Complete the colon cancer treatment puzzle with a RELIABLE STAGE II RISK OF RECURRENCE SCORE.

GeneFx Colon

RISK OF RECURRENCE GENE SIGNATURE

PERSONALIZED TREATMENT

The oncology community is uncertain about whether chemotherapy can be beneficial to a stage II colon cancer patient and treatment guidelines suggest that only patients considered “high-risk” receive adjuvant chemotherapy.

This high-risk determination has historically been reached by unreliable clinical and pathologic factors, including poorly differentiated histology, lymphatic/vascular invasion, and mismatch repair (MMR)/microsatellite instability (MSI) status. The NCCN guidelines state that the current high-risk definition is “clearly inadequate.”

Because the majority of patients have at least one of these high-risk features and may be treated with adjuvant chemotherapy while in reality, only 15-20% will actually recur, many patients are exposed to unnecessary, toxic therapies and incur large costs with minimal benefits.

GeneFx Colon is a more accurate indicator of a patient’s true risk of recurrence.

ALWAYS ACTIONABLE RESULT

The GeneFx Colon test reports only two possible results: High-risk and Low-risk, with no intermediate category. This means that a physician is always delivered a result than can be utilized to make a treatment decision.

GeneFx Colon is prognostic for RFS and is independent from other commonly utilized prognostic factors.

INCREASED CONFIDENCE

A high risk result from GeneFx colon indicates that a patient is 2.5 times more likely to recur within five years of initial surgery than a patient with a low-risk result.

Compare this to the success of currently used clinical and pathologic factors, which typically only identify a high-risk patient who is less than 1.5 times more likely to recur than a low risk patient.

GeneFx Colon has been further prospectively validated using formalin-fixed, paraffin-embedded specimens collected as a part of the CALGB Alliance phase III trial, C9581.

SAVE COSTS

The clinical use of a multigene test to assess risk of recurrence like GeneFx Colon can decrease the number of patients who receive unnecessary or harmful chemotherapy drugs, thereby eliminating the expense of therapy for those patients and their third-party payers.

Patients classified High-Risk by GeneFx Colon experienced significantly shorter RFS (Recurrence-Free Survival) than those classified Low-Risk [HR: 2.53, 95% CI 1.54-4.15, p-value<0.001]

GeneFx Colon High-Risk patients are 2.5 times more likely to recur within five years of surgery than those classified Low-Risk.
Each cancer patient is unique... 
THEIR TREATMENT SHOULD BE, TOO.

**GENEX™**

**RISK OF RECURRENCE GENE SIGNATURE**

**COMPARE GENEFX COLON**
WITH CALGB ALLIANCE 9581 PATIENT COHORT

Although not a direct head-to-head comparison, GeneFx Colon and Oncotype DX Colon risk of recurrence test were both validated using the CALGB Alliance 9581 patient cohort.4,5

<table>
<thead>
<tr>
<th>Test Name</th>
<th>GeneFx® Colon</th>
<th>Oncotype DX Colon®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Company</td>
<td>Helomics Corp.</td>
<td>Genomic Health, Inc.</td>
</tr>
<tr>
<td>Tissue Platforms</td>
<td>FFPE</td>
<td>FFPE</td>
</tr>
<tr>
<td>Number of Genes</td>
<td>482 Genes</td>
<td>12 Genes</td>
</tr>
<tr>
<td>Technology/Expression Platform</td>
<td>Custom Microarray (Affymetrix)</td>
<td>RT-PCR</td>
</tr>
<tr>
<td>Results Reporting</td>
<td>7-10 Days</td>
<td>10-12 Days</td>
</tr>
<tr>
<td>Endpoints</td>
<td>5 yr Recurrence (RFI)</td>
<td>3 yr, 5 yr Recurrence</td>
</tr>
<tr>
<td></td>
<td>High or Low Risk</td>
<td>High, Intermediate, or Low Risk</td>
</tr>
<tr>
<td>CALGB Multivariate Hazard Ratio</td>
<td><strong>2.13</strong> 4</td>
<td><strong>1.68</strong> 5</td>
</tr>
</tbody>
</table>

**COMPARE GENEFX COLON**
WITH STANDARD PATHOLOGIC PARAMETERS.4

<table>
<thead>
<tr>
<th>Endpoints</th>
<th>HR</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tumor Stage (T4 v T3)</td>
<td>0.78</td>
<td>0.72</td>
</tr>
<tr>
<td>Nodes Examined (Continuous)</td>
<td>0.98</td>
<td>0.11</td>
</tr>
<tr>
<td>Tumor Location (Proximal v Distal)</td>
<td>1.24</td>
<td>0.41</td>
</tr>
<tr>
<td>Tumor Grade (High v Low)</td>
<td>1.47</td>
<td>0.19</td>
</tr>
<tr>
<td>MMR (Deficient v Intact)</td>
<td>0.55</td>
<td>0.05</td>
</tr>
<tr>
<td>Risk Score (High v Low)</td>
<td><strong>2.13</strong></td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>

**Results:** Patients classified as High Risk experienced a significantly shorter recurrence-free interval than Low Risk patients. Multivariate analysis showed GeneFx Colon is prognostic of RFI and is independent from known prognostic factors.

**A Prognostic Gene Signature** to assess risk of recurrence within 5 years of initial surgery, utilizing a Microarray Gene Expression and Proprietary Algorithm

**Qualified Patients:**
Diagnosed stage II colon cancer patients awaiting a treatment decision.

**How to Order:**
GeneFx Colon must be ordered by a treating physician. Physicians should contact Helomics® Client Services to be sent a FFPE Tissue Transport Kit. Following surgery, a fixed sample of the patient’s tumor is enclosed in the kit along with necessary paperwork, then shipped to the Helomics lab.

**Tissue Sample Size:**
All samples must contain >50% tumor. Tissue must measure >3mm and can be submitted in either FFPE block or FFPE slides.

**Turn Around Time:**
10-14 days after the receipt of the sample with all required paperwork at Helomics

**CPT Codes:**
CPT 81479: GeneFx Colon

**Test Cost:**
The list price for GeneFx Colon for third party insurances is $3850.