Oncotype DX®: Scientific Publications and Presentations

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A Tool for Individualized Breast Cancer Treatment

Oncotype DX is a clinically validated, multi-gene assay that assesses the benefit from certain types of chemotherapy and provides a quantitative assessment of the likelihood of distant breast cancer recurrence. The Oncotype DX assay provides valuable, patient-specific information used to assist physicians in optimizing and individualizing treatment plans. This brochure provides a listing of journal articles, abstracts, presentations, and posters that address the development, validation, predictive power and impact on treatment planning of the Oncotype DX assay.

Key Oncotype DX Publications

Clinical Validation

1. A Multigene Assay to Predict Recurrence of Tamoxifen-Treated, Node-Negative Breast Cancer
   S Paik, S Shak, G Tang, C Kim, J Baker, M Cronin, FL Baehner, MG Walker, D Watson, T Park, W Hiller, ER Fisher, DL Wickerham, J Bryant, N Wolmark

2. A Population-Based Study of Tumor Gene Expression and Risk of Breast Cancer Death Among Lymph Node-Negative Patients
   LA Habel, S Shak, M Jacobs, A Capra, C Alexander, M Pho, J Baker, MG Walker, D Watson, J Hackett, N Blick, D Greenberg, L Fehrenbacher, B Langholz, CP Quesenberry
   *Breast Cancer Res.* 2006;8(3):R25

3. Gene Expression and Benefit of Chemotherapy in Women with Node-Negative, Estrogen Receptor-Positive Breast Cancer
   S Paik, G Tang, S Shak, C Kim, J Baker, W Kim, M Cronin, FL Baehner, D Watson, J Bryant, JP Costantino, C Geyer Jr., DL Wickerham, N Wolmark
   *J Clin Oncol.* 2006;24(23):3726-3734

   LJ Goldstein, R Gray, S Badve, BH Childs, C Yoshizawa, S Rowley, S Shak, FL Baehner, PM Ravdin, NE Davidson, GW Sledge Jr, EA Perez, LN Shulman, S Martino, JA Sparano
5. 21-Gene Expression Profile Assay on Core Needle Biopsies Predicts Responses to Neoadjuvant Endocrine Therapy in Breast Cancer Patients

S Akashi-Tanaka, C Shimizu, M Ando, T Shibata, N Katsumata, T Kouno, K Terada, T Shien, M Yoshida, T Hojo, T Kinoshita, Y Fujiwara, K Yoshimura

The Breast (2009), doi:10.1016/j.breast.2009.03.005


K Albain, W Barlo, S Shak, G Hortobagyi, R Livingston, J-T Yeh, P Ravdin, R Bugariin, FL Baehner, NE Davidson, GW Sledge, E Winer, C Hudis, J Ingle, E Perez, K Pritchard, L Shepherd, J Gralow, C Yoshizawa, D Allred, C Osborne, D Hayes

Lancet Oncology 2009, (Published online ahead of print)

Decision Impact

7. Impact of a Commercial Reference Laboratory Test Recurrence Score on Decision Making in Early-Stage Breast Cancer

R Oratz, D Paul, AL Cohn, SM Sedlacek


Neoadjuvant Treatment

8. Gene Expression Profiles in Paraffin-Embedded Core Biopsy Tissue Predict Response to Chemotherapy in Women with Locally Advanced Breast Cancer

I. Gianni, M Zambetti, K Clark, J Baker, M Cronin, J Wu, G Mariani, J Rodriguez, M Carcangiu, D Watson, P Valagussa, R Rouzier, WF Symmans, JS Ross, GN Hortobagyi, L Pusztai, S Shak

J Clin Oncol. 2005;23(29):7265-7277

9. Gene Expression Patterns in Formalin-Fixed, Paraffin-Embedded Core Biopsies Predict Docetaxel Chemosensitivity in Breast Cancer Patients


Breast Cancer Res Treat. 2007 (Published online ahead of print)

Health Economics


J Hornberger, LE Cosler, GH Lyman


11. Impact of a 21-Gene RT-PCR Assay on Treatment Decisions in Early-Stage Breast Cancer, An Economic Analysis Based on Prognostic and Predictive Validation Studies

GH Lyman, LE Cosler, NM Kuderer, J Hornberger

Cancer. 2007;109(6):1011-1018
12. Does Oncotype DX Recurrence Score Affect the Management of Patients with Early-Stage Breast Cancer?

