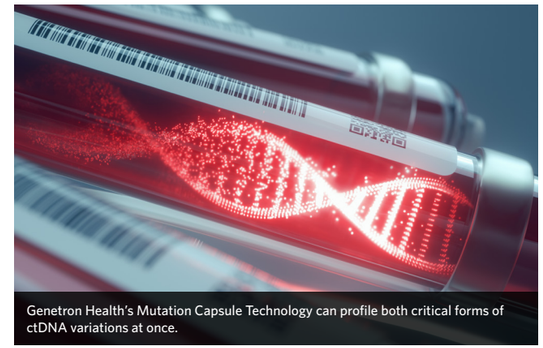
ADVERTISEMENT FEATURE

Leading advances in precision oncology

Diagnostic tools developed by Genetron Health AIM TO REDUCE TUMOUR RECURRENCE.

Performing nucleic acid quality inspection in Genetron Health's Beijing laboratory.



Genetron Health's Mutation Capsule Technology can profile both critical forms of ctDNA variations at once.

Genetron Health's Beijing laboratory is Clinical Laboratory Improvement Amendments (CLIA) certified, accredited by the College of American Pathologists (CAP), as well as ISO 15189:2012 for medical laboratory quality and competence.

Just a small number of drug-resistant cancer cells left in the body after treatment can trigger tumour recurrence. Known as minimal residual disease (MRD), these cells might not cause symptoms, and are typically not detectable through a microscope, or via imaging scans. A global team at Genetron Health, a precision oncology platform company, established in 2015, is tackling MRD.

"We are committed to improving access to precision oncology in three areas: products and services, technology research and development, and the initiation of new concepts," says Sizhen Wang, Genetron Health's co-founder and CEO. "We have also witnessed a strong demand for companion diagnostics (CDx) in China, and government policies to raise awareness about enhanced cancer diagnosis capabilities, such as the National Health Commission's Oncology Diagnosis and Treatment Quality Improvement Action Plan, as well as the National Medical Products Administration's increasing focus on genomic testing for targeted immunotherapies."

These resonate with Genetron Health's goal to harness advanced technologies for molecular profiling and data science to cover the spectrum of cancer management, from early screening and diagnosis, to continuous monitoring and follow-up care.

"A prominent research and development priority at Genetron Health is to spot relapse as early as possible to improve patient outcomes," says Yun-Fu Hu, Genetron Health's chief medical officer, and a former deputy division director at the US Food and Drug Administration (FDA). During his tenure at the FDA, Hu led a team of staff in premarket reviews and post-market compliance of in vitro diagnostic (IVD) products and laboratory-developed tests for cancer diagnostics including CDx.

KEEPING TRACK OF RESIDUAL CANCER CELLS

Solid tumours account for 90% of all tumours, so there's a great need for MRD detection. As Hu explains, a new MRD detection approach is to test for circulating tumour-derived DNA (ctDNA), or the DNA fragments released from tumour cells into circulating blood.

"This approach has been shown to be effective for liquid or haematological tumour MRD, in which tumour cells or their DNA in bone marrow or peripheral blood samples can be directly detected."

Several obstacles have to be overcome, however, to reach testing efficiencies good enough for solid tumours, explains Hu. "The biggest challenge for detecting solid tumour MRD is that the amount of ctDNA in the blood is so low, and there are so many potential biomarkers to read in order to determine whether or not a patient has MRD."

Compared to many technologies currently in the market, which can only detect either mutations or DNA methylations in a blood sample. Genetron Health's Mutation Capsule Technology can profile both of these critical forms of ctDNA variations in parallel, requiring just one blood sample for both. It allows various genetic alterations in a ctDNA sample to be amplified and stored in a library for up to 10 assays, saving time and money.

Tumour-informed assays for personalized ctDNA detection and analysis can then be easily designed based on sequencing of a patient's tumour tissue to identify a set of specific mutations, methylations and other genetic variations.

In addition to this personalized strategy with high sample coverage and mutation detection rate, Genetron Health is also developing non-personalized universal assays to provide patients with an option of lower cost and more rapid results. The development and improvement of universal assays is largely dependent on the Mutation Capsule Technology's ability to directly compare between multiple MRD strategies.

SIMPLIFYING SAMPLING PROCESS

Genetron Health also optimizes current clinical diagnostic tools, such as Seq-MRD® for haematological cancers. Using the proprietary One-Step Seq Method and fully automated bioinformatics solutions, Seq-MRD® extracts and amplifies DNA to construct a DNA library with a single PCR reaction for high-throughput sequencing and analysis.

"It basically simplifies procedures to benefit both lab technicians and patients," says Hu. "For other traditional detection methods, you have to open the tubes multiple times to complete the complex sequencing processes, thus allowing opportunity for cross-sample contaminations, especially from pre-treatment samples that contain significantly higher amounts of DNA sequences that are used to track MRD in subsequent samples. The likelihood of sample contamination is much lower with our One-step Seq."

This simpler method brings greater accuracy, lower cost and more rapid results. Seq-MRD® reduces the overall DNA-to-library time to 1.5 hours, compared with 8-24 hours with other methods.

Hu suggests that many technologies claiming to reach 100% specificity were based on regionalized small sample data, and may not fit the broader population. "To be patient-centric and data-driven, we have invested deeply in analytical validation and clinical studies to make sure our products perform as intended," he says.

Notably, Seq-MRD® has been tested with thousands of samples from patients in China with acute lymphoblastic leukaemia (ALL), multiple myeloma (MM), and chronic lymphoid leukaemia (CLL). The performance of Seq-MRD® was also validated in vitro and showed promising results for detecting MRD in B-lymphoid malignancies.

BENEFITING THE WIDER PUBLIC

Hu says the next big step is for Genetron Health to optimize these technologies for various clinical applications, and reduce the cost to make its products accessible to the wider public. It plans to partner with AstraZeneca to further develop its tumour-informed MRD assay for solid tumours, and with Jiangsu Fosun Pharma, to commercialize Seq-MRD®.

Other products in its full-cycle cancer management strategy include the development of a blood-based early screening test for liver cancer called HCCscreen™ based on Mutation Capsule technology, which was recognized in the FDA's Breakthrough Device programme in 2020. ■

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ANSWERS FOR CANCER

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