IQlung™
TREATMENT GUIDANCE

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

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

biodesix®

THE CHALLENGE:

Delayed time to treatment and incomplete biomarker information

26
days is the average time from diagnosis to molecular testing results[1]

51%
of NSCLC patients have insufficient tissue for molecular testing[2]

~50%
of NSCLC patients do not have biomarker results prior to starting first-line treatment[3]

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

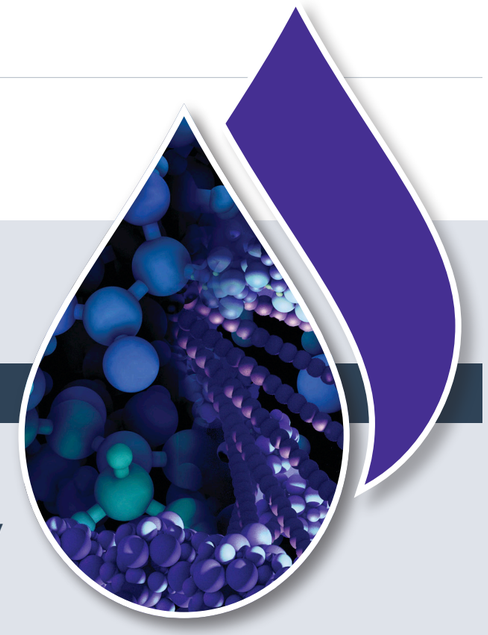
A SOLUTION:

Additional information to optimize personalized treatment decisions for patients, faster

IQLung™ TREATMENT GUIDANCE

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.



3 business days

Patients have the best chance to fight cancer when they receive personalized therapy from the very beginning[6]

3 TESTS FOR EARLY THROUGH ADVANCED NSCLC

genestrat® genomic test	The GeneStrat targeted genomic test identifies actionable tumor mutations in early and advanced stage NSCLC patients
genestrat NGS® genomic test	The GeneStrat NGS genomic test identifies actionable tumor mutations in advanced stage NSCLC patients
veristrat® proteomic test	The VeriStrat proteomic test identifies a patient's immune response to cancer across stages

genestrat® genomic test

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.

GeneStrat Combined Variants[7]:

91% Clinical Sensitivity

100% Clinical Specificity

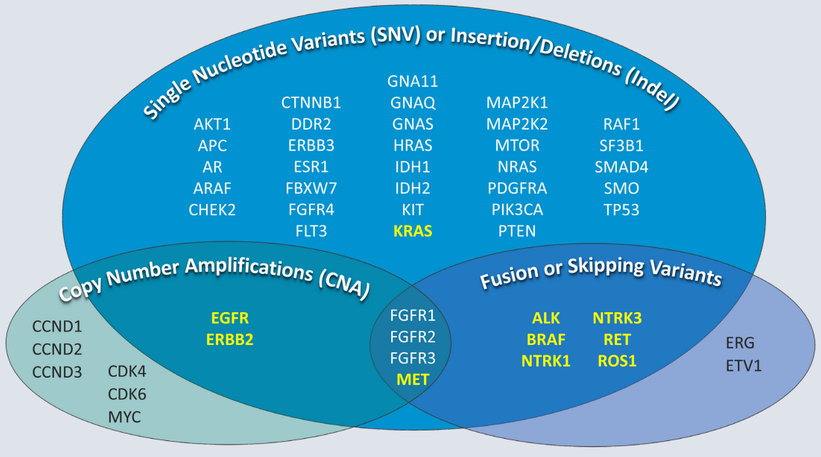
97% Tissue Concordance

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

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

genestrat® NGS genomic test

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.



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

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.

veristrat® proteomic test

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

Blood draw at the time of biopsy or diagnosis

Test Request Form submitted with clinical information

Early Stage NSCLC

genestrat® genomic test

MUTATION +
Identifies patients that may benefit from adjuvant targeted therapy

MUTATION –
Consider targeted tissue-based testing

veristrat® proteomic test

VS POOR
Identifies patients that may benefit from enhanced surveillance or additional treatment

VS GOOD
Consider adjuvant therapy based on pretreatment evaluation and surgical findings

Advanced Stage NSCLC
(or Metastatic, Recurrent, Refractory or Relapse)

genestrat® NGS genomic test

MUTATION +
Identifies patients that may benefit from targeted therapy or clinical trial enrollment

MUTATION –
Consider tissue-based NGS or targeted testing

veristrat® proteomic test

VS POOR
Identifies patients that may benefit from immunotherapy combinations or chemotherapy

VS GOOD
Consider immunotherapy regimen based on PD-L1 expression

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

IQlung™ TREATMENT GUIDANCE

Our powerful combination of genomic and proteomic testing reveals a broader view of each patient's disease state

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 DAYS[1]
On-Market Tissue-Based NGS Tests		Tissue → Results: 7–26 DAYS[1]

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

biodesix®

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 Boulder, Colorado.

2970 Wilderness Place, Ste 100
Boulder, CO 80301

IQLung Testing Can Help You:

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

Biodesix Products Across the Lung Cancer Continuum of Care

nodify lung® NODULE RISK ASSESSMENT

nodify cdt® PROTEOMIC TEST	Identify **likely malignant** nodules
nodify xl2® PROTEOMIC TEST	Identify **likely benign** nodules

IQlung™ TREATMENT GUIDANCE

genestrat® genomic test	Identify **actionable tumor mutations** in early stage NSCLC
genestrat NGS® genomic test	Identify **actionable tumor mutations** in advanced stage NSCLC
veristrat® proteomic test	Identify a patient's **immune response** to cancer

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

biodesix.com
1.866.432.5930
2970 Wilderness Place, Ste 100
Boulder, CO 80301

biodesix®