

## One Test - Three Clinical Answers

EndoPredict is the only test that answers three critical clinical questions:

1. Risk at 10 years - Can chemotherapy be avoided?
2. Chemotherapy benefit - What is the absolute benefit from chemotherapy?
3. Risk between 5 and 15 years - Can the extension of endocrine therapy be avoided?

EndoPredict is a second-generation gene expression assay that combines a molecular score with clinical features (tumor size and nodal status). The five-page report provides the risk of developing distant recurrence (0-10 and 5-15 years) and the absolute chemotherapy benefit at 10 years for a woman with ER+, HER2- breast cancer. Results are summarized by treatment planning stage on the front page. Detailed information is available on the pages that follow.

The EndoPredict Result Report uses the colors of the arrows of the product logo to provide a clear and **immediate indication of the patient's risk**: blue EPclin Risk Score and EPclin Risk Class indicate high risk, while green indicates low risk.

## Elements of the EndoPredict Result Report

### Front Page

#### EPclin Risk Score: Patient's predictor of distant recurrence and chemobenefit

- Calculated using an algorithm including three independent variables:
  1. 12-Gene Molecular Score
  2. Tumor size (pT)
  3. Nodal status (pN).
- Reported on a scale of 1 to 6. The value of 3.32867 is associated with 10% risk of breast cancer recurrence within 10 years.
- EPclin Risk Score is reported with up to four digits to clearly assign low or high risk class.

#### EPclin Risk Class: Patient's risk category

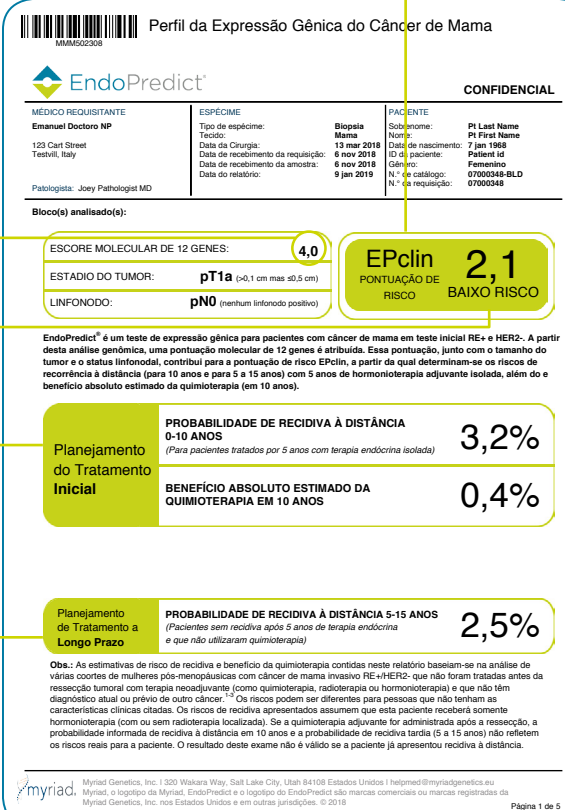
- **Low** if EPclin Risk Score < 3.32867
- **High** if EPclin Risk Score ≥ 3.32867

#### 12-Gene Molecular Score (previously called EP Score)

- A measurement of expression levels of the genes included in the EndoPredict test (range 0-15).

#### Summary of result interpretations for the individual patient organized by treatment planning stage

- 10-year likelihood of distant recurrence
- Absolute chemotherapy benefit at 10 years
- Likelihood of late distant recurrence within years 5-15



**Perfil da Expressão Gênica do Câncer de Mama**

**CONFIDENCIAL**

<b>MÉDICO REQUISITANTE</b> Emanuel Doctoro NP 123 Carl Street Testilli, Italy	<b>ESPÉCIME</b> Tipo de espécime: Tumor Data da Cirurgia: 6 nov 2018 Data de recebimento da amostra: 6 nov 2018 Data do relatório: 9 jan 2019	<b>BIOPSIA</b> Mama 13 mar 2018 6 nov 2018 9 jan 2019	<b>PACIENTE</b> Nome: Data de nascimento: 7 jan 1968 ID do paciente: Gênero: Feminino N.º de catálogo: 07000348-BLD N.º de requisição: 07000348
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**Bloco(s) analisado(s):**

<b>ESCORE MOLECULAR DE 12 GENES:</b>	<b>4,0</b>
<b>ESTÁDIO DO TUMOR:</b>	<b>pT1a</b> (p<0,1 cm mas ≤0,5 cm)
<b>LINFONODO:</b>	<b>pN0</b> (nenhum linfonodo positivo)

**EPclin 2,1**  
PONTUAÇÃO DE RISCO  
**BAIXO RISCO**

EndoPredict<sup>®</sup> é um teste de expressão gênica para pacientes com câncer de mama em teste inicial RE+ e HER2-. A partir desta análise genômica, uma pontuação molecular de 12 genes é atribuída. Essa pontuação, junto com o tamanho do tumor e o status linfonodal, contribui para a pontuação de risco EPclin, a partir da qual determinam-se os riscos de recorrência à distância (para 10 anos e para 5 a 15 anos) com 5 anos de hormonioterapia adjuvante isolada, além do benefício absoluto estimado da quimioterapia (em 10 anos).

