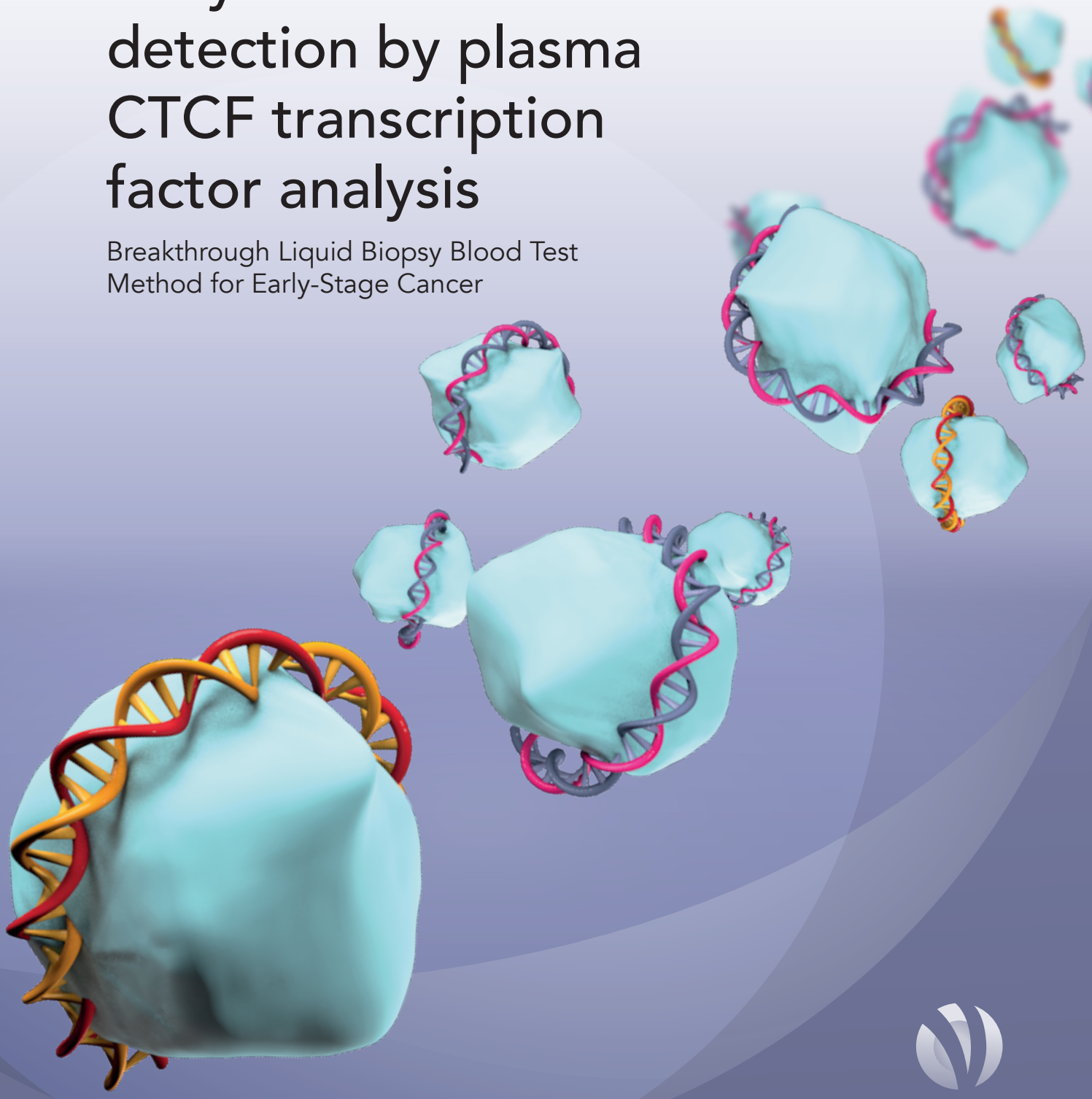
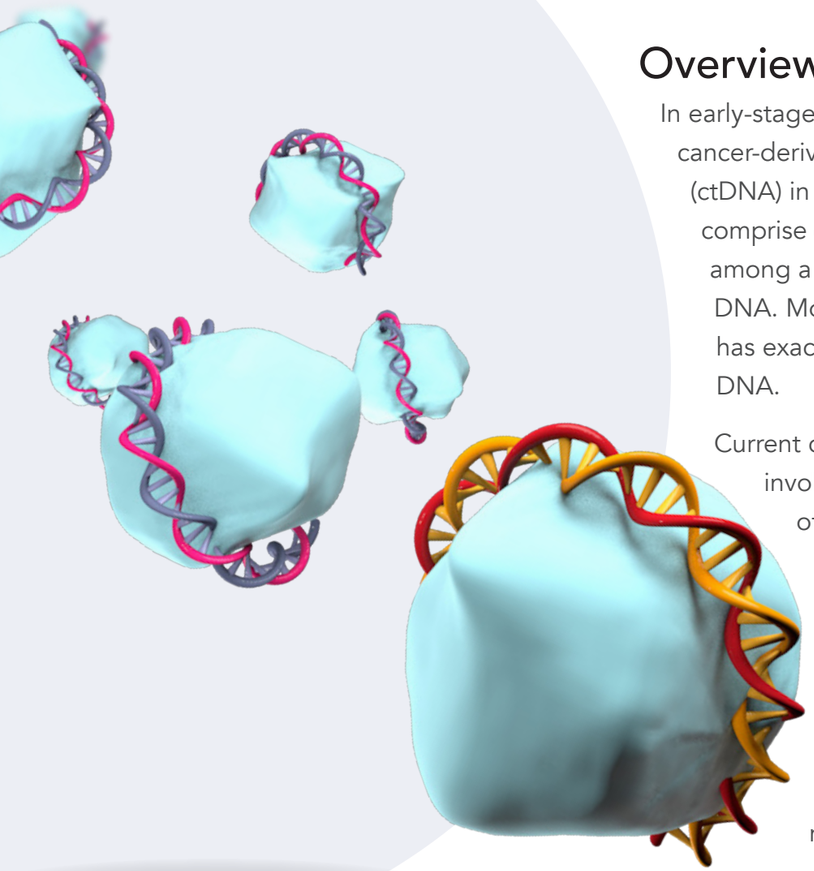
capture pcr