J Asad, AF Jacobson, A Estabrook, SR Smith, SK Boolbol, SM Feldman, MP Osborne, K Boachie-Adjei, W Twardzik, PI Tartter


Platform Technology

13. Measurement of Gene Expression in Archival Paraffin-Embedded Tissues

M Cronin, M Pho, D Dutta, JC Stephans, S Shak, MC Kiefer, JM Esteban, JB Baker


M Cronin, C Sangli, ML Liu, M Pho, D Dutta, A Nguyen, J Jeong, J Wu, KC Langone, D Watson


Assay Development

15. Prognostic Role of a Multigene Reverse Transcriptase-PCR Assay in Patients with Node-Negative Breast Cancer Not Receiving Adjuvant Systemic Therapy

FJ Esteva, AA Sahin, M Cristofanilli, K Coombes, SJ Lee, J Baker, M Cronin, MG Walker, D Watson, S Shak, GN Hortobagyi

Clin Cancer Res. 2005;11(9):3315-3319

16. Tumor Gene Expression and Prognosis in Breast Cancer Patients with 10 or More Positive Lymph Nodes

MA Cobleigh, B Tabesh, P Bitterman, J Baker, M Cronin, ML Liu, R Borchik, JM Mosquera, MG Walker, S Shak

Clin Cancer Res. 2005;11(24 Pt 1):8623-8631

17. Predicting Response to Primary Chemotherapy: Gene Expression Profiling of Paraffin-Embedded Core Biopsy Tissue

I Mina, SE Soule, S Badve, FL Baehner, J Baker, M Cronin, D Watson, ML Liu, GW Sledge Jr, S Shak, KD Miller

Breast Cancer Res Treat. 2007;103(2):197-208

Estrogen Receptor and Progesterone Receptor

18. Estrogen- and Progesterone-Receptor Status in ECOG 2197: Comparison of Immunohistochemistry by Local and Central Laboratories and Quantitative Reverse Transcription Polymerase Chain Reaction by Central Laboratory

SS Badve, FL Baehner, RP Gray, BH Childs, T Maddala, Mei-Lan Liu, SC Rowley, S Shak, ED Perez, LJ Shulman, S Martino, NE Davidson, GW Sledge, LJ Goldstein, and JA Sparano


19. Problems and Solutions in the Evaluation of Hormone Receptors in Breast Cancer

D. Craig Allred

Additional Oncotype DX Related Articles

Roadmap for Developing and Validating Therapeutically Relevant Genomic Classifiers
R Simon
*J Clin Oncol.* 2005;23(29):7332-7341

Adjuvant Chemotherapy for Patients with Estrogen Receptor-Positive Breast Cancer
HJ Burstein, S Paik, P Ravdin, K Albain
*ASCO Educational Book 2006*

Development and Clinical Utility of a 21-Gene Recurrence Score Prognostic Assay in Patients with Early Breast Cancer Treated with Tamoxifen
S Paik
*Oncologist.* 2007;12(6):631-635

American Society of Clinical Oncology 2007 Update of Recommendations for the Use of Tumor Markers in Breast Cancer
*J Clin Oncol.* 2007;25(33):5287-5312

Development of the 21-Gene Assay and Its Application in Clinical Practice and Clinical Trials
J Sparano, S Paik

An ideal prognostic test for estrogen receptor-positive breast cancer?
S Paik, G Tang, D Fumagalli

Association Between Standard Clinical and Pathologic Characteristics and the 21-Gene Recurrence Score in Breast Cancer Patients
I Wolf, N Ben-Baruch, R Shapira-Frommer, S Rizel, H Goldberg, N Yaal-Haloshen, B Klein, D Geffen, B Kaufman

Thresholds for therapies: highlights of the St Gallen International Expert Consensus on the Primary Therapy of Early Breast Cancer 2009
A Goldhirsch, JN Ingle, RD Gelber, AS Coates, B Thurlimann, HJ Senn
*Ann Oncol.* 2009 Jun 17. [Epub ahead of print]

The Influence of a Gene Expression Profile on Breast Cancer Decisions
L Henry, A Stojadinovic, S Swain, S Prindiville, R Cordes, P Soballe
*Journal of Surgical Oncology* 2009;99:319-323

Gene Expression-Based Prognostic and Predictive Markers for Breast Cancer: A Primer for Practicing Pathologists
C Kim, Y Taniyama, S Paik
TAILORx Trial Articles

The TAILORx Trial: Individualized Options for Treatment
JA Sparano
Commun Oncol. 2006;3:494-496

