

# LungTrack Advance

NGS based liquid biopsy test

High precision  
multibiomarker

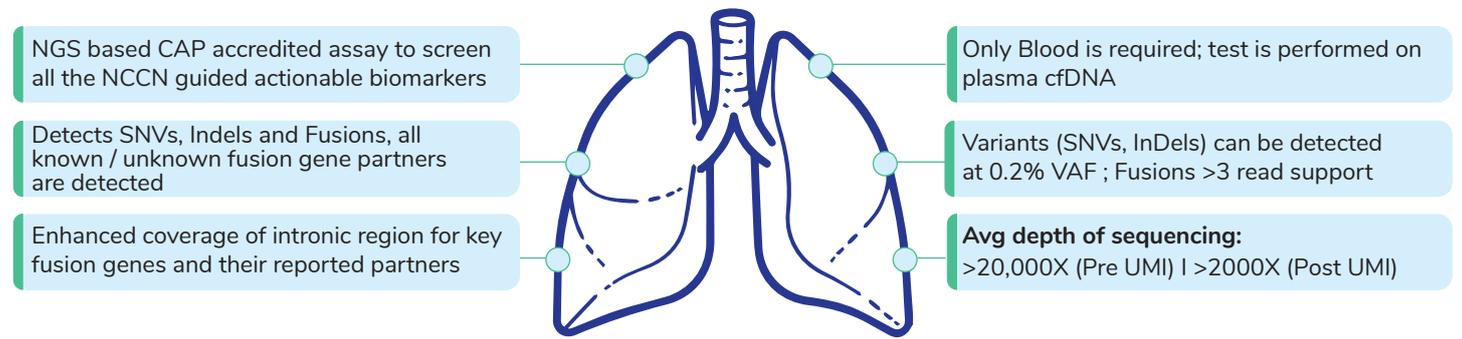
CAP accredited & extensively  
validated assay

Depth of sequencing  
≥20,000X (pre UMI)

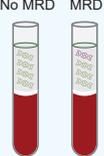
Comprehensive analysis of SNVs, InDels & Fusions in Non-small cell lung cancer (NSCLC) patients using Blood (Plasma cfDNA)

Can be used as a **Complementary, Alternative, Reflex and Serial** to Tissue Biopsy Test

## MedGenome Lung Cancer Liquid Biopsy Panel



## Clinical Applications

Diagnosis	MRD detection	Early detection of recurrence & new clones	Acquired Resistance
 <p><b>Identifies Driver Mutations</b></p> <p>Sensitizing <i>EGFR</i> mutations <i>ALK</i>, <i>ROS1</i>, <i>RET</i> rearrangements <i>BRAF V600E</i> <i>NTRK</i> gene fusions <i>MET</i> exon 14 skipping</p>	 <p><b>Screening for patient-specific alterations</b></p> <p>Comprehensive characterization of the primary tumor and design of tumor-informed high-resolution assays to guide adjuvant treatment and estimate prognosis</p>	 <p><b>Monitoring of patient-specific alterations</b></p> <p>ctDNA recurrence after surgery can predict clinical relapse</p>	 <p><b>Determines acquired resistance</b></p> <p>Comprehensive characterization of ctDNA to detect resistance mechanism and identify novel occurring actionable targets</p>

## Limit of Detection (LOD)

Alteration Type	Analytical Sensitivity <sup>#</sup>	Limit of Detection (LOD)	Analytical Specificity <sup>##</sup>
		30ng	
SNVs*	≥95%	>0.2 AF%	100%
INDELS*	≥95%	>0.2 AF%	100%
Fusions **	≥95%	≥3 Reads	100%

<sup>#</sup>Analytical Sensitivity defined as the Detection Rate for variants present at or above the limit of detection (LoD).

<sup>##</sup>Analytical Specificity defined as 1 minus the per-sample false positive rate

\* Tested on cfDNA reference standards  
\*\* Tested on Lung track advance

MRD: Minimal Residual Disease

ESMO: European Society for Medical Oncology: <https://www.esmo.org/>

Heitzer, E et al. "Recommendations for a practical implementation of circulating tumor DNA mutation testing in metastatic non-small-cell lung cancer." ESMO open vol. 7,2 (2022): 100399. doi:10.1016/j.esmoop.2022.100399

## Assay Specifications

Well - validated as per CAP guidelines

100% Scored in CAP proficiency evaluation program

High throughput Illumina's sophisticated NGS sequencing platforms

Global standards for the best laboratory practices followed

## Test Details

### Sample Type

Peripheral Blood in Streck Tube (10ml X 2)  
**Test Code:** MGM2623

### Shipping Condition

Ship same or next day at room temperature. Do not freeze or refrigerate

### TAT

14 Working days from sample receipt at the laboratory to result

## Gene List (SNVs, InDels & Fusions)

### Point Mutations (SNVs), Insertion and Deletion Variants (InDels) - 24 Genes

ALK	ERBB3	KRAS	<b>NTRK2</b>	<b>BRAF</b>	ERBB4	MAP2K1 (MEK)	<b>NTRK3</b>	CDKN2A	<b>FGFR1</b>	<b>MET</b>	PIK3CA
CTNNB1	<b>FGFR2</b>	NRAS	<b>RET</b>	EGFR	<b>FGFR3</b>	<b>NRG1</b>	<b>ROS1</b>	ERBB2	KIT	<b>NTRK1</b>	TP53

Fusions will be determined in genes highlighted as bold (12 genes) | Novel fusion partners can also be detected

## Clinical scenarios for liquid biopsy test

### Identifies driver mutations

Brain metastasis

Stage IV NSCLC

Adrenal metastasis



#### Patient Profile

47-year-old woman  
 Smoking history: None  
 Adenocarcinoma from good quality biopsy  
 Molecular diagnosis (panel NGS) no driver mutations found

Liquid biopsy test identified EGFR L858R mutation at 20.8% VAF

### Tissue Biopsy not possible/ Tissue not sufficient

Stage IV NSCLC

Adrenal metastasis

Sclerotic bone lesions



#### Patient Profile

43-year-old Male  
 Smoking history: None  
 PD-L1 IHC negative on tumor cells  
 No further results from NGS due to low tissue quality and quantity

EZR-ROS1 fusion at good confidence

### Identifies resistance

EGFR+ NSCLC



#### Patient Profile

40-year-old man  
 Smoking history: None  
 Bronchoscopy and transbronchial biopsy  
 Progression on 1L TKI

Identified driver EGFR Exon 19 del at 12% VAF along with EGFR T790M at 5.6% VAF. EGFR T790M is a known TKI resistance mutation

### Complementary Testing

Primary tumor left upper lobe

Spleen and liver metastasis



#### Patient Profile

85-year-old man  
 Smoking history: 15 pack - years  
 Patient takes anticoagulants risk for hemorrhagic diathesis  
 Re-biopsy not possible

Both Tissue and Liquid biopsy test identified EML4-ALK fusion in this patient

## MedGenome Liquid Biopsy NGS Assays

**OncoTrack Ultima**  
 (Solid Tumors)

**LungTrack Advance**  
 (SNVs, InDels, Fusions)

**OncoTrack**  
 (EGFR, BRAF, KRAS, NRAS)

**HRR Track**  
 (15 HRR Gene including BRCA1 & BRCA2)