<b>Planejamento do Tratamento Inicial</b>	<b>PROBABILIDADE DE RECIDIVA À DISTÂNCIA 0-10 ANOS</b> (Para pacientes tratados por 5 anos com terapia endócrina isolada)	<b>3,2%</b>
	<b>BENEFÍCIO ABSOLUTO ESTIMADO DA QUIMIOTERAPIA EM 10 ANOS</b>	<b>0,4%</b>

<b>Planejamento de Tratamento a Longo Prazo</b>	<b>PROBABILIDADE DE RECIDIVA À DISTÂNCIA 5-15 ANOS</b> (Pacientes sem recidiva após 5 anos de terapia endócrina e que não utilizaram quimioterapia)	<b>2,5%</b>
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**Obs.:** As estimativas de risco de recidiva e benefício da quimioterapia contidas neste relatório baseiam-se na análise de várias coortes de mulheres pós-menopáusicas com câncer de mama invasivo RE+HER2- que não foram tratadas antes da ressecção tumoral com terapia neoadjuvante (como quimioterapia, radioterapia ou hormonioterapia) e que não têm diagnóstico atual ou prévio de outro câncer. Os riscos podem ser diferentes para pessoas que não tenham as características clínicas citadas. Os riscos de recidiva apresentados assumem que esta paciente receberá somente hormonioterapia (com ou sem radioterapia localizada). Se a quimioterapia adjuvante for administrada após a ressecção, a probabilidade informada de recidiva à distância em 10 anos e a probabilidade de recidiva tardia (5 a 15 anos) não refletem os riscos reais para a paciente. O resultado deste exame não é válido se a paciente já apresentou recidiva à distância.

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## Page 2

### LIKELIHOOD OF DISTANT RECURRENCE WITHIN YEARS 0-10

#### EPclin Risk Score's continuous risk curve

- Graphically illustrates the patient's individualized risk of distant recurrence within years 0-10 based on the ABCSG 6&8 validation studies.

#### 10-year likelihood of distant recurrence for the individual patient

- Patient's individual risk of distant recurrence when treated with 5 years of endocrine therapy alone.

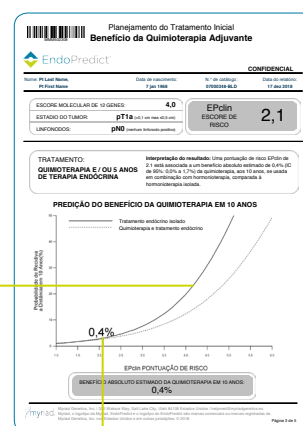


## Page 3

### ABSOLUTE CHEMOTHERAPY BENEFIT AT 10 YEARS

#### EPclin Risk Score's continuous risk curves to determine the chemotherapy benefit

- Graphically illustrates the patient's individualized chemotherapy benefit based on the ABCSG 6&8, TransATAC, GEICAM/2003-02 and GEICAM/9906 studies.



#### Absolute chemotherapy benefit for the individual patient

- Patient's individual absolute chemotherapy benefit.

With the new report EndoPredict answers a second question: **What is the personalized absolute chemotherapy benefit?** This leads to a confident chemotherapy treatment decision for your patient.

## Page 4

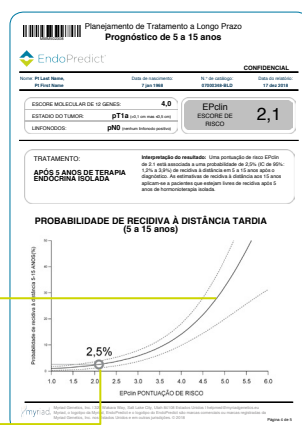
### LIKELIHOOD OF LATE DISTANT RECURRENCE WITHIN YEARS 5-15

#### EPclin Risk Score's continuous risk curve

- Graphically illustrates the patient's individualized risk of distant recurrence within years 5-15 based on the ABCSG 6&8 validation studies.

#### 10-year likelihood of late distant recurrence for the individual patient

- Patient's individual late distant recurrence risk. Provides estimates of distant recurrence at 15 years for patients who are distant recurrence-free after 5 years of endocrine therapy alone and who do not receive extended endocrine therapy.



## Page 5

Page 5 of the **Result Report** provides additional details on the EndoPredict assay design, intended use, and its clinical applications.

## Important Note

An **EndoPredict Result Report** is only generated if both patient's tumor size and nodal status are available. If an EndoPredict test is performed on a biopsy specimen, and therefore patient's tumor pathological information is not yet available, the EndoPredict Result Report is not provided. However, the 12-Genes Molecular Score and a table showing the EPclin Risk Score and the EPclin Risk Class for all possible combinations of Tumor Size and Nodal Status will be available in the EndoPredict Table Report. If you would like an updated report with all risk curves you can send us the tumor size and nodal status after resection and request an amended report.

The third answered question is: **What is your patient's risk of late recurrence (5-15 years)?** This information guides treatment decisions to extend endocrine therapy beyond 5 years.

For additional information regarding the EndoPredict Result and Summary Reports, please refer to the EndoPredict Quick Guides and the EndoPredict Instruction Manuals, available from Myriad International. Please contact: [epsupport@myriadgenetics.eu](mailto:epsupport@myriadgenetics.eu).