

Oncotype DX Breast Recurrence Score® Report

Node Negative

EXACT
SCIENCES

Age ≤ 50 Years

PATIENT, SAMPLE

Date of Birth: 01-Jan-1950 Gender: Female Report Number: OR000123456-3091 Report Date: 04-Jun-2025

Specimen Source/ID: Breast/SP-16_0123456 Date of Collection: 20-May-2025

Ordering Physician: Dr. First-Name I. Ordering-Physician-Last-Name

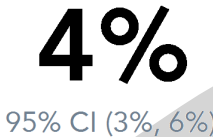
Recurrence Score® (RS) Result



Clinical factors may be considered with the RS when making individual treatment decisions

Distant Recurrence Risk at 10 Years

With AI or TAM Alone

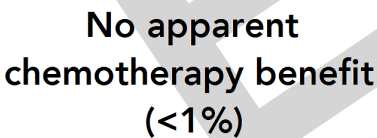


TAILORx¹

AI = Aromatase Inhibitor / TAM = Tamoxifen
CI = Confidence Intervals

Group Average Absolute Chemotherapy (CT) Benefit

RS 0-10



NSABP B-20²

Quantitative Single-Gene Scores^{3,4}



TAILORx and NSABP B-20 Studies^{1,2,5}

Results in this report are based on the Recurrence Score (RS) and data from the TAILORx and NSABP B-20 clinical trials. TAILORx is a prospective, multinational phase III clinical trial that enrolled 10,273 patients (≥18 years) with hormone receptor-positive (HR+), HER2-negative, node-negative invasive breast cancer. Patients with a RS result between 11-25 were randomized to receive 5 years of endocrine therapy alone or standard-of-care chemotherapy followed by 5-years of endocrine therapy. Patients with a RS result of 0-10 and 26-100 were not randomized but were recommended to receive endocrine therapy alone or chemotherapy followed by endocrine therapy, respectively. The primary endpoint of the TAILORx trial was Invasive Disease-Free Survival (IDFS); however, a key secondary endpoint was Distant Recurrence-Free Interval (DRFI).

The prospective-retrospective analysis of the NSABP B-20 clinical trial included 651 patients with node-negative, HR+ invasive breast cancer. These patients were randomized to tamoxifen alone or concurrent tamoxifen plus chemotherapy (MF or CMF). The primary endpoint of the NSABP B-20 analysis was DRFI.

The individualized **Distant Recurrence Risk** at 10 years is for patients ≤50 years of age with a RS result of 0-10 who were treated with endocrine therapy alone. The group average **Absolute Benefit of Chemotherapy** for patients with a RS result of 0-10 was <1% and was derived from the NSABP B-20 analysis as patients in the TAILORx trial were not randomized to receive endocrine therapy alone or chemotherapy followed by endocrine therapy.

Oncotype DX Breast Recurrence Score® Report

Node Negative

EXACT
SCIENCES

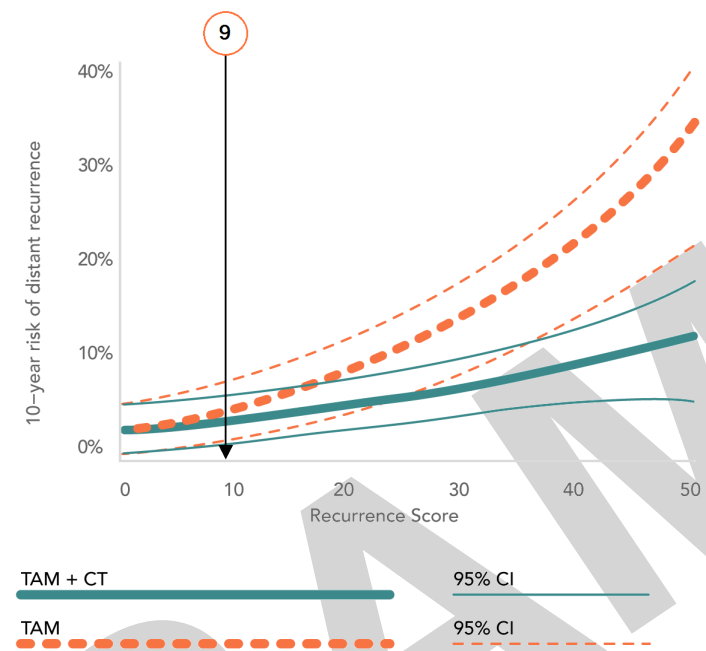
Age ≤ 50 Years

PATIENT, SAMPLE

Date of Birth: 01-Jan-1950 Gender: Female Report Number: OR000123456-3091 Report Date: 04-Jun-2025
Specimen Source/ID: Breast/SP-16_0123456 Date of Collection: 20-May-2025
Ordering Physician: Dr. First-Name I. Ordering-Physician-Last-Name

Medical Record/Patient #: 1234567-01 Client: Community Medical Center
Specimen Received: 22-May-2025
Additional Recipient: Dr. First-Name I. Recipient-Physician-Last-Name
Pathologist: Dr. First-Name I. Pathologist-Last-Name

NSABP B-20; All ages^{2,6}



Methods and Limitations

The Oncotype DX Breast Recurrence Score test uses RT-PCR to provide information on prognosis and the magnitude of chemotherapy benefit to guide chemotherapy treatment decisions in patients with early-stage, HR+, HER2-negative and lymph node-negative or lymph node-positive (N1) breast cancer. Decisions on treatment should also be based on independent medical judgement of the treating physician taking into consideration all available information concerning the patient's medical condition, in accordance with your community's standard of care.

The **Recurrence Score (RS) Result** which ranges from 0-100 is calculated from the quantitative RT-PCR analysis of 21 specific genes.

Quantitative Single-Gene Scores for quality control. The Oncotype DX test uses quantitative RT-PCR to determine the RNA expression of ER, PR and HER2, using the published validated cut-offs.^{3,4} The standard deviations of single-gene results are less than 0.5 units. The RT-PCR single-gene results may differ from ER, PR, or HER2 results reported using other methods or reported by other laboratories.

Distant Recurrence-Free Interval (DRFI): Time from randomization to distant recurrence or death from breast cancer.

References:
1. Sparano et al. *NEJM Evid* 2024. 2. Paik et al. *J Clin Oncol*. 2006. 3. Badve et al. *J Clin Oncol*. 2008. 4. Baehner et al. *J Clin Oncol*. 2010. 5. Sparano et al. *N Engl J Med*. 2018. 6. Data on File.

Laboratory Director(s): NhuThuy Thi Can, M.D.

This test was developed and its performance characteristics determined by Genomic Health, Inc. It has not been cleared or approved by the FDA, nor is it currently required to be. The laboratory is regulated under CLIA and qualified to perform high-complexity testing. This test is used for clinical purposes. It should not be regarded as investigational or for research.

The Oncotype DX Breast Recurrence Score Test is an in vitro diagnostic device, CE marked under Regulation (EU) 2017/46 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices. In Japan, the test has received manufacturing and marketing approval from the Ministry of Health, Labour and Welfare as the Oncotype DX Breast Recurrence Score Program and is covered by National Health Insurance.

Genomic Health, Inc.
301 Penobscot Drive, Redwood City, CA 94063, USA
USA/Canada +1.866.ONCOTYPE (+1.866.662.6897)

<https://precisiononcology.exactsciences.com/>
CLIA Number 05D1018272

Oncotype DX Breast Recurrence Score® Report

Node Negative

EXACT
SCIENCES

Age ≤ 50 Years

PATIENT, SAMPLE

Date of Birth: 01-Jan-1950 Gender: Female Report Number: OR000123456-3009 Report Date: 04-Jun-2025

Specimen Source/ID: Breast/SP-16_0123456 Date of Collection: 20-May-2025

Ordering Physician: Dr. First-Name I. Ordering-Physician-Last-Name

Recurrence Score®
(RS) Result

15

Distant Recurrence
Risk at 10 Years

With AI or TAM Alone

4%

95% CI (3%, 6%)

TAILORx¹

Group Average Absolute
Chemotherapy (CT)
Benefit

RS 11-15

No apparent
chemotherapy benefit
(<1%)

95% CI (-3.0%, 2.7%)

TAILORx¹

Clinical factors may be considered with the RS when making individual treatment decisions

AI = Aromatase Inhibitor / TAM = Tamoxifen
CI = Confidence Intervals

Quantitative Single-Gene Scores^{2,3}



TAILORx Study^{1,4}

Results in this report are based on the Recurrence Score (RS) and data from the TAILORx clinical trial. TAILORx is a prospective, multinational phase III clinical trial that enrolled 10,273 patients (≥18 years) with hormone receptor-positive (HR+), HER2-negative, node-negative invasive breast cancer. Patients with a RS result between 11-25 were randomized to receive 5 years of endocrine therapy alone or standard-of-care chemotherapy followed by 5-years of endocrine therapy. Patients with a RS result of 0-10 and 26-100 were not randomized but were recommended to receive endocrine therapy alone or chemotherapy followed by endocrine therapy, respectively. The primary endpoint of the TAILORx clinical trial was Invasive Disease-Free Survival (IDFS); however, a key secondary endpoint was Distant Recurrence-Free Interval (DRFI).

The individualized **Distant Recurrence Risk** at 10 years is for patients ≤50 years of age with a RS result of 11-15 who received endocrine therapy alone. The group average **Absolute Benefit of Chemotherapy** for patients ≤50 years of age with a RS result of 11-15 was <1%.

