ColoPrint® is a microarray-based expression profile that was developed using an unbiased analysis of the entire human genome (~25,000 genes). The gene signature was validated in multiple independent validation sets\(^1,2\) and accurately predicts the risk of relapse in stage II colon cancer patients. ColoPrint® results are independent of MSI status.

**COLOPRINT® ASSAY DESCRIPTION**

ColoPrint® is a microarray-based expression profile that was developed using an unbiased analysis of the entire human genome (~25,000 genes). The gene signature was validated in multiple independent validation sets\(^1,2\) and accurately predicts the risk of relapse in stage II colon cancer patients. ColoPrint® results are independent of MSI status.

**COLOPRINT® RESULT**

A Low Risk result means that a patient with stage II colon cancer has an 8% risk of relapse within 3 years and an 11% risk of relapse within 5 years\(^3\) without adjuvant systemic therapy.

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**ColoPrint® High Risk patients have a 1 in 5 risk of relapse within 3 years.**

**ColoPrint® Low Risk patients have a 1 in 13 risk of relapse within 3 years.**

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Probability of Relapse\(^3\).
The combination of ColoPrint® with clinical and pathological factors further personalizes the estimate of a patient’s risk of relapse. Patients who are ColoPrint® Low Risk and have at least one clinical high risk factor have an estimated 12% risk of experiencing relapse in 3 years, while ColoPrint® Low Risk patients with no clinical high risk factors have an estimated 5% risk of relapse in 3 years without adjuvant systemic therapy.

Guidelines⁴ are used to classify patients as clinical low or clinical high risk. Stage II patients with T4 tumors, grade 3-4 (exclusive of those cancers that are MSI-H), lymphatic/vascular invasion, obstructions, less than 12 LN assessed, perineural invasion, localized perforation or positive margins are classified as high risk.

Based on meta-analysis of multiple clinical trials⁵, the absolute benefit of chemotherapy for patients with low relapse risk is estimated to be less than 2%.

In other words, 50 patients need to be treated so that 1 patient will benefit from chemotherapy.

References:
3. Taberner et al. J. Clin Oncol. 2012 30 (suppl 4;abstr 384)
4. NCCN Guideline Version 2012.3 Colon Cancer

For In Vitro Diagnostic Use
Caution: Federal law restricts this device to sale by or on the order of a physician.
Agendia is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high-complexity clinical testing. ColoPrint profile is an aid in estimating the prognosis of patients diagnosed with colon cancer. Decisions regarding care and treatment should not be based on a single test such as this test. Rather, decisions on care and treatment should be based on the independent medical judgment of the treating physician taking into consideration all available information concerning the patient’s condition, including other pathological tests, in accordance with the standard of care in a given community.
This test was performed at Agendia’s Irvine, California laboratory (05D1089250).