Oncotype DX®: Scientific Publications and Presentations

www.oncotypedx.com
The Oncoctype DX Colon Cancer Assay is a clinically validated diagnostic assay based on an individual patient’s colon tumor expression of 12 genes, which quantifies the likelihood of recurrence in stage II colon cancer following surgery. The continuous Recurrence Score® has the greatest clinical utility for T3, Mismatch Repair Proficient (MMR-P) patients, who constitute the majority of patients diagnosed with stage II colon cancer. This brochure provides a listing of journal articles, abstracts, presentations, and posters that address the development, validation, prognostic power and impact on treatment planning of the Oncoctype DX Colon Cancer Assay.

Key Oncoctype DX Publications

Review of Clinical Data
Validation study of a quantitative multigene reverse transcriptase–polymerase chain reaction assay for assessment of recurrence risk in patients with stage II colon cancer.
Gray RG, Quirke P, Handley K, et al.

Prognostic and predictive markers in stage II colon cancer: Is there a role for gene expression profiling?
Kelley K, Venook AP, et al.

Relationship between tumor gene expression and recurrence in four independent studies of stage II/III colon cancer patients treated with surgery alone and surgery plus adjuvant fluorouracil plus leucovorin.

Translating tumor biology into personalized treatment planning: analytical performance characteristics of the Oncoctype DX® Colon Cancer Assay.
Clark-Langone et al.
*BMC Cancer.* 2010, 10:691.
**Oncotype DX assay for predicting recurrence of stage II colon cancer.**
Schwartzberg L, Babkowski R.

**Gene profiling in early stage disease.**
*Cancer J*. 2010;16(3):3937-44.

**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.

**QUASAR Results: The prognostic validity of a colon cancer Recurrence Score and the role of multigene profiles in determining risk.**
Rasul K, Kerr D.

**Biomarker discovery for colon cancer using a 761 gene RT-PCR assay.**

### Scientific Presentations, Posters & Abstracts

**2011 CAP - Grapevine, TX**

**Abstract #56**
Relationship of tumor grade and recurrence in the context of mismatch repair (MMR) status, tumor location, grading schema, mucinous histology, and the 12-gene Recurrence Score in 504 stage II colon cancer Patients treated with surgery alone at the Cleveland Clinic
Iezza G., Baehner F., Lopatin M., Millward C., Clark-Langone K., M. Lee M., Lavery I.

**2011 ASCO - Chicago, IL.**

**Abstract #3518**
Validation of a 12-gene colon cancer Recurrence Score (RS) in patients (pts) with stage II colon cancer (CC) from CALGB 9581.
Venook A., Niedzwiecki D., Lopatin M.

**2011 ASCO-GI - San Francisco, CA.**

**Abstract #403**
Assay result variability during determination of mismatch repair deficiency status using immunohistochemistry: A transatlantic comparative study.
Hutchins G., Gray G., Quirke P.

**Abstract #491**
Use of a multigene prognostic assay for selection of adjuvant chemotherapy in patients with stage II colon cancer: Impact on quality-adjusted life expectancy and costs.
Meropol N.J., Lyman G.H., Chien R., Hornberger J.C.
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 I.C., 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 American Society of Clinical Oncology (ASCO) Chicago, IL.

Abstract #3503
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. O’Connell MJ, Lavery IC, Gray R, 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. Lavery IC, O’Connell MJ, Lopatin M, et al.

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. O’Connell MJ, Lavery IC, Gray RG, et al.

2009 American Society of Clinical Oncology (ASCO) - Orlando, FL.

Abstract #4000
A quantitative multi-gene RT-PCR assay for prediction of recurrence in stage II colon cancer: Selection of the genes in four large studies and results of the independent, prospectively-designed QUASAR validation study. Kerr D, Gray R, Quirke P, et al.
Abstract #301
Relationship between tumor gene expression and recurrence in patients with stage II/III colon cancer treated with surgery + 5-FU/LV in NSABP C-06: Consistency of results with two other independent studies.

Abstract #302
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.

2006 American Society of Clinical Oncology (ASCO) - Atlanta, GA.

Abstract #3518
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.