

CELL-FREE TECHNOLOGY FOR DETECTING CANCER

A NEW SCREENING PLATFORM developed by Genetron Health can identify the early markers of cancer

In the global fight against cancer, tools for early detection are critical to reducing death rates and achieving better patient outcomes. Genetron Health, an emerging precision oncology firm in China, has developed a cell-free screening platform that is capable of detecting the biological changes associated with the early stages of cancer.

AT THE PUSH OF A BUTTON

Unlike technologies that only detect a subset of alterations, Genetron Health's Mutation Capsule Technology can identify a broad spectrum of circulating tumour cell-released DNA (ctDNA) alterations in a blood sample, such as single nucleotide variants, gene insertions or deletions, complicated mutations like translocations, viral genome integration, as well as DNA methylation.

The genetic and epigenetic alterations in cell-free DNA (cfDNA) are barcoded, amplified and stored in the Mutation Capsule library, which can support 10 tests

without sacrificing sensitivity like dividing a single cfDNA sample into multiple reactions. In each test, different panels of biomarkers such as mutation and methylation can be profiled in one reaction. With the Mutation Capsule technology, a blood sample can be further used to profile new biomarkers which would help save the time and cost of sample collection.

MUTATION CAPSULE PRODUCES A SYSTEMIC CANCER MOLECULAR PROFILE

IDENTIFYING EARLY MARKERS OF LIVER CANCER

Liver cancer is the fourth-most common cause of cancer-related deaths and the sixth-most common in terms of incidence. Timely intervention, such as the removal of early-stage tumours, increase an individual's chance of survival significantly.

Mutation Capsule can read out the integration of the hepatitis B virus (HBV)

gene in a fraction of human gene sequences, as well as the copy-number of the HBV gene, which provides an important piece of information for the early detection of liver cancer. Mutation Capsule also checks other mutations and methylation changes and produces a systemic cancer molecular profile. This data is used to generate an algorithm to differentiate cancer-containing samples.

Based on Mutation Capsule, Genetron Health has developed a blood-based early screening test called HCCscreen™, which is capable of detecting the biological changes that are associated with hepatocellular carcinoma (HCC), the most common tumour type of early liver cancer. Unlike traditional screening technologies that focus on DNA mutations, HCCscreen™ simultaneously detects both DNA mutations and DNA methylation changes.

DETECTING SMALL TUMOURS

Unlike conventional diagnosis methods that often require biopsies, HCCscreen™ only

needs a blood sample to detect ctDNA which indicates the presence of a tumour. As such, many HCC patients can be identified at a stage when the surgical removal of smaller tumours could prevent further deterioration. The platform has also been tested in groups of patients, such as those with hepatitis B viral infection, who are at high-risk of liver cancer.

"The ability to detect small-size tumours is an advantage in early prediction because patients may not be able to notice change to the symptoms associated with small liver tumours," says Yunfu Hu, chief medical officer at Genetron Health.

SCREENING INITIATIVES

In 2020, the U.S. Food and Drug Administration recognized HCCscreen™ as a 'Breakthrough Device' for the early detection of hepatocellular carcinoma in people as at high risk for HCC due to chronic HBV infection and/or liver cirrhosis. The FDA's Breakthrough Device Program is designed to accelerate the



A researcher performing nucleic acid quality inspection in Genetron Health's Beijing laboratory. The laboratory has obtained CAP, CLIA, and ISO 15189 certifications.



approval process for novel devices that treat or diagnose life-threatening or irreversibly debilitating diseases or conditions.

In China, HCCscreen™ has been adopted by a public health initiative in Wuxi for large-scale, early liver cancer

screening and prevention, under the supervision of the China Cancer Center. In this project, HCCscreen™ will be used in 150,000 tests across local communities in Wuxi over the next three years.

Currently, Genetron Health is the only company in China

participating in national key research and development projects for the early screening of liver, lung, and digestive cancers.

"We believe that our precision oncology product will provide enormous social and economic benefits," says Hu. ■

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