

# AN INNOVATIVE EVIDENCE-BASED LABORATORY MEDICINE (EBLM) TEST TO HELP DOCTORS IN THE ASSESSMENT OF THE RENAL FUNCTION

**Sergio J. Calleja, MSc, Kience, Wilmington, Delaware, U.S**

**Adrià Roca, MSc, Blueberry Diagnostics, Barcelona, Spain**

**José D. Santotoribio, PhD, Hospital Universitario Puerto Real, Cádiz, Spain**

## Abstract (300 word limit)

### Objective

To evaluate the accuracy of a novel non-invasive Evidence-Based Laboratory Medicine (EBLM) test for the assessment of the renal function and the prediction of chronic kidney disease (CKD).

### Materials & Methods

This study is a part of a previous one already published at the European Society for Medical Oncology (ESMO) Congress 2024 about the accuracy evaluation of a novel non-invasive test for Multi-Cancer Early Detection (MCED)<sup>1</sup>. The validation of the algorithmic test was performed through a randomized controlled trial (RCT) with a sample size of 152 patients. Their blood and urine samples were tested by Laboratorio Echevarne (Sant Cugat del Vallès, Barcelona, Spain), with their own biochemistry and urinalysis techniques and procedures.

### Results

For the RCT, we achieved a sensitivity of 1.00 and a specificity of 1.00. The area under the receiver operating characteristic (AUROC) curve, the positive predictive value (PPV), and the negative predictive value (NPV), were 1.00, 1.00, and 1.00, respectively. In almost all patients, at least one abnormality in their main metabolic systems and functions was found. 24 patients (15.79%) had an alteration regarding its renal function.

### Conclusions

This innovative non-invasive blood and urine-based biomarker algorithm holds promise in providing timely and accurate assessment patient's renal function. These results advocate for further exploration, prompting our intention to conduct a clinical study involving 26,000 participants to validate and enhance our findings and inform clinical practice.

## Recent Publications (minimum 5)

1. Santotoribio J D, Calleja S J, Roca A. An innovative evidence-based laboratory medicine (EBLM) test to help doctors in multi-cancer early detection (MCED), Santotoribio, J.D. et al., Annals of Oncology, Volume 35, S298. DOI: 10.1016/j.annonc.2024.08.2208
2. Calleja S J, Roca A. An Innovative Evidence-Based Laboratory Medicine (EBLM) Test to Help Doctors in the Assessment of Lung Cancer. 2024 World Conference on Lung Cancer (WCLC)
3. Santotoribio J D, Calleja S J, Roca A. An Innovative Evidence-Based Laboratory Medicine (EBLM) Test to Help Doctors in the Screening of Ovarian Cancer
4. Santotoribio J D, Calleja S J, Roca A. An innovative evidence-based laboratory medicine (EBLM) test to help doctors in the screening of hepatocellular carcinoma (HCC). Annals of Oncology, Volume 35, S90. DOI: 10.1016/j.annonc.2024.05.214
5. Calleja S J et al. Diagnostic accuracy of the CxPREVENTIVE Colon model for early detection of colorectal cancer. JCO 40, e15518-e15518(2022). DOI: 10.1200/JCO.2022.40.16\_suppl.e15518.
6. Calleja S J et al. Diagnostic accuracy of the CxPREVENTIVE breast model for early detection of breast cancer. JCO 40, e13578-e13578(2022). DOI: 10.1200/JCO.2022.40.16\_suppl.e13578

### **Biography (150 word limit)**

Sergio J Calleja is member of American Society of Clinical Oncology (ASCO), European Society for Medical Oncology (ESMO) and Association for Diagnosis and Laboratory Medicine (ADLM), formerly American Association for Clinical Chemistry (AACC).



In addition to his individual accomplishments, Sergio forged a key partnership with Dr. Rafael Molina, an internationally recognized leader in oncology and biomarkers. Dr. Molina was the former president of the International Society of Oncology and Biomarkers (ISOBM) and the founder and former president of the European Group on Tumor Markers (EGTM), both of which play pivotal roles in the global advancement of biomarker research and its applications in cancer diagnostics and therapy. Together, Sergio and Dr. Molina have been at the forefront of efforts to improve the understanding and use of biomarkers in cancer detection and treatment, driving forward initiatives that have the potential to transform patient outcomes worldwide.

Email: sergio.calleja@kience.com

### **Notes/Comments**

Presenting author details

Full name: Sergio J Calleja

Contact number: +34 620 309 808

Twitter account: None

Linked In account: <https://www.linkedin.com/in/sergio-calleja/>

Session name/ number:

Category: Poster presentation