A Case Study

oncotype DX® Colon Cancer Assay

PATIENT CASE

78-year-old female with 4.8-cm tumor

Tumor Type: Adenocarcinoma
Tumor Size: 4.8 cm
T Stage: 3
Histologic Grade: 3
Lymph Node Status: Negative
Number of Lymph Nodes Assessed: 3
Mismatch Repair (MMR) Status: MMR-P (IHC)
Lymphovascular Invasion: No
Perforation: No
Obstruction: No
Other Information: Based on high Recurrence Score, physician recommended and patient chose adjuvant chemotherapy

CASE SUBMITTED BY:
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COLON CANCER ASSAY DESCRIPTION

Onco*type* DX Colon Cancer Assay uses RT-PCR to determine the expression of a panel of 12 genes in tumor tissue. The Recurrence Score® is calculated from the gene expression results. The Recurrence Score range is from 0-100.

RESULTS

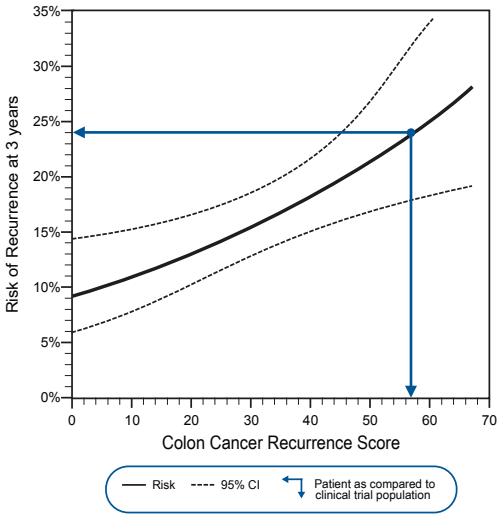
Colon Cancer Recurrence Score = 57

The findings summarized in the Clinical Experience section below are applicable to stage II colon cancer patients with adenocarcinoma or mucinous carcinoma. It is unknown whether the findings apply to other patients outside these criteria.

CLINICAL EXPERIENCE: STAGE II COLON CANCER

In the clinical validation study*, patients with stage II colon cancer randomized to surgery alone who had a Recurrence Score of 57 had a risk of recurrence at 3 years of 24% (95% CI: 18%-32%).

Risk of Recurrence at 3 Years vs Recurrence Score



Aid for Interpretation

Impact of Nodes Assessed

The 3-year recurrence risk for patients with ≥ 12 nodes examined was ~3% (range 2% - 5%) lower than that shown in the figure. For patients with < 12 nodes examined, the 3-year recurrence risk was ~2% higher.

5 years vs 3 years Recurrence Risk

The 5-year recurrence risk was ~5% higher (range 4% - 8%), than that shown in the figure for 3 years.

Relevance for Chemotherapy Benefit

Similar proportional reductions in recurrence risk with 5FU/LV chemotherapy treatment were observed across the range of Recurrence Scores.

**The clinical experience with Oncotype DX on this page is from a clinical validation study with prospectively defined endpoints involving 1,436 patients with stage II colon cancer from the QUASAR clinical trial; 711 randomized to surgery alone and 725 to surgery followed by 5FU/LV chemotherapy. There were no patients who had a Recurrence Score > 67. Kerr D et al, ASCO 2009, Abstract 4000.*

Laboratory Directors: Steven Shak, MD, Frederick Baehner, MD, and Patrick Joseph, MD CLIA Number 05D1018272

This test was developed and its performance characteristics determined by Genomic Health, Inc. The laboratory is regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high-complexity clinical testing. This test is used for clinical purposes. It should not be regarded as investigational or for research. These results are adjunctive to the ordering physician's workup.

Online Ordering and Reports Available — Please contact Customer Service at customerservice@genomichealth.com

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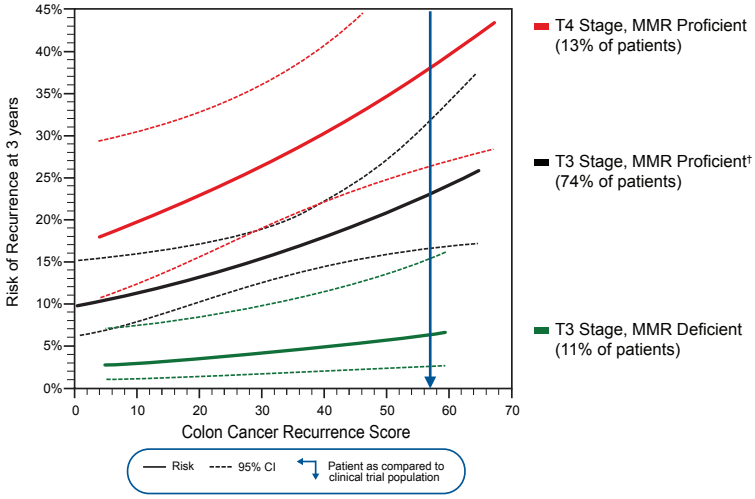
CLINICAL EXPERIENCE: STAGE II COLON CANCER (continued)

In the clinical validation study*, three groups of patients with different risks of recurrence that are clinically important were identified by pre-specified analysis of the Recurrence Score, tumor stage (T stage) and mismatch repair (MMR) status.

- 13% of patients had T4 Stage, MMR Proficient (MMR-P) tumors and generally higher recurrence risk.
- 11% of patients had T3 Stage, MMR Deficient (MMR-D) tumors and generally lower recurrence risk.
- 74% of patients had T3 Stage, MMR-P tumors† with recurrence risk similar to that shown on page 1.

Recurrence Score, T stage, and MMR were each significant independent predictors of recurrence risk.

Risk of Recurrence at 3 Years by Recurrence Score, T Stage and MMR Status



†*Rare patients (2% of all patients) with T4, MMR-D tumors had estimated recurrence risks that approximated (with large confidence intervals) those for patients with T3 stage, MMR-P tumors and were not included in this figure.*

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