TAILORx: Trial Assigning Individualized Options for Treatment (Rx)
JA Sparano

Design of and Rationale for the Trial Assigning Individualized Options for Treatment (TAILORx)
JA Sparano
ASCO Educational Book 2007

Scientific Presentations, Posters & Abstracts

2009 San Antonio Breast Cancer Symposium (SABCS) - San Antonio, TX

Abstract # 112
Prediction of 10-year chemotherapy benefit and breast cancer-specific survival by the 21-gene Recurrence Score (RS) assay in node-positive, ER-positive breast cancer-An update of SWOG-8814 (INT0100)

Abstract # 2031
Effect of 21-Gene Recurrence Score Results on Treatment Recommendations in Patients with Lymph Node-Positive, Estrogen Receptor-Positive Breast Cancer
R. Oratz, C. Chao, S. Skrzypczak, B. Kim, M. Broder

Abstract # 5165
Gene Expression Profiling of Phenotypically-Defined Hormone-Receptor Positive Breast Cancer: Evidence for Increased Transcriptional Activity of the Insulin Growth Factor Receptor Pathway and Other Pathways

Abstract # 6004
HER2 amplification, Polysomy Status and Breast Cancer Survival in a Large Kaiser Permanente Case-Control Study: Assessment of HER2 by Quantitative Reverse Transcriptase Polymerase Chain Reaction (RT-PCR) and Fluorescence in Situ Hybridization (FISH)
J.E. Bachner, N. Achacoso, T. Maddala, C. Alexander, S. Shak, C.P. Quesenberry, L.A. Habel

Abstract # 6021
Molecular Characterization of Breast Cancer Core Biopsy Specimens by Gene Expression Analysis Using Standardized Quantitative RT-PCR
2009 American Society of Clinical Oncology (ASCO) Breast Cancer Symposium- San Francisco, CA

Abstract # 64
Biopsy Cavities in Breast Cancer Specimens: Their Impact on Quantitative RT-PCR Gene Expression Profiles and Recurrence Risk Assessment
FL Baehner, C. Quale, D. Cherbavaz, C. Sangli, C. Pomeroy, A. Chen, F. Lane, L. Intagliatta, A. Goddard, S. Shak

Abstract # 175
Gene Expression Profiles Of Synchronous Breast Tumors

2009 ASCO Annual Meeting_ Orlando, FL

Abstract # 500
Genotypic characterization of phenotypically defined triple-negative breast cancer

Abstract # 549
Molecular characterization of male breast cancer by standardized quantitative RT-PCR analysis: First large genomic study of 347 male breast cancers compared to 82,434 female breast cancers.

2009 Kyoto Breast Cancer Consensus Conference International Convention Kyoto, Japan

Abstract
The First Report Of The Association Between The Recurrence Score And The Risk Of Recurrence In A Japanese Population

2009 United States and Canadian Academy of Pathology (USCAP) Annual Meeting Boston, MA

Abstract # 1421
HER2 Concordance between Central Laboratory Immunohistochemistry, FISH and Quantitative RT-PCR in Intergroup Trial E2197

Abstract # 1574
Biopsy Cavities in Breast Cancer Specimens: Impact on Quantitative RT-PCR Gene Expression Profiles and Recurrence Risk Assessment
FL. Bachner, C Quale, C Pomeroy, D Cherbavaz, S Shak
Abstract # 2285
ER and PR Assessment by Central IHC: Examination and Comparison of Percent Positive Cells and Nuclear Staining Intensity in ECOG Breast Cancer Study 2197
S Badve, R Gray, B Childs, T Maddala, M Liu, S Rowley, N Davidson, S Shak, LJ Goldstein, GW Sledge, JA Sparano, FL Baehner

2008 San Antonio Breast Cancer Symposium (SABCS)-San Antonio, TX

Abstract # 25
GRB7-dependent pathways are potential therapeutic targets in triple-negative breast cancer

Abstract # 53
Risk of distant recurrence using oncotype DX in postmenopausal primary breast cancer patients treated with anastrozole or tamoxifen: a TransATAC study
Dowsett M, Cuzick J, Wales C, Forbes J, Mallon L, Salter J, Quinn E, Bugarini R, Baehner FL, Shak S, on Behalf of the ATAC Trialists’ Group Royal Marsden Hospital, London, United Kingdom; Wolfson Institute for Preventive Medicine, London, United Kingdom; Newcastle Mater Hospital, Newcastle, Australia; Royal Infirmary, Glasgow, United Kingdom; Genomic Health Institute, Redwood, CA

Abstract # 2066
Quantitative gene expression analysis using Oncotype DX in ductal carcinoma in situ that is adjacent to invasive ductal carcinoma

