

## 検査報告書変更のお知らせ

謹啓 時下ますますご清栄のこととお喜び申し上げます。  
平素は格別のご高配を賜り厚くお礼申し上げます。  
このたび下記検査項目におきまして、報告書様式が変更となる旨、  
委託先より連絡が入りました。  
大変急ではございますが、以下の通り変更させていただきたく  
ご案内いたします。  
何卒ご了承賜りますよう、よろしくお願い申し上げます。

敬白

### 記

#### ■変更実施日

2018年7月25日（水）ご報告分より順次変更

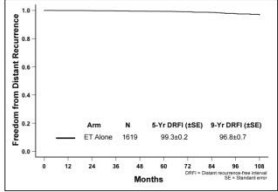
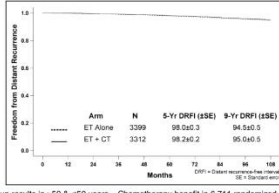
#### ■変更項目

| 項目コード  | 項目名称              |
|--------|-------------------|
| M781 3 | OncotypeDX Breast |

# ● OncotypeDX Breast

2018年6月に発表された大規模前向き臨床試験TAILORx(テイラーエックス)のデータより、リンパ節転移陰性で再発スコア™結果が0~25のOncotypeDX Breastの報告書に、TAILORxの結果が記載された英語の補足資料が1ページ追加されます。尚、本補足資料は今後英語から日本語へ変更される予定です。

