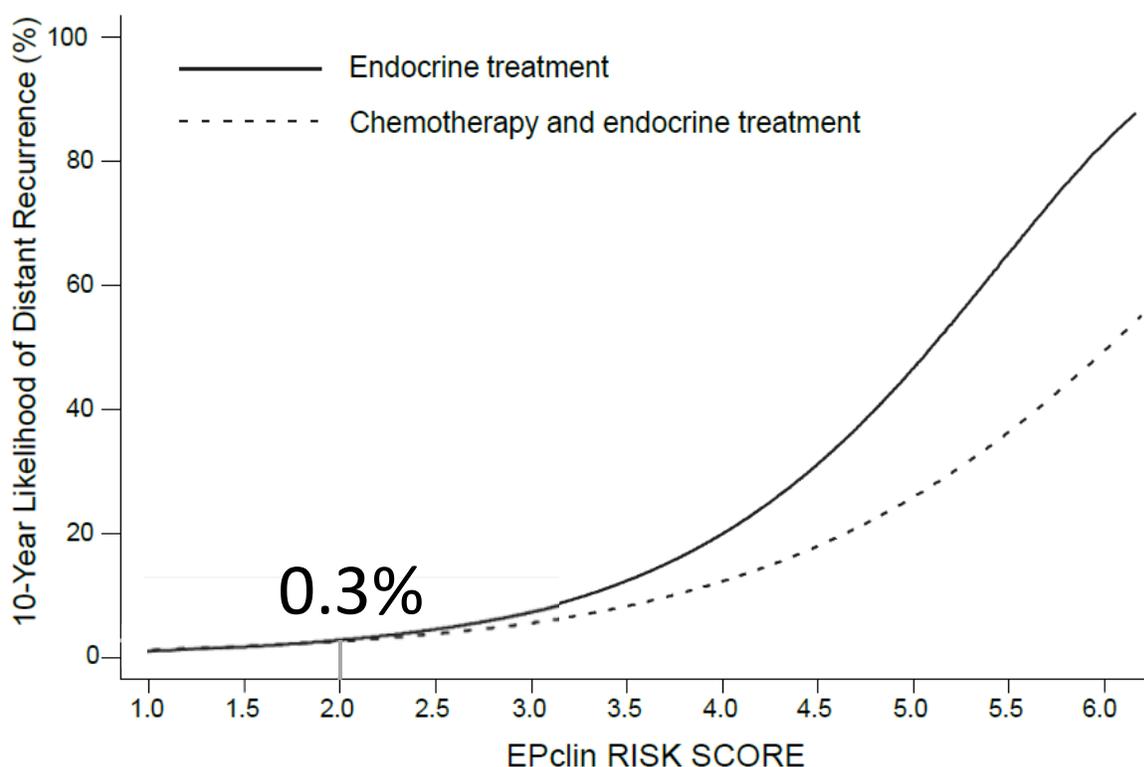
EPclin RISK SCORE **2.0**

TREATMENT:

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

Result Interpretation: At 10 years, an EPclin Risk Score of 2.0 is associated with an estimated 0.3% (95% CI: -1.1% - 1.4%) 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

0.3%



Long-term Treatment Planning 5-15 Year Prognostic



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DOB: **Jan 7, 1968**

Accession #: **07001035-BLD**

Report Date: **Jan 5, 2018**

12-GENE MOLECULAR SCORE: **3.7**

TUMOR STAGE: **pT1b** (>0.5 cm but ≤1 cm)

NODALSTATUS: **pN0** (zero positive nodes)