Early cancer detection by plasma CTCF transcription factor analysis

Breakthrough Liquid Biopsy Blood Test Method for Early-Stage Cancer



Volition



Overview.

In early-stage cancer, it is difficult to detect cancer-derived circulating tumor DNA (ctDNA) in the blood because it may comprise only 0.01% of the DNA present among a background of 99.99% normal DNA. Moreover, most of the cancer DNA has exactly the same sequence as normal DNA.

Current ctDNA detection methods involve DNA extraction, sequencing of all (cancer and normal) circulating DNA and analysis of the sequencing data using sophisticated computer bioinformatics to tell them apart. Physical separation of tumor-derived and healthy circulating DNA has previously never been reported.

Our solution.

We have developed a novel method for liquid biopsy involving the first reported physical isolation of a class of tumor-derived ctDNA fragments from blood. Cancer-derived ctDNA fragments are then extracted after removal of all normal background DNA of the same sequence for detection with a simple, low cost PCR test. Our breakthrough method obviates expensive, time-consuming DNA sequencing and bioinformatics - allowing for rapid, cost-effective detection in a routine blood test. It may also be suitable for automation, enabling application in hospital laboratories.

Fast

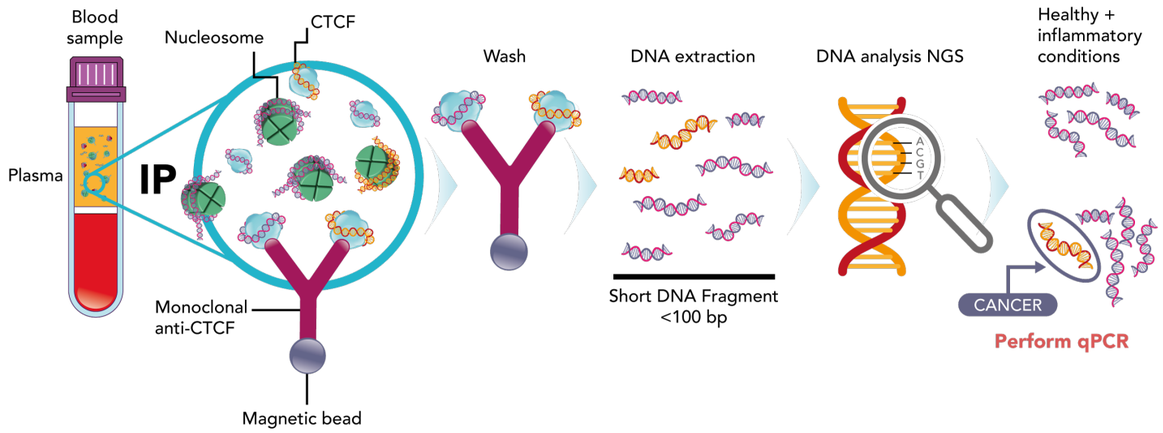
Cost-effective

Routine blood test

Workflow.

Based on over a decade of work on the chemistry of circulating chromatin fragments, we have developed a transformational wet chemistry pathway that identifies and physically isolates chromatin fragments that we know are tumor-derived from background DNA of the same sequence, using Chromatin Immunoprecipitation (ChIP).

Quantitative real-time PCR (qPCR) testing is undertaken to establish whether cancer is present.



Application.

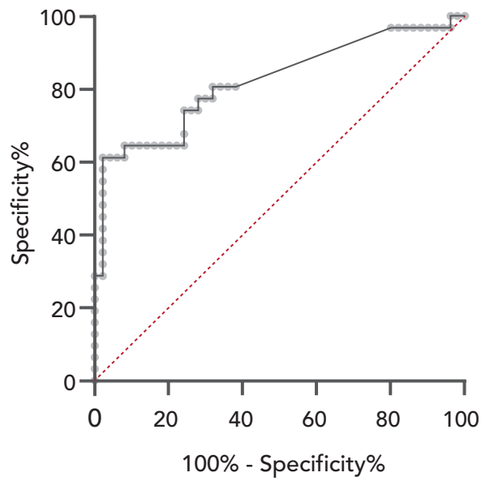
We tested the new method in a first small clinical experiment and detected a range of liquid and solid cancers, including at early-stage I disease.

