

# epigenomics

## **Epigenomics DNA Methylation Test Successfully Detects Colorectal Cancer in Blood**

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**Press release, Berlin, Germany and Seattle, WA, USA**

**- Clinical Studies Demonstrate Proof-of-Concept for Early Detection of Disease -**

Epigenomics AG (Frankfurt, Prime Standard: ECX), a molecular diagnostics company developing tests based on DNA methylation, announced today positive results of a series of large clinical studies, demonstrating that its molecular diagnostic test developed in collaboration with Roche Diagnostics was able to detect colorectal cancer from a standard, non-invasive blood draw. Epigenomics believes that this diagnostic, which works by interpreting changes in DNA methylation, has the potential to support large-scale, general population colorectal cancer screening since early detection of colorectal cancer significantly improves treatment outcome. The test targets asymptomatic men and women over the age of 50 who are recommended to take an early detection test for colorectal cancer on a regular basis.

Successfully meeting this milestone led to the full payment to Epigenomics of the milestone that had been agreed in the companies' collaboration agreement. Roche Diagnostics now has a worldwide exclusive license to this test and will commence to transfer the marker and technologies onto Roche Diagnostics' platforms in 2006.

At a set specificity of 95%, the lead marker demonstrated sensitivity values of 51%, 65% and 50%, respectively in three independent clinical studies, matching or surpassing the performance of today's best molecular screening tests. Importantly, early-stage cancers were identified with the same sensitivity as later stage cancers, proving the utility of this approach for general population screening. Results were obtained measuring only a single DNA methylation anchor marker. In addition, the test was able to detect colorectal cancers regardless of their location, addressing a critical medical need and shortfall of the existing fecal occult blood tests (FOBT), currently the most widely used screening test.

Epigenomics conducted the studies to identify and validate DNA methylation-based markers using blood plasma. In two of those studies Roche Diagnostics had previously blinded all samples. In total, approximately 2,000 samples were tested comprising over 600 plasma samples from colorectal cancer patients with a representative distribution of disease at all four stages. In addition, a comprehensive collection of 600 so-called 'critical controls', representing the most likely confounding other diseases, as well as over 600 normal controls from an age-matched, colonoscopy-verified population, were included.

We are thrilled, and obviously immensely relieved, that our DNA

methylation-based screening test for colorectal cancer based on plasma was successful in clinical studies, stated Alexander Olek, Epigenomics CEO. Within a few years of research, we have developed a novel technology, discovered proprietary biomarkers, and have shown clear evidence that these markers can be used for the early detection of cancer. This work provides a solid foundation for developing a broad pipeline of leading molecular diagnostics. It's really the beginning, not the culmination of Epigenomics' success story.

The sample material in all studies was plasma obtained from standard blood draws. Plasma DNA was extracted using the Roche Diagnostics MagnaPure® system. Detection of methylation signals was performed using LightCycler® real-time PCR systems. The studies were run using standard LIMS (Laboratory Information Management Systems) controls and the overall quality was shown to be very high for a pre-development process. Although Epigenomics' successful handling of these intricate large-scale processes shows how robust even the current methods are, there are indications that the use of not yet standardized reagents has led to the observed variability between the studies.

Roche Diagnostics are the experts in some critical steps of our process such as standardization of blood-draws, plasma processing, DNA extraction, and real-time PCR analysis. We have clear indications that adding Roche Diagnostics' development power and Good Manufacturing Practice (GMP) to our process will significantly improve performance without even adding further markers, commented Andrew Sledziewski, Epigenomics' Vice President R&D. With these data we are now in a position to work towards identifying and validating further complementary marker candidates with reasonable effort, added Cathy Lofton-Day, Epigenomics' program manager for the colorectal cancer screening test.

Today, Monday, December 19, 2005, Epigenomics' management will host a conference call at 2.30 PM/CET. The dial-in number for the call is:

+49 (0)69 58 999 0808 for European participants, and  
+1 480 629 9564 for US participants.

### **DNA Methylation**

Methylation is a natural process that occurs on one of DNA's four base pairs, cytosine. The presence of methylation can modify the activity of genes. Differences in the pattern of methylation between healthy and disease tissue can be detected and may indicate a change in gene activity that could trigger diseases such as cancer. Our knowledge of the changes caused by methylation is limited. However, a number of initiatives, such as the Human Epigenome Project, are being conducted to map all methylation sites on the human genome thereby linking methylation patterns and gene expression.

### **Colorectal Cancer Screening**

Colorectal cancer is the second leading cause of cancer death. With over a 90% cure rate if caught early enough, early detection through screening is vitally important. The market for this type of test could reach 246 million people worldwide. The gold standard screening test is colonoscopy, an invasive test whereby the physician visually inspects the inside of the

colon. This procedure, which has excellent specificity and sensitivity characteristics, not only identifies cancer but also precancerous lesions known as adenomas. Due to the nature of this procedure and its high cost, it is not viable for use in large screening programs. A non-invasive screening test therefore should be used to screen larger numbers to identify individuals at risk of having the disease so that they then undergo colonoscopy. Currently, most non-invasive screening is carried out with the FOBT procedure. However due to the nature of the test, the compliance rate is comparatively low (approximately 20%). The introduction of a more convenient, patient-friendly, competitively performing screening test could potentially increase the number of individuals tested and so increase the chances of disease being caught early with the goal to reducing mortality from colorectal cancer.

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### **About Epigenomics**

Epigenomics is a molecular diagnostic company with a focus on the development of novel products for cancer. By detecting and interpreting DNA methylation patterns, Epigenomics tests can potentially diagnose disease at an early stage and help guide physicians to select an appropriate therapy. Epigenomics collaborates with Roche Diagnostics on the development of several diagnostic products in cancer. The company has its headquarters in Berlin, Germany, and a wholly owned subsidiary in Seattle, USA. For more information, please visit our website at [www.epigenomics.com](http://www.epigenomics.com).

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