Abstract # 3049
Associations between estrogen receptor (ER) Alpha expression levels and ER genotypes
Henry NL, Shak S, Banerjee M, Skaar T, Palmer G, Bramer M, Stearns V, Flockhart DA, Kleer C, Hayes DF, Rae J University of Michigan, Ann Arbor, MI; Genomic Health,Inc., Redwood City, CA; Indiana University, Indianapolis, IN; Johns Hopkins University,Baltimore, MD

2008 American Society of Clinical Oncology (ASCO) Breast Cancer Symposium-Washington DC

Abstract #13
HER2 Concordance Between Central Laboratory Immunohistochemistry & Quantitative Reverse Transcription Polymerase Chain Reaction in Intergroup Trial E2197
FL Baehner, R Gray, B Childs, T Maddala, S Rowley, S Shak, NE Davidson, GW Sledge, LJ Goldstein, JA Sparano, S Badve

Abstract #41
HER2 Assessment in a Large Kaiser Permanente Case-Control Study: Comparison of Fluorescence In Situ Hybridization (FISH) and Quantitative Reverse Transcription Polymerase Chain Reaction (RT-PCR) Performed by Central Laboratories
FL Baehner, Achacoso, T Maddala, C Alexander, S Shak, CP Quesenberry, LC Goldstein, AM Gown, LA Habel
Abstract #82: Oral Presentation
Analysis of Revised Nottingham Tumor Grade Constitutive Components and Recurrence Free Interval in ECOG Breast Cancer Study E2197
FL Baehner, LJ Goldstein, R Gray, T Maddala, S Shak, GW Sledge, JA Sparano, S Badve

Abstract #44: Poster Session
Comparison of ER and PR Assessment by Local IHC, Central IHC, and Central Quantitative RT-PCR in ECOG Breast Cancer Study 2197
S Badve, FL Baehner, R Gray, B Childs, T Maddala, M Liu, S Rowley, N Davidson, LJ Goldstein, GW Sledge, JA Sparano

Abstract #47: Poster Session
A Kaiser-Permanente Population-Based Study of Breast Cancer ER and PR Expression by the Standard Method, Immunohistochemistry, Compared to a New Method, Quantitative Reverse Transcription Polymerase Chain Reaction
FL Baehner, T Maddala, C Alexander, A Gown, LC Goldstein, y, S Shak, CP Quesenberry, L Habel

Abstract #50: Poster Session
Heterogeneity of Quantitative RT-PCR Measurement of Estrogen and Progesterone Receptor Expression: Comparison of Tissue Microarray Cores to Whole Sections of Paraffin Embedded Breast Cancer Tissue
FL Baehner, J Baker, J Salter, ML Liu, C Yoshizawa, T Maddala, M Dowsett, M Cronin, S Shak

2008 Hematology/Oncology Pharmacy Association (HOPA) - Anaheim, CA

Poster Session
Low Recurrence Score by the Oncotype DX Breast Cancer Assay Rarely Results in Recommendation for or Administration of Chemotherapy: A Pooled Analysis
P Hall, S Skrzypczak, G Palmer

2008 American Society of Clinical Oncology (ASCO) - Chicago, Ill

Abstract #3512: Oral Presentation
Evaluation of tumor gene expression and K-Ras mutations in FFPE tumor tissue as predictors of response to cetuximab in metastatic colorectal cancer
JB Baker, D Dutta, D Watson, T Maddala, S Shak, EK Rowinsky, L Xu, E Clark, DJ Mauro, S Khambata-Ford

Abstract #557: Poster Session
Predictive utility of progesterone receptor (PR) and multigene expression in identifying benefit from adjuvant doxorubicin plus cyclophosphamide (AC) or docetaxel (AT) in intergroup trial E2197
LJ Goldstein, RJ Gray, R Bugarini, S Shak, SS Badve, FL Baehner, NE Davidson, GW Sledge, JA Sparano
2008 United States and Canadian Academy of Pathology (USCAP) 97th Annual Meeting - Denver, CO

Abstract #82: Oral Presentation
Analysis of Revised Nottingham Tumor Grade Constitutive Components and Recurrence Free Interval in ECOG Breast Cancer Study E2197
FL Baehner, LJ Goldstein, R Gray, T Maddala, S Shak, GW Sledge, JA Sparano, S Badve