Oncotype DX Breast Recurrence Score® Report

Node Negative

Age ≤ 50 Years

EXACT
SCIENCES

PATIENT, SAMPLE

Date of Birth: 01-Jan-1950

Gender: Female

Report Number: OR000123456-3009

Report Date: 04-Jun-2025

Specimen Source/ID: Breast/SP-16_0123456

Date of Collection: 20-May-2025

Ordering Physician: Dr. First-Name I. Ordering-Physician-Last-Name

Medical Record/Patient #: 1234567-01

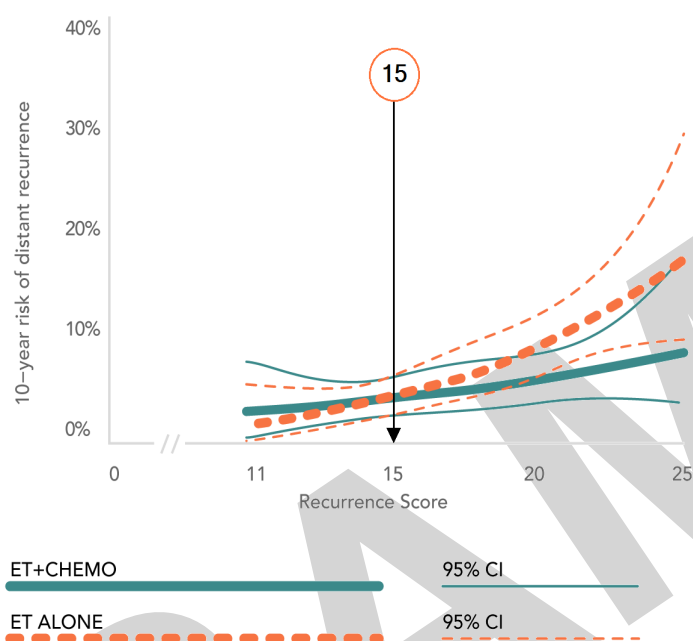
Client: Community Medical Center

Specimen Received: 22-May-2025

Additional Recipient: Dr. First-Name I. Recipient-Physician-Last-Name

Pathologist: Dr. First-Name I. Pathologist-Last-Name

TAILORx RS 11-25; Age ≤ 50 Years^{1,6}



Methods and Limitations

The Oncotype DX Breast Recurrence Score test uses RT-PCR to provide information on prognosis and the magnitude of chemotherapy benefit to guide chemotherapy treatment decisions in patients with early-stage, HR+, HER2-negative and lymph node-negative or lymph node-positive (N1) breast cancer. Decisions on treatment should also be based on independent medical judgement of the treating physician taking into consideration all available information concerning the patient's medical condition, in accordance with your community's standard of care.

The **Recurrence Score (RS) Result** which ranges from 0-100 is calculated from the quantitative RT-PCR analysis of 21 specific genes.

Quantitative Single-Gene Scores for quality control. The Oncotype DX test uses quantitative RT-PCR to determine the RNA expression of ER, PR and HER2, using the published validated cut-offs.^{2,3} The standard deviations of single-gene results are less than 0.5 units. The RT-PCR single-gene results may differ from ER, PR, or HER2 results reported using other methods or reported by other laboratories.

Distant Recurrence-Free Interval (DRFI): Time from randomization to distant recurrence or death from breast cancer.

References:

1. Sparano et al. *NEJM Evid* 2024. 2. Badve et al. *J Clin Oncol*. 2008. 3. Baehner et al. *J Clin Oncol*. 2010. 4. Sparano et al. *N Engl J Med*. 2018. 5. Paik et al. *J Clin Oncol*. 2006. 6. Data on File.

Laboratory Director(s): NhuThuy Thi Can, M.D.

This test was developed and its performance characteristics determined by Genomic Health, Inc. It has not been cleared or approved by the FDA, nor is it currently required to be. The laboratory is regulated under CLIA and qualified to perform high-complexity testing. This test is used for clinical purposes. It should not be regarded as investigational or for research.

The Oncotype DX Breast Recurrence Score Test is an in vitro diagnostic device, CE marked under Regulation (EU) 2017/46 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices. In Japan, the test has received manufacturing and marketing approval from the Ministry of Health, Labour and Welfare as the Oncotype DX Breast Recurrence Score Program and is covered by National Health Insurance.

Genomic Health, Inc.

301 Penobscot Drive, Redwood City, CA 94063, USA

USA/Canada +1.866.ONCOTYPE (+1.866.662.6897)

<https://precisiononcology.exactsciences.com/>

CLIA Number 05D1018272

Oncotype DX Breast Recurrence Score® Report

Node Negative

EXACT
SCIENCES

Age ≤ 50 Years

PATIENT, SAMPLE

Date of Birth: 01-Jan-1950 Gender: Female Report Number: OR000123456-3015 Report Date: 04-Jun-2025

Specimen Source/ID: Breast/SP-16_0123456 Date of Collection: 20-May-2025

Ordering Physician: Dr. First-Name I. Ordering-Physician-Last-Name

Recurrence Score® (RS) Result

20

Clinical factors may be considered with the RS when making individual treatment decisions

Distant Recurrence Risk at 10 Years

With AI or TAM Alone

7%

95% CI (5%, 9%)

TAILORx¹

AI = Aromatase Inhibitor / TAM = Tamoxifen
CI = Confidence Intervals

Group Average Absolute Chemotherapy (CT) Benefit

RS 16-20

No apparent chemotherapy benefit (<1%)*

95% CI (-2.9%, 4.2%)

TAILORx¹

*Chemotherapy benefit may vary by clinical risk

Quantitative Single-Gene Scores^{2,3}



TAILORx Study^{1,4}

Results in this report are based on the Recurrence Score (RS) and data from the TAILORx clinical trial. TAILORx is a prospective, multinational phase III clinical trial that enrolled 10,273 patients (≥18 years) with hormone receptor-positive (HR+), HER2-negative, node-negative invasive breast cancer. Patients with a RS result between 11-25 were randomized to receive 5 years of endocrine therapy alone or standard-of-care chemotherapy followed by 5-years of endocrine therapy. Patients with a RS result of 0-10 and 26-100 were not randomized but were recommended to receive endocrine therapy alone or chemotherapy followed by endocrine therapy, respectively. The primary endpoint of the TAILORx clinical trial was Invasive Disease-Free Survival (IDFS); however, a key secondary endpoint was Distant Recurrence-Free Interval (DRFI).

Chemotherapy benefit stratified by clinical risk*

Patients ≤50 years of age with a RS result of 16-20 showed a <1% group average absolute benefit of chemotherapy in addition to endocrine therapy for the endpoint of 10-year DRFI. However, for this RS range, there was a difference in chemotherapy benefit between low and high clinical-risk** patients. Whereas patients with low clinical-risk tumors showed a <1% absolute benefit of chemotherapy, patients with high clinical-risk tumors showed a 3.1% absolute benefit of chemotherapy at 12 years.

The individualized **Distant Recurrence Risk** at 10 years is for patients ≤50 years of age with a RS result of 16-20 who received endocrine therapy alone. The group average **Absolute Benefit of Chemotherapy** for patients ≤50 years of age with a RS result of 16-20 was <1%.

**Low clinical-risk: sum of grade and tumor size in cm ≤4; High clinical-risk: sum of grade and tumor size in cm >4

Oncotype DX Breast Recurrence Score® Report

Node Negative

Age ≤ 50 Years

EXACT
SCIENCES

PATIENT, SAMPLE

Date of Birth: 01-Jan-1950

Gender: Female

Report Number: OR000123456-3015

Report Date: 04-Jun-2025

Specimen Source/ID: Breast/SP-16_0123456

Date of Collection: 20-May-2025

Ordering Physician: Dr. First-Name I. Ordering-Physician-Last-Name

Medical Record/Patient #: 1234567-01

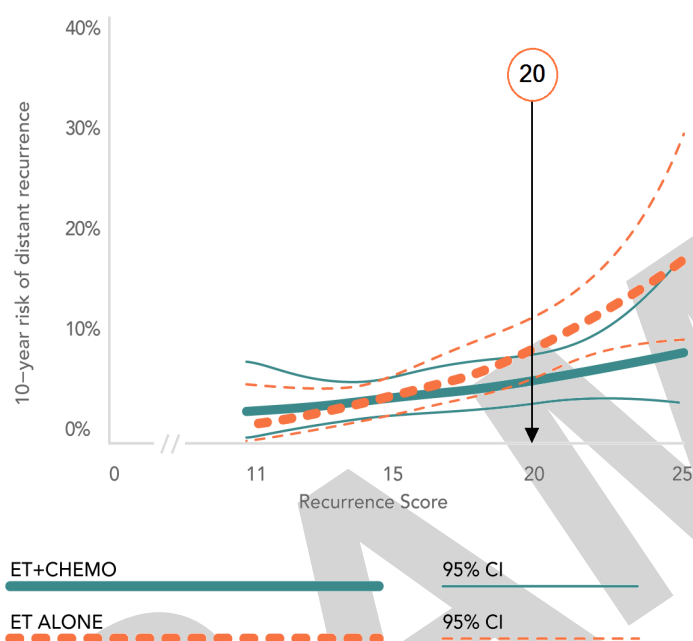
Client: Community Medical Center

Specimen Received: 22-May-2025

Additional Recipient: Dr. First-Name I. Recipient-Physician-Last-Name

Pathologist: Dr. First-Name I. Pathologist-Last-Name

TAILORx RS 11-25; Age ≤ 50 Years^{1,6}



Methods and Limitations

The Oncotype DX Breast Recurrence Score test uses RT-PCR to provide information on prognosis and the magnitude of chemotherapy benefit to guide chemotherapy treatment decisions in patients with early-stage, HR+, HER2-negative and lymph node-negative or lymph node-positive (N1) breast cancer. Decisions on treatment should also be based on independent medical judgement of the treating physician taking into consideration all available information concerning the patient's medical condition, in accordance with your community's standard of care.

The **Recurrence Score (RS) Result** which ranges from 0-100 is calculated from the quantitative RT-PCR analysis of 21 specific genes.

Quantitative Single-Gene Scores for quality control. The Oncotype DX test uses quantitative RT-PCR to determine the RNA expression of ER, PR and HER2, using the published validated cut-offs.^{2,3} The standard deviations of single-gene results are less than 0.5 units. The RT-PCR single-gene results may differ from ER, PR, or HER2 results reported using other methods or reported by other laboratories.

Distant Recurrence-Free Interval (DRFI): Time from randomization to distant recurrence or death from breast cancer.

References:

1. Sparano et al. *NEJM Evid* 2024. 2. Badve et al. *J Clin Oncol*. 2008. 3. Baehner et al. *J Clin Oncol*. 2010. 4. Sparano et al. *N Engl J Med*. 2018. 5. Paik et al. *J Clin Oncol*. 2006. 6. Data on File.

Laboratory Director(s): NhuThuy Thi Can, M.D.

This test was developed and its performance characteristics determined by Genomic Health, Inc. It has not been cleared or approved by the FDA, nor is it currently required to be. The laboratory is regulated under CLIA and qualified to perform high-complexity testing. This test is used for clinical purposes. It should not be regarded as investigational or for research.

The Oncotype DX Breast Recurrence Score Test is an in vitro diagnostic device, CE marked under Regulation (EU) 2017/46 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices. In Japan, the test has received manufacturing and marketing approval from the Ministry of Health, Labour and Welfare as the Oncotype DX Breast Recurrence Score Program and is covered by National Health Insurance.