## 補足資料の種類

| ① 再発スコア結果0~10の補足資料   | ② 再発スコア結果11~25の補足資料   |               |                  |                  |                  |          |           |           |               |               |                  |                  |                  |           |               |               |                  |                  |                  |
|--|---|---------------|------------------|------------------|------------------|----------|-----------|-----------|---------------|---------------|------------------|------------------|------------------|-----------|---------------|---------------|------------------|------------------|------------------|
| <p>Generated by TailorX NET 4.0 Evaluation</p> <p><b>Genomic Health   OncotypeDX</b><br/>Breast Recurrence Score</p> <p>Genomic Health, Inc.<br/>201 Piedmont Drive, Redwood City, CA 94063 USA<br/>USA/Canada: +1 866.ONCOTYPEx<br/>www.oncotypedx.com<br/>CLIA Number: 05C1193272</p> <p><b>Important Update on the TAILORx Trial Results</b></p> <p><b>For patients with Recurrence Score® results of 0 to 10 and node-negative disease</b></p> <p>The Phase III prospective TAILORx trial included 10,273 patients with node-negative, hormone receptor-positive, HER2-negative breast cancer.</p> <p>The long-term outcomes were favorable (see Kaplan-Meier plot below) among 1,619 patients with Recurrence Score results 0-10 treated with endocrine therapy (ET) alone and no chemotherapy, regardless of patient age, tumor size, or tumor grade.</p>  <p>References: 1. Sparano JA, et al. N Engl J Med 2015; 2. Sparano JA, et al. N Engl J Med 2018; Tables 1 and 2 and Supplemental Figure S4.<br/>Click here to unlock TailorX NET 4.0</p> | <p>Generated by TailorX NET 4.0 Evaluation</p> <p><b>Genomic Health   OncotypeDX</b><br/>Breast Recurrence Score</p> <p>Genomic Health, Inc.<br/>201 Piedmont Drive, Redwood City, CA 94063 USA<br/>USA/Canada: +1 866.ONCOTYPEx<br/>www.oncotypedx.com<br/>CLIA Number: 05C1193272</p> <p><b>Important Update on the TAILORx Trial Results</b></p> <p><b>For patients with Recurrence Score® results of 11 to 25 and node-negative disease</b></p> <p>The Phase III prospective TAILORx trial in 10,273 patients with node-negative, hormone receptor-positive, HER2-negative breast cancer randomized 6,711 patients with Recurrence Score results 11-25, two-thirds of all patients, to endocrine therapy (ET) alone versus endocrine therapy plus chemotherapy (CT).</p> <p>Patients with Recurrence Score results 26-100 were all assigned to endocrine therapy plus chemotherapy treatment since the Recurrence Score predicts a large chemotherapy benefit when the score is ≥31 or &gt;25.<sup>1,2</sup></p> <p><b>TAILORx Overall Results - Effect of chemotherapy in 6,711 randomized patients RS 11-25</b></p> <p>Endocrine therapy alone is not inferior to endocrine therapy plus chemotherapy for the primary endpoint of invasive disease-free survival (HR 1.08, 95%CI 0.94, 1.24, p=0.26 indicating no chemotherapy benefit).<sup>3</sup></p> <p>No significant effect of chemotherapy was demonstrated for all the other endpoints, including freedom from distant recurrence, freedom from any recurrence, and overall survival. The effect of chemotherapy at 5 years was ≤1% for all endpoints (Kaplan-Meier plot below for freedom from distant recurrence, the NSABP B-14 and B-20 endpoints).</p> <p>There was a significant chemotherapy treatment interaction with patient age and Recurrence Score result (p=0.004). The chemotherapy treatment interaction with tumor size and tumor grade was not significant.</p>  <p><b>TAILORx subgroup results in &gt;50 &amp; ≤50 years - Chemotherapy benefit in 6,711 randomized patients RS 11-25</b></p> <p>The prediction of chemotherapy benefit is largely binary at a Recurrence Score result of 20. The absolute reduction of distant recurrence at 5 years from chemotherapy for patients &gt;50 years and ≤50 years is shown below.<sup>3,4</sup></p> <table border="1" data-bbox="917 1052 1332 1108"> <thead> <tr> <th>Age</th> <th>RS 0-10</th> <th>RS 11-15</th> <th>RS 16-20</th> <th>RS 21-25</th> <th>RS 26-100</th> </tr> </thead> <tbody> <tr> <td>&gt;50 years</td> <td>No CT Benefit</td> <td>No CT Benefit</td> <td>-1.6% CT Benefit</td> <td>-6.5% CT Benefit</td> <td>Large CT Benefit</td> </tr> <tr> <td>≤50 years</td> <td>No CT Benefit</td> <td>No CT Benefit</td> <td>-1.6% CT Benefit</td> <td>-6.5% CT Benefit</td> <td>Large CT Benefit</td> </tr> </tbody> </table> <p>Click here to unlock TailorX NET 4.0</p> | Age           | RS 0-10          | RS 11-15         | RS 16-20         | RS 21-25 | RS 26-100 | >50 years | No CT Benefit | No CT Benefit | -1.6% CT Benefit | -6.5% CT Benefit | Large CT Benefit | ≤50 years | No CT Benefit | No CT Benefit | -1.6% CT Benefit | -6.5% CT Benefit | Large CT Benefit |
| Age  | RS 0-10   | RS 11-15      | RS 16-20         | RS 21-25         | RS 26-100        |          |           |           |               |               |                  |                  |                  |           |               |               |                  |                  |                  |
| >50 years  | No CT Benefit   | No CT Benefit | -1.6% CT Benefit | -6.5% CT Benefit | Large CT Benefit |          |           |           |               |               |                  |                  |                  |           |               |               |                  |                  |                  |
| ≤50 years  | No CT Benefit   | No CT Benefit | -1.6% CT Benefit | -6.5% CT Benefit | Large CT Benefit |          |           |           |               |               |                  |                  |                  |           |               |               |                  |                  |                  |

## 変更点

| 新  | 現                          |
|--|----------------------------|
| <p>再発スコア結果に応じて、一部のリンパ節転移陰性症例の報告書に補足資料が添付されます。<br/>(報告内容自体には変更はありません。)</p> <p>補足資料</p> <p>① 再発スコア結果0~10 : 補足資料①</p> <p>② 再発スコア結果11~25 : 補足資料②</p> <p>③ 再発スコア結果26~100 : 補足資料なし</p> | <p>リンパ節転移陰性症例の報告書(日本語)</p> |

## ※報告書 参考文献欄

1. Paik S, et al. J Clin Oncol. 2006.
2. Sparano JA, Paik, S. J Clin Oncol. 2008.
3. Sparano JA, et al. N Engl J Med. 2018.