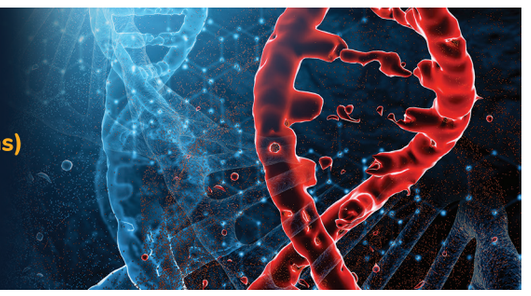
MEDGENOME

CAP ACCREDITED
COLLEGE of AMERICAN PATHOLOGISTS

# OncoTrack Advance

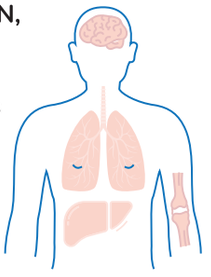
**NGS based genomic profiling of solid tumors from blood (SNVs, InDels & Fusions)**

| High precision multibiomarker | CAP accredited & extensively validated assay | Depth of sequencing ≥20,000X (pre UMI) |
|---|---|---|



## Salient Features

- Tumor agnostic assay covering **117 Pan cancer** genes as recommended by **guidelines (FDA, NCCN, ASCO, ESMO etc.)** for SNVs, InDels & **15 genes for fusion** analysis.
- Comprehensive coverage of **complete coding regions** of all the genes and **intron/exon boundaries** for **SNVs & InDels** detection
- **Intronic regions of fusion genes & key partners covered for fusion detection on cfDNA**
- Highly sensitive and can accurately detect low frequency mutations upto **0.2% Variant Allele Frequency (VAF)** at high confidence
- Analysis and reporting as per **AMP/ASCO/CAP** guidelines
- Detects **Primary driver mutation** and **Secondary resistance** markers
- Enables **Minimal Residual Disease (MRD)** detection



Can be Complementary, Alternative, Reflex and Serial to Tissue Biopsy NGS Test

## Use in Clinical Practice

**Indicated for**

Advanced solid tumors
Before first-line therapy or at progression

**Average depth of sequencing**

≥20,000X (pre UMI)
≥2000X (post UMI)

**Sample type**

Peripheral Blood in Streck Tube (10ml X 2)

**Overall concordance with tissue testing**

98% (PMID: 29379323)

## 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% |

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

#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

## 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:** MGM2718

### 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 - 117 Genes)

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| *ABL1* | *BAP1* | *CDX2* | *EZH2* | *GNAQ* | *KIT* | *MYC* | *PDGFRA* | *RAD54L* | *SMO* |
| *ABL2* | *BARD1* | *CHEK1* | *FANCL* | *GNAS* | *KRAS* | *MYCN* | *PIK3CA* | *RAF1* | *SPOP* |
| *AKT1* | *BRAF* | *CHEK2* | *FBXW7* | *HNF1A* | *MAP2K1* | *MYD88* | *PMS2* | *RB1* | *SRC* |
| *ALK* | *BRCA1* | *CSF1R* | *FGFR1* | *HRAS* | *MAP2K2* | *NF1* | *POLD1* | *RET* | *STK11* |
| *APC* | *BRCA2* | *CTNNB1* | *FGFR2* | *IDH1* | *MAPK1* | *NF2* | *POLE* | *RHEB* | *TERT* |
| *AR* | *BRIP1* | *DDR2* | *FGFR3* | *IDH2* | *MET* | *NOTCH1* | *PPP2R2A* | *RHOA* | *TP53* |
| *ARAF* | *C11orf65* | *EGFR* | *FGFR4* | *JAK1* | *MLH1* | *NPM1* | *PTCH1* | *RIT1* | *TSC1* |
| *ARID1A* | *CCND1* | *ERBB2* | *FLT3* | *JAK2* | *MPL* | *NRAS* | *PTEN* | *ROS1* | *TSC2* |
| *ARID1B* | *CDH1* | *ERBB3* | *FOXA1* | *JAK3* | *MSH2* | *NTRK1* | *PTPN11* | *SETD2* | *VHL* |
| *ATM* | *CDK12* | *ERBB4* | *FOXL2* | *KDM5C* | *MSH6* | *NTRK3* | *RAD51B* | *SF3B1* | |
| *ATR* | *CDK4* | *ERCC2* | *GATA3* | *KDM6A* | *MTOR* | *PALB2* | *RAD51C* | *SMAD4* | |
| *ATRX* | *CDKN2A* | *ESR1* | *GNA11* | *KEAP1* | *MUTYH* | *PBRM1* | *RAD51D* | *SMARCB1* | |

*All HRR genes are covered including BRCA1 and BRCA2*

## Gene List (Fusions - 15 Genes)

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| *ALK* | *EGFR* | *FGFR1* | *FGFR3* | *MET* | *NTRK1* | *NTRK3* | *ROS1* |
| *BRAF* | *ERBB2* | *FGFR2* | *FGFR4* | *NRG1* | *NTRK2* | *RET* | |

## Case Study

Identify resistance mutations
Test performed - Oncotrack Advance

**52-year-old Female**

### Diagnosis

- Diagnosed in 2020 with high grade **lung adenocarcinoma** in right lung legion
- Tested **positive for *ROS1* fusion by FISH** in 90% of cell in **tumour block**
- *ALK* & *EGFR* was negative
- Treated with *ROS1* inhibitor and responded well
- **Relapse observed in 2023**

### Test Performed

- Rebiopsy was not clinically recommended
- NGS test on Liquid Biopsy sample was advised.
- **OncoTrack Advance** - Liquid Biopsy test by NGS (SNVs, InDels & Fusions) was performed at MedGenome lab

### Results

- The test precisely **detected *CD74/ROS1* fusion** at good confidence on blood (plasma cfDNA)
- Additionally, a well- known **resistance mutation *G2032R* was detected in *ROS1* gene** that could have contributed to relapse on *ROS1* inhibitor
- Due to the presence of resistance mutation, patient was not responding to *ROS1* inhibitor

Precise report of Ontrack Advance empowered the clinician to put the patient on alternate and improved treatment plan.

**Talk to the Experts:** 1800 296 96 96 diagnostics@medgenome.com www.medgenome.com