Genomic Health, Inc.

301 Penobscot Drive, Redwood City, CA 94063, USA

USA/Canada +1.866.ONCOTYPE (+1.866.662.6897)

<https://precisiononcology.exactsciences.com/>

CLIA Number 05D1018272

Oncotype DX Breast Recurrence Score® Report

Node Negative

EXACT
SCIENCES

Age ≤ 50 Years

PATIENT, SAMPLE

Date of Birth: 01-Jan-1950 Gender: Female Report Number: OR000123456-3018 Report Date: 04-Jun-2025

Specimen Source/ID: Breast/SP-16_0123456 Date of Collection: 20-May-2025

Ordering Physician: Dr. First-Name I. Ordering-Physician-Last-Name

Recurrence Score®
(RS) Result

Clinical factors may be considered with the RS when making individual treatment decisions

Distant Recurrence Risk at 10 Years

With AI or TAM Alone

TAILORx¹

AI = Aromatase Inhibitor / TAM = Tamoxifen
CI = Confidence Intervals

Group Average Absolute Chemotherapy (CT) Benefit

RS 21-25

TAILORx¹

*Chemotherapy benefit may vary by clinical risk

Quantitative Single-Gene Scores^{2,3}



TAILORx Study^{1,4}

Results in this report are based on the Recurrence Score (RS) and data from the TAILORx clinical trial. TAILORx is a prospective, multinational phase III clinical trial that enrolled 10,273 patients (≥18 years) with hormone receptor-positive (HR+), HER2-negative, node-negative invasive breast cancer. Patients with a RS result between 11-25 were randomized to receive 5 years of endocrine therapy alone or standard-of-care chemotherapy followed by 5-years of endocrine therapy. Patients with a RS result of 0-10 and 26-100 were not randomized but were recommended to receive endocrine therapy alone or chemotherapy followed by endocrine therapy, respectively. The primary endpoint of the TAILORx clinical trial was Invasive Disease-Free Survival (IDFS); however, a key secondary endpoint was Distant Recurrence-Free Interval (DRFI).

Chemotherapy benefit stratified by clinical risk*

Patients ≤50 years of age with a RS result of 21-25 showed a 7.1% group average absolute benefit of chemotherapy in addition to endocrine therapy for the endpoint of 10-year DRFI. However, for this RS range, there was a difference in chemotherapy benefit between low and high clinical-risk** patients. Whereas patients with low clinical-risk tumors showed a 5.9% absolute benefit of chemotherapy, patients with high clinical-risk tumors showed a 11.7% absolute benefit of chemotherapy at 12 years.

The individualized **Distant Recurrence Risk** at 10 years is for patients ≤50 years of age with a RS result of 21-25 who received endocrine therapy alone. The group average **Absolute Benefit of Chemotherapy** for patients ≤50 years of age with a RS result of 21-25 was 7.1%.

**Low clinical-risk: sum of grade and tumor size in cm ≤4; High clinical-risk: sum of grade and tumor size in cm >4

Oncotype DX Breast Recurrence Score® Report

Node Negative

Age ≤ 50 Years

EXACT
SCIENCES

PATIENT, SAMPLE

Date of Birth: 01-Jan-1950

Gender: Female

Report Number: OR000123456-3018

Report Date: 04-Jun-2025

Specimen Source/ID: Breast/SP-16_0123456

Date of Collection: 20-May-2025

Ordering Physician: Dr. First-Name I. Ordering-Physician-Last-Name

Medical Record/Patient #: 1234567-01

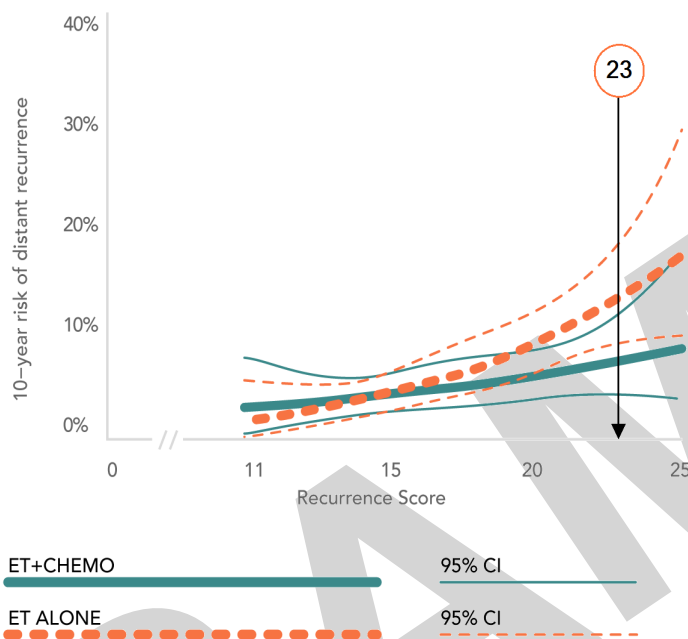
Client: Community Medical Center

Specimen Received: 22-May-2025

Additional Recipient: Dr. First-Name I. Recipient-Physician-Last-Name

Pathologist: Dr. First-Name I. Pathologist-Last-Name

TAILORx RS 11-25; Age ≤ 50 Years^{1,6}



Methods and Limitations

The Oncotype DX Breast Recurrence Score test uses RT-PCR to provide information on prognosis and the magnitude of chemotherapy benefit to guide chemotherapy treatment decisions in patients with early-stage, HR+, HER2-negative and lymph node-negative or lymph node-positive (N1) breast cancer. Decisions on treatment should also be based on independent medical judgement of the treating physician taking into consideration all available information concerning the patient's medical condition, in accordance with your community's standard of care.

The **Recurrence Score (RS) Result** which ranges from 0-100 is calculated from the quantitative RT-PCR analysis of 21 specific genes.

Quantitative Single-Gene Scores for quality control. The Oncotype DX test uses quantitative RT-PCR to determine the RNA expression of ER, PR and HER2, using the published validated cut-offs.^{2,3} The standard deviations of single-gene results are less than 0.5 units. The RT-PCR single-gene results may differ from ER, PR, or HER2 results reported using other methods or reported by other laboratories.

Distant Recurrence-Free Interval (DRFI): Time from randomization to distant recurrence or death from breast cancer.

References:

1. Sparano et al. *NEJM Evid* 2024. 2. Badve et al. *J Clin Oncol*. 2008. 3. Baehner et al. *J Clin Oncol*. 2010. 4. Sparano et al. *N Engl J Med*. 2018. 5. Paik et al. *J Clin Oncol*. 2006. 6. Data on File.

Laboratory Director(s): NhuThuy Thi Can, M.D.

This test was developed and its performance characteristics determined by Genomic Health, Inc. It has not been cleared or approved by the FDA, nor is it currently required to be. The laboratory is regulated under CLIA and qualified to perform high-complexity testing. This test is used for clinical purposes. It should not be regarded as investigational or for research.

The Oncotype DX Breast Recurrence Score Test is an in vitro diagnostic device, CE marked under Regulation (EU) 2017/46 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices. In Japan, the test has received manufacturing and marketing approval from the Ministry of Health, Labour and Welfare as the Oncotype DX Breast Recurrence Score Program and is covered by National Health Insurance.

Genomic Health, Inc.

301 Penobscot Drive, Redwood City, CA 94063, USA

USA/Canada +1.866.ONCOTYPE (+1.866.662.6897)

<https://precisiononcology.exactsciences.com/>

CLIA Number 05D1018272

Oncotype DX Breast Recurrence Score® Report

Node Negative

EXACT
SCIENCES

Age ≤ 50 Years

PATIENT, SAMPLE

Date of Birth: 01-Jan-1950 Gender: Female Report Number: OR000123456-3026 Report Date: 04-Jun-2025
Specimen Source/ID: Breast/SP-16_0123456 Date of Collection: 20-May-2025
Ordering Physician: Dr. First-Name I. Ordering-Physician-Last-Name

Recurrence Score® (RS) Result



Clinical factors may be considered with the RS when making individual treatment decisions

Distant Recurrence Risk at 10 Years

With TAM Alone

22%

95% CI (14%, 35%)

NSABP B-14¹

TAM = Tamoxifen
CI = Confidence Intervals

Group Average Absolute Chemotherapy (CT) Benefit

RS 26-100

For women with a Recurrence Score result of 26-100 and node-negative disease, guidelines recommend chemotherapy in addition to hormone therapy.

Quantitative Single-Gene Scores^{2,3}

11.2 ER Positive

<3.7 6.5 ≥12.5

4.1 PR Negative

<3.2 5.5 ≥10.0

7.9 HER2 Negative

<7.6 10.7 11.5 ≥13.0

NSABP B-14 and NSABP B-20 Studies^{1,4}

Results in this report are based on the Recurrence Score (RS) and data from the NSABP B-14 and NSABP B-20 clinical trials. The prospective-retrospective analysis of the NSABP B-14 clinical trial included 668 patients with node-negative, hormone receptor-positive (HR+) invasive breast cancer. These patients received tamoxifen alone. The primary endpoint of the NSABP B-14 analysis was Distant Recurrence-Free Interval (DRFI).

The prospective-retrospective analysis of the NSABP B-20 clinical trial included 651 patients with node-negative, HR+ invasive breast cancer. These patients were randomized to tamoxifen alone or concurrent tamoxifen plus chemotherapy (MF or CMF). The primary endpoint of the NSABP B-20 analysis was DRFI.

The individualized **Distant Recurrence Risk** at 10 years is for patients ≤50 years of age and >50 years of age with a RS result of 26-100 who were treated with tamoxifen alone in the NSABP B-14 trial. Due to the limited availability of data in the subset of patients with RS results of 26-100 in the NSABP B-20 trial, precise estimates for **Absolute Benefit of Chemotherapy** are not provided; however, guidelines recommend that patients ≤50 years of age and >50 years of age with a RS result of 26-100 receive a combination of chemotherapy and endocrine therapy.

