Biofidelity.

ASPYRE-Lung helps every patient with lung cancer get the treatment they deserve

Why aren't people with lung cancer getting the best treatment?

Everyone who is diagnosed with lung cancer deserves access to the best treatment available. There are now dozens of targeted therapies that offer improved outcomes for patients, including more than twenty for patients with non-small cell lung cancer (NSCLC). However, despite the availability of these new life-saving therapies, they aren't reaching the patients who need them.[1]

Targeted therapies rely on biomarker testing to determine which treatment is right for each individual patient. However, fewer than half of patients receive the recommended biomarker tests. Without complete biomarker testing, patients cannot access the treatments that are most likely to make a difference to their outcome.[2,3]

So what's the problem?

1. Biomarker testing takes too long.
2. Tests are expensive.
3. Results may not be clinically useful.
4. Limited to large testing centers.

Our ASPYRE-Lung testing technology breaks through all these barriers, opening up access to targeted therapies for all patients with lung cancer and giving them the best chance of survival.

1. Majeed et al (2021) Journal of Hematology and Oncology 14:108 doi: 10.1186/s13045-021-01121-2
2. Smeltzer et al (2020) Journal of Thoracic Oncology 15:1434 doi: 10.1016/j.jtho.2020.05.002
3. Gierman et al (2019) Journal of Clinical Oncology 37(suppl; abstr 1585) doi: 10.1200/JCO.2019.37.15_suppl.1585

Waiting for test results delays treatment

Lung cancer grows fast, so patients need to receive the most effective therapy as soon as possible, preferably within days of diagnosis.

However, biomarker testing with next-generation sequencing (NGS) often results in a 4-5 week delay between diagnosis and the identification of the best targeted therapy for the patient. Polymerase chain reaction (PCR) assays, although theoretically faster, can also take weeks to yield definitive results as they only test for a single gene at a time.

Because of the lack of availability of rapid, comprehensive biomarker testing, doctors often skip this testing altogether, instead prescribing toxic and less effective chemotherapies straight away rather than waiting weeks for biomarker test results.

Biofidelity's ASPYRE-Lung assay is an entirely new way of detecting clinical biomarkers for targeted therapy. It uses a panel of carefully designed probes combined with a highly specific chemical reaction that rapidly picks out and amplifies specific molecular biomarkers with pinpoint accuracy. ASPYRE-Lung tests for all the current actionable NSCLC biomarkers in a single assay, giving rapid results that enable physicians to prescribe the most appropriate personalized targeted therapy within days rather than weeks.

> "We have all these amazing new therapies, but right now we can't access the tests that allow us to get these therapies to the people who need them."

Wendy J. Levin MD MS
Chief Medical Officer, Biofidelity

Current biomarker tests require large biopsy samples

During cancer diagnosis, samples are taken from the tumor site. Surgical biopsy techniques are designed to be as non-invasive as possible, but this can mean that samples are often very small.

Biomarker testing performed using NGS or PCR assays typically requires a significant amount of tissue. However, after the initial diagnostic workup and staging, which frequently uses up most of the biopsy tissue available, there is often insufficient tissue remaining for biomarker testing.[4]

In this situation, the patient must either endure a repeat biopsy and increased waiting time or forego testing altogether, meaning they miss out on the potential benefits of targeted therapies.

ASPYRE is extremely sensitive, with the ability to detect as little as a single molecule containing an actionable biomarker.[5] As a result, it can give results from much smaller biopsy samples than NGS or PCR. ASPYRE can even provide accurate, actionable tumor biomarker status from a blood sample (liquid biopsy), removing the need for tissue biopsy samples altogether.

4. Ofiara et al (2012) Current Oncology 19(Suppl 1): S16–S23. doi: 10.3747/co.19.1062
5. Silva et al (2021) Scientific Reports 11, 6068. doi: 10.1038/s41598-021-85545-3

Physicians need actionable answers, not science projects

NGS analyzes millions of basepairs of DNA, with sequencing reports often containing twenty or more pages of information. However, most of these results are not actionable because targeted therapies only exist for a limited number of genomic variants.

This complexity makes NGS data overwhelming and difficult for physicians to interpret. Furthermore, many payors are hesitant to reimburse NGS, as this depth of genomic data does not necessarily provide immediate clinical value.

PCR can provide a more efficient readout of actionable biomarkers. However, even multiple gene PCR is limited to a relatively small number of biomarkers per assay, often requiring multiple tests to get comprehensive information (assuming enough tumor tissue is available).

ASPYRE-Lung analyzes a comprehensive panel of more than 100 biomarkers recommended by the National Comprehensive Cancer Network (NCCN) in a single test. This test covers all FDA-approved targeted therapeutic options for NSCLC. ASPYRE-Lung ensures that physicians have the actionable information they need to inform treatment decisions without overwhelming them with pages of experimental data.

Less complexity, more clarity

The science of precision medicine is advancing at a significant pace and the number of experimental and approved targeted therapies is constantly expanding. This is great news for cancer patients, but makes it challenging for physicians to keep up with all the latest discoveries and therapeutics that could improve their outcomes.

As a result, doctors feel unsure about using new testing technologies and treatments that rely on biomarker testing and complex data interpretation. Many may have concerns about the clinical implications of making the wrong decision based on such complex tests. Instead, they choose to bypass biomarker testing and rely on tried-and-true protocols, even though it may not be the best path for their patients.

ASPYRE-Lung simplifies biomarker testing and treatment decisions, providing a short, easy to interpret report that only includes approved biomarkers and straightforward, actionable results and treatment options.

The simplicity of ASPYRE-Lung makes clinical decisions easier, opening the door to biomarker testing and targeted therapies for every patient who could benefit from them.

There are currently

29

targeted therapeutics on the market for lung cancer patients in the US.[6]

There are more than

200

targeted therapeutics for all cancers.[6]

6. https://www.cancer.gov Targeted Cancer Therapeutics Fact Sheet 12/6/2021

Current biomarker tests are too expensive

Not only is NGS biomarker testing slow, it's also expensive. An external comprehensive genomic biomarker profile using NGS can cost as much as $4,000-$5,000, while in-house sequencing requires costly specialized equipment and highly-skilled staff. Such high costs mean that insurance providers may require pre-authorization before approving NGS biomarker testing, adding further delays to starting treatment.

As well as adding time, this barrier causes frustration for both the patient and the physician, who may need to follow up and lobby for biomarker testing to be covered by the insurer. The high costs of biomarker testing also mean that there can be a significant co-insurance payment or high deductible for the patient, which may be more than they can afford.

ASPYRE-Lung is a highly cost-effective diagnostic tool for identifying actionable mutations. As a result, it has the potential to increase the number of patients who undergo biomarker testing which means more patients will have the opportunity to benefit from highly effective targeted therapies.

In summary

Breaking down the barriers to optimized therapy for all.

- Patients with cancer are currently missing out on optimal treatment because they don't have access to biomarker testing.
- The barriers to biomarker testing include long waits for results, the requirement for sufficient biopsy tissue, increased complexity, inactionable results, high costs, and delays due to off-site testing and analysis.
- ASPYRE-Lung is a new, rapid, and highly sensitive biomarker test that provides simple, actionable results at a fraction of the cost of NGS and greater coverage than PCR.
- The ASPYRE technology overcomes the barriers to biomarker testing so every lung cancer patient can get the treatment they deserve.