

Validation of Blood-based MiRNAs for Early Diagnosis of Lung Cancer

MiRNA signatures from blood validated towards clinical application for non-small cell lung cancer

HEIDELBERG, December 14, 2015 – This month the Comprehensive Biomarker Center GmbH announced the publication of a pioneering Lung Cancer study in *Oncotarget* (Leidinger et al. 2015). Performed in close collaboration with Saarland University (Dept. Human Genetics, Prof. E. Meese, Clinical Bioinformatics, Prof. A. Keller), the study represents a key advance in translating novel biomarkers from research to clinical use by independent validation of miRNA signatures.

As one of the leading causes of cancer-related deaths, the diagnosis of lung cancer is challenging because there are no validated minimally invasive screening procedures, late detection is typically associated with poor outcomes, and the differential diagnosis to chronic obstructive pulmonary disease (COPD) is complex.

Following-up on an initial screening initiative for miRNA biomarkers in lung cancer (Leidinger et al. 2009), miRNA profiles from the whole blood of 120 patients were analysed using high-throughput qRT-PCR. The samples included blood from patients diagnosed with the most common type of lung cancer, patients with COPD, as well as healthy controls, and was designed to determine if miRNAs hold promise as a tool for lung cancer screening and differential diagnosis from COPD.

The study showed that lung cancer patients could be precisely differentiated from healthy controls and COPD patients by a blood based miRNA signature illustrating its potential for early diagnosis of lung cancer. These preliminary results show strong evidence that blood-based miRNA signatures can be well replicated, have a substantial potential for lung cancer diagnosis, and are novel powerful biomarker candidates for clinical applications.

“While this study is small, our methods were able to differentiate a patient with cancer from a disease-free individual with 95% accuracy with a simple blood test.” said Jochen Kohlhaas, Chief Executive Officer of CBC. “We’ll certainly continue the development of lung-related biomarkers and work on extending our approach to other diseases.”

About Lung Cancer:

Lung Cancer is the second most common cancer in men and women. The disease is estimated to be diagnosed in 224,210 new cases and to sum up to 159,260 death in the US. The lack of validated screening procedures leads to an unfavorable late diagnosis of the malignant disease. Detection of lung cancer in an advanced stage results in poor prognosis. Since only 15.4% of lung cancer patients are being diagnosed with the disease still at a localized stage, the 5-year overall survival rate is only 16.8% according to the National Cancer Institute's (NCI) SEER statistics. There is an urgent need for reliable biomarkers to improve accuracy and time of diagnosis of lung cancer as well as the differential diagnosis to COPD.

About CBC:

Located in the Biotechnology Park in Heidelberg, Germany, CBC is specialized in innovative biomarker discovery and validation with focus on miRNA biomarkers from body fluids. CBC has built a robust and fine-tuned platform to generate and validate bio-fluid based markers and IP for IVD, companion diagnostics and drug discovery. At the core of CBC is a proven, quality-controlled Biomarker engine combined with an unrivalled high-quality miRNA whole blood database. CBC is an „Agilent Certified Services Provider” and accredited according to DIN EN ISO/IEC 17025:2005.

Reference:

P. Leidinger et al., High-throughput qRT-PCR validation of blood microRNAs in non-small cell lung cancer, *Oncotarget* 2015, DOI: 10.18632/oncotarget.6566

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