EPclin
RISK SCORE **2.0**

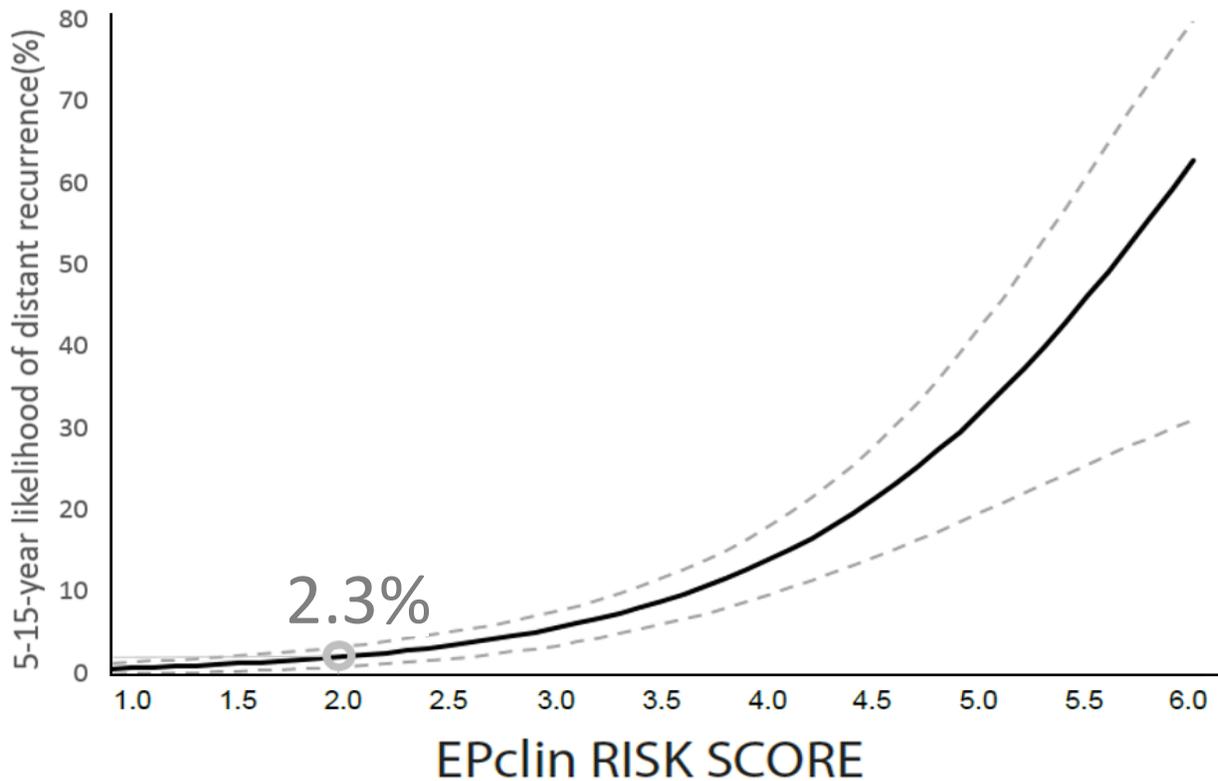
TREATMENT:

**AFTER 5 YEARS ENDOCRINE
THERAPY ALONE**

Result Interpretation: An EPclin Risk Score of 2.0 is associated with a 2.3% (95% CI: 1.0% - 3.6%) 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





Breast Cancer Gene Expression Profile



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ORDERING PHYSICIAN	SPECIMEN	PATIENT
Bob Doctor MD 123 Grand Ave Anywhere, NV 89109 Pathologist: Jonathan Pathologist MD	Specimen Type: Resection Tissue: Breast Surgery Date: Oct 13, 2017 TRF Received: Jan 2, 2018 Sample Received: Jan 2, 2018 Report Date: Jan 5, 2018	Last Name: Pt Last Name First Name: Pt First Name Date of Birth: Jan 7, 1968 Patient ID: Patient id Gender: Female Accession #: 07001035-BLD Requisition #: 07001035

Block(s) Analyzed:

Test Description: EndoPredict is a gene expression test that predicts 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) for patients with estrogen receptor-positive and HER2-negative invasive female breast cancer.¹⁻³ 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-Genes Molecular Score is calculated.¹ The risk association based solely on 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-Genes 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 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 endocrine therapy alone, the distant recurrence risk at 15 years without extended endocrine therapy is also provided.

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, Rudas M, Jakesz R, et al. A new molecular predictor of distant recurrence in ER-positive, HER2-negative breast cancer adds independent information to conventional clinical risk factors. *Clin Cancer Res.* 2011;17(18):6012-6020.
2. Muller BM, Brase JC, Haufe F, et al. Comparison of the RNA-based EndoPredict multigene test between core biopsies and corresponding surgical breast cancer sections. *J Clin Pathol.* 2012;65(7):660-662.
3. Data on file.

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:

Benjamin B. Roa, Ph.D.
 Diplomate ABMG
 Senior Laboratory Director

Karla R. Bowles, Ph.D.
 Diplomate ABMG
 Senior Laboratory Director

Johnathan M. Lancaster, M.D. Ph.D.
 Diplomate ABOG, FACOG, FACS
 Chief Medical Officer

Hillary Zalaznick, M.D.
 Diplomate FCAP
 Laboratory Director Anatomic Pathology

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.





