Reproducibility of Autoantibody Measurements in Normal Individuals Using the EarlyCDT-Lung™ Test
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PURPOSE

The EarlyCDT-Lung™ test is intended as an aid to the early detection of lung cancer in high-risk individuals and measures autoantibodies (AAb) against a panel of six tumor-associated antigens (p53, SOX2, CAGE, NY-ESO-1, GBU4-5 & Annexin 1). The aim of this study was to investigate the variability of this assay between repeated samples from the same patient.

METHODS

Subjects: Serial serum samples were collected once a week for 4 weeks from pre-menopausal female smokers (n=43, mean age = 39.9 years) and once every 2 weeks for 4 weeks from post-menopausal female smokers (n=19, mean age = 54.7 years) and male smokers (n=10, mean age = 58.4 years). Local ethical approval had been given for the collection.

Assay: Samples were analyzed using the EarlyCDT-Lung, a semi-automated indirect enzyme-linked immunosorbent assay (ELISA), designed to measure AAb specific for a panel of tumor-associated antigens1,2.

Statistical Analysis: Comparisons between weeks were performed using paired t-tests (p<0.01). Coefficients of variation (CVs) for between-sampling-time (within-patient) reproducibility were compared for all samples and also for only those with values higher than the lower limit of quantification (LLOQ).

RESULTS

Paired t-tests showed no significant differences between the first sample taken from pre-menopausal women and any of the other three samples. In addition, no significant differences were observed in the two samples taken from post-menopausal women or male smokers. Comparison of CVs showed that between-sample-time reproducibility was comparable with inter-assay CVs found for this assay. This confirmed that the within patient AAb levels were not varying over the menstrual cycle.

CONCLUSIONS

• The EarlyCDT-Lung test demonstrates a high degree of reproducibility in measurements of serial samples taken from the same patient.
• AAb levels do not show variation due to cyclic hormonal changes.

CLINICAL IMPLICATIONS

The between sample reproducibility demonstrated by this assay provides confidence that its measurements of AAb levels are reliable.

REFERENCES


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