

Providing
biological information
to support personalized
treatment decisions for
patients, *faster*.

**A simple blood draw
can optimize lung cancer treatment strategies
regardless of stage**

THE CHALLENGE:

Delayed time to treatment and a lack of biomarker information



26

days is the average time from diagnosis to molecular testing results¹



51%

of NSCLC patients have insufficient tissue for molecular testing²



~50%

of NSCLC patients do not have biomarker results prior to starting first-line treatment³

PATIENT IMPACT:

Starting first-line treatment without biomarker results may lead to worse outcomes

RISK OF TREATMENT INITIATION WITHOUT MOLECULAR RESULTS^{4,5}



Patients with actionable mutations have a lower response rate to targeted therapy if they receive first-line immunotherapy



Potential to miss out on rare mutation clinical trials that have treatment naïve enrollment criteria



55% of patients with high PD-L1 expression do not respond to single agent immunotherapy

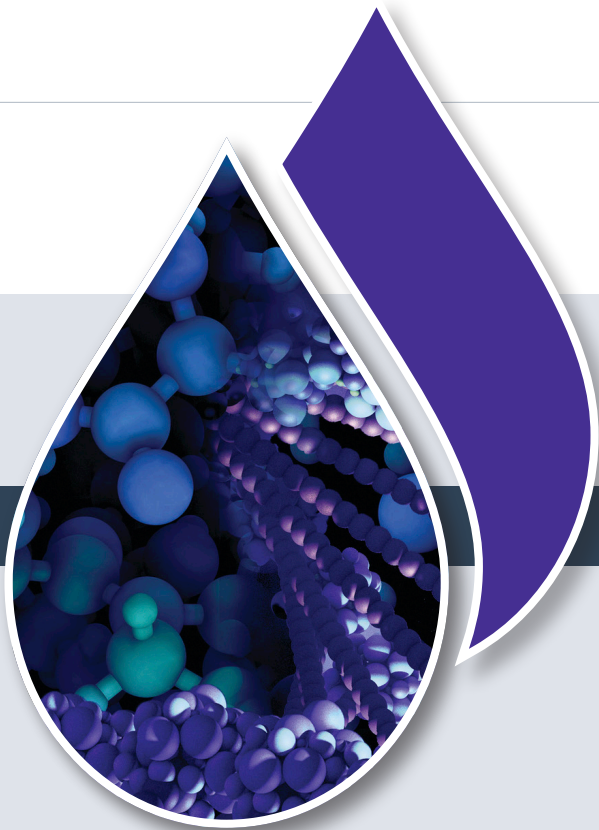
A SOLUTION:

Additional information to optimize personalized treatment decisions for patients, faster



IQLung Treatment Guidance Testing

From a simple blood draw, IQLung Testing provides pivotal information with an unmatched turnaround time. Coupled with a multidisciplinary strategy, get treatment relevant information for your patients, faster.



Patients have the best chance to fight cancer when they receive personalized therapy from the very beginning⁶



3 TESTS FOR EARLY THROUGH ADVANCED NSCLC



The GeneStrat targeted genomic test identifies actionable tumor mutations in early and advanced stage NSCLC patients



The GeneStrat NGS genomic test identifies actionable tumor mutations in advanced stage NSCLC patients



The VeriStrat proteomic test identifies a patient's immune response to cancer across stages



GeneStrat Combined Variants⁷:

91% Clinical Sensitivity

100% Clinical Specificity

97% Tissue Concordance

- Not restricted by stage of NSCLC or recurrence
- Multiple tests per patient per cancer when medically necessary

The **GeneStrat targeted** test evaluates the presence of actionable mutations in NSCLC. These mutations inform eligibility for adjuvant targeted therapy or clinical trial enrollment for early stage NSCLC patients.