Oncotype DX Breast Recurrence Score® Report

Node Negative

EXACT
SCIENCES

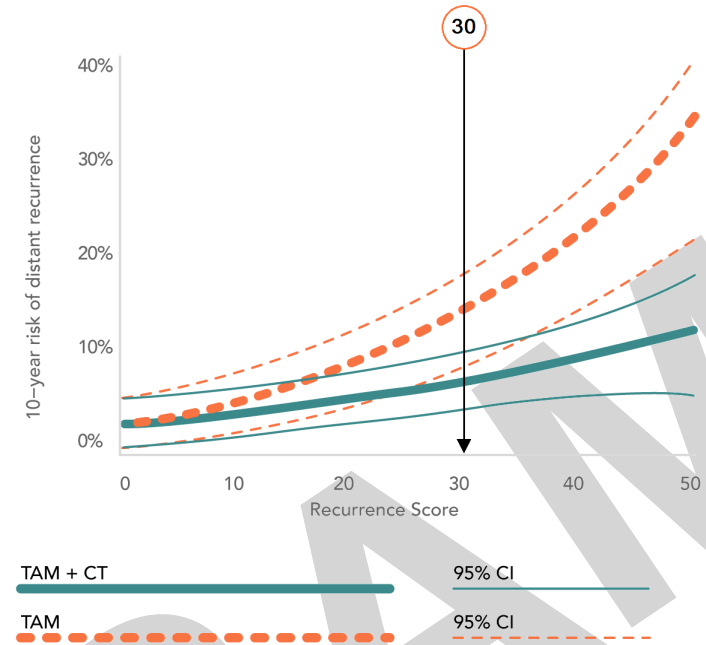
Age ≤ 50 Years

PATIENT, SAMPLE

Date of Birth: 01-Jan-1950 Gender: Female Report Number: OR000123456-3026 Report Date: 04-Jun-2025
Specimen Source/ID: Breast/SP-16_0123456 Date of Collection: 20-May-2025
Ordering Physician: Dr. First-Name I. Ordering-Physician-Last-Name

Medical Record/Patient #: 1234567-01 Client: Community Medical Center
Specimen Received: 22-May-2025
Additional Recipient: Dr. First-Name I. Recipient-Physician-Last-Name
Pathologist: Dr. First-Name I. Pathologist-Last-Name

NSABP B-20; All ages^{4,7}



Methods and Limitations

The Oncotype DX Breast Recurrence Score test uses RT-PCR to provide information on prognosis and the magnitude of chemotherapy benefit to guide chemotherapy treatment decisions in patients with early-stage, HR+, HER2-negative and lymph node-negative or lymph node-positive (N1) breast cancer. Decisions on treatment should also be based on independent medical judgement of the treating physician taking into consideration all available information concerning the patient's medical condition, in accordance with your community's standard of care.

The **Recurrence Score (RS) Result** which ranges from 0-100 is calculated from the quantitative RT-PCR analysis of 21 specific genes.

Quantitative Single-Gene Scores for quality control. The Oncotype DX test uses quantitative RT-PCR to determine the RNA expression of ER, PR and HER2, using the published validated cut-offs.^{2,3} The standard deviations of single-gene results are less than 0.5 units. The RT-PCR single-gene results may differ from ER, PR, or HER2 results reported using other methods or reported by other laboratories.

Distant Recurrence-Free Interval (DRFI): Time from randomization to distant recurrence or death from breast cancer.

References:
1. Paik et al. *N Engl J Med*. 2004. 2. Badve et al. *J Clin Oncol*. 2008. 3. Baehner et al. *J Clin Oncol*. 2010. 4. Paik et al. *J Clin Oncol*. 2006. 5. Sparano et al. *NEJM Evid* 2024. 6. Sparano et al. *N Engl J Med*. 2018. 7. Data on File.

Laboratory Director(s): NhuThuy Thi Can, M.D.

This test was developed and its performance characteristics determined by Genomic Health, Inc. It has not been cleared or approved by the FDA, nor is it currently required to be. The laboratory is regulated under CLIA and qualified to perform high-complexity testing. This test is used for clinical purposes. It should not be regarded as investigational or for research.

The Oncotype DX Breast Recurrence Score Test is an in vitro diagnostic device, CE marked under Regulation (EU) 2017/46 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices. In Japan, the test has received manufacturing and marketing approval from the Ministry of Health, Labour and Welfare as the Oncotype DX Breast Recurrence Score Program and is covered by National Health Insurance.

Genomic Health, Inc.
301 Penobscot Drive, Redwood City, CA 94063, USA
USA/Canada +1.866.ONCOTYPE (+1.866.662.6897)

<https://precisiononcology.exactsciences.com/>
CLIA Number 05D1018272

Oncotype DX Breast Recurrence Score® Report

Node Negative

EXACT
SCIENCES

Age ≤ 50 Years

PATIENT, SAMPLE

Date of Birth: 01-Jan-1950 Gender: Female Report Number: OR000123456-3059 Report Date: 04-Jun-2025
Specimen Source/ID: Breast/SP-16_0123456 Date of Collection: 20-May-2025
Ordering Physician: Dr. First-Name I. Ordering-Physician-Last-Name

Recurrence Score® (RS) Result



60

Clinical factors may be considered with the RS when making individual treatment decisions

Distant Recurrence Risk at 10 Years

With TAM Alone
RS > 50

>50%

95% CI (34%, 67%)

NSABP B-14¹

TAM = Tamoxifen
CI = Confidence Intervals

Group Average Absolute Chemotherapy (CT) Benefit

RS 26-100

For women with a Recurrence Score result of 26-100 and node-negative disease, guidelines recommend chemotherapy in addition to hormone therapy.

Quantitative Single-Gene Scores^{2,3}



NSABP B-14 and NSABP B-20 Studies^{1,4}

Results in this report are based on the Recurrence Score (RS) and data from the NSABP B-14 and NSABP B-20 clinical trials. The prospective-retrospective analysis of the NSABP B-14 clinical trial included 668 patients with node-negative, hormone receptor-positive (HR+) invasive breast cancer. These patients received tamoxifen alone. The primary endpoint of the NSABP B-14 analysis was Distant Recurrence-Free Interval (DRFI).

The prospective-retrospective analysis of the NSABP B-20 clinical trial included 651 patients with node-negative, HR+ invasive breast cancer. These patients were randomized to tamoxifen alone or concurrent tamoxifen plus chemotherapy (MF or CMF). The primary endpoint of the NSABP B-20 analysis was DRFI.

The individualized **Distant Recurrence Risk** at 10 years is for patients ≤50 years of age and >50 years of age with a RS result of 26-100 who were treated with tamoxifen alone in the NSABP B-14 trial. Due to the limited availability of data in the subset of patients with RS results of 26-100 in the NSABP B-20 trial, precise estimates for **Absolute Benefit of Chemotherapy** are not provided; however, guidelines recommend that patients ≤50 years of age and >50 years of age with a RS result of 26-100 receive a combination of chemotherapy and endocrine therapy.

Oncotype DX Breast Recurrence Score® Report

Node Negative

EXACT
SCIENCES

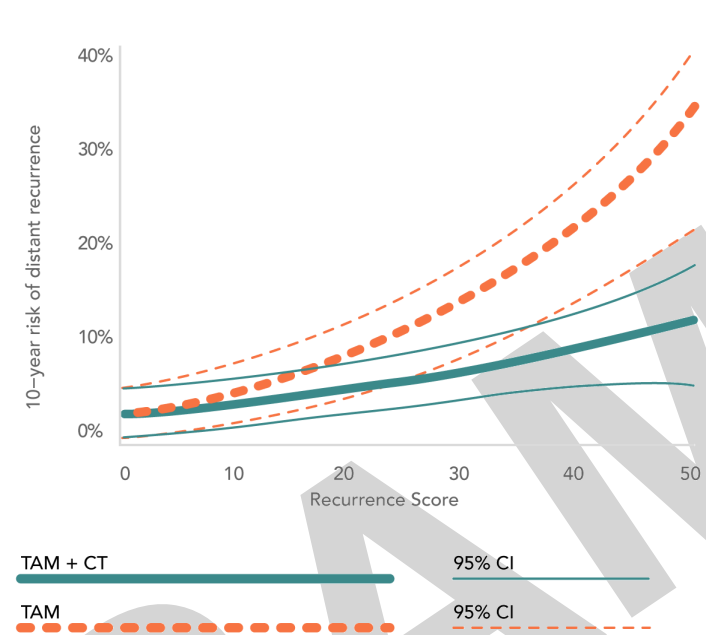
Age ≤ 50 Years

PATIENT, SAMPLE

Date of Birth: 01-Jan-1950 Gender: Female Report Number: OR000123456-3059 Report Date: 04-Jun-2025
Specimen Source/ID: Breast/SP-16_0123456 Date of Collection: 20-May-2025
Ordering Physician: Dr. First-Name I. Ordering-Physician-Last-Name

Medical Record/Patient #: 1234567-01 Client: Community Medical Center
Specimen Received: 22-May-2025
Additional Recipient: Dr. First-Name I. Recipient-Physician-Last-Name
Pathologist: Dr. First-Name I. Pathologist-Last-Name

NSABP B-20; All ages^{4,7}



Methods and Limitations

The Oncotype DX Breast Recurrence Score test uses RT-PCR to provide information on prognosis and the magnitude of chemotherapy benefit to guide chemotherapy treatment decisions in patients with early-stage, HR+, HER2-negative and lymph node-negative or lymph node-positive (N1) breast cancer. Decisions on treatment should also be based on independent medical judgement of the treating physician taking into consideration all available information concerning the patient's medical condition, in accordance with your community's standard of care.

The **Recurrence Score (RS) Result** which ranges from 0-100 is calculated from the quantitative RT-PCR analysis of 21 specific genes.

Quantitative Single-Gene Scores for quality control. The Oncotype DX test uses quantitative RT-PCR to determine the RNA expression of ER, PR and HER2, using the published validated cut-offs.^{2,3} The standard deviations of single-gene results are less than 0.5 units. The RT-PCR single-gene results may differ from ER, PR, or HER2 results reported using other methods or reported by other laboratories.

Distant Recurrence-Free Interval (DRFI): Time from randomization to distant recurrence or death from breast cancer.

References:
1. Paik et al. *N Engl J Med*. 2004. 2. Badve et al. *J Clin Oncol*. 2008. 3. Baehner et al. *J Clin Oncol*. 2010. 4. Paik et al. *J Clin Oncol*. 2006. 5. Sparano et al. *NEJM Evid* 2024. 6. Sparano et al. *N Engl J Med*. 2018. 7. Data on File.

Laboratory Director(s): NhuThuy Thi Can, M.D.

This test was developed and its performance characteristics determined by Genomic Health, Inc. It has not been cleared or approved by the FDA, nor is it currently required to be. The laboratory is regulated under CLIA and qualified to perform high-complexity testing. This test is used for clinical purposes. It should not be regarded as investigational or for research.

