

TITLE: LUNG CANCER DIAGNOSIS KIT

DESCRIPTION OF THE TECHNOLOGY

Nowadays, Lung cancer is the leading cause of cancer-related death for both men and women. Late diagnosis in lung cancer is one of the main reasons of the extremely high mortality of this disease. Early diagnosis is difficult because many of the common symptoms of lung cancer, such as cough or breathlessness, are similar to those of smokers' lung (chronic obstructive pulmonary disease or COPD) or pulmonary inflammatory diseases. Besides, low sensitivity associated with minimally invasive cytologies is also a current hurdle for the accurate diagnosis of lung cancer.

Researchers of the Medical Research Institute Hospital La Fe, the Bellvitge Biomedical Research Institute and the University of Navarra's Center for Applied Medical Research have generated a new epigenetic (DNA methylation) that allows the diagnosis with high levels of confidence of Lung Cancer (LC) patients using minimally invasive samples. Researchers have built a multivariate logistic regression model based on the combination of four-genes that generates a Probability of Cancer value specific for each patient.

The epigenetic model provides a balanced and flexible approach able to cater to both extreme scenarios: the high sensitivity and low specificity of low dose CT in screening programs and the high specificity and low sensitivity of cytology in respiratory specimens routinely used for lung cancer diagnosis. Our signature improves the predictions of cytology by providing a method for continuous predictions. Cytology is a useful dichotomized classifier producing two types of predictions: 100 % positive or 0% positive (100% negative). Our signature, represented by a nomogram, is able to produce a continuous range of predictions between 100% positive and 0% negative; Thus, a clinician could take different actions according to the (un)certainty of the predictions, maybe performing additional tests in borderline cases.

Finally, the evaluation of the epigenetic state of the selected genes included in the model could be performed in a hospital as a daily basis routine. Since, pyrosequencing is the quantitative, reproducible and affordable technique used in this technology.

The herein obtained epigenetic model in combination with current diagnostic protocols may improve early diagnosis and outcome of lung cancer patients. The combination of current diagnostic protocol with new epigenetic nomograms will be of great help for diagnosis of lung cancer and consequently improving the outcome of lung cancer patients.

MARKET APPLICATION SECTORS

Clinical Diagnosis.

TECHNICAL ADVANTAGES AND BUSINESS BENEFITS

- Balanced and flexible approach (sensitivity/ specificity) compare to other techniques.
- The kit, represented by a nomogram, is able to produce a continuous range of predictions between 100% positive and 0% negative.
- Decision support kit, clinician could take different actions according to the (un)certainty of the predictions, maybe performing additional tests in borderline cases.
- The kit is able to identify false negative patients derived from cytology.
- Early identification of patients at higher risk of developing LC.
- Minimally invasive testing.
- Economically affordable so it can be widely used.

CURRENT STATE OF DEVELOPMENT

The biomarkers used in the kit have been identified by a DNA methylation microarray in tumoral DNA obtained from 237 stage I patients with LC and have been validated by a single-methylation pyrosequencing assay in different minimally invasive independent cohorts of 122 paraffin tumor samples, 51 bronchioalveolar aspirates, 82 bronchialvolar tumor lavages and 72 sputum samples. In near future researchers will test the epigenetic model in non-invasive blood samples.

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European Patent EP16382007

Priority Date: January 2016

COLABORATION SOUGHT

Researchers are looking for a company willing to sign a license agreement for commercial exploitation of the kit.

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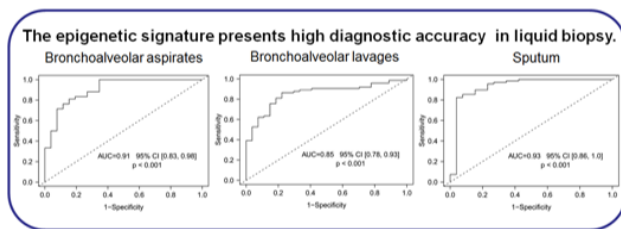


Image 1: Roc Curves

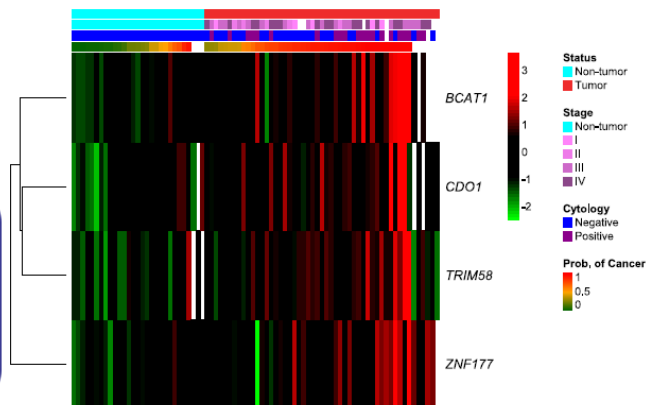


Image 2:Heatmap

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