Test	Variant
EGFR Sensitizing	Exon 19 ΔE746–A750
	Exon 21 L858R
	Exon 18 G719A, G719C, G719S Exon 20 S768I Exon 21 L861Q
EGFR Resistance	Exon T790M
ALK Fusion	EML4
KRAS Mutations	G12C
	G12D
	G12V
BRAF Mutation	V600E



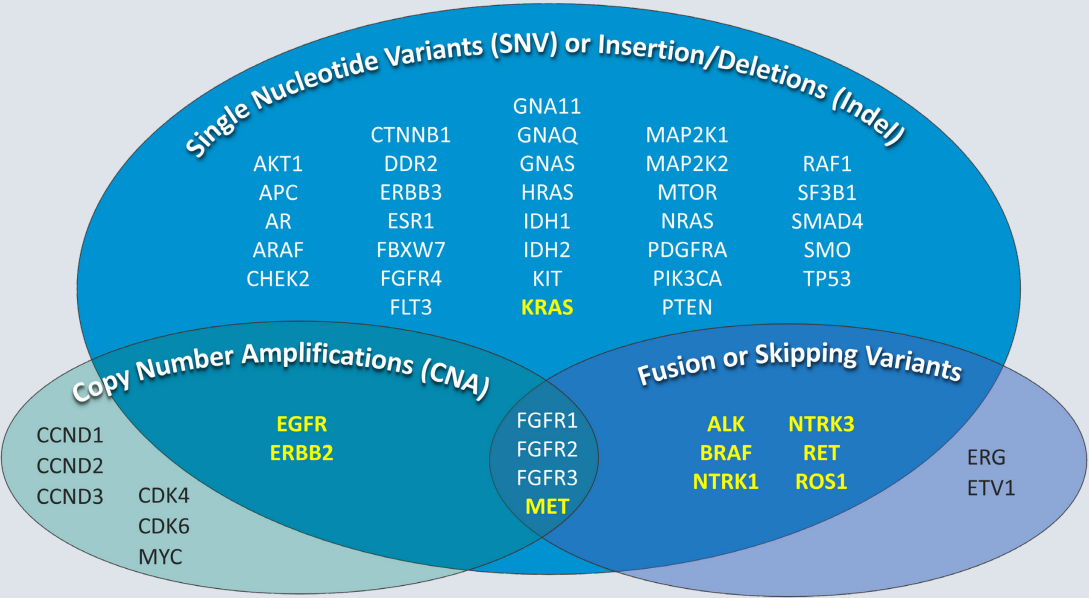
The **GeneStrat NGS** test is a broad 52 gene panel, including guideline recommended mutations that help identify advanced stage patients eligible for targeted therapy or clinical trial enrollment.



Mellert, H. et al. Targeted Next-Generation Sequencing of Liquid Biopsy Samples from Patients with NSCLC. *Diagnostics*, 2021; 11(2):155.



Audetat, A. et al. Analytic and Clinical Validation of a Pan-Cancer NGS Liquid Biopsy Test for the Detection of CNAs, Fusions and Exon Skipping Variants. *Diagnostics*, 2022; Mar 17;12(3):729.



NOTE: Yellow represents genes with guideline recommended mutations for advanced stage NSCLC



The **VeriStrat** immune profiling test is a novel predictive and prognostic blood-based host immune classifier that is independent of ECOG performance status, mutation status, PD-L1 expression, treatment choice, and line of therapy.

