

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>Genomic Health OncotypeDX Breast Recurrence Score</p> <p>Genomic Health, Inc. 201 Piedmont Drive, Redwood City, CA 94063 USA USA/Canada: +1 866.ONCOTYPEx www.oncotypedx.com CLIA Number: 05C1193272</p> <p>Important Update on the TAILORx Trial Results</p> <p>For patients with Recurrence Score® results of 0 to 10 and node-negative disease</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. Click here to unlock TailorX NET 4.0</p>	<p>Generated by TailorX NET 4.0 Evaluation</p> <p>Genomic Health OncotypeDX Breast Recurrence Score</p> <p>Genomic Health, Inc. 201 Piedmont Drive, Redwood City, CA 94063 USA USA/Canada: +1 866.ONCOTYPEx www.oncotypedx.com CLIA Number: 05C1193272</p> <p>Important Update on the TAILORx Trial Results</p> <p>For patients with Recurrence Score® results of 11 to 25 and node-negative disease</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 ≥ 25.^{1,2}</p> <p>TAILORx Overall Results - Effect of chemotherapy in 6,711 randomized patients RS 11-25</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).³</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 $\leq 1\%$ 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>TAILORx subgroup results in ≥ 50 & ≤ 50 years - Chemotherapy benefit in 6,711 randomized patients RS 11-25</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 ≥ 50 years and ≤ 50 years is shown below.^{3,4}</p> <table border="1"> <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>≥ 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。 (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.