The Oncotype DX Breast Recurrence Score Test is an in vitro diagnostic device, CE marked under Regulation (EU) 2017/46 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices. In Japan, the test has received manufacturing and marketing approval from the Ministry of Health, Labour and Welfare as the Oncotype DX Breast Recurrence Score Program and is covered by National Health Insurance.

Genomic Health, Inc.
301 Penobscot Drive, Redwood City, CA 94063, USA
USA/Canada +1.866.ONCOTYPE (+1.866.662.6897)

<https://precisiononcology.exactsciences.com/>
CLIA Number 05D1018272

Oncotype DX Breast Recurrence Score® Report

Node Negative

EXACT
SCIENCES

Age > 50 Years

PATIENT, SAMPLE

Date of Birth: 01-Jan-1950 Gender: Female Report Number: OR000123456-3091 Report Date: 04-Jun-2025

Specimen Source/ID: Breast/SP-16_0123456 Date of Collection: 20-May-2025

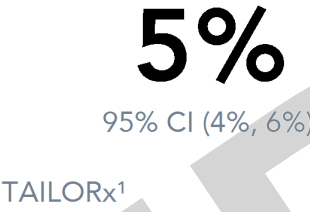
Ordering Physician: Dr. First-Name I. Ordering-Physician-Last-Name

Recurrence Score®
(RS) Result



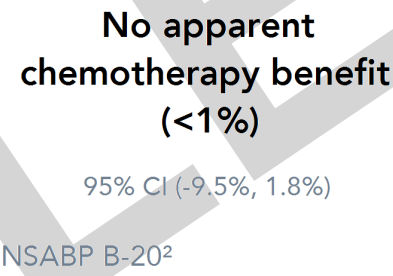
Distant Recurrence
Risk at 10 Years

With AI or TAM Alone



Group Average Absolute
Chemotherapy (CT)
Benefit

RS 0-10



Clinical factors may be considered with the RS when making individual treatment decisions

AI = Aromatase Inhibitor / TAM = Tamoxifen
CI = Confidence Intervals

Quantitative Single-Gene Scores^{3,4}



TAILORx and NSABP B-20 Studies^{1,2,5}

Results in this report are based on the Recurrence Score (RS) and data from the TAILORx and NSABP B-20 clinical trials. TAILORx is a prospective, multinational phase III clinical trial that enrolled 10,273 patients (≥18 years) with hormone receptor-positive (HR+), HER2-negative, node-negative invasive breast cancer. Patients with a RS result between 11-25 were randomized to receive 5 years of endocrine therapy alone or standard-of-care chemotherapy followed by 5-years of endocrine therapy. Patients with a RS result of 0-10 and 26-100 were not randomized but were recommended to receive endocrine therapy alone or chemotherapy followed by endocrine therapy, respectively. The primary endpoint of the TAILORx trial was Invasive Disease-Free Survival (IDFS); however, a key secondary endpoint was Distant Recurrence-Free Interval (DRFI).

The prospective-retrospective analysis of the NSABP B-20 clinical trial included 651 patients with node-negative, HR+ invasive breast cancer. These patients were randomized to tamoxifen alone or concurrent tamoxifen plus chemotherapy (MF or CMF). The primary endpoint of the NSABP B-20 analysis was DRFI.

The individualized **Distant Recurrence Risk** at 10 years is for patients >50 years of age with a RS result of 0-10 who were treated with endocrine therapy alone. The group average **Absolute Benefit of Chemotherapy** for patients with a RS result of 0-10 was <1% and was derived from the NSABP B-20 analysis as patients in the TAILORx trial were not randomized to receive endocrine therapy alone or chemotherapy followed by endocrine therapy.

Oncotype DX Breast Recurrence Score® Report

Node Negative

EXACT
SCIENCES

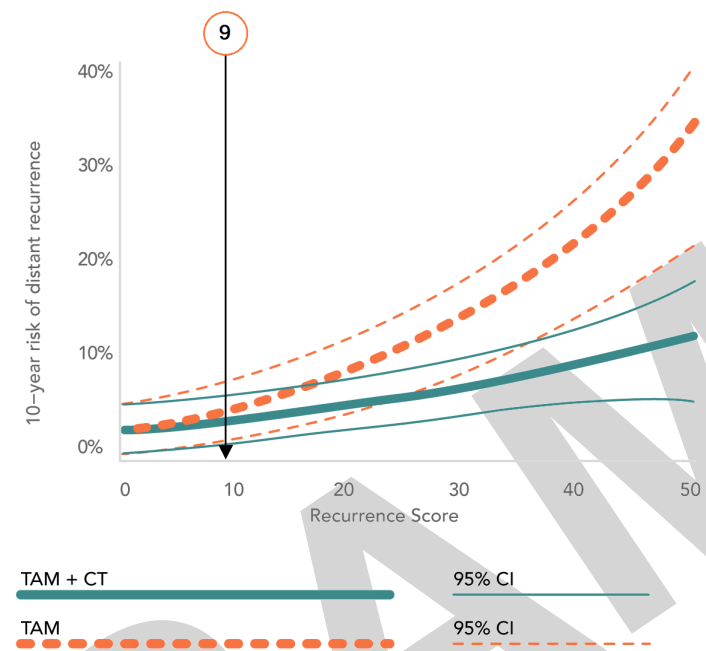
Age > 50 Years

PATIENT, SAMPLE

Date of Birth: 01-Jan-1950 Gender: Female Report Number: OR000123456-3091 Report Date: 04-Jun-2025
Specimen Source/ID: Breast/SP-16_0123456 Date of Collection: 20-May-2025
Ordering Physician: Dr. First-Name I. Ordering-Physician-Last-Name

Medical Record/Patient #: 1234567-01 Client: Community Medical Center
Specimen Received: 22-May-2025
Additional Recipient: Dr. First-Name I. Recipient-Physician-Last-Name
Pathologist: Dr. First-Name I. Pathologist-Last-Name

NSABP B-20; All ages^{2,6}



Methods and Limitations

The Oncotype DX Breast Recurrence Score test uses RT-PCR to provide information on prognosis and the magnitude of chemotherapy benefit to guide chemotherapy treatment decisions in patients with early-stage, HR+, HER2-negative and lymph node-negative or lymph node-positive (N1) breast cancer. Decisions on treatment should also be based on independent medical judgement of the treating physician taking into consideration all available information concerning the patient's medical condition, in accordance with your community's standard of care.

The **Recurrence Score (RS) Result** which ranges from 0-100 is calculated from the quantitative RT-PCR analysis of 21 specific genes.

Quantitative Single-Gene Scores for quality control. The Oncotype DX test uses quantitative RT-PCR to determine the RNA expression of ER, PR and HER2, using the published validated cut-offs.^{3,4} The standard deviations of single-gene results are less than 0.5 units. The RT-PCR single-gene results may differ from ER, PR, or HER2 results reported using other methods or reported by other laboratories.

Distant Recurrence-Free Interval (DRFI): Time from randomization to distant recurrence or death from breast cancer.

References:
1. Sparano et al. *NEJM Evid* 2024. 2. Paik et al. *J Clin Oncol*. 2006. 3. Badve et al. *J Clin Oncol*. 2008. 4. Baehner et al. *J Clin Oncol*. 2010. 5. Sparano et al. *N Engl J Med*. 2018. 6. Data on File.

Laboratory Director(s): NhuThuy Thi Can, M.D.

This test was developed and its performance characteristics determined by Genomic Health, Inc. It has not been cleared or approved by the FDA, nor is it currently required to be. The laboratory is regulated under CLIA and qualified to perform high-complexity testing. This test is used for clinical purposes. It should not be regarded as investigational or for research.

The Oncotype DX Breast Recurrence Score Test is an in vitro diagnostic device, CE marked under Regulation (EU) 2017/46 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices. In Japan, the test has received manufacturing and marketing approval from the Ministry of Health, Labour and Welfare as the Oncotype DX Breast Recurrence Score Program and is covered by National Health Insurance.

Genomic Health, Inc.
301 Penobscot Drive, Redwood City, CA 94063, USA
USA/Canada +1.866.ONCOTYPE (+1.866.662.6897)

<https://precisiononcology.exactsciences.com/>
CLIA Number 05D1018272

Oncotype DX Breast Recurrence Score® Report

Node Negative

EXACT
SCIENCES

Age > 50 Years

PATIENT, SAMPLE

Date of Birth: 01-Jan-1950 Gender: Female Report Number: OR000123456-3009 Report Date: 04-Jun-2025

Specimen Source/ID: Breast/SP-16_0123456 Date of Collection: 20-May-2025

Ordering Physician: Dr. First-Name I. Ordering-Physician-Last-Name

Recurrence Score®
(RS) Result

15

Clinical factors may be considered with the RS when making individual treatment decisions

Distant Recurrence Risk at 10 Years

With AI or TAM Alone

5%

95% CI (4%, 6%)

TAILORx¹

AI = Aromatase Inhibitor / TAM = Tamoxifen
CI = Confidence Intervals

Group Average Absolute Chemotherapy (CT) Benefit

RS 11-15

No apparent chemotherapy benefit (<1%)

95% CI (-2.0%, 2.3%)

TAILORx¹

Quantitative Single-Gene Scores^{2,3}



TAILORx Study^{1,4}

Results in this report are based on the Recurrence Score (RS) and data from the TAILORx clinical trial. TAILORx is a prospective, multinational phase III clinical trial that enrolled 10,273 patients (≥18 years) with hormone receptor-positive (HR+), HER2-negative, node-negative invasive breast cancer. Patients with a RS result between 11-25 were randomized to receive 5 years of endocrine therapy alone or standard-of-care chemotherapy followed by 5-years of endocrine therapy. Patients with a RS result of 0-10 and 26-100 were not randomized but were recommended to receive endocrine therapy alone or chemotherapy followed by endocrine therapy, respectively. The primary endpoint of the TAILORx clinical trial was Invasive Disease-Free Survival (IDFS); however, a key secondary endpoint was Distant Recurrence-Free Interval (DRFI).

The individualized **Distant Recurrence Risk** at 10 years is for patients >50 years of age with a RS result of 11-25 who received endocrine therapy alone. The group average **Absolute Benefit of Chemotherapy** for patients >50 years of age with a RS result of 11-25 was <1%.

