

## TECHNOLOGY OFFERS

# Reliable noninvasive biomarkers for early detection of colorectal cancer (P-1455)

*Five marker panel with high sensitivity for detecting early, all-stage stage CRC and advance adenomas.*

## EXECUTIVE SUMMARY

Sigmoidoscopy and colonoscopy, the current gold standards for detection of CRC are limited by several disadvantages, such as high costs, limited resources and poor compliance. Therefore, other cost-effective and sensitive methods are urgently needed for the early detection of colorectal cancer. The need of an efficient and cheap test is very important from the health economic standpoint.

Using blood samples this invention offers a set of proteins that can be used as a diagnostic tool for accurate diagnosis, and/or monitoring of therapy in colorectal cancer (CRC). The panel has the sensitivity of 83% for detecting early stage CRC at specificity 80% and the AUC of 0.86. For detecting all-stage CRC an AUC of 0.82 is observed.



*Kateryna\_Kon, stock.adobe.com*

### Category

Diagnostic

### Indication

Colorectal cancer

### Development stage

Validated in a true screening cohort

### Seeking

Licensing partner

## BENEFITS

- Remarkable diagnostic performance is competitively better than any other protein biomarker study and also more accurate than the only other FDA approved blood based test DNA-Epi-proColon-2.0.
- Performed with blood samples (and not via stool sample or invasive colonoscopy)
- Highly robust score – accounts for overoptimism
- Used two different analytical methods for detecting proteins in blood samples

## TECHNOLOGY BACKGROUND

Our invention involves determining the concentration of 4 and 5 protein marker combinations (AREG, MASP1, OPN, PON3, TR) in a blood sample. When compared to the reference value, they can detect and predict stage specific CRC. None of the existing biomarker searches and studies have validated the measurements of proteins in same samples for the same proteins using two different detection methods. Our invention is the first that uses a three stage design and not only validates the findings in an independent validation set of participants of screening colonoscopy, but also confirms quantitation of proteins in same samples using two different technologies. Therefore, it confirms not only the diagnostic potential of markers but also that the association of proteins with CRC is not random. The protein markers in the signature would serve as potential candidates for blood based tests for population based screening for early detection.

## DEVELOPMENT STAGE

Most of the existing CRC diagnostic markers have been identified in clinical setting sample, which is not precise enough but our invention is validated in samples from true screening participants of screening colonoscopy. This makes it robust and reliable and takes the potential licensee closer to commercialisation.

## APPLICATIONS

The method can be used as a diagnostic tool for diagnosis and potentially for stratification and/or monitoring of a therapy of colorectal cancer.

## INTELLECTUAL PROPERTY

Priority patent application "COLORECTAL CANCER SCREENING EXAMINATION AND EARLY DETECTION METHOD" EP19173318.7 was filed at the European Patent Office 8 May 2019.

## PUBLICATIONS & REFERENCES

- Bhardwaj, M. et al. Evaluation and validation of plasma proteins using two different protein detection methods for early detection of colorectal cancer. [submitted]
- Bhardwaj, M. et al. "Blood-Based Protein Signatures for Early Detection of Colorectal Cancer: A Systematic Review." Clin Transl Gastroenterol 8, no. 11 (Nov 30 2017): e128. <https://doi.org/10.1038/ctg.2017.53>
- Bhardwaj M, et al. Blood-Based Protein Signatures for Early Detection of Colorectal Cancer: A Systematic Review. Clin Transl Gastroenterol. 2017;8(11):e128. Published 2017 Nov 30. doi:10.1038/ctg.2017.53

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## ABOUT THE DKFZ INNOVATION MANAGEMENT

Working at the interface of research and industry, the Innovation Management of the German Cancer Research Center (DKFZ) helps to get new cancer medications, diagnostic tests, and research instruments onto the market as quickly as possible.

The DKFZ with its more than 3,000 employees is the largest biomedical research institution in Germany. At the Center more than 1,300 scientists investigate how cancer develops, identify cancer risk factors and endeavor to find new strategies to prevent people from getting cancer. They develop novel approaches to make tumor diagnosis more precise and treatment of cancer patients more successful. DKFZ is a member of the Helmholtz Association of National Research Centers, with ninety percent of its funding coming from the German Federal Ministry of Education and Research and the remaining ten percent from the State of Baden-Württemberg