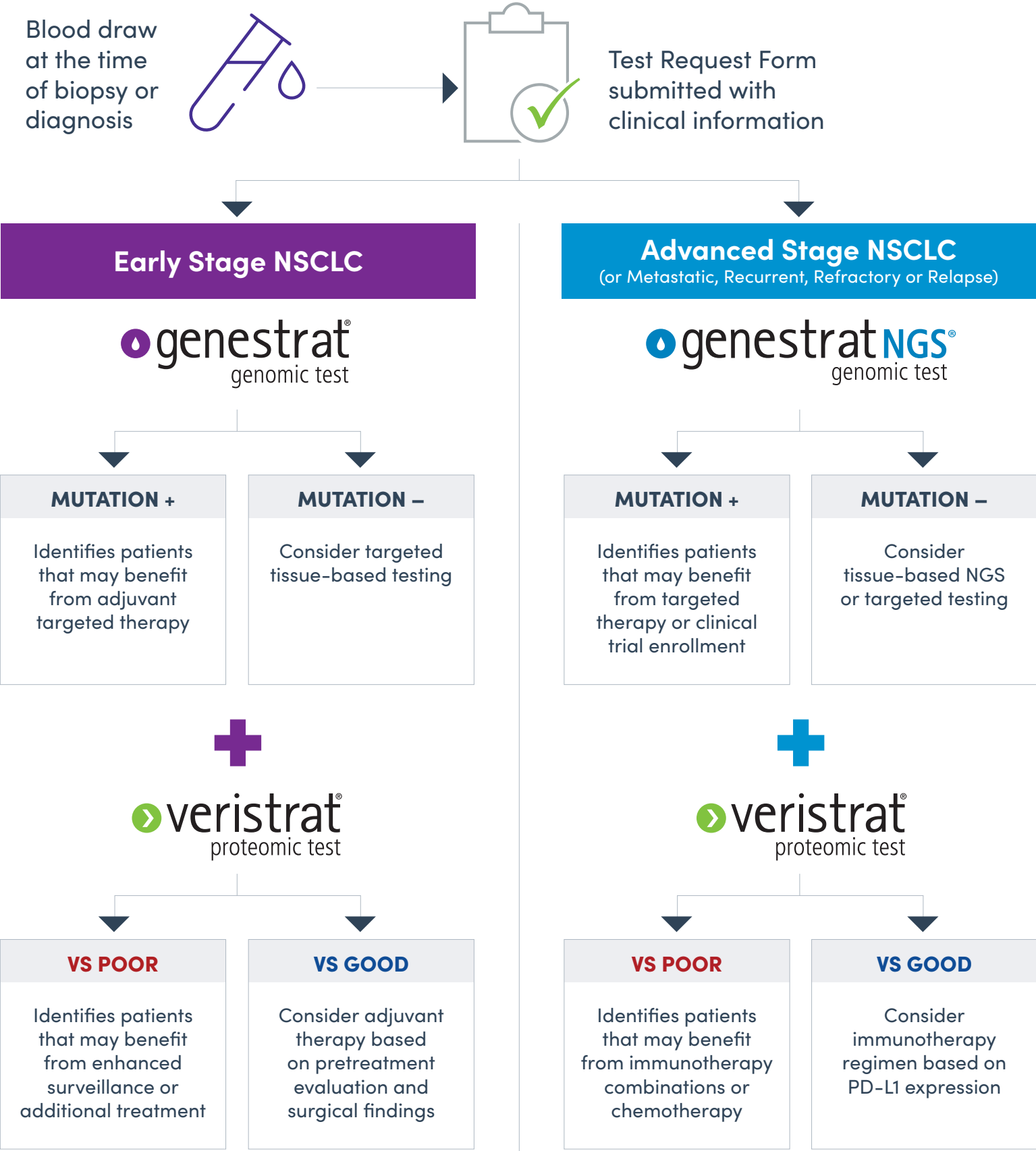
Median Overall Survival of Patients with Advanced Stage NSCLC [>50% PD-L1, and ECOG PS 0-1 receiving immunotherapy (ICI)]		
	ICI MONOTHERAPY	ICI + CHEMOTHERAPY
VeriStrat Good (HIC-Hot)	Not Reached (n=40)	Not Reached (n=22)
VeriStrat Poor (HIC-Cold)	2.6 months (n=18)	Not Reached (n=11)

Published data on the VeriStrat test shows that patients with high PD-L1 expression and a classification of **VeriStrat Poor** had superior median overall survival when receiving ICI plus chemotherapy vs. ICI alone (not reached* vs. 2.6 months, respectively).⁸

*Median overall survival not reached at 18 months

IQLUNG TESTING WORKFLOW

A simple blood draw can optimize lung cancer treatment strategies at any stage



NOTE: If stage or disease status is not indicated at specimen receipt, the assay will not commence until provided, which may affect time to result

WHEN DO I ORDER IQLUNG TESTING?

- AT DIAGNOSIS

 - At time of biopsy or surgery
 - Upon confirmed lung cancer diagnosis
 - At the first oncology visit
- AT PROGRESSION

 - For longitudinal monitoring of resistance mutations and changes in disease state
 - At oncology visit for lung cancer progression

WHO IS ELIGIBLE FOR TESTING?



NSCLC



ALL STAGES



ALL HISTOLOGIES




ALL LINES OF THERAPY

GeneStrat targeted, GeneStrat NGS, and VeriStrat tests are covered by Medicare and many private payers

Clinical Questions?