Oncotype DX Breast Recurrence Score® Report

Node Negative

EXACT
SCIENCES

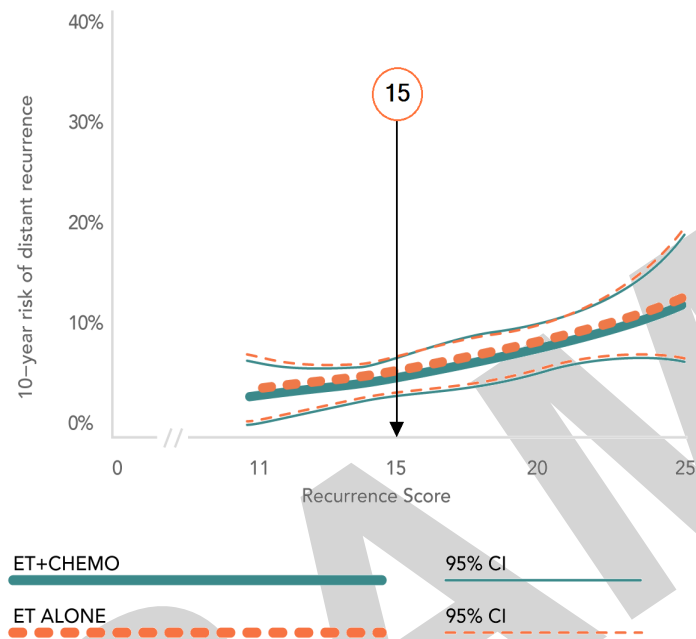
Age > 50 Years

PATIENT, SAMPLE

Date of Birth: 01-Jan-1950 Gender: Female Report Number: OR000123456-3009 Report Date: 04-Jun-2025
Specimen Source/ID: Breast/SP-16_0123456 Date of Collection: 20-May-2025
Ordering Physician: Dr. First-Name I. Ordering-Physician-Last-Name

Medical Record/Patient #: 1234567-01 Client: Community Medical Center
Specimen Received: 22-May-2025
Additional Recipient: Dr. First-Name I. Recipient-Physician-Last-Name
Pathologist: Dr. First-Name I. Pathologist-Last-Name

TAILORx RS 11-25; Age > 50 Years^{1,6}



Methods and Limitations

The Oncotype DX Breast Recurrence Score test uses RT-PCR to provide information on prognosis and the magnitude of chemotherapy benefit to guide chemotherapy treatment decisions in patients with early-stage, HR+, HER2-negative and lymph node-negative or lymph node-positive (N1) breast cancer. Decisions on treatment should also be based on independent medical judgement of the treating physician taking into consideration all available information concerning the patient's medical condition, in accordance with your community's standard of care.

The **Recurrence Score (RS) Result** which ranges from 0-100 is calculated from the quantitative RT-PCR analysis of 21 specific genes.

Quantitative Single-Gene Scores for quality control. The Oncotype DX test uses quantitative RT-PCR to determine the RNA expression of ER, PR and HER2, using the published validated cut-offs.^{2,3} The standard deviations of single-gene results are less than 0.5 units. The RT-PCR single-gene results may differ from ER, PR, or HER2 results reported using other methods or reported by other laboratories.

Distant Recurrence-Free Interval (DRFI): Time from randomization to distant recurrence or death from breast cancer.

References:
1. Sparano et al. *NEJM Evid* 2024. 2. Badve et al. *J Clin Oncol*. 2008. 3. Baehner et al. *J Clin Oncol*. 2010. 4. Sparano et al. *N Engl J Med*. 2018. 5. Paik et al. *J Clin Oncol*. 2006. 6. Data on File.

Laboratory Director(s): NhuThuy Thi Can, M.D.

This test was developed and its performance characteristics determined by Genomic Health, Inc. It has not been cleared or approved by the FDA, nor is it currently required to be. The laboratory is regulated under CLIA and qualified to perform high-complexity testing. This test is used for clinical purposes. It should not be regarded as investigational or for research.

The Oncotype DX Breast Recurrence Score Test is an in vitro diagnostic device, CE marked under Regulation (EU) 2017/46 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices. In Japan, the test has received manufacturing and marketing approval from the Ministry of Health, Labour and Welfare as the Oncotype DX Breast Recurrence Score Program and is covered by National Health Insurance.

Genomic Health, Inc.
301 Penobscot Drive, Redwood City, CA 94063, USA
USA/Canada +1.866.ONCOTYPE (+1.866.662.6897)

<https://precisiononcology.exactsciences.com/>
CLIA Number 05D1018272

Oncotype DX Breast Recurrence Score® Report

Node Negative

EXACT
SCIENCES

Age > 50 Years

PATIENT, SAMPLE

Date of Birth: 01-Jan-1950 Gender: Female Report Number: OR000123456-3015 Report Date: 04-Jun-2025

Specimen Source/ID: Breast/SP-16_0123456 Date of Collection: 20-May-2025

Ordering Physician: Dr. First-Name I. Ordering-Physician-Last-Name

Recurrence Score®
(RS) Result

20

Clinical factors may be considered with the RS when making individual treatment decisions

Distant Recurrence Risk at 10 Years

With AI or TAM Alone

6%

95% CI (5%, 7%)

TAILORx¹

AI = Aromatase Inhibitor / TAM = Tamoxifen
CI = Confidence Intervals

Group Average Absolute Chemotherapy (CT) Benefit

RS 16-20

No apparent chemotherapy benefit (<1%)

95% CI (-2.8%, 1.9%)

TAILORx¹

Quantitative Single-Gene Scores^{2,3}



TAILORx Study^{1,4}

Results in this report are based on the Recurrence Score (RS) and data from the TAILORx clinical trial. TAILORx is a prospective, multinational phase III clinical trial that enrolled 10,273 patients (≥18 years) with hormone receptor-positive (HR+), HER2-negative, node-negative invasive breast cancer. Patients with a RS result between 11-25 were randomized to receive 5 years of endocrine therapy alone or standard-of-care chemotherapy followed by 5-years of endocrine therapy. Patients with a RS result of 0-10 and 26-100 were not randomized but were recommended to receive endocrine therapy alone or chemotherapy followed by endocrine therapy, respectively. The primary endpoint of the TAILORx clinical trial was Invasive Disease-Free Survival (IDFS); however, a key secondary endpoint was Distant Recurrence-Free Interval (DRFI).

The individualized **Distant Recurrence Risk** at 10 years is for patients >50 years of age with a RS result of 11-25 who received endocrine therapy alone. The group average **Absolute Benefit of Chemotherapy** for patients >50 years of age with a RS result of 11-25 was <1%.

Oncotype DX Breast Recurrence Score® Report

Node Negative

Age > 50 Years

EXACT
SCIENCES

PATIENT, SAMPLE

Date of Birth: 01-Jan-1950

Gender: Female

Report Number: OR000123456-3015

Report Date: 04-Jun-2025

Specimen Source/ID: Breast/SP-16_0123456

Date of Collection: 20-May-2025

Ordering Physician: Dr. First-Name I. Ordering-Physician-Last-Name

Medical Record/Patient #: 1234567-01

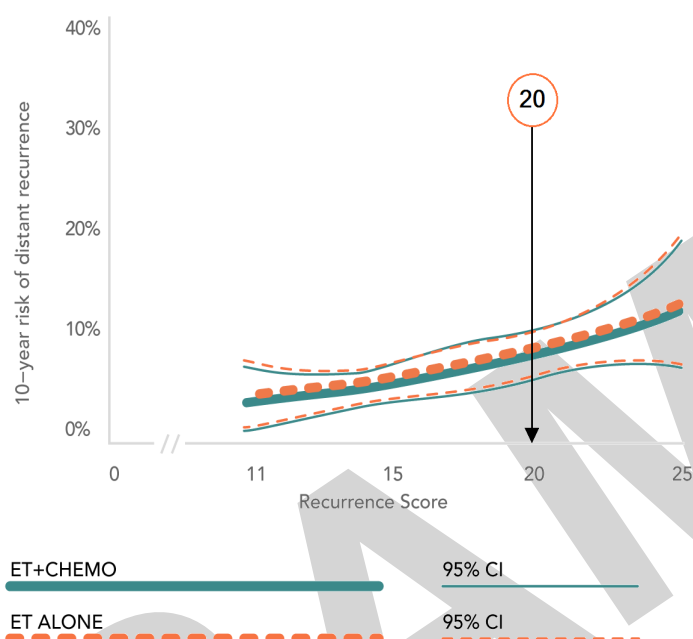
Client: Community Medical Center

Specimen Received: 22-May-2025

Additional Recipient: Dr. First-Name I. Recipient-Physician-Last-Name

Pathologist: Dr. First-Name I. Pathologist-Last-Name

TAILORx RS 11-25; Age > 50 Years^{1,6}



Methods and Limitations

The Oncotype DX Breast Recurrence Score test uses RT-PCR to provide information on prognosis and the magnitude of chemotherapy benefit to guide chemotherapy treatment decisions in patients with early-stage, HR+, HER2-negative and lymph node-negative or lymph node-positive (N1) breast cancer. Decisions on treatment should also be based on independent medical judgement of the treating physician taking into consideration all available information concerning the patient's medical condition, in accordance with your community's standard of care.

The **Recurrence Score (RS) Result** which ranges from 0-100 is calculated from the quantitative RT-PCR analysis of 21 specific genes.

Quantitative Single-Gene Scores for quality control. The Oncotype DX test uses quantitative RT-PCR to determine the RNA expression of ER, PR and HER2, using the published validated cut-offs.^{2,3} The standard deviations of single-gene results are less than 0.5 units. The RT-PCR single-gene results may differ from ER, PR, or HER2 results reported using other methods or reported by other laboratories.

Distant Recurrence-Free Interval (DRFI): Time from randomization to distant recurrence or death from breast cancer.

References:

1. Sparano et al. *NEJM Evid* 2024. 2. Badve et al. *J Clin Oncol*. 2008. 3. Baehner et al. *J Clin Oncol*. 2010. 4. Sparano et al. *N Engl J Med*. 2018. 5. Paik et al. *J Clin Oncol*. 2006. 6. Data on File.

Laboratory Director(s): NhuThuy Thi Can, M.D.

This test was developed and its performance characteristics determined by Genomic Health, Inc. It has not been cleared or approved by the FDA, nor is it currently required to be. The laboratory is regulated under CLIA and qualified to perform high-complexity testing. This test is used for clinical purposes. It should not be regarded as investigational or for research.

