Simply Put: The Latest News From Biofidelity

Biofidelity

Welcome to 2025's first Biofidelity quarterly newsletter. We hope this newsletter reaches anyone taking care of patients with NSCLC, so those patients might get access to the life-changing benefits of modern targeted therapies. Share it with a friend today.

Our innovative molecular technologies offer solutions that are simple to implement, simple to run, and simple to analyze including two newly launched products:

Aspyre Clinical Test for Lung – Blood

(Tissue already commercially available)

	DNA SNVs and Indels	RNA Fusions	*MET* Exon 14 skipping
Sensitivity (Median panel-wide LoD95)	0.3% VAF	6 amplifiable copies	200 amplifiable copies
Specificity	100%	100%	100%

This highly sensitive test delivers exceptional performance and provides comprehensive coverage of all guideline-recommended genes associated with first-line therapies for NSCLC. Our CLIA-certified, CAP-accredited laboratory, located in Morrisville, North Carolina works overtime to ensure a 2-day turnaround time. Importantly, our Laboratory Director, Dr. Shari Brown and energetic lab team, successfully resulted clinical patient samples that had been rejected by NGS due to quantity not sufficient (QNS) enabling a patient to stop chemotherapy and begin targeted therapy – **jump to patient case study**.

Aspyre Lung Reagents – Tissue and Blood

Tissue

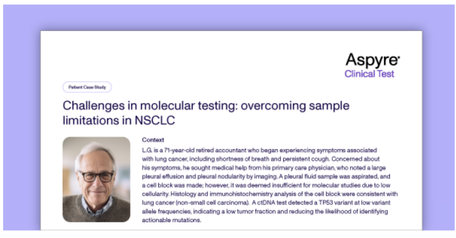
	DNA SNVs and Indels	RNA Fusions	*MET* Exon 14 skipping
Sensitivity (Median panel-wide LoD95)	1.10% VAF	8 amplifiable copies	262 amplifiable copies
Specificity	100%	100%	100%

Blood

	DNA SNVs and Indels	RNA Fusions	*MET* Exon 14 skipping
Sensitivity (Median panel-wide LoD95)	0.19% VAF	1 amplifiable copy	69 amplifiable copies
Specificity	100%	100%	100%

Due to the exquisite design of the 4-step test and its ability to take on the most challenging samples, Biofidelity launched Aspyre Lung Reagents for Research Use to enable pathologists to keep control of all samples. Now laboratories worldwide have access to purpose-built solutions that enable laboratories to run both tissue and blood samples in a single run, analyzing both DNA and RNA at the same time in a more cost-effective and reliable way than was previously available.

Patient case study with Aspyre Clinical Test for Lung


Aspyre Clinical Test

Patient Case Study

Challenges in molecular testing: overcoming sample limitations in NSCLC

Context

L.G. is a 71-year-old retired accountant who began experiencing symptoms associated with lung cancer, including shortness of breath and persistent cough. Concerned about his symptoms, he sought medical help from his primary care physician, who noted a large pleural effusion and pleural nodularity by imaging. A pleural fluid sample was aspirated, and a cell block was made; however, it was deemed insufficient for molecular studies due to low cellularity. Histology and immunohistochemistry analysis of the cell block were consistent with lung cancer (non-small cell carcinoma). A ctDNA test detected a TP53 variant at low variant allele frequencies, indicating a low tumor fraction and reducing the likelihood of identifying actionable mutations.

After a lung cancer diagnosis, 71-year-old L.G. faced limited options when his initial pleural biopsy was deemed insufficient for molecular testing. Biofidelity stepped in, analyzing the challenging sample in just 34 hours. The results revealed an EGFR L858R mutation, enabling targeted therapy with an EGFR inhibitor. This breakthrough spared L.G. the harsh effects of chemotherapy, improving his quality of life and allowing him to focus on what he loves – **read the full case study**.

Attend our webinar

Interested in learning more about Biofidelity and our life-changing technology? Consider attending our upcoming webinar hosted by CAPToday on Wednesday, January 22 at 12pmET/9amPT.

Register today

What will you learn from this webinar?

- Examine advantages of guideline recommended simplified genomic profiling (SGP) over CGP in NSCLC
- Demonstrate the impact of a rapid 2-day TAT on NSCLC patient care
- Learn how to maximize biomarker detection in challenging sample types
- Evaluate the impact of benefits to patients and community with Aspyre technology
- Ask questions of our distinguished presenters

Interested in NSCLC research?

Contact us today to learn how you can join our **neoadjuvant study** and help expand testing options for Early Stage NSCLC.