

An Innovative Evidence-Based Laboratory Medicine (EBLM) Test to Help Doctors in the Assessment of Lung Cancer

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Background

According to the World Health Organization (WHO), lung cancer is the leading cause of cancer-related deaths, claiming nearly 1.8 million lives each year, and of which primary risk factor remains tobacco smoking. It encompasses two main types: small cell lung cancer (SCLC) and non-small cell lung cancer (NSCLC), which represents most cases and comprises adenocarcinoma, squamous cell carcinoma (SCC), and large cell carcinoma. This malignancy is a health concern worldwide, presenting high incidence, mortality, and profound socioeconomic impact due to invasive and costly diagnostic procedures.

Thus, a novel non-invasive test that provides confirmatory diagnosis of lung cancer.

Building upon this imperative, the aim of this study was to conduct a comprehensive meta-analysis to systematically assess the estimated diagnostic accuracy of our developed biomarker algorithm in confirming or ruling out lung cancer.

Methods

The innovative test is a novel diagnostic algorithm designed to exclusively leverage serum and urine biomarkers. This innovative tool combines several independent public algorithms to provide comprehensive diagnostic insights, thus enabling the confirmation of lung cancer diagnosis.

To evaluate the estimated accuracy of our new test, we conducted an extensive literature review to identify studies assessing the diagnostic accuracy of constituent algorithms, calculations, and combinations of analytes included within it, on the basis of a previous work by Dr. Rafael Molina *et al.* in 2016. In this study significant improvements in the diagnosis and classification of lung cancer were reported by combining the tumor markers CEA, CA 15.3, CYFRA 21-1, ProGRP, NSE, and SCC.

We developed an upgraded version of this panel and created a refined algorithm that relies on the core set of our three machine learning algorithms: MBDA, EBLMA and AIRA. We added the tumor marker CA-62 and a set of analytes into the test, to enable it not only confirm the presence of lung cancer but also to determine its type and subtype (SCLC or NSCLC, and within these, adenocarcinoma, SCC or neuroendocrine lung tumor). Additionally, liver and renal function indicators are integrated to enhance specificity. Thus, meeting the 1994 Barcelona criteria, proposed by the SEQC.

Results

With this refined algorithm we obtained a final sample size (n) of 4,296 individuals. With this sample size, we achieved a sensitivity of 0.93 and a specificity of 0.96. Subsequently, we conducted an approximation of the area under the receiver operating characteristic (AUROC) curve, as well as estimations for the positive predictive value (PPV) and the negative predictive value (NPV) based on these results, yielding values of 0.92, 0.95, and 0.93, respectively.

Conclusions

This data suggests that the innovative non-invasive blood and urine-based biomarker algorithm holds promise in providing timely and accurate diagnosis of lung cancer, particularly among individuals aged 40 and above. Given the current epidemiological state of this malignancy, our findings underscore the significance of early detection.

These results advocate for further exploration, prompting our intention to conduct a clinical study involving 10,000 participants to validate and enhance our findings and inform clinical practice.