74% of leukemias were detected at **96%** specificity with a single q-PCR assay

77% of colorectal cancers were detected at **92%** specificity with 2-qPCR assays.

These early assays were developed using a leukemia model, but surprisingly also detected many other cancers including detecting colorectal cancer in a blood test with an accuracy approaching that of current Fecal Immunochemical Tests (FIT).

ROC curve: Leukaemia (single qPCR assay)



Solid cancers	patients	positive	sensitivity
CRC	13	10	77%
Breast	10	4	40%
Prostate	10	7	70%
Liver	10	7	70%
Total	43	28	65%

Solid cancers	patients	positive	sensitivity
Stage I	9	4	44%
Stage II	9	3	33%
Stage III	9	6	67%
Stage IV	16	12	75%
Total	43	25	58%

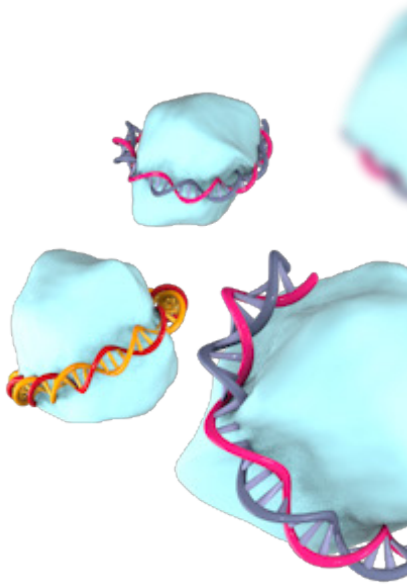
capture pcr

Next steps.

Results to date are exciting and may pave the way for a whole new class of undiscovered biomarkers.

We are now developing a range of cancer-specific assays which we expect to be more accurate and look forward to sharing our progress throughout 2024 and beyond.

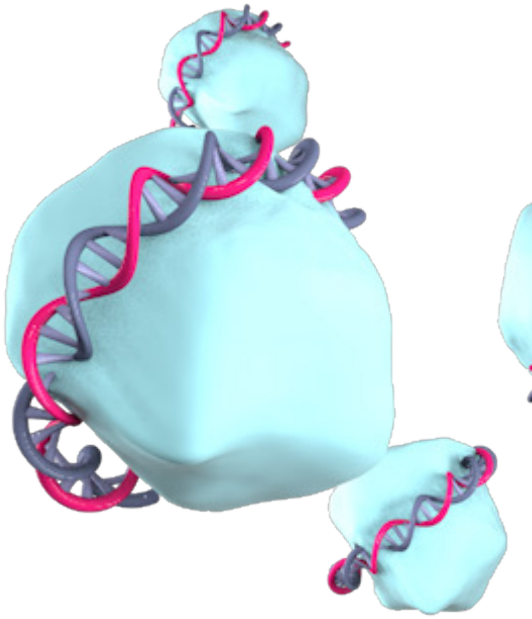
Our commercial strategy is to license this proprietary technology to industry leaders.

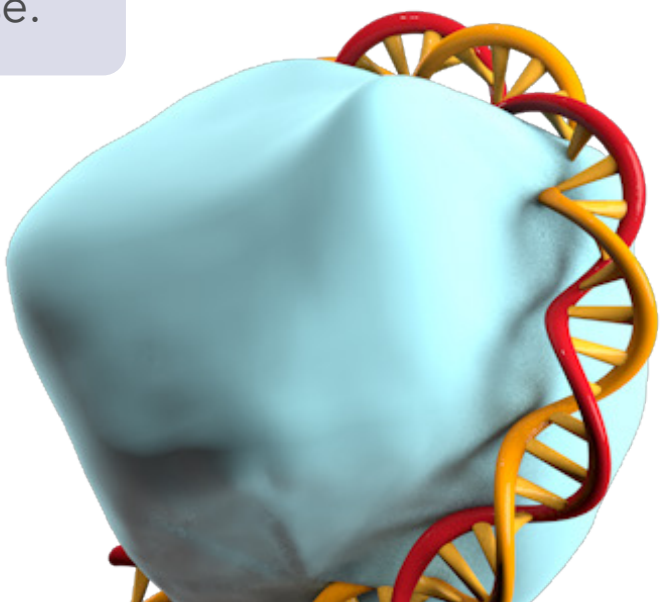


Testimonial.

Dr Jake Micallef, Chief Scientific Officer, VolitionRx said:

"Capture PCR, our novel CTCF-ChIP/qPCR method shows great promise for the accurate, rapid, low-cost detection of cancer. Because the test is simple, it can be processed in any hospital laboratory and may be suitable for automation. Capture PCR has the potential to reach the high levels of sensitivity and specificity required to detect cancer at early-stage disease. "





Speak to our commercial team

sales@volition.com.

https://volition.com

Date of production: September 2024