Abstract #44: Poster Session
Comparison of ER and PR Assessment by Local IHC, Central IHC, and Central Quantitative RT-PCR in ECOG Breast Cancer Study 2197
S Badve, FL Baehner, R Gray, B Childs, T Maddala, M Liu, S Rowley, N Davidson, LJ Goldstein, GW Sledge, JA Sparano

Abstract #47: Poster Session
A Kaiser-Permanente Population-Based Study of Breast Cancer ER and PR Expression by the Standard Method, Immunohistochemistry, Compared to a New Method, Quantitative Reverse Transcription Polymerase Chain Reaction
FL Baehner, T Maddala, C Alexander, A Gown, LC Goldstein, y, S Shak, CP Quesenberry, L Habel

Abstract #50: Poster Session
Heterogeneity of Quantitative RT-PCR Measurement of Estrogen and Progesterone Receptor Expression: Comparison of Tissue Microarray Cores to Whole Sections of Paraffin Embedded Breast Cancer Tissue
FL Baehner, J Baker, J Salter, ML Liu, C Yoshizawa, T Maddala, M Dowsett, M Cronin, S Shak

2008 ASCO Gastrointestinal Cancers Symposium
Orlando, FL

Abstract #301: Poster Session
Relationship between tumor gene expression and recurrence in patients with stage II/III colon cancer treated with surgery + 5-FU/LV in NSABPC-06: Consistency of results with two other independent studies
MJ O’Connell, G Yother, S Paik, IC Lavery, JW Cowens, KM Clark-Langone, MLopatin, JR Hackett, FL Baehner, N Wolmark

Abstract #302: Poster Session
Relationship between tumor gene expression and recurrence in an observational cohort of patients with stage II/III colon cancer treated with surgery only: Quantitative RT-PCR assay of 375 genes in fixed paraffin-embedded (FPE) tissue
I Lavery, J Hammel, J Cowens, K Clark-Langone, J Hackett, F Baehner, G Yothers, M O’Connell, N Wolmark

2007 San Antonio Breast Cancer Symposium (SABCS) — San Antonio, TX

Abstract #10: Oral Presentation
Prognostic and Predictive Value of the 21-Gene Recurrence Score Assay in Postmenopausal, Node-Positive, ER-Positive Breast Cancer
K Albain, W Barlow, S Shak, G Hortobagyi, R Livingston, I Yeh, P Ravdin, C Yoshizawa, FL Baehner, N Davidson, G Sledge, E Winer, C Hudis, J Ingle, E Perez, K Pritchard, L Shepherd, C Allred, K Osborne, D Hayes
Abstract #63: Oral Presentation
Prognostic Utility of the 21-Gene Assay Compared with Adjuvant! in Hormone Receptor (HR) Positive Operable Breast Cancer with 0-3 Positive Axillary Nodes Treated with Adjuvant Chemohormonal Therapy (CHT): An Analysis of Intergroup Trial E2197
L Goldstein, P Ravdin, R Gray, C Yoshizawa, B Childs, S Rowley, S Shak, S Badve, FL Baehner, N Davidson, GW Sledge, JA Sparano

Abstract #1043: Poster Session
Recurrence Score by OncoType DX Evaluated on the Primary Breast Tumor Predicts the 2-Year Survival after First Relapse
G Bianchini, M Zambetti, P Mariani, A Moliterni, G Bianchi, G Mariani, A Fasolo, ML Carcangiu, P Valagussa, L Gianni

Abstract #1092: Poster Session
Prospective Multi-Center Study of the Impact of the 21-Gene Recurrence Score Assay on Patient Satisfaction, Anxiety and Decisional Conflict for Adjuvant Breast Cancer Treatment Selection
PB Mumby, SS Lo, J Norton, J Smerage, K Joseph, HK Chew, D Hayes, KS Albain

Abstract #2061: Poster Session
A Retrospective Analysis of the Impact of OncoType DX Low Recurrence Score Results on Treatment Decisions in a Single Academic Breast Cancer Center
H Liang, AM Brufsky, BB Lembersky, P Rastogi, VG Vogel

Abstract #3028: Poster Session
Gene Expression by Standardized Quantitative RT-PCR in the Special Histologic Subtypes of Estrogen Receptor-Positive Invasive Breast Cancer
FL Baehner, D Watson, JT Ballard, G Palmer, S Shak

Abstract #3082: Poster Session
Evaluation of Practice Patterns in the Treatment of Node-Negative, Hormone-Receptor Positive Breast Cancer Patients with the Use of the OncoType DX Assay at the University of Pennsylvania
C Erb, KR Fox, M Patel, K Hook, A DeMichele, C Kaplan, S Domchek

