

PATIENT/ID

Patient: Jane Doe
DOB: 31-Oct-1963
Patient #: 024836267
Gender: Female

SPECIMEN

Requisition: DP 90022403
Date of Surgery: 25-Mar-2012
Date Received: 25-Mar-2012
Report Date: 29-Mar-2012
Specimen Type: Surgical

PHYSICIAN

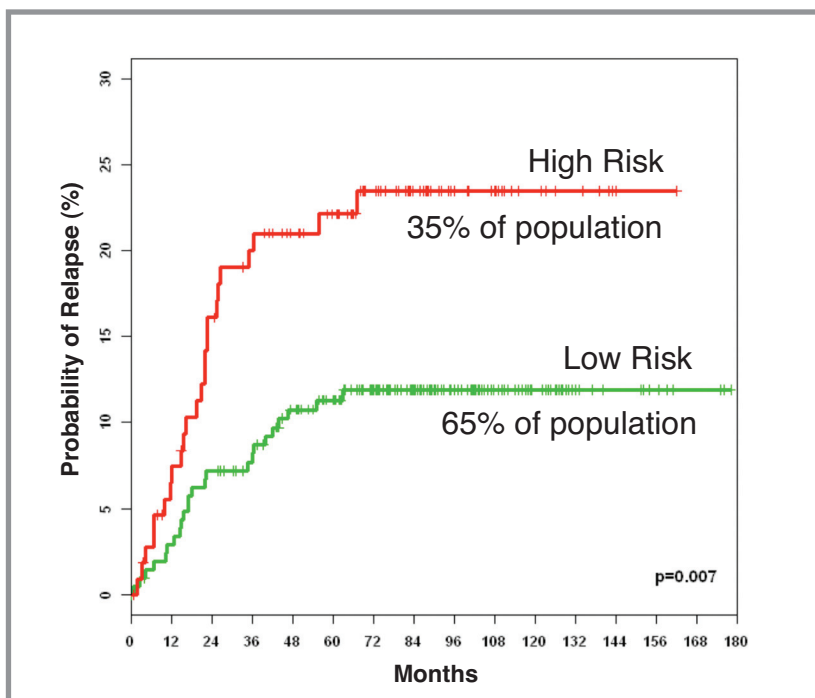
Ordering Physician: James Edney, MD
Ordering Facility: Univ. of Nebraska Med. Ctr
Address: 42nd and Emile
City, St., Zip: Omaha, NE 68198

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
HIGH RISK

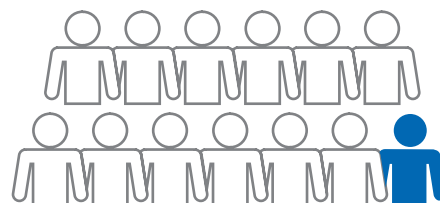
A High Risk result means that a patient with stage II colon cancer has a 20% risk of relapse within 3 years and a 22% risk of relapse within 5 years³ without adjuvant systemic treatment.

COLOPRINT® CLINICAL RELEVANCE


Probability of Relapse³.



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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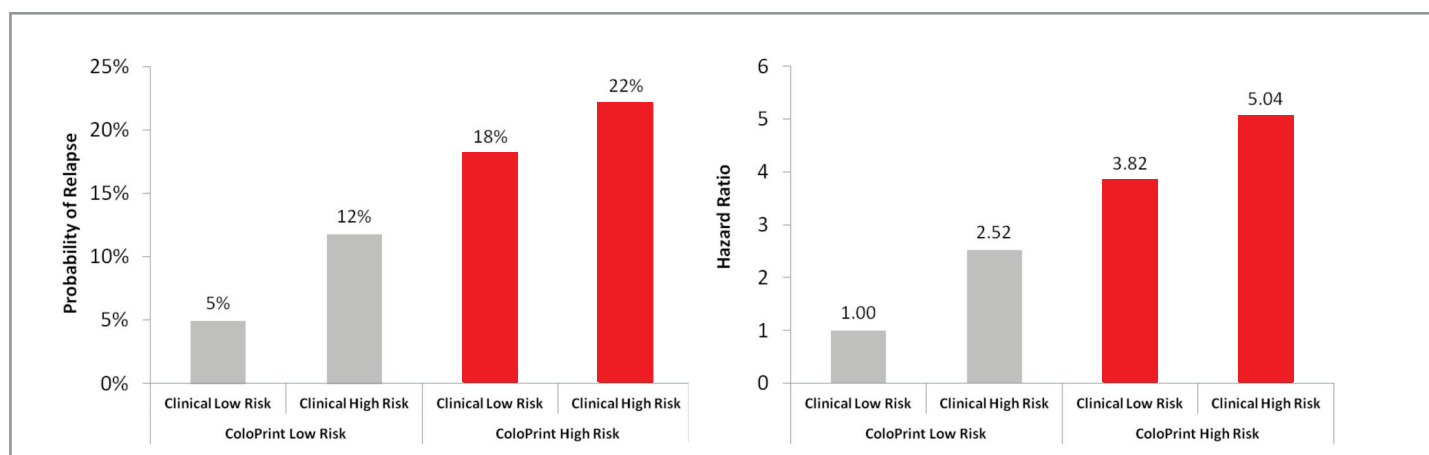
DOB: Oct-31-196

Patient #: 024836267

Report Date : Mar-29-2012

COLOPRINT® RELEVANCE IN COMBINATION WITH OTHER RISK FACTORS

The combination of ColoPrint® with clinical and pathological factors further personalizes the estimate of a patient's risk of relapse. Patients who are ColoPrint® High Risk and have at least one clinical high risk factor have an estimated 22% risk of experiencing relapse in 3 years, while ColoPrint® High Risk patients with no clinical high risk factors have an estimated 18% 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 high relapse risk is estimated to be 5%.

Treatment number= **1/20**

In other words, 20 patients need to be treated so that 1 patient will benefit from chemotherapy.

Sign Off
Paul Kirshman, MD
Pathologist, Laboratory Director

References:

1. Salazar et al. J Clin Oncol. 2011 Jan 1;29(1):17-24
2. Maak et al. Annals of Surgery. 2012 (in press)
3. Tabernero et al. J. Clin Oncol. 2012 30 (suppl 4;abstr 384)
4. NCCN Guideline Version 2012.3 Colon Cancer
5. Sargent et al. J Clin Oncol. 2009 Feb 20;27(6):872-7

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).