

検査内容変更のお知らせ

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、米国 GHI から専用報告書フォーマット変更の連絡がございました。
大変急ではございますが以下のとお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お願い申し上げます。

敬 白

記

■ 実施日 平成26年6月4日（水）ご報告分より

●米国 GHI 報告日より逆算した目安です。

■ 変更項目

案内書掲載頁	項目J-ド No.	検査項目
166	M781 3	OncotypeDX Breast

● OncotypeDX Breast

本検査におきまして、検査報告書をリンパ節転移の程度別に3パターンのフォーマットに分け、より見やすいレイアウトに変更いたします。
 なお、報告内容および検査要項の変更はございません。

項目コード No.	検査項目	変更箇所	新	現
M781 3	OncotypeDX Breast	報告書枚数	リンパ節転移(N)程度別のフォーマットを使用。 N- : 3枚セット N+1~3 : 2枚セット N+4以上 : 2枚セット	同一報告フォーマットを使用。 N- : 3枚セット N+ : 4枚セット (N+は、3,4頁のみを参照いただく形)

▼新 検査報告書見本（リンパ節転移陽性（N+1~3）の場合）

Genomic Health | **oncotype DX**
Breast Cancer Report - Node Positive Prognosis and Chemotherapy Benefit (1-3 N+)

Genomic Health, Inc.
301 Parkwest Drive, Redwood City, CA 94063 USA
USA Contact: +1.888.ONCOTYPEDX
International: www.oncotypedx.com/askus
www.oncotypedx.com
CLIA Number 05D1018272

Patient ID: D06LJMH6
Sex: Female
Date of Birth: 01-Jan-1950
Medical Record/Patient #: 00677771
Specimen ID: Breast/196-0001

Request#: R6000039
Specimen Received: 05-May-2009
Date Reported: 15-May-2009
Ordering Physician: Dr. Harry D Smith
Submitting Pathologist: Dr. John P Williams

Recurrence Score® Result
6

The findings are applicable to women who have estrogen receptor positive (ER+) breast cancer with 1-3 positive nodes, and who will be treated with 5 years of tamoxifen (tam). It is unknown whether the findings apply to other patients outside these criteria.

Prognosis and Chemotherapy Benefit: 5-Year Risk of Recurrence or Mortality after 5 Years of Tam, Based on the Recurrence Score Result

1-3 Positive Nodes
5-Year Risk of Recurrence or Mortality

Tam Alone
8% (95% CI: 4%-15%)

Tam + Chemo
11% (95% CI: 7%-17%)

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Genomic Health | **oncotype DX**
Quantitative Single Gene Report

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International: www.oncotypedx.com/askus
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The Oncotype DX® assay uses RT-PCR to determine the RNA expression of the genes below. These results may differ from estrogen receptor (ER), progesterone receptor (PR), or human epidermal growth factor receptor 2 (HER2) results reported using other methods or reported by other laboratories. The ER, PR, and HER2 scores are also included in the calculation of the Recurrence Score result.

ER Score - 10.0 Positive

The ER Score positive/negative cut-off of 8.5 units was validated from a study of 761 samples using the 1D5 antibody (immunohistochemistry) and 637 samples using the SP1 antibody (immunohistochemistry). The standard deviation for the ER Score is less than 0.5 units.*

PR Score - 8.0 Positive

The PR Score positive/negative cut-off of 5.5 units was validated from a study of 761 samples using the PR20 antibody (immunohistochemistry) and another study of 637 samples using the PR22 antibody (immunohistochemistry). The standard deviation for the PR Score is less than 0.5 units.*

HER2 Score - 9.5 Negative

The HER2 positive cut-off of 11.5 units, equivalent range from 13.7 to 11.4 units, and negative cut-off of < 10.7 units were validated from concordance studies of 765 samples using the HercepTest™ assay (immunohistochemistry) and another study of 689 samples using the PathCyto™ assay (FISH). The standard deviation for the HER2 Score is less than 0.5 units.*

Reference:
1. ER Score based on paraffin (IHC) expression (average sample); PR Score based on paraffin (IHC) expression (average sample); HER2 Score based on paraffin (IHC).
2. ER Score based on paraffin (IHC) expression (average sample); PR Score based on paraffin (IHC) expression (average sample); HER2 Score based on paraffin (IHC).
3. Slamon et al. J Clin Oncol 2005; 23:116-125.
4. Slamon et al. J Clin Oncol 2005; 23:116-125.

Laboratory Director: Patrick Joseph, MD

This test was developed and its performance characteristics determined by Genomic Health, Inc. The laboratory is certified under the Clinical Laboratory Improvement Amendments of 2008 (CLIA) as qualified to perform high-complexity clinical testing. This test is used for clinical purposes. It should not be regarded as investigational or for research. These results are applicable to the testing procedure used.

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(35%縮小)