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**Reproducibility of autoantibody measurements in normal individuals using the
*EarlyCDT-Lung*TM test**

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Background: The *EarlyCDT-Lung* test is an assay, intended as an aid to the early diagnosis of lung cancer, which measures autoantibodies (AAb) against a panel of six tumour associated antigens (p53, SOX2, CAGE, NY-ESO-1, GBU4-5 and Annexin 1). The aim of this study was to investigate the variability between repeated samples from the same patient.

Methods: Serial serum samples were collected once a week for 4 weeks from pre-menopausal female smokers (n=46, 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. Comparisons between weeks were performed using paired *t*-tests. Coefficients of variation (CVs) for between-sampling-time (within-patient) reproducibility were compared with historical estimates of between-assay CVs.

Results: Paired *t*-tests showed no significant differences between the paired samples from male smokers. No significant differences were observed between the first sample taken from pre-menopausal women and any of the other 3 samples. The only significant difference out of 30 *t*-tests performed was p53 levels in samples from post-menopausal women taken 2 weeks apart ($p=0.021$). These findings showed that there was no directional trend over time for the patient set while graphics showed constant AAb levels over time within-patient. The comparison of CVs showed that between-sampling-time reproducibility was no higher than that for between-assay CVs for any of the three groups. This confirmed that the within-patient AAb level was not varying over the monthly cycle.

Conclusions: The *EarlyCDT-Lung* test demonstrates a high degree of reproducibility in measurements of serial samples taken from the same patient. Cyclic hormonal changes do not appear to affect assay results.