Aspect
Liquid Biopsy





REVOLUTIONARY CANCER cfDNA BIOMARKERS DETECTION IN A SIMPLE BLOOD TEST

NON-INVASIVE | PAIN FREE | INNOVATIVE

Aspect Liquid Biopsy guides treatment decisions by detecting cfDNA biomarkers in real-time through an innovative yet simple blood test.

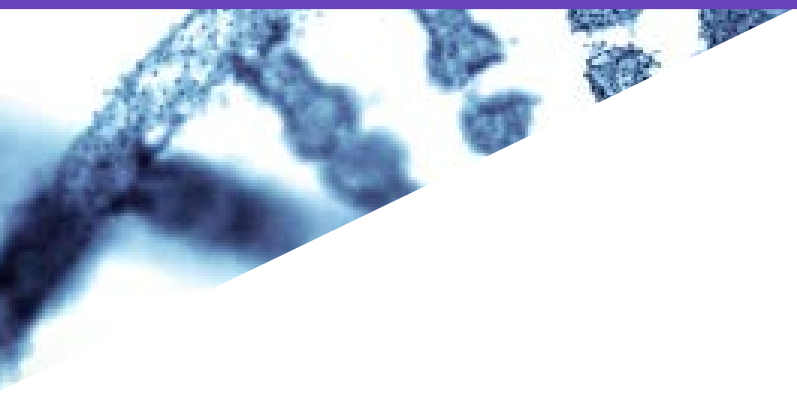
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Aspect
Liquid Biopsy

MINIMALLY-INVASIVE
HIGHLY SENSITIVE
RELIABLE, TIMELY RESULTS
REAL-TIME MONITORING
SERIAL ASSESSMENT
DETECTION OF EARLY CANCER RELAPSES
GUIDANCE TO THE MOST EFFECTIVE TREATMENT OPTIONS

Australian Clinical Labs is proud to be the first national private laboratory in Australia to introduce the innovation of liquid biopsy. Aspect Liquid Biopsy, is a simple blood test that can be used to non-invasively detect cancer genetic alterations, monitor responses to treatment and help explain why some cancers are resistant to therapies using advanced technology. Liquid biopsy will assist clinicians toward treatment decisions.



Cancer is a Genetic Disease

Cancer, a leading cause of mortality, is associated with mutated genes. Analysis of tumour associated genetic alterations is increasingly used for diagnostic, prognostic and treatment purposes. Precision or Personalised Medicine harnesses genomic knowledge banks to tailor individualised treatments based on patients' or their tumours' genetic signatures.

Somatic Mutation in Solid Cancer Tumours

A high-quality genomic analysis is critical for personalised pharmacotherapy in patients with cancer. Identifying activated therapeutic gene targets (e.g., *BRAF* in melanoma, *EGFR* in lung cancer and *KRAS* in colorectal cancer) with established cancer associations using focused panels for targeted cancer sequencing, allows for deeper coverage of those genes and higher sensitivity to confidently call rare variants (e.g., *PTEN* and *KIT*) in rare tumour subclones, including FFPE tissue. The advent of therapies targeting genomic alterations has improved the care of patients with certain types of cancer dramatically. Thus, elucidating the genetic profile of a given tumour is potentially useful in designing tailored treatment regimens that avoid unnecessary toxic therapy.



Liquid Biopsy

The genetic profile of solid tumours is currently obtained from surgical or biopsy specimens; however, performing biopsies, particularly in lung cancer, is not always possible in advanced disease stages and is associated with potential complications. Also, information acquired from a single biopsy provides a limited snap-shot of a tumour and might fail to reflect its true genetic and cellular heterogeneity.

While molecular targets were initially detected in nucleic acid samples extracted from tumour solid tissues, detection of circulating nucleic acids in blood has enabled the development of what has become known as “liquid biopsy”.

