MEDGENOME | Prima Cancer Genetics

CAP ACCREDITED
COLLEGE of AMERICAN PATHOLOGISTS

LungTrack Advance

NGS based liquid biopsy test

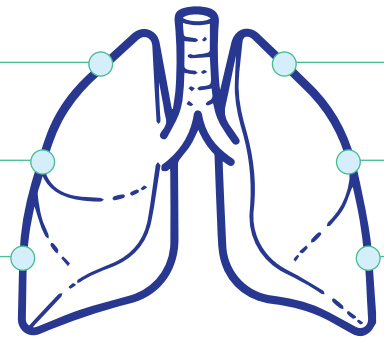
Minimally invasive	High precision multibiomarker	CAP accredited & extensively validated assay

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

- NGS based CAP accredited assay to screen all the NCCN guided actionable biomarkers
- Detects SNVs, Indels and Fusions, all known / unknown fusion gene partners are detected
- Enhanced coverage of intronic region for key fusion genes and their reported partners



- Only Blood is required; test is performed on plasma cfDNA
- Variants (SNVs, InDels) can be detected at 0.2% VAF ; Fusions >3 read support
- **Avg depth of sequencing:** >20,000X (Pre UMI) I >1000X (Post UMI)

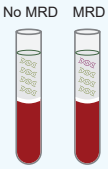
Clinical Applications

Diagnosis

Identifies Driver Mutations

Sensitizing *EGFR* mutations
ALK, ROS1, RET rearrangements
BRAF V600E
NTRK gene fusions
MET exon 14 skipping

MRD detection



Screening for patient-specific alterations

Comprehensive characterization of the primary tumor and design of tumor-informed high-resolution assays to guide adjuvant treatment and estimate prognosis

Early detection of recurrence & new clones

Monitoring of patient-specific alterations

ctDNA recurrence after surgery can predict clinical relapse

Acquired Resistance

Determines acquired resistance

Comprehensive characterization of ctDNA to detect resistance mechanism and identify novel occurring actionable targets

Limit of Detection (LOD)

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

[#]Analytical Sensitivity defined as the Detection Rate for variants present at or above the limit of detection (LoD).

[##]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	**NTRK2**	**BRAF**	ERBB4	MAP2K1 (MEK)	**NTRK3**	CDKN2A	**FGFR1**	**MET**	PIK3CA
CTNNB1	**FGFR2**	NRAS	**RET**	EGFR	**FGFR3**	**NRG1**	**ROS1**	ERBB2	KIT	**NTRK1**	TP53

Fusions will be determined in genes highlighted as bold (12 genes) I 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

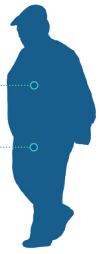
EGFR+ NSCLC

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 T709M 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*)

Talk to the Experts: 1800 103 3691 techsupport@medgenome.com www.medgenome.com