Scientific Publications and Presentations

Not all colon cancer patients are alike. One assay helps you see the difference.
WHAT MAKES AN ASSAY CLINICALLY USEFUL?

LEVEL 1 EVIDENCE

ECONOMIC UTILITY

CLINICAL UTILITY

CLINICAL VALIDITY

ANALYTIC VALIDITY
Molecular characterization is expanding our understanding of underlying tumor biology, which may inform treatment decisions and individualize patient discussions. The Onco type DX® Colon Cancer Assay is clinically validated and, based on an individual patient’s colon tumor expression of 12 genes, quantifies the risk of recurrence in stage II and III A/B colon cancer following surgery.

This brochure provides a listing of journal articles, reviews and abstracts that address the development, validation, prognostic value and clinical impact of the Onco type DX Colon Cancer Assay.

**KEY ONCOTYPE DX PUBLICATIONS**

**VALIDATION STUDIES**

VALIDATION STUDIES (Continued)
Validation study of a quantitative multigene reverse transcriptase–polymerase chain reaction assay for assessment of recurrence risk in patients with stage II colon cancer.

Validation of the 12-gene colon cancer Recurrence Score as a predictor of recurrence risk in stage II and III rectal cancer patients.

CLINICAL UTILITY STUDIES
Prospective multicenter study of the impact of Oncotype DX Colon Cancer Assay results on treatment recommendations in stage II colon cancer patients.

Effect of the 12-gene colon cancer assay results on adjuvant treatment recommendations in patients with stage II colon cancer.

ECONOMIC UTILITY STUDIES
Comparative Economics of a 12-Gene Assay for Predicting Risk of Recurrence in Stage II Colon Cancer.

A multigene prognostic assay for selection of adjuvant chemotherapy in patients with T3, stage II colon cancer: impact on quality-adjusted life expectancy and costs.
DEVELOPMENT STUDIES

REVIEWS
Multigene assays to improve assessment of recurrence risk and benefit from chemotherapy in early-stage colon cancer: has the time finally arrived, or are we still stage locked? Tabernero J, Baselga J. J Clin Oncol. 2010;28(25):3937-44.
The 12-gene colon cancer assay validation and utility: Summary of clinical evidence.

Prospective evaluation of a 12-gene assay on patient treatment decisions and physician confidence in mismatch repair-proficient (MMR-P) stage IIa colon cancer patients.

Assay result variability during determination of mismatch repair deficiency status using immunohistochemistry: A transatlantic comparative study.
Hutchins G, Gray RG, Quirke P.
Abstract #526
Reproducibility of colon tumor grade and relationship to recurrence in the context of clinical, pathologic, and genomic tumor features in 504 patients with stage II colon cancer treated with surgery alone at the Cleveland Clinic.
Lavery IC, Clark-Langone K, Lee M.

2010 EUROPEAN SOCIETY FOR MEDICAL ONCOLOGY (ESMO) — MILAN, ITALY
Abstract #83PD
Considerations in the development and validation of genomic tests for cancer recurrence.
Kerr DJ, O’Connell MJ, Lavery IC, et al.

2010 SOCIETY OF SURGICAL ONCOLOGY (SSO) — ST. LOUIS, MO.
Abstract #P162
Number of nodes examined and the 12 gene colon cancer Recurrence Score predict recurrence in stage II colon cancer in two independent studies.

2010 AMERICAN SOCIETY OF CLINICAL ONCOLOGY, GASTROINTESTINAL CANCERS SYMPOSIUM (ASCO-GI) — ORLANDO, FL.
Abstract #331
Correlation of number of nodes examined and the 12-gene colon cancer Recurrence Score with recurrence in stage II colon cancer patients from QUASAR.
Gray RG, Quirke P, Handley K, et al.

Abstract #280
Comparison of molecular and pathologic features of stage II and stage III colon cancer in four large studies conducted for development of the 12-gene colon cancer Recurrence Score.
TUMOR BIOLOGY HOLDS THE KEY

1. Published health economic study
2. Published clinical utility studies
3. Published prospectively-designed validation studies

=1 TEST THAT HELPS YOU SEE THE DIFFERENCE

www.oncotypeDX.com
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