Abstract Body

**Rationale:** Molecular biomarkers may assist with the identification of patients with lung cancer, improving the selection of patients for lung cancer screening and the evaluation of indeterminate lung nodules. A combination of multi-plexed serum proteins and an auto-antibody, each previously associated with the presence of lung cancer, may be more accurate than any one of these markers alone.

**Methods:** 604 samples obtained from 4 commercial sources were included in a training set. All subjects had smoked at least 20 pack-years. The validation set included 400 subjects from the Cleveland Clinic. Control subjects in the validation set were current and former smokers. CEA, CA125, CYFRA, HGF, and the auto-antibody NYESO1 were measured in all samples on a multiplexed assay developed on the Luminex xMAP technology platform. Outliers were removed (9 from training and 8 from testing set). Logistic regression models were built from the results of the training set. Model accuracies were assessed on the validation set.

**Results:** The training set included 268 lung cancer patients (mean age 64.0 years, 43.7% female) and 336 at risk controls (mean age 64.5 years, 39.9% female). 56.3% of cancers were adenocarcinoma, and 33.2% were squamous cell carcinoma. 53.7% were stage I, 24.3% were stage II, 17.9% were stage III, and 4.1% were stage IV. The validation set included 155 untreated lung cancer patients (mean age 65.3
years, 40.0% female) and 245 at risk controls (mean age 68.3 years, 51.9% female).
47.7% of cancers were adenocarcinoma, and 39.4% were squamous cell carcinoma.
33.5% were stage I, 12.3% stage II, 37.4% were stage III, and 16.8% were stage IV.
The model developed in the training set had a C-statistic of 0.774. When applied to
the validation set, the sensitivity was 88.2%, specificity 71.6%, and overall accuracy
74.4%.

**Conclusions:** A multi-plexed panel of serum biomarkers is capable of accurately
identifying patients with lung cancer from a population of individuals at high risk of
developing lung cancer. Next steps include additional validation to optimize
biomarker performance and assessment within a screening algorithm.