Abstract #5029: Poster Session
Estrogen Receptor and Breast Cancer Survival in a Kaiser Permanente Population-Based Study: Comparison of Quantitative Reverse Transcriptase Polymerase Chain Reaction and Immunohistochemistry
LA Habel, N Achacoso, T Maddala, C Alexander, FL Baehner, S Shak, C Quesenberry, AM Gown, LC Goldstein

2007 American Society of Clinical Oncology (ASCO)
Breast Cancer Symposium — San Francisco, CA

Abstract #27
Association of Individual Genes with Risk of Relapse in Operable Breast Cancer: Analysis of E2197
JA Sparano, L Goldstein, B Childs, C Yoshizawa, S Shak, J Baez, S Rowley, N Davidson, S Badve, GW Sledge Jr., R Gray
Abstract #87
ER and PR Assessment in ECOG 2197: Comparison of Locally Determined IHC with Centrally Determined IHC and Quantitative RT-PCR
SS Badve, FL Baehner, R Gray, B Childs, T Maddala, M Liu, S Rowley, N Davidson, S Shak, GW Sledge Jr., JA Sparano

Abstract #88
A Kaiser-Permanente Population-Based Study of ER and PR Expression by the Standard Method, Immunohistochemistry (IHC), Compared to a New Method, Quantitative Reverse Transcription Polymerase Chain Reaction (RT-PCR)
FL Baehner, T Maddala, C Alexander, A Gown, LC Goldstein, NS Achacoso, S Shak, CP Quesenberry, LA Habel

Abstract #106
Use of Estrogen Receptor (ER) Expression by Quantitative RT-PCR to Identify an ER-Negative Subgroup by IHC Who Might Benefit from Hormonal Therapy
G Bianchini, M Zambetti, L Pusztai, M Carcangiu, P Valagussa, L Gianni

2007 ASCO Annual Meeting — Chicago, IL

Abstract #526: Poster Discussion
Prognostic Utility of the 21-Gene Assay in Hormone Receptor (HR)-Positive Operable Breast Cancer and 0-3 Positive Axillary Nodes Treated with Adjuvant Chemohormonal Therapy (CHT): An Analysis of Intergroup Trial E2197
LJ Goldstein, R Gray, B Childs, D Watson, S Rowley, S Shak, S Badve, NE Davidson, GW Sledge, JA Sparano

Abstract #577: Poster Session
Prospective Multi-Center Study of the Impact of the 21-Gene Recurrence Score (RS) Assay on Medical Oncologist (MO) and Patient (PT) Adjuvant Breast Cancer (BC) Treatment Selection
SS Lo, J Norton, PB Mumby, J Smerage, J Kash, HK Chew, D Hayes, A Epstein, KS Albain

2007 American Association for Cancer Research (AACR) Annual Meeting — Los Angeles, CA

Abstract #4423: Poster Session
Optimized RNA Extraction and RT-PCR Provide Successful Molecular Analysis on a Variety of Archival Fixed Tissues
M Zhou, M Bronner, C Magi-Galluzzi, R Tuthill, FL Baehner, ML Liu, D Dutta, J Jeong, YT Chen, JR Hackett, M Cronin

2006 Association for Molecular Pathology (AMP) Annual Meeting — Orlando, FL

Poster ST23 — see Publication #10
Analytical Validation for the Oncotype DX Breast Cancer Assay, a High Complexity, Multi-Analyte Molecular Diagnostic Test Service
M Cronin, C Sangli, ML Liu, M Pho, D Dutta, A Nguyen, J Jeong, J Wu, K Clark, D Watson
Abstract #45: Oral Presentation
Quantitative RT-PCR Analysis of ER and PR by Oncotype DX Indicates Distinct and Different Associations with Prognosis and Prediction of Tamoxifen Benefit
FL Baehner, LA Habel, CP Quesenberry, A Capra, G Tang, S Paik, N Wolmark, D Watson, S Shak

Abstract #3116: Poster Presentation
A Comparison of Estrogen Receptor (ER) Measurement by Three Methods in Node-Negative, Estrogen Receptor (ER)-Positive Breast Cancer: Ligand Binding (LB), Immunohistochemistry (IHC), and Quantitative RT-PCR
C Kim, G Tang, FL Baehner, D Watson, JP Costantino, S Paik, S Shak, N Wolmark

Abstract #6039: Poster Presentation
The Impact on the Recurrence Score Due to Patient Variation in the Quantitative Expression of Individual Genes or Gene Groups
D Watson, G Palmer, J Baker, S Shak

