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Use of Serum Autoantibodies to Identify Early-Stage Lung Cancer: A Significant Step Forward in Early Detection

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Background: EarlyCDT-Lung™ measures autoantibodies to a panel of six cancer-associated antigens (p53, NY-ESO1, CAGE, GBU4-5, Annexin1 and SOX2) with a specificity of 90% and a sensitivity of 45% for small cell lung cancer (SCLC) and 34% for non-small cell lung cancer (NSCLC). We report confirmatory data for clinical sensitivity and specificity determined in an independent, prospective, post-validation dataset.

Methods: Four hundred and fifty three (453) patients with newly diagnosed, untreated lung cancer were matched for age, sex, and smoking history to high-risk individuals. Patient and control samples were collected from multiple locations in the USA, Canada, and Europe and measured on EarlyCDT-Lung (Oncimmune USA LLC). 258/359 (72%) of NSCLC were known early-stage disease (ie stage 1 or 2), 10/28 (36%) of SCLC were limited disease, and 66 were unknown stage. A larger series of 211 SCLC patients with matched high-risk controls obtained from a single European center was measured for autoantibodies to the same six cancer-associated antigens (Oncimmune Ltd, Nottingham, UK).

Results: In the multi-centre group (n=453), for early-stage disease the positivity rate was 35% (89/258) for NSCLC and 40% (4/10) for SCLC. In the single centre SCLC dataset (n=211) the positivity rate for limited disease was 47% (41/87). Combining both groups (n=664 lung cancers) gave an overall positivity of 40% of lung cancers. For early-stage disease, the positivity rate was 35% (89/258) of NSCLC and 46% (45/97) for SCLC. Overall specificity for all high-risk individuals (n=1029) was 88%.

Conclusions: This large dataset further confirms that up to 40% of lung cancer, including early-stage disease, can be identified through a blood test. EarlyCDT-Lung and CT scanning have the potential for early detection of a large subset of lung-cancers.