An Innovative Evidence-Based Laboratory Medicine (EBLM) Test to Help Doctors in Multi-Cancer Early Detection (MCED)

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Background

Tumor markers (TMs) are a heterogeneous group of molecules used in the diagnosis, prognosis, and follow-up of cancer patients. However, TMs present some drawbacks, like their low specificity, as their levels also increase in benign diseases, which can result in false positives (e.g. they are catabolized in the liver and excreted through the kidneys so, any pathology related with these organs could impact in their concentration, even above their upper reference limit).

The objective of this study is to evaluate the efficacy of different algorithms that can detect most of benign diseases that can increase TMs levels together with an innovative MCED algorithm.

Methods

We studied a novel non-invasive EBLM test for MCED, developed to use 18 serum TMs and other analytes. Powered by public and proprietary machine learning (ML) algorithms, this diagnostic tool aims to accurately detect up to 42 solid tumors and 5 hematological malignancies. Additionally, it screens for up to 303 non-malignant diseases, many of which increase TMs' concentration in the absence of neoplasia, as the Barcelona criteria of 1994 already suggested.

This test comprises a computation of individual tests tailored to different diagnostic targets, some studies of which have been presented in ASCO 2022 (breast, colon) and ESMO 2024 (liver, lung, ovarian, prostate), from different clinical research studies conducted among the last 8 years.

Besides, parallel and serial approximations were conducted to optimize overall sensitivity (Se) and specificity (Sp), respectively.

Results

For the 303 benign diseases screening, we achieved a final sample size (*n*) of 151,357 individuals and the results of Se, Sp, AUROC, PPV, and the NPV were 0.97, 0.95, 0.85, 0.97, and 0.96, respectively. For the MCED, we achieved an *n* of 192.090 individuals and the values of Se, Sp, AUROC, PPV, and NPV were 0.95, 0.73, 0.92, 0.77, and 0.93, respectively.

Conclusions

This data supports that integrating different laboratory analytes to identify diverse comorbidities helps to achieve higher sensitivity and specificity values to detect various cancer types using TMs. However, further research should be conducted to confirm these findings.