Abstract #6111: Poster Presentation
Relationship Between Proliferation Genes and Expression of Hormone and Growth Factor Receptors: Quantitative RT-PCR in 10,618 Breast Cancers
S Shak, FL Baehner, G Palmer, JT Ballard, J Baker, D Watson

Abstract #6118: Poster Presentation
Subtypes of Breast Cancer Defined by Standardized Quantitative RT-PCR Analysis of 10,618 Tumors
S Shak, FL Baehner, G Palmer, JT Ballard, J Baker, D Watson

2006 ASCO Annual Meeting — Atlanta, GA

Abstract #538: Poster Discussion — see Publication #6
Gene Expression Profiles in Formalin-Fixed, Paraffin-Embedded (FFPE) Core Biopsies Predict Docetaxel Chemosensitivity
JC Chang, A Makris, SG Hilsenbeck, JR Hackett, J Jeong, ML Liu, J Baker, K Sexton, CK Osborne, S Shak

Abstract #3518: Poster Discussion
Relationship Between Tumor Gene Expression and Recurrence in Stage II/III Colon Cancer: Quantitative RT-PCR Assay of 757 Genes in Fixed Paraffin-Embedded (FPE) Tissue
MJ O'Connell, S Paik, G Yohers, JP Costantino, JW Cowens, KM Clark, J Baker, J Hackett, D Watson, N Wolmark

Abstract #6024: Poster Discussion — see Publication #8
LE Cosler, NM Kuderer, J Hornberger, GH Lyman
Multiple GSTM Gene Family Members Are Recurrence Risk Markers in Breast Cancer
M Kiefer, K Hoyt, J Hackett, MG Walker, J Baker

Association Between the 21-Gene Recurrence Score Assay (RS) and Risk of Loco-Regional Failure in Node-Negative, ER-Positive Breast Cancer: Results from NSABP B-14 and NSABP B-20
E Mamounas, G Tang, J Bryant, S Paik, S Shak, JP Costantino, D Watson, DL Wickerham, N Wolmark

Measurement of Gene Expression Using Tissue Microarray Cores of Paraffin-Embedded Breast Cancer Tissue
J Baker, J Salter, ML Liu, JR Hackett, M Cronin, S Shak, M Dowsett

Impact of Oncotype DX™ on Decision Making in Breast Cancer Clinical Practice
R Oratz, D Paul, A Cohn, S Sedlacek

Expression of the 21 Genes in the Recurrence Score Assay and Tamoxifen Clinical Benefit in the NSABP Study B-14 of Node-Negative, Estrogen Receptor-Positive Breast Cancer
S Paik, S Shak, G Tang, C Kim, J Baker, M Cronin, D Watson, J Bryant, JP Costantino, N Wolmark

Gene Expression and Breast Cancer Mortality in Northern California Kaiser Permanente Patients: A Large Population-Based Case Control Study
LA Habel, CP Quesenberry, M Jacobs, D Greenberg, L Fehrenbacher, C Alexander, J Baker, D Watson, J Hackett, S Shak

Expression of the 21 Genes in the Recurrence Score Assay and Prediction of Clinical Benefit from Tamoxifen in NSABP Study B-14 and Chemotherapy in NSABP Study B-20
S Paik, S Shak, G Tang, C Kim, H Joo, J Baker, M Cronin, D Watson, J Bryant, JP Costantino, N Wolmark

Risk Classification of Breast Cancer Patients by the Recurrence Score Assay: Comparison to Guidelines Based on Patient Age, Tumor Size, and Tumor Grade
S Paik, S Shak, G Tang, C Kim, J Baker, M Cronin, FL Baehner, MG Walker, D Watson, J Bryant, N Wolmark
Abstract #2081: Poster Discussion
A 21-Gene RT-PCR Assay in Lymph Node-Negative (LN-), Estrogen Receptor-Positive (ER+) Early-Stage Breast Cancer (ESBC): An Age-Specific Economic Analysis
GH Lyman, L Cosler, J Hornberger

2004 ASCO Annual Meeting — New Orleans, LA

Abstract #501: Oral Presentation — see Publication #5
Gene Expression Profiles of Paraffin-Embedded Core Biopsy Tissue Predict Response to Chemotherapy in Patients with Locally Advanced Breast Cancer
I Gianni, M Zambetti, K Clark, J Baker, M Cronin, G Mariani, J Rodriguez, M Carcangiu, D Watson, P Valagussa, S Shak

