Biofidelity.

Every day matters for people with lung cancer

Biofidelity's ASPYRE-Lung assay gets the answers for patients faster than ever before

A new era of lung cancer treatment

Lung cancer is the leading cause of cancer mortality worldwide and the third most common cancer in the United States, accounting for around 235,000 new cases and 131,000 deaths in the US every year.[1,2]

Twenty-five years ago, chemotherapy was the sole therapy we could offer people with lung cancer. Chemotherapy is renowned for its potentially life-threatening and unpleasant side effects, which can cause distress for patients and their families. Additionally, efficacy rates for chemotherapy in lung cancer are often low, resulting in five-year survival rates of around 5-10% for those with advanced disease.[3]

In recent years, the shift towards precision medicine has drastically changed the outlook for patients with lung cancer. New therapeutics have been approved that are designed to target specific mutations within cancer cells. To find the right treatment for each individual patient, a tissue or blood sample must be tested for actionable biomarkers that have been shown to respond to targeted therapies. Once the most appropriate treatment is identified, it is likely to be more effective than chemotherapy and cause fewer harmful side effects.

As a result of these new therapies, the outlook for people living with lung cancer has dramatically improved.

1. Sung et al (2021) CA Cancer J Clin 71: 209 doi:10.3322/caac.21660
2. American Cancer Society - Lung cancer statistics
3. American Cancer Society - Lung cancer survival rates

Lengthy waits for biomarker test results are blocking access to targeted therapies

The patient's journey from diagnosis to starting treatment can be long and complex. Initially, a biopsy is performed that provides a tissue sample for the pathologist to determine a definitive diagnosis and stage of disease. Then, if there is enough tissue remaining, it may be used for molecular testing. Once the results are returned and reviewed by an oncologist, the best treatment option can finally be prescribed.

While there are many targeted therapies available for people with lung cancer, delivering on the promise of personalized medicine relies on access to timely and accurate information about the biomarkers present in a tumor.

Many patients wait five weeks or more after their initial diagnosis for the results of biomarker testing in order to begin therapy and benefit from these advances. One of the most significant contributors to the delay in identifying the best treatment option for cancer patients is the time it takes to get results back from biomarker testing.

Every year in the USA

235,000

new cases of lung cancer are diagnosed.

Patients can wait up to around

5 weeks

before starting targeted therapies.

> "Every patient should have the opportunity to benefit from new therapies that could significantly improve their chances of survival, while minimizing side effects. It's heartbreaking that many patients are still missing out."

Wendy J. Levin MD MS
Chief Medical Officer, Biofidelity

Results from NGS genomic testing can take weeks

In-depth genomic testing usually involves using next-generation sequencing (NGS). Although NGS testing can provide valuable information about targeted treatment options, it also contributes significantly to delays.

Firstly, NGS requires a relatively large tissue sample, which may require a repeat biopsy to get enough tissue for sequencing. Nearly half of lung cancer patients experience multiple biopsies prior to diagnosis and treatment,[4] adding pain, stress, safety issues and further delays.

The process of NGS itself then takes weeks to complete and return the results.The high cost of NGS can be an additional barrier, and may require pre-authorization by the patient's insurer, adding more time to the process.

Finally, interpreting the results of NGS genomic testing can be challenging. Reports are lengthy and complex, providing an overwhelming amount of detailed genomic information. Furthermore, a significant number of reported mutations are not actionable, requiring further research and time to uncover other treatments or clinical trials that might be suitable.

The best way to break down the barriers to identifying treatment options is to cut the cost and shorten the time required to obtain an actionable biomarker test result.

4. Zhang el al (2020) Lung Cancer Management 9:4 doi: 10.2217/lmt-2020-0022

PCR is not the answer to rapid biomarker testing

PCR-based biomarker testing is less costly than NGS, and because the technology is easily accessible and often available in local facilities it can provide faster results. Unfortunately, PCR is limited by low sensitivity and poor scalability, making it unsuitable to the requirements of precision oncology.

While several multiplexed PCR lung cancer assays are already available, the number of mutations you can look for with PCR in each analysis is very limited. As a result, multiple rounds of PCR must be conducted to obtain all necessary data, looking at different sets of mutations in multiple PCR runs, before obtaining a comprehensive result. For example, the first round of testing may look for EGFR mutations, before analysing ALK mutations in the second, and so on.

With each round of testing, the costs and waiting time continue to add up. And because PCR is not very sensitive, each assay requires a relatively large amount of tissue, quickly using up precious biopsy samples.

Despite its promising appearance, it's clear that PCR is not the answer for reducing the time from diagnosis to definitive treatment plan.

Long waiting times are devastating for patients

Long waiting times between diagnosis and treatment are extremely challenging for patients and their families. People often feel more comfortable with a devastating diagnosis if they know there is a plan to treat their cancer and they can begin therapy immediately. The longer the delay, the greater the anxiety and suffering the patient must endure - a barrier to better care that must be broken down.

