

# **An innovative evidence-based laboratory medicine (EBLM) test to help doctors in the assessment of the pancreatic endocrine function**

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

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

**José Diego Santotoribio Camacho, PhD, Hospital Universitario Puerto Real, Cádiz, Spain**

## **Background-aim**

To develop a novel non-invasive, evidence-based laboratory medicine (EBLM) test to assist doctors in assessing the pancreatic endocrine function and to evaluate its accuracy in detecting the main pancreatic endocrine diseases, such as insulin resistance (IR), prediabetes, and type 2 diabetes mellitus (DM2), as well as the 7.5-year risk of developing DM2.

## **Materials & Methods**

This study is part of a previous one already published at the European Society for Medical Oncology (ESMO) Congress 2024, which is focused on the accuracy evaluation of a novel non-invasive test for Multi-Cancer Early Detection (MCED). To develop the algorithm, several combinations of analytes were analyzed to identify the most significant groupings related to the pancreatic endocrine function. The algorithm's efficiency was then enhanced using serial and parallel approximation techniques. Its performance was trained with a dataset of 9,391 patients. 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 (Spain), using their biochemistry techniques.

## **Results**

For the RCT, the sensitivity achieved was 1.00 and the specificity was 1.00. Additionally, 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. This indicates a strong correlation between the algorithm outcomes and the high likelihood of having pancreatic endocrine diseases, something very important with the global obesity epidemic, a primary risk factor for them.

## **Conclusions**

This innovative non-invasive blood and urine-based biomarker algorithm holds promise in helping doctors in providing timely and accurate assessment of pancreatic endocrine diseases—even in early stages—, as well as reduce medical errors or misdiagnoses. These results advocate further exploration, prompting our intention to conduct a new RCT involving 26,000 participants.