Speak with our Medical Affairs Team
medicalaffairs@biodesix.com

Resources and Support




SPECIMEN COLLECTION SUPPORT

We offer convenient sample collection through **our network of certified phlebotomists** at local laboratory locations or from the comfort of your patient’s home.



MANAGED CARE AND REIMBURSEMENT

We develop and publish scientific data to support an evidence-based approach to care. We work directly with health plans to ensure all patients have access to our services.



FINANCIAL SUPPORT PROGRAM FOR PATIENTS

We are committed to making Biodesix testing available to all patients. The Biodesix Assist Financial Support Program™ is available to all patients. Patients may apply to pre-qualify for financial assistance at any point, including before the test is performed.

REFERENCES

1. Bowling, M. et al. ECU clinical experience study: Utilization of liquid biopsy to determine time to diagnosis and treatment in NSCLC. *Journal of Clinical Oncology*, 2018; 36:15_suppl, abstract e18519.

2. Thompson, J. et al. Detection of Therapeutically Targetable Driver and Resistance Mutations in Lung Cancer Patients by Next-Generation Sequencing of Cell-Free Circulating Tumor DNA. *Clinical Cancer Research*, 2016; 22 (23): 5772–5782.

3. Robert, N.J. et al. Biomarker testing and tissue journey among patients with metastatic NSCLC receiving first-line therapy in The US Oncology Network. *Lung Cancer*, 2021; 166, P197–204.

4. Calles, A. et al. Checkpoint Blockade in Lung Cancer With Driver Mutation: Choose the Road Wisely. *ASCO Educational Book*, 2020; 40, 372–384.


5. Reck, M. et al. Pembrolizumab vs. Chemo for PD-L1-Positive NSCLC. *The New England Journal of Medicine*, 2016; 375:1823–1833.

6. Krzyszczyk, P. et al. The growing role of precision and personalized medicine for cancer treatment. *Technology (Singap World Sci)*, 2018; Sep-Dec; 6(3–4):79–100.

7. Mellert, H. et al. Development and Clinical Utility of a Blood-Based Test Service for the Rapid Identification of Actionable Mutations in Non-Small Cell Lung Carcinoma. *The Journal of Molecular Diagnostics*, 2017; May;19(3):404–416.

8. Rich, P. et al. Real-world performance of blood-based proteomic profiling in first-line immunotherapy treatment in advanced stage NSCLC. *The Journal for ImmunoTherapy of Cancer*, 2021; 9:e002989.

IQLung Publications:




TIME IS ON YOUR SIDE

3 business days to results

DIAGNOSIS		TREATMENT	
Pulmonologist		Medical Oncologist or Thoracic Surgeon	
IQLung Testing		Blood	Results
		3 DAYS	
On-Market Blood-Based NGS Tests		Blood	Results
		7–14 DAYS¹	
On-Market Tissue-Based NGS Tests		Tissue	Results
		7–26 DAYS¹	

PLEASE CONTACT BIODESIX CUSTOMER CARE TO ORDER TEST KITS AND RECEIVE ACCESS TO THE ONLINE BIODESIX PHYSICIAN PORTAL



Call: 1.866.432.5930

Visit: biodesix.com/order-a-test

Complete your IQLung Testing order using the Blood Specimen Collection Kit and enclosed IQLung Test Request Form.

IQLung Testing is performed in a CLIA/CAP accredited, NYS CLEP approved, and ISO 13485:2016 certified clinical laboratory in Louisville, Colorado.

919 W Dillon Road
Louisville, CO 80027

IQLung Testing Can Help You:

- ✓ Expedite the time to personalized treatment for each patient
- ✓ Enhance existing workflows with a simple blood draw
- ✓ Drive optimal treatment decisions with genomic and proteomic insights
- ✓ Ensure that each patient has the best chance to fight cancer

Biodesix Products Across the Lung Cancer Continuum of Care



Identify **likely malignant** nodules



Identify **actionable tumor mutations** in early stage NSCLC



Identify **likely benign** nodules



Identify **actionable tumor mutations** in advanced stage NSCLC



Identify a patient's **immune response** to cancer

Nodify Lung Testing and IQLung Testing Support Clinical Decision-Making in Lung Cancer