

PRODUCT

A saliva-based diagnostic assay.

INDICATION

Diagnostic test for HCC.

VALUE PROPOSITION

- Early detection of HCC with higher sensitivity and specificity resulting in better clinical outcomes.
- Differentiates between HCC and cirrhosis.
- Home-based sample collection

DEVELOPMENT STAGE

Validated in patient/healthy samples.

INTELLECTUAL PROPERTY PCT/US2022/028612 PCT/US22/15365

RELATED PUBLICATIONS

Hershberger, C.E., et al. (2021). Salivary Metabolites...Promising Non-Invasive Biomarkers...Chronic Liver Disease. <u>Liver cancer</u> <u>international, 2(2), 33-44</u>.

Miller-Atkins, G., et al. (2020). Breath Metabolics...Non-Invasive Approach for Screening ... <u>Hepatology communications, 4(7),</u> <u>1041-1055</u>.

CONTACT INFORMATION

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Saliva-based Diagnostic for Hepatocellular Carcinoma

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OPPORTUNITY

Liver cancer is a leading cause of cancer deaths, and hepatocellular carcinoma (HCC) accounts for 80% of primary liver cancers. Early detection drastically improves HCC survival. Current HCC screening tools, such as alpha-fetoprotein (AFP), lack prognostic and diagnostic value (40–64% sensitivity), resulting in false negative test results. Other methods, such as imaging (ultrasound) and blood testing to detect AFP, are also not adequately sensitive (40-64%). Therefore, there is an urgent need to develop highly sensitive and specific methods to detect hepatocellular carcinoma.

PRODUCT

Researchers at Cleveland Clinic have developed two saliva-based diagnostic tests for HCC. One uses a panel of microRNAs (miRNAs), and the other uses a panel of metabolites with both providing a direct correlation with HCC with improved accuracy over currently available methods. miRNAs in saliva have previously been associated with oral, lung, and breast cancers, but not for HCC. Because saliva collection is non-invasive, and both metabolites and miRNAs are stable at room temperature, sample collection can occur in the home with samples mailed to diagnostic labs.

- miRNA assay HCC was predicted with a sensitivity of 95% and specificity of 90%
- Metabolite assay HCC was predicted with a sensitivity of 86% and specificity of 93%



Fig 1A: Four metabolites – acetophenone, octadecanol, lauric acid, 3-hydroxybutyric acid – were significantly different between two or more groups. Acetophenone was significantly different in all three pair-wise comparisons: Compared to healthy individuals, it was significantly decreased in patients with cirrhosis and significantly decreased further in patients with HCC.