Breast Cancer Gene Expression Profile



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ORDERING PHYSICIAN Bob Doctor MD 123 Grand Ave Anywhere, NV 89109 Pathologist: Jonathan Pathologist MD	SPECIMEN Specimen Type: Resection Tissue: Breast Surgery Date: Oct 13, 2017 TRF Received: Jan 2, 2018 Sample Received: Jan 2, 2018 Report Date: Jan 5, 2018	PATIENT Last Name: Pt Last Name First Name: Pt First Name Date of Birth: Jan 7, 1968 Patient ID: Patient id Gender: Female Accession #: 07001035-BLD Requisition #: 07001035
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Block(s) Analyzed:

12-GENE MOLECULAR SCORE:	8.1
TUMOR STAGE:	pT2 (>2 cm but ≤5 cm)
NODAL STATUS:	pN0 (zero positive nodes)

EPclin
RISK SCORE

4.0

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 <i>(For patients treated with 5 years of endocrine therapy alone)</i>	18%
ESTIMATED ABSOLUTE CHEMOTHERAPY BENEFIT AT 10 YEARS	7.4%

LONG-TERM
Treatment
Planning

LIKELIHOOD OF LATE DISTANT RECURRENCE YEARS 5-15 <i>(For patients with no recurrence after 5 years of endocrine therapy and no chemotherapy administered)</i>	14%
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Note: Recurrence risk and chemotherapy benefit estimates contained within this report are based on an analysis of multiple cohorts of post-menopausal 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.¹⁻³ 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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Name: Last Name, First Name

DOB: Jan 7, 1968

Accession #: 07001035-BLD

Report Date: Jan 5, 2018

12-GENE MOLECULAR SCORE: **8.1**

TUMOR STAGE: **pT2** (>2 cm but ≤5 cm)

NODALSTATUS: **pN0** (zero positive nodes)

EPclin
RISK SCORE

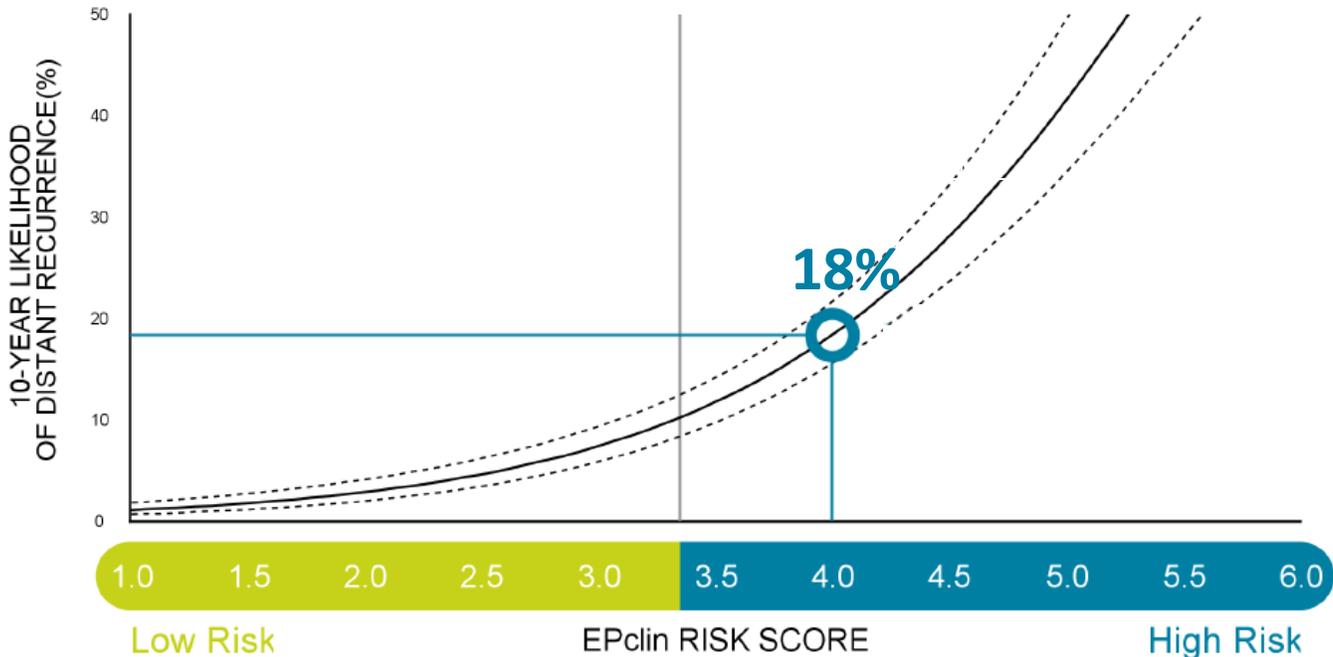
4.0 HIGH
RISK

TREATMENT:

