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3038 **Poster Session**

A novel three-biomarker signature (CA-62, CEA, CYFRA 21-1) and early-stage NSC lung cancer detection.

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Background: A double-blind clinical study was conducted on 304 clinically verified blood serum samples, including 141 non-small cell lung cancer (NSCLC), 133 healthy volunteers and 30 patients with chronic obstructive pulmonary disease (COPD). The objectives of the study were: The assessment of various cancer markers and their possible combinations for detection of early (I-II) stages of non-small cell lung cancer (NSCLC) and evaluation of the best cancer markers panel as a pre-screening tool for NSCLC before Low-Dose CT scan. **Methods:** Quantitative measurement of various tumor markers for serum samples was carried out using electrochemiluminescent immunoassays Elecsys CA-125, ELECSYS CA 19-9, ELECSYS CYFRA 21-1 and ELECSYS SCC (COBAS, Roche Diagnostics GmbH, Germany, EU), enzyme immunoassay CA15-3-ELISA-BEST, CEA-ELISA-BEST, NSE-ELISA-BEST (JSC "VECTOR-BEST", RF) and immunochemiluminescent analysis CLIA-CA-62 (LLC "JVS Diagnostics", RF). The results were compared to the literature data for other biomarkers and their panels. **Results:** Unlike other tumor markers, which are expressed proportionally to tumor size, the marker for epithelial carcinomas CA-62 is expressed from Stage I and demonstrated the highest diagnostic results in detecting early stages (I-II) of NSCLC. The biomarkers CYFRA 21-1 and SCC do not have sufficient sensitivity and specificity to diagnose asymptomatic lung cancer. However, the addition of cytokeratin 19 CYFRA 21-1 to glycoproteins CA-62 and CEA increases the specificity by eliminating false positive results, which significantly improves the diagnostic value of the cancer marker signature (CA-62, CEA and CYFRA 21-1): 100% Specificity, 93% Sensitivity, 100% PPV, 94% NPV and 94% test accuracy. **Conclusions:** The results of the study demonstrated that using the biomarkers signature (CA-62, CEA and CYFRA 21-1) allows increasing the specificity of CT scan for patients with suspicious abnormalities on the tomogram, improving the interpretation of visualized localized lesion, and improving the accuracy of differential diagnosis at detecting early stages of LC up to 94%. In the prospective, adding cancer markers panel signature (CA-62, CEA and CYFRA 21-1) to the current lung cancer risk assessment system as a pre-screening tool for LDCT may improve the quality of early-stage Lung cancer detection by significant increasing the sensitivity and by reducing the proportion of false positive results. Research Sponsor: UCM Technologies Inc.

Diagnostic characteristics obtained for different cancer markers and their panels.

Cancer Marker	Sensitivity, %	Specificity, %	PPV, %	NPV, %	Accuracy, %
CEA	48.2	93.8	84.5	65.2	72.7
CA-62	96.4	97.0	96.4	96.0	96.7
NSE	9.2	96.0	68.4	26.7	55.6
SCC	18.4	98.0	896	58.2	61.2
CYFRA 21-1	44.0	96.0	91.2	66.4	72.0
CA 19-9	7.1	95.0	55.5	54.2	54.3
CA-125	22.0	97.0	86.1	58.9	62.2
CA 15-3	19.0	98.0	93.0	58.5	61.8
CA-62, CEA, CYFRA 21-1	93.0	100.0	100.0	94.0	94.0

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