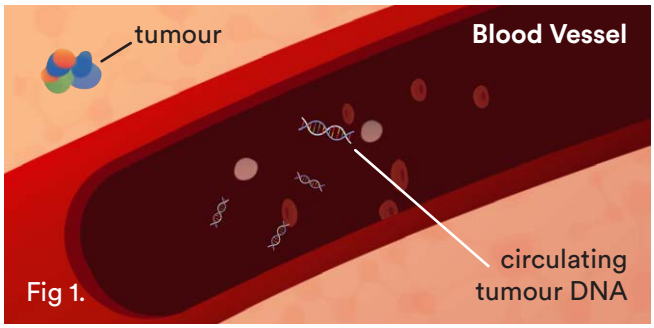


Fig 1.

Certain fragments of DNA, cell-free DNA (cfDNA), have been shown to be elevated in the plasma of patients with cancer. This increase is the result of the rapid turnover of cells within the tumour, releasing DNA into the circulation[1] (see Fig. 1). With new highly sensitive technologies, cell-free circulating DNA can now be isolated and analysed. cfDNA analysis can complement and in many instances correlate to solid tissue biopsies[3,4] for real-time molecular monitoring of treatment, detection of recurrence, and tracking resistance. Circulating tumour DNA (ctDNA) reflects the overall tumour information, and is not biased by analysing only a small fraction of the tumour and is always accessible in contrast to the lung cancer tissue.

Implementation of Aspect Liquid Biopsy

Clinical Labs has validated a comprehensive mutation profiling assay for clinical oncology patients using circulating tumour derived DNA extracted from blood.

Our technology, including Next Generation Sequencing (NGS), Mass Array Agena Biosciences ULTRASeek and Digital PCR, is able to identify clinically relevant variants at a sensitivity down to <0.5% or less.



Aspect Liquid Biopsy is Less Invasive

Surgical tissue biopsies have some inherent shortcomings and risks, as well as not guaranteeing enough material collected for accurate analysis in clinical practice. Liquid biopsy provides a non-invasive alternative sample source, allowing the identification of genomic alterations that can be addressed by targeted therapy. This non-invasive type of liquid biopsy can be taken easily and repeatedly over the course of a patient’s treatment. ctDNA provides new insight into diagnosis, prognosis and patient follow-up compared to traditional tissue biopsy.

The Quality Choice for Cancer Monitoring

Early detection is the holy grail of cancer management. The biggest advantage of liquid biopsy is to detect the cancer biomarkers in blood earlier than conventional methods. It has been demonstrated that monitoring for tumour-derived DNA in the plasma can identify relapse or drug resistance well before clinical signs and symptoms appear, enabling earlier intervention and better outcomes.

In the future, instead of extensive imaging and invasive tissue biopsies, employing ctDNA as liquid biopsies could be used to guide cancer treatment decisions and perhaps even screen for tumours that are not yet visible on imaging.

Over the past several years there have been multiple studies demonstrating the clinical utility of liquid biopsy ctDNA analysis following surgical resection of colorectal cancers (CRCs)[7]. Most studies demonstrate better outcomes when no tumour-derived DNA is found in patients following surgery, or chemotherapy in colorectal cancer patients[7] whereas those where tumour DNA is still present do better with the addition of more aggressive targeted treatment or chemotherapy.



Australian Clinical Labs is proud to assist clinicians using advanced technology and a Personalised Medicine approach. We combine knowledge with high-throughput sequencing technology to improve our diagnostic accuracy and patient outcomes.

Aspect Liquid Biopsy Guides Treatment Decisions

Liquid biopsy can offer valuable insights into how best to treat cancer. ctDNA can be used to monitor the effects of cancer treatment and give an early warning about possible recurrence. The detection of resistant clones can offer clues to the reasons for treatment resistance[5,6] (see Fig.2). Recently, a third-generation *EGFR* Tyrosine Kinase Inhibitor *(TKI)*, that is effective in tumours harbouring the T790M *EGFR* mutation (~50-60% of lung cancer patients[5,6,10]), was approved in Australia for patients with NSCLC harbouring the *EGFR* T790M mutation following progression on an *EGFR* TKI[9]. Serial analysis of ctDNA from the time of diagnosis throughout treatment can provide a dynamic picture of molecular disease changes, providing evidence that this non-invasive approach could also be used to monitor the development of secondary resistance and identify heterogeneous sub-clonal populations of tumour cells developing during the course of treatment. NCCN guidelines[8] recommend the use of liquid biopsy for lung cancer patients as an alternate for tissue in initial T790M *EGFR* testing[2,6]. However, if the plasma is negative, then a tissue biopsy is recommended, if feasible.