**AFTER 5 YEARS ENDOCRINE
THERAPY ALONE**

Result Interpretation: An EPclin Score of 4.0 is categorized as HIGH RISK and is associated with a 18% (95% CI: 15% - 22%) 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



CONFIDENTIAL

Name: Last Name, First Name

DOB: Jan 7, 1968

Accession #: 07001035-BLD

Report Date: Jan 5, 2018

12-GENE MOLECULAR SCORE: **8.1**

TUMOR STAGE: **pT2** (>2 cm but ≤5 cm)

NODALSTATUS: **pN0** (zero positive nodes)

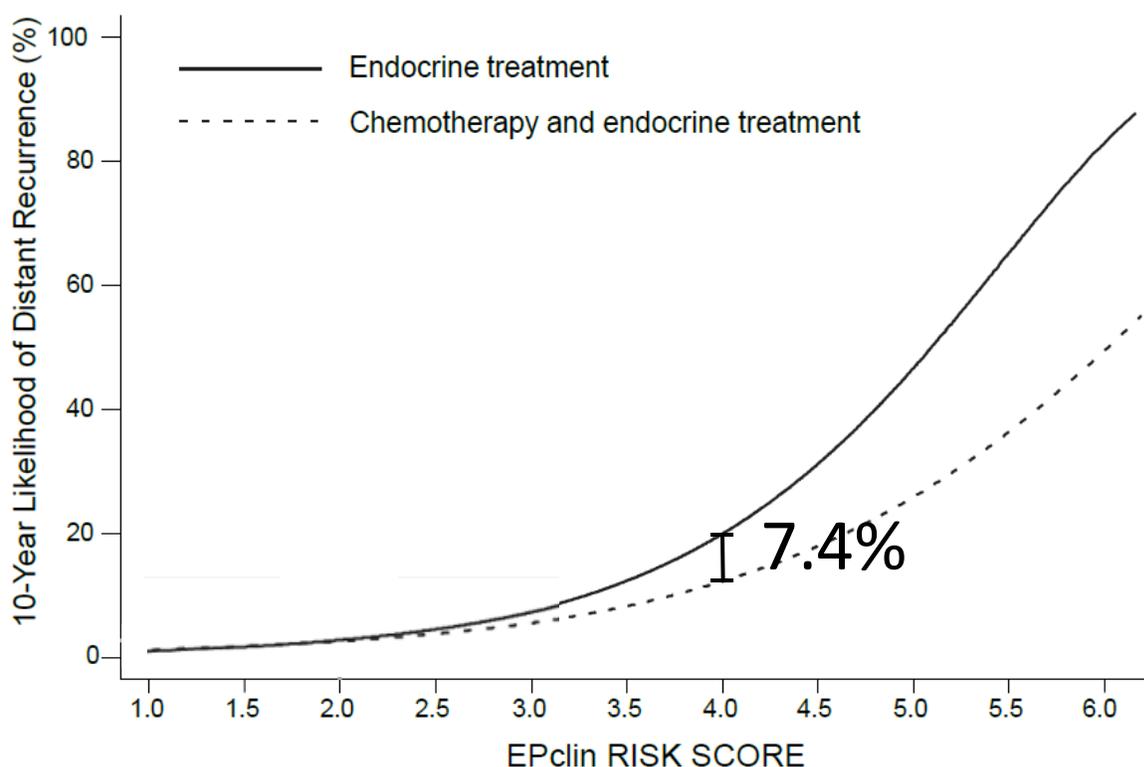
EPclin RISK SCORE **4.0**

TREATMENT:

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

Result Interpretation: At 10 years, an EPclin Risk Score of 4.0 is associated with an estimated 7.4% (95% CI: 4.1% - 11%) 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

