

A prognostic marker for stage II colorectal cancer combining analyses of DNA ploidy and tumour stroma



ColoProg workflow steps 1–6:



- Patient receives surgery
- Formalin fixed paraffin embedded (FFPE) tissue used for pathology



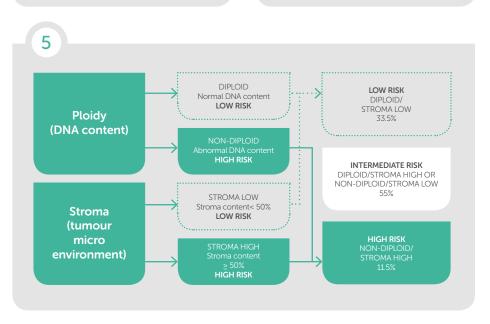
- Treatment discussed with patient
- ColoProg test requested by clinician
- FFPE slide sent to OCB laboratory



- Sample and requisition form received and logged by laboratory
- Tumour sample processed for stroma and ploidy analysis



- Digital image analysis carried out for
 - Stroma (tumour image analysis)
 - Ploidy (DNA content determination)
- Stroma and ploidy data combined to produce risk category designation
- Final data set approved by pathologist













a prognostic marker for Stage II colorectal cancer recurrence



What is ColoProg?

- A clinical digital pathology tool that combines analyses of Stage II DNA ploidy and tumour stroma content
- initially validated using the QUASAR2 clinical trial^(1,2) and two other studies providing over 1000 Stage II patients for analysis³

What does ColoProg do?

- Uses the proprietary ColoProg algorithm to determine patient risk category
- Stratifies patients into low, intermediate and high-risk groups³



Why use ColoProg?

- Difficult to identify which Stage II colorectal cancer tumour patients require adjuvant chemotherapy
 - About 50% Stage II patients are given chemotherapy in UK³
- ColoProg enables clinicians to determine risk of recurrence, potentially sparing overtreatment of patients who would not benefit from adjuvant chemotherapy⁵
 - 33.5% of Stage II tumours are low risk according to ColoProg validation³
 - Long term effects of unnecessary chemotherapy can be avoided
 - May provide healthcare cost savings by avoiding unnecessary chemotherapy
- $^{\circ}$ ColoProg combines DNA and tumour microenvironment markers to stratify patients into groups of high and low risk of recurrence with a hazard ratio of 2.95 (P<0.001) compared to the leading competitor (HR = 1.47, P=0.046)³
- Meets patient safety and enhanced patient experience standards (NHS Outcomes Framework)⁶

References:

- 1. Kerr RS, et al. Adjuvant capecitabine plus bevacizumab versus capecitabine alone in patients with colorectal cancer (QUASAR 2): an open-label, randomised phase 3 trial. Lancet Oncol. 2016 Sep 19. pii: S1470-2045(16)30172-3.
- 2. Fotheringham S et al. A prognostic marker for colorectal cancer: combining analyses of ploidy and stroma. Annals of Oncology 27 (Supplement 2): ii118-ii128, 2016.
- 3. Danielsen HE et al. A prognostic marker for colorectal cancer: combining ploidy, stromal, and mutational analyses. Submitted Annals of Oncology 2017.
- 4. Quasar Collaborative Group, et al. Adjuvant chemotherapy versus observation in patients with colorectal cancer: a randomised study. Lancet 2007; 370(9604): 2020-9.
- 5. Benson AB 3rd, et al. American Society of Clinical Oncology recommendations on adjuvant chemotherapy for stage II colon cancer. J Clin Oncol. 2004 Aug 15;22(16):3408-19
- $\textbf{6.} \quad \text{NHS Outcomes Framework: at-a-glance. Department of Health 2016}.$