The Oncotype DX Breast Recurrence Score Test is an in vitro diagnostic device, CE marked under Regulation (EU) 2017/46 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices. In Japan, the test has received manufacturing and marketing approval from the Ministry of Health, Labour and Welfare as the Oncotype DX Breast Recurrence Score Program and is covered by National Health Insurance.

Genomic Health, Inc.

301 Penobscot Drive, Redwood City, CA 94063, USA

USA/Canada +1.866.ONCOTYPE (+1.866.662.6897)

<https://precisiononcology.exactsciences.com/>

CLIA Number 05D1018272

Oncotype DX Breast Recurrence Score® Report

Node Negative

EXACT
SCIENCES

Age > 50 Years

PATIENT, SAMPLE

Date of Birth: 01-Jan-1950 Gender: Female Report Number: OR000123456-3018 Report Date: 04-Jun-2025

Specimen Source/ID: Breast/SP-16_0123456 Date of Collection: 20-May-2025

Ordering Physician: Dr. First-Name I. Ordering-Physician-Last-Name

Recurrence Score®
(RS) Result

23

Clinical factors may be considered with the RS when making individual treatment decisions

Distant Recurrence Risk at 10 Years

With AI or TAM Alone

8%

95% CI (6%, 10%)

TAILORx¹

AI = Aromatase Inhibitor / TAM = Tamoxifen
CI = Confidence Intervals

Group Average Absolute Chemotherapy (CT) Benefit

RS 21-25

No apparent chemotherapy benefit (<1%)

95% CI (-4.2%, 3.0%)

TAILORx¹

Quantitative Single-Gene Scores^{2,3}



TAILORx Study^{1,4}

Results in this report are based on the Recurrence Score (RS) and data from the TAILORx clinical trial. TAILORx is a prospective, multinational phase III clinical trial that enrolled 10,273 patients (≥18 years) with hormone receptor-positive (HR+), HER2-negative, node-negative invasive breast cancer. Patients with a RS result between 11-25 were randomized to receive 5 years of endocrine therapy alone or standard-of-care chemotherapy followed by 5-years of endocrine therapy. Patients with a RS result of 0-10 and 26-100 were not randomized but were recommended to receive endocrine therapy alone or chemotherapy followed by endocrine therapy, respectively. The primary endpoint of the TAILORx clinical trial was Invasive Disease-Free Survival (IDFS); however, a key secondary endpoint was Distant Recurrence-Free Interval (DRFI).

The individualized **Distant Recurrence Risk** at 10 years is for patients >50 years of age with a RS result of 11-25 who received endocrine therapy alone. The group average **Absolute Benefit of Chemotherapy** for patients >50 years of age with a RS result of 11-25 was <1%.

Oncotype DX Breast Recurrence Score® Report
Node Negative

Age > 50 Years

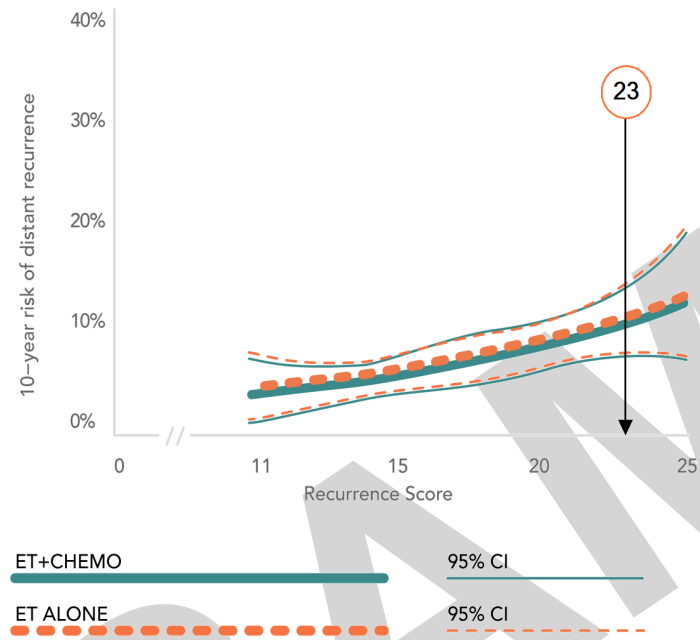
EXACT
SCIENCES

PATIENT, SAMPLE

Date of Birth: 01-Jan-1950 Gender: Female Report Number: OR000123456-3018 Report Date: 04-Jun-2025
Specimen Source/ID: Breast/SP-16_0123456 Date of Collection: 20-May-2025
Ordering Physician: Dr. First-Name I. Ordering-Physician-Last-Name

Medical Record/Patient #: 1234567-01 Client: Community Medical Center
Specimen Received: 22-May-2025
Additional Recipient: Dr. First-Name I. Recipient-Physician-Last-Name
Pathologist: Dr. First-Name I. Pathologist-Last-Name

TAILORx RS 11-25; Age > 50 Years^{1,6}



Methods and Limitations

The Oncotype DX Breast Recurrence Score test uses RT-PCR to provide information on prognosis and the magnitude of chemotherapy benefit to guide chemotherapy treatment decisions in patients with early-stage, HR+, HER2-negative and lymph node-negative or lymph node-positive (N1) breast cancer. Decisions on treatment should also be based on independent medical judgement of the treating physician taking into consideration all available information concerning the patient's medical condition, in accordance with your community's standard of care.

The **Recurrence Score (RS) Result** which ranges from 0-100 is calculated from the quantitative RT-PCR analysis of 21 specific genes.

Quantitative Single-Gene Scores for quality control. The Oncotype DX test uses quantitative RT-PCR to determine the RNA expression of ER, PR and HER2, using the published validated cut-offs.^{2,3} The standard deviations of single-gene results are less than 0.5 units. The RT-PCR single-gene results may differ from ER, PR, or HER2 results reported using other methods or reported by other laboratories.

Distant Recurrence-Free Interval (DRFI): Time from randomization to distant recurrence or death from breast cancer.

References:
1. Sparano et al. *NEJM Evid* 2024. 2. Badve et al. *J Clin Oncol*. 2008. 3. Baehner et al. *J Clin Oncol*. 2010. 4. Sparano et al. *N Engl J Med*. 2018. 5. Paik et al. *J Clin Oncol*. 2006. 6. Data on File.

Laboratory Director(s): NhuThuy Thi Can, M.D.

This test was developed and its performance characteristics determined by Genomic Health, Inc. It has not been cleared or approved by the FDA, nor is it currently required to be. The laboratory is regulated under CLIA and qualified to perform high-complexity testing. This test is used for clinical purposes. It should not be regarded as investigational or for research.

The Oncotype DX Breast Recurrence Score Test is an in vitro diagnostic device, CE marked under Regulation (EU) 2017/46 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices. In Japan, the test has received manufacturing and marketing approval from the Ministry of Health, Labour and Welfare as the Oncotype DX Breast Recurrence Score Program and is covered by National Health Insurance.

Genomic Health, Inc.
301 Penobscot Drive, Redwood City, CA 94063, USA
USA/Canada +1.866.ONCOTYPE (+1.866.662.6897)

<https://precisiononcology.exactsciences.com/>
CLIA Number 05D1018272

Oncotype DX Breast Recurrence Score® Report

Node Negative

Age > 50 Years

PATIENT, SAMPLE

Date of Birth: 01-Jan-1950 Gender: Female Report Number: OR000123456-3026 Report Date: 04-Jun-2025

Specimen Source/ID: Breast/SP-16_0123456 Date of Collection: 20-May-2025

Ordering Physician: Dr. First-Name I. Ordering-Physician-Last-Name

Recurrence Score®
(RS) Result

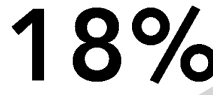


30

Clinical factors may be considered with the RS when making individual treatment decisions

Distant Recurrence Risk at 10 Years

With TAM Alone



18%

95% CI (12%, 25%)

NSABP B-14¹

TAM = Tamoxifen
CI = Confidence Intervals

Group Average Absolute Chemotherapy (CT) Benefit

RS 26-100

For women with a Recurrence Score result of 26-100 and node-negative disease, guidelines recommend chemotherapy in addition to hormone therapy.

Quantitative Single-Gene Scores^{2,3}



NSABP B-14 and NSABP B-20 Studies^{1,4}

Results in this report are based on the Recurrence Score (RS) and data from the NSABP B-14 and NSABP B-20 clinical trials. The prospective-retrospective analysis of the NSABP B-14 clinical trial included 668 patients with node-negative, hormone receptor-positive (HR+) invasive breast cancer. These patients received tamoxifen alone. The primary endpoint of the NSABP B-14 analysis was Distant Recurrence-Free Interval (DRFI).

The prospective-retrospective analysis of the NSABP B-20 clinical trial included 651 patients with node-negative, HR+ invasive breast cancer. These patients were randomized to tamoxifen alone or concurrent tamoxifen plus chemotherapy (MF or CMF). The primary endpoint of the NSABP B-20 analysis was DRFI.

The individualized **Distant Recurrence Risk** at 10 years is for patients ≤50 years of age and >50 years of age with a RS result of 26-100 who were treated with tamoxifen alone in the NSABP B-14 trial. Due to the limited availability of data in the subset of patients with RS results of 26-100 in the NSABP B-20 trial, precise estimates for **Absolute Benefit of Chemotherapy** are not provided; however, guidelines recommend that patients ≤50 years of age and >50 years of age with a RS result of 26-100 receive a combination of chemotherapy and endocrine therapy.