Clinical application of liquid biopsies to inform molecular-based risk stratification and guide therapeutic intervention strategies may help reduce morbidity, increased waiting times, and overall costs, particularly for cancers where obtaining repeated tumour biopsies is challenging or unsafe. Further research is ongoing to explore the clinical applicability for ctDNA in oncology. Indeed, ctDNA holds great promise to fundamentally change how we approach patient treatment and clinical management.

Tumour Progression

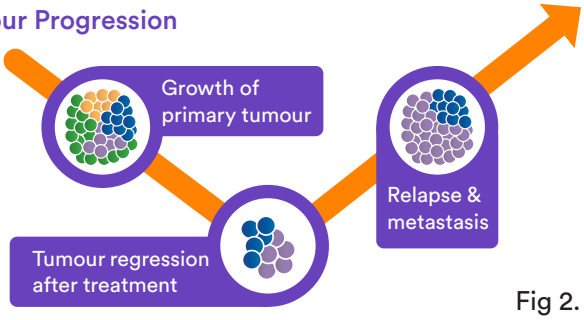


Fig 2.

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"A Personalised Medicine approach in cancer care is not new. What is new, however, is our ability to predict cancer recurrence based on the differences between individuals at molecular levels. This means that we can sub-group, or sub-stratify patients in a more meaningful way, with the potential to modify therapeutic regimes to match their individual genetic profile."

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Associate Professor Mirette Saad is a Consultant Chemical Pathologist and the National Clinical Director of Molecular Genetic Pathology at Australian Clinical Labs. Associate Professor Saad's PhD research allowed her to gain unique experience in a wide range of biochemical, molecular genetics and cancer targeting; having published several articles both locally and internationally. At Clinical Labs, Assoc. Prof Mirette Saad leads the Molecular Genetic testing for hereditary disorders, personalised drug therapy, somatic mutation and gene expression profile testing in cancer.

How to order

Health Practitioners can order Aspect Liquid Biopsy for cancer patients using the Aspect request form. Some required information is listed on the form, including type of cancer and whether it is a new diagnosis and if the patient is on anti-tumour therapy (if known). Health Practitioners can download the Aspect Liquid Biopsy form on the Clinical Labs website at clinicallabs.com.au/aspect

When should it be ordered?

Health Practitioners can order liquid Biopsy for cancer patients any time during diagnosis or monitoring stages.

What is the cost?

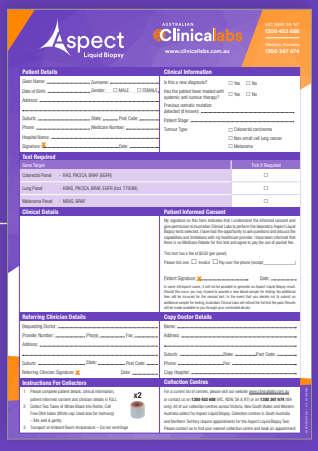
Please visit clinicallabs.com.au/aspect for current pricing. No Medicare rebate available.

When will results be available?

Results will be available after 5-7 business days from the sample receipt date.

How is it collected?

This test requires two 10ml blood samples which can be taken at any of our collection centres.



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Liquid Biopsy

The word *aspect* is defined as a unique view of perspective. Through Aspect Liquid Biopsy, we can offer an unprecedented view of the genetic signatures of cancer relapse, allowing clinicans to catch it early and make the most effective treatment decisions.

Advanced Technology

Highly Sensitive and Specific Assay

Expertise in Diagnostic Oncology

Accurate and Comprehensive Reports

High-Quality, Personalised Cancer Care

Rapid Turnaround Time

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