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Demographics of Populations at High Risk of Lung Cancer and Results of the *Early*CDT-Lung™ Test

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Background: EarlyCDT-Lung™ measures autoantibodies (AABs) to six cancer-associated antigens (p53, NY-ESO-1, CAGE, GBU4-5, Annexin1, and SOX2) and has been reported to identify up to 40% of lung cancers, both early- and late-stage disease.
Methods: Prospective blood collections (with individual questionnaires) were carried out in three different community-based locations in two countries (US, two sites; UK, one site) in order to assess demographic features of high-risk populations. Some demographic features were not recorded at all sites. For the statistical comparisons, analysis of variance was generally used, taking into account imbalance in subgroup numbers, unevaluable data and multiplicity of testing, where necessary, and with sample-matching, where appropriate.
Results: *Unmatched Datasets* - from separate analyses of the US (Florida n=320, Midwest n=940) and UK (n=2046) datasets there was no difference for any of the AAB assays between i) males and females, ii) the main ethnic groups (US only) for participants in samples collected in Florida and the Midwest and iii) the presence or absence of benign autoimmune diseases (UK data only). There was evidence for an effect of age for some antigens, with mean AAB levels rising with age (especially >70yrs). This may be confounded by the fact that the incidence of cancer also increases with age. Further investigation is required. *Matched Datasets* – for sets of samples matched for age, sex, and smoking, there was no significant difference for any autoantibody assay between i) US (n=353) and UK (n=353) high-risk individuals and ii) within US (Florida, n=275 and Midwest, n=275) samples.
Conclusions: Within a high risk population the demographic features described above should not be used to exclude individuals from AAB testing as an aid to early detection of lung cancer.