

## **Predictor C: A tissue-based IVD predicting progression of disease in colorectal cancer UICC stages II or III.**

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### Abstract:

**Background:** We discovered a prognostic gene signature (Predictor-C) containing 32 Affymetrix probesets in a cohort of 55 pts with colorectal cancer (CRC) UICC stage I or stage II. From all pts snap-frozen tumor samples and a minimum follow-up of 5 years were available. Predictor-C discriminates between pts with high risk vs. low risk of progression of disease. We now report on a performance evaluation of Predictor-C in an independent set of CRC pts with UICC stage II or stage III disease. **Methods:** We tested the hypothesis that the lower one-sided 95% exact confidence limit of the correct classification rate (CCR) of Predictor-C in the validation set is higher than 0.55 with a power of > 0.85, given the true CCR is 0.68. For this hypothesis test, data from 164 pts would be required. We selected 164 pts from a total of 393 pts who were recruited into an international multicenter study of CRC. Pts were operated on between 1990 and 2000 in Denmark, Finland, Germany, Austria, Netherlands and Canada. For all 393 pts frozen CRC tissue, Affymetrix array data (U133 Plus 2.0, U133A) and a follow-up of five years were available. The validation set is comprised of 90 pts with stage II and 74 pts with stage III. Seventy-two pts suffered from a progression of disease, while 92 pts had no progression. **Results:** Applying Predictor-C to the validation set revealed a CCR of 0.63 (95% exact confidence limits [CI]: 0.555-0.708), a sensitivity of 0.64 (95% CI: 0.517-0.749), a specificity of 0.63 (95% CI: 0.523-0.729), a positive predictive value (PPV) of 0.58 (95% CI: 0.459-0.685), and a negative predictive value of 0.69 (95% CI: 0.580-0.787). The point estimate for progression-free survival at 5 years after surgery for pts classified as low-risk is 0.62 (95% CI: 0.458-0.789), and for pts classified as high-risk this estimate is 0.45 (95% CI: 0.332-0.564). The baseline characteristics of these 164 pts were representative for the whole population of CRC patients diagnosed with UICC stage II or stage III, in almost all aspects. **Conclusions:** Predictor-C was successfully validated in an independent set of pts with UICC stage II or UICC stage III. The clinical utility of Predictor-C lies in its PPV of 58% justifying the adjuvant treatment of the high-risk group.

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