



## **An Innovative Evidence-Based Laboratory Medicine (EBLM) Test to Help Doctors in the Screening of Hepatocellular Carcinoma (HCC)**

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### **Background**

Hepatocellular carcinoma (HCC) accounts for 75-85% of liver malignancies and ranks as the 3rd leading cause of cancer-related mortality globally. Unfortunately, HCC often presents at advanced stages, posing significant challenges for treatment and management.

Thus, we present Venient Sx Liver Basic (HCC) (Kience Inc., Wilmington, US) a novel non-invasive test for primary liver cancer early detection. This diagnostic tool aims to accurately detect HCC, even in early stages, before symptoms appear and when treatment is most likely to succeed.

### **Methods**

Venient Sx Liver Basic (HCC) is designed specifically around serum and urine biomarkers for HCC diagnosis. It is primarily based on the GALAD, GALAD-C, GALADUS, GAAD and GAAP scores, a set of independent algorithms that estimate the likelihood of HCC in patients with chronic liver disease. Key biomarkers incorporated into our test encompass alpha-fetoprotein (AFP), AFP-L3, protein induced by vitamin K absence or antagonist-II (PIVKA-II).

# kience

To assess the estimated accuracy of our test, we conducted an extensive literature review of diagnostic accuracy studies about constituent algorithms, calculations, and combinations of analytes included within it.

Thereafter, we conducted parallel approximations to optimize overall sensitivity (Se), followed by serial approximations to enhance specificity (Sp), a process performed by our own machine learning (ML) algorithm.

## Results

We obtained a final sample size (n) of 4,581 individuals and achieved a Se of 0.94 and a Sp 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 0.95, 0.96, and 0.94, respectively.

## Conclusions

This data suggests that the innovative non-invasive blood and urine-based biomarker algorithm, Venient Sx Liver Basic (HCC), holds promise in providing timely HCC screening, particularly among individuals aged 40 and above.

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