While the patient is waiting, their cancer may be progressing and their prognosis worsening with each day that passes. Rather than wait, many patients are started on less effective and poorly tolerated chemotherapy to halt or minimize the progression of their disease.

However, because of the low efficacy rates of chemotherapy, this strategy may be ineffective. Additionally, it exposes patients to avoidable side effects, making the wait even more unbearable.

> "Just like no two fingerprints are exactly alike, no two patients' cancers are exactly the same. Receiving the best treatment involves ensuring a patient gets appropriate tests that inform the most effective treatment option available for their specific cancer. Sadly, fewer than 50% of patients in the US who could benefit from targeted therapy receive the testing needed. To significantly improve cancer treatment outcomes, more patients need to have access to testing at the time of diagnosis before they start treatment and, when appropriate, throughout their treatment."

Andrea Connors
Executive Director, Patient Empowerment Network

ASPYRE-Lung - the new alternative to NGS and PCR

Biofidelity's ASPYRE-Lung assay is a precision molecular diagnostic test for lung cancer that offers a faster alternative to NGS and PCR, delivered through our Clinical Laboratory Improvement Amendments (CLIA) certified lab in North Carolina, US.

ASPYRE is an entirely new way of detecting mutations that is ultra-sensitive, actionable, cost effective and returns comprehensive results in as little as one day. It can be carried out on tumor or liquid biopsy (blood) samples, offering a route for biomarker testing in cases where there is little tissue available.

Our proprietary ASPYRE technology works in a completely different way to PCR or NGS. We use a panel of carefully designed probes in combination with a highly specific chemical reaction that picks out and amplifies specific mutations with pinpoint accuracy.

The ASPYRE-Lung assay detects actionable mutations for precision medicine in lung cancer recommended by the NCCN and ESMO guidelines.

Learn more about how ASPYRE works

Explore our ASPYRE-Lung testing panel

ASPYRE® LUNG

ASPYRE slashes time to treatment

ASPYRE combines sensitivity, scalability, low cost, accessibility and speed, making it the ideal alternative to NGS and PCR for biomarker testing in lung cancer.

The extreme specificity of the ASPYRE reaction provides single-molecule sensitivity, with a variant allele-fraction (VAF) sensitivity of just 0.1%, meaning that you can get the answers needed from a small tissue sample. ASPYRE is so sensitive it can even detect genomic markers in blood draws, giving you an alternative to repeat biopsy if there is no remaining tumor.

Furthermore, with ASPYRE, both DNA and RNA are simultaneously tested. There is no need for repeated rounds of analysis while the clock ticks and your precious sample gets used up. Through our CLIA accredited laboratory you receive actionable information within two days of sample receipt. This enables optimal treatment plans to be determined in a timely manner for all lung cancer patients, ensuring they can benefit from the best treatment options.

This swift turnaround means that all lung cancer patients can benefit.

ASPYRE-Lung

Breaking down the barriers to optimized therapies for all

Right now, less than 50% of lung cancer patients receive the recommended biomarker testing for their disease,[5] meaning that hundreds of thousands of patients are missing out on targeted therapies that could benefit them.

ASPYRE-Lung detects over a hundred actionable markers across multiple genes in a single assay, making it more informative than PCR-based approaches, and much faster and less expensive than next-generation sequencing.

Using ASPYRE-Lung significantly reduces the time from diagnosis to treatment and eliminates the need for repeat biopsies, so patients get started on the right therapy sooner. Results are returned from our lab in a couple of days, along with an easy-to-interpret report to help you create a treatment plan in minutes, without the need for guesswork or further research.

ASPYRE-Lung provides the answers that are needed to get patients started on the treatment that's right for them, in a fraction of the time and at a fraction of the cost of current methods, improving their journey and increasing their chances of long-term survival.

5. Smeltzer et al (2020) Journal of Thoracic Oncology 15:1434 doi: 10.1016/j.jtho.2020.05.002

ASPYRE brings the benefits of precision therapy to all patients

- The ever-increasing number of new targeted therapies is improving the outlook for patients with lung cancer.
- Targeted therapies require genomic testing that identifies key mutations, indicating the best treatment for individual patients.
- NGS is widely used for genomic analysis, but is costly and can take weeks to get results.
- PCR is quicker, but is less sensitive and often requires multiple rounds to provide definitive results, increasing the waiting times and risk of running out of tumor tissue.
- Delays in targeted treatment decisions cause distress for patients and can mean they need to start chemotherapy to control their disease.
- Biofidelity's ASPYRE-lung assay is a new way to detect mutations that offers an alternative to NGS and PCR, which combines speed, low cost, sensitivity and specificity, and can be used on blood or tissue.

ASPYRE®