Abstract #6036: Poster Session — see Publication #7
Economic Analysis of Targeting Chemotherapy (CT) Using a 21-Gene RT-PCR Assay in Lymph Node-Negative (LN-), Estrogen Receptor-Positive (ER+) Early-Stage Breast Cancer (ESBC)
LE Cosler, J Hornberger, GH Lyman

2004 United States and Canadian Academy of Pathology (USCAP) Annual Meeting — Vancouver, British Columbia

Comparison of ER, PR, HER2, and Ki-67 Quantitative Expression in Formalin-Fixed, Paraffin-Embedded Breast Carcinomas by RT-PCR with Protein Expression by Immunohistochemistry
P Bitterman, D Watson, M Cronin, JM Mosquera, M Cobleigh, R Baehner, S Shak, J Baker

Use of Macrodissection in Multi-Gene RNA Analysis of Fixed Paraffin-Embedded Tumor Tissue
R Baehner, B Hiller, CY Kim, C Alexander, ML Liu, M Pho, D Dutta, J Jeong, A Nguyen, M Walker, M Cronin, J Baker, S Paik

Reproducibility of Quantitative Gene Expression Analysis by a New RT-PCR Assay Using Fixed Paraffin-Embedded Tissues: A Molecular Tomographic Scanning Study
M Cronin, D Watson, D Dutta, ML Liu, M Pho, R Baehner, J Esteban, J Baker, S Shak

2003 SABCS — San Antonio, TX

Abstract #16: Oral Presentation — see Publication #1
Multi-Gene RT-PCR Assay for Predicting Recurrence in Node-Negative Breast Cancer Patients — NSABP Studies B-20 and B-14
S Paik, S Shak, G Tang, C Kim, J Baker, M Cronin, FL Baehner, MG Walker, D Watson, T Park, W Hiller, ER Fisher, DL Wickerham, J Bryant, N Wolmark

Abstract #17: Oral Presentation — see Publication #11
Prognostic Role of a Multigene Reverse Transcriptase-PCR Assay in Patients with Node-Negative Breast Cancer Not Receiving Adjuvant Systemic Therapy
FJ Esteva, AA Sahin, M Cristofanilli, K Coombes, SJ Lee, J Baker, M Cronin, MG Walker, D Watson, S Shak, GN Hortobagyi
2003 ASCO Annual Meeting — Chicago, IL

Abstract #763: Oral Presentation
Quantitative Gene Expression in Non-Small Cell Lung Cancer from Paraffin-Embedded Tissue Specimens: Predicting Response to Gefitinib, an EGFR Kinase Inhibitor
RB Natale, S Shak, N Aronson, S Averbuch, W Fox, D Luthringer, K Clark, J Baker, M Cronin, DB Agus

Abstract #3415: Poster Session — see Publication #12
Tumor Gene Expression Predicts Distant Disease-Free Survival (DDFS) in Breast Cancer Patients with 10 or More Positive Nodes: High Throughput RT-PCR Assay of Paraffin-Embedded Tumor Tissues
MA Cobleigh, P Bitterman, J Baker, M Cronin, ML Liu, R Borchik, B Tabesh, J Mosquera, MG Walker, S Shak

Abstract #3416: Poster Discussion
Tumor Gene Expression and Prognosis in Breast Cancer: Multi-Gene RT-PCR Assay of Paraffin-Embedded Tissue
JM Esteban, J Baker, M Cronin, ML Liu, MG Llamas, MG Walker, R Mena, S Shak

Abstract #3466: Poster Session
Predicting Response to Neoadjuvant Chemotherapy in Invasive Breast Cancer: Gene Expression Profiling of Paraffin-Embedded Core Biopsy Tissue
SE Soule, S Shak, J Baker, M Cronin, ML Liu, S Badve, KD Miller, GW Sledge

2003 AACR Oncogenomics Meeting — Phoenix, AZ
Poster Session — see Publication #9
Gene Expression Profiling of Fixed, Paraffin-Embedded Tumor Specimens, Using a 192 Gene Panel RT-PCR Assay
M Kiefer, J Stephans, ML Liu, D Dutta, M Pho, A Nguyen, J Jeong, M Cronin, JM Esteban

EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics
Strategies to Optimize Anti-Receptor Therapies
J Baselga

2002 ASCO Annual Meeting — Orlando, FL
Abstract #3017 — see Publication #9
Gene Expression Profiling of Fixed Paraffin-Embedded Breast Cancer Tissues
M Kiefer, J Stephans, S Abulaban, S Shodhan, MC Alexander, JM Esteban