Oncotype DX Breast Recurrence Score® Report

Node Negative

EXACT
SCIENCES

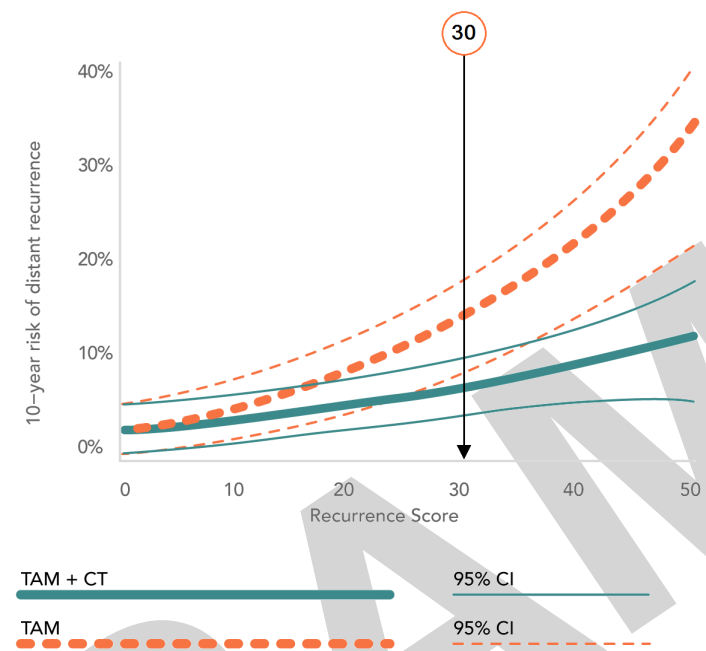
Age > 50 Years

PATIENT, SAMPLE

Date of Birth: 01-Jan-1950 Gender: Female Report Number: OR000123456-3026 Report Date: 04-Jun-2025
Specimen Source/ID: Breast/SP-16_0123456 Date of Collection: 20-May-2025
Ordering Physician: Dr. First-Name I. Ordering-Physician-Last-Name

Medical Record/Patient #: 1234567-01 Client: Community Medical Center
Specimen Received: 22-May-2025
Additional Recipient: Dr. First-Name I. Recipient-Physician-Last-Name
Pathologist: Dr. First-Name I. Pathologist-Last-Name

NSABP B-20; All ages^{4,7}



Methods and Limitations

The Oncotype DX Breast Recurrence Score test uses RT-PCR to provide information on prognosis and the magnitude of chemotherapy benefit to guide chemotherapy treatment decisions in patients with early-stage, HR+, HER2-negative and lymph node-negative or lymph node-positive (N1) breast cancer. Decisions on treatment should also be based on independent medical judgement of the treating physician taking into consideration all available information concerning the patient's medical condition, in accordance with your community's standard of care.

The **Recurrence Score (RS) Result** which ranges from 0-100 is calculated from the quantitative RT-PCR analysis of 21 specific genes.

Quantitative Single-Gene Scores for quality control. The Oncotype DX test uses quantitative RT-PCR to determine the RNA expression of ER, PR and HER2, using the published validated cut-offs.^{2,3} The standard deviations of single-gene results are less than 0.5 units. The RT-PCR single-gene results may differ from ER, PR, or HER2 results reported using other methods or reported by other laboratories.

Distant Recurrence-Free Interval (DRFI): Time from randomization to distant recurrence or death from breast cancer.

References:
1. Paik et al. *N Engl J Med*. 2004. 2. Badve et al. *J Clin Oncol*. 2008. 3. Baehner et al. *J Clin Oncol*. 2010. 4. Paik et al. *J Clin Oncol*. 2006. 5. Sparano et al. *NEJM Evid* 2024. 6. Sparano et al. *N Engl J Med*. 2018. 7. Data on File.

Laboratory Director(s): NhuThuy Thi Can, M.D.

This test was developed and its performance characteristics determined by Genomic Health, Inc. It has not been cleared or approved by the FDA, nor is it currently required to be. The laboratory is regulated under CLIA and qualified to perform high-complexity testing. This test is used for clinical purposes. It should not be regarded as investigational or for research.

The Oncotype DX Breast Recurrence Score Test is an in vitro diagnostic device, CE marked under Regulation (EU) 2017/46 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices. In Japan, the test has received manufacturing and marketing approval from the Ministry of Health, Labour and Welfare as the Oncotype DX Breast Recurrence Score Program and is covered by National Health Insurance.

Genomic Health, Inc.
301 Penobscot Drive, Redwood City, CA 94063, USA
USA/Canada +1.866.ONCOTYPE (+1.866.662.6897)

<https://precisiononcology.exactsciences.com/>
CLIA Number 05D1018272

Oncotype DX Breast Recurrence Score® Report

Node Negative

EXACT
SCIENCES

Age > 50 Years

PATIENT, SAMPLE

Date of Birth: 01-Jan-1950 Gender: Female Report Number: OR000123456-3059 Report Date: 04-Jun-2025
Specimen Source/ID: Breast/SP-16_0123456 Date of Collection: 20-May-2025
Ordering Physician: Dr. First-Name I. Ordering-Physician-Last-Name

Recurrence Score® (RS) Result



60

Distant Recurrence Risk at 10 Years

With TAM Alone
RS > 50

>32%

95% CI (21%, 47%)

NSABP B-14¹

Group Average Absolute Chemotherapy (CT) Benefit

RS 26-100

For women with a Recurrence Score result of 26-100 and node-negative disease, guidelines recommend chemotherapy in addition to hormone therapy.

Clinical factors may be considered with the RS when making individual treatment decisions

TAM = Tamoxifen
CI = Confidence Intervals

Quantitative Single-Gene Scores^{2,3}



NSABP B-14 and NSABP B-20 Studies^{1,4}

Results in this report are based on the Recurrence Score (RS) and data from the NSABP B-14 and NSABP B-20 clinical trials. The prospective-retrospective analysis of the NSABP B-14 clinical trial included 668 patients with node-negative, hormone receptor-positive (HR+) invasive breast cancer. These patients received tamoxifen alone. The primary endpoint of the NSABP B-14 analysis was Distant Recurrence-Free Interval (DRFI).

The prospective-retrospective analysis of the NSABP B-20 clinical trial included 651 patients with node-negative, HR+ invasive breast cancer. These patients were randomized to tamoxifen alone or concurrent tamoxifen plus chemotherapy (MF or CMF). The primary endpoint of the NSABP B-20 analysis was DRFI.

The individualized **Distant Recurrence Risk** at 10 years is for patients ≤50 years of age and >50 years of age with a RS result of 26-100 who were treated with tamoxifen alone in the NSABP B-14 trial. Due to the limited availability of data in the subset of patients with RS results of 26-100 in the NSABP B-20 trial, precise estimates for **Absolute Benefit of Chemotherapy** are not provided; however, guidelines recommend that patients ≤50 years of age and >50 years of age with a RS result of 26-100 receive a combination of chemotherapy and endocrine therapy.

Oncotype DX Breast Recurrence Score® Report

Node Negative

EXACT
SCIENCES

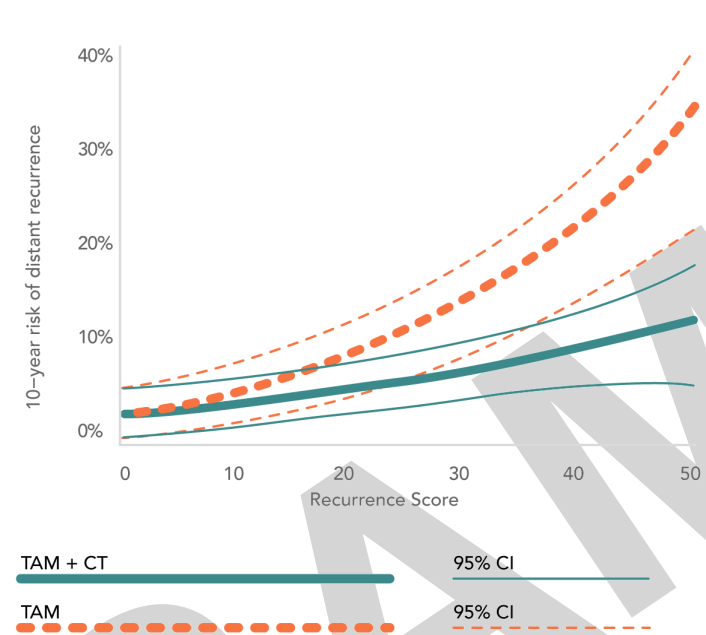
Age > 50 Years

PATIENT, SAMPLE

Date of Birth: 01-Jan-1950 Gender: Female Report Number: OR000123456-3059 Report Date: 04-Jun-2025
Specimen Source/ID: Breast/SP-16_0123456 Date of Collection: 20-May-2025
Ordering Physician: Dr. First-Name I. Ordering-Physician-Last-Name

Medical Record/Patient #: 1234567-01 Client: Community Medical Center
Specimen Received: 22-May-2025
Additional Recipient: Dr. First-Name I. Recipient-Physician-Last-Name
Pathologist: Dr. First-Name I. Pathologist-Last-Name

NSABP B-20; All ages^{4,7}



Methods and Limitations

The Oncotype DX Breast Recurrence Score test uses RT-PCR to provide information on prognosis and the magnitude of chemotherapy benefit to guide chemotherapy treatment decisions in patients with early-stage, HR+, HER2-negative and lymph node-negative or lymph node-positive (N1) breast cancer. Decisions on treatment should also be based on independent medical judgement of the treating physician taking into consideration all available information concerning the patient's medical condition, in accordance with your community's standard of care.

The **Recurrence Score (RS) Result** which ranges from 0-100 is calculated from the quantitative RT-PCR analysis of 21 specific genes.

Quantitative Single-Gene Scores for quality control. The Oncotype DX test uses quantitative RT-PCR to determine the RNA expression of ER, PR and HER2, using the published validated cut-offs.^{2,3} The standard deviations of single-gene results are less than 0.5 units. The RT-PCR single-gene results may differ from ER, PR, or HER2 results reported using other methods or reported by other laboratories.

Distant Recurrence-Free Interval (DRFI): Time from randomization to distant recurrence or death from breast cancer.

References:
1. Paik et al. *N Engl J Med*. 2004. 2. Badve et al. *J Clin Oncol*. 2008. 3. Baehner et al. *J Clin Oncol*. 2010. 4. Paik et al. *J Clin Oncol*. 2006. 5. Sparano et al. *NEJM Evid* 2024. 6. Sparano et al. *N Engl J Med*. 2018. 7. Data on File.

Laboratory Director(s): NhuThuy Thi Can, M.D.

This test was developed and its performance characteristics determined by Genomic Health, Inc. It has not been cleared or approved by the FDA, nor is it currently required to be. The laboratory is regulated under CLIA and qualified to perform high-complexity testing. This test is used for clinical purposes. It should not be regarded as investigational or for research.

The Oncotype DX Breast Recurrence Score Test is an in vitro diagnostic device, CE marked under Regulation (EU) 2017/46 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices. In Japan, the test has received manufacturing and marketing approval from the Ministry of Health, Labour and Welfare as the Oncotype DX Breast Recurrence Score Program and is covered by National Health Insurance.

Genomic Health, Inc.
301 Penobscot Drive, Redwood City, CA 94063, USA
USA/Canada +1.866.ONCOTYPE (+1.866.662.6897)

<https://precisiononcology.exactsciences.com/>
CLIA Number 05D1018272