

Improvement in Performance of the EarlyCDT-Lung Test for Detection of Lung Cancer by Addition of Antigenic Biomarkers

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Hypothesis: Antigenic biomarkers used in combination with autoantibody panels leads to improvement in assay the performance parameters of the combined assay compared with either types of biomarker alone.

Objectives: The EarlyCDT-Lung Test measures a panel of seven autoantibodies and is intended to be used as an aid to early detection of lung cancer. It has high specificity but moderate sensitivity. The aim of this study was to investigate the performance of known antigenic biomarkers in lung cancer both alone and in combination with EarlyCDT-Lung.

Methods: A cohort consisting of 97 cases of lung cancer (71% stage 1 and 2, 71% male, median age 61y) and 97 controls were selected from the Oncimmune biobank. All lung cancer cases were individually matched to controls by age, gender and smoking history. The antigenic biomarkers, CEA and CYFRA 21-1, were measured by ELISA (Fujirebio) according to manufacturers' instructions. The EarlyCDT-Lung test was measured according to Oncimmune standard procedures. Commercial cut-offs were applied for the EarlyCDT-Lung test and cut-offs for the antigenic assays were set manually to achieve high specificity.

Result: The performance of each of the biomarkers alone and in combination is given in Table 1

Biomarker	Sensitivity	Specificity	PPV*
EarlyCDT-Lung	25.0%	93.4%	8.5%
CYFRA 21-1	27.1%	97.8%	11.1%
CEA	17.7%	98.8%	11.2%
EarlyCDT-Lung plus CYFRA 21-1	44.8%	91.2%	11.1%
EarlyCDT-Lung plus CEA	39.6%	92.3%	11.2%
EarlyCDT-Lung plus both antigens	54.8%	91.2%	13.3%

PPV (Positive Predictive Value) assumes 2.4% lung cancer prevalence

Conclusions: Combining antigenic markers with autoantibody panels leads to increased sensitivity whilst maintaining high specificity. The improved assay performance characteristics could lead to greater clinical utility. The antigens were measured using ELISA in this study and so will be easily integrated into the EarlyCDT-Lung platform.

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