7.4%



Long-term Treatment Planning 5-15 Year Prognostic



CONFIDENTIAL

Name: **Last Name, First Name**

DOB: **Jan 7, 1968**

Accession #: **07001035-BLD**

Report Date: **Jan 5, 2018**

12-GENE MOLECULAR SCORE: **8.1**

TUMOR STAGE: **pT2** (>2 cm but ≤5 cm)

NODALSTATUS: **pN0** (zero positive nodes)

EPclin
RISK SCORE **4.0**

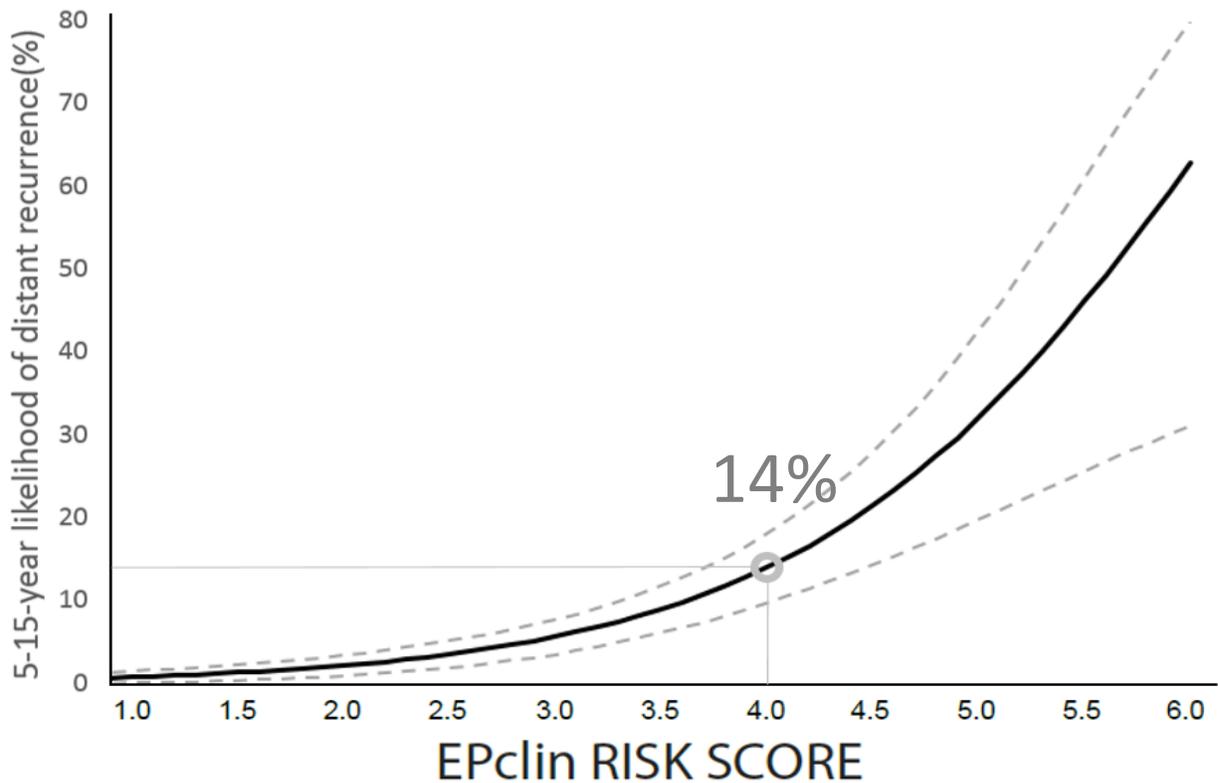
TREATMENT:

**AFTER 5 YEARS ENDOCRINE
THERAPY ALONE**

Result Interpretation: An EPclin Risk Score of 4.0 is associated with a 14% (95% CI: 9.9% - 18%) 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





Breast Cancer Gene Expression Profile



CONFIDENTIAL

ORDERING PHYSICIAN	SPECIMEN	PATIENT
Bob Doctor MD	Specimen Type: Resection	Last Name: Pt Last Name
123 Grand Ave Anywhere, NV 89109	Tissue: Breast	First Name: Pt First Name
Pathologist: Jonathan Pathologist MD	Surgery Date: Oct 13, 2017	Date of Birth: Jan 7, 1968
	TRF Received: Jan 2, 2018	Patient ID: Patient id
	Sample Received: Jan 2, 2018	Gender: Female
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Block(s) Analyzed:

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