MEDGENOME

CAP ACCREDITED
COLLEGE of AMERICAN PATHOLOGISTS

# HRR Track

**Homologous Recombination Repair (HRR) genes including *BRCA1* & *BRCA2* analysis through blood.**

| High precision multibiomarker | NGS based genomic profiling | Depth of sequencing ≥20,000X (pre UMI) |
|---|---|---|

**Complementary, Alternative, Reflex and Serial** to Tissue Biopsy.

## Salient Features

- Screens for the mutations (SNVs and InDels) in 15 Homologous Recombination Repair (HRR) genes including *BRCA1* and *BRCA2* genes
- Complete coding regions and splice site boundaries (+ /-10 bp) are covered
- Detects both somatic and germline* variants.
- Informs PARPi eligibility.

*Germline variants to be confirmed on whole blood DNA

Breast Cancer | Ovarian Cancer | Pancreatic Cancer | Prostate Cancer

## Use in Clinical Practice

**Indicated for**

- Prostate, Ovarian, Breast and Pancreatic cancer

**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% |

#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

## Assay Specifications

| | | | | |
|---|---|---|---|---|
| Well - validated as per CAP guidelines | 100% Precision on Reference standards | 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:** MGM2455

### 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 (15 Homologous Recombination Repair (HRR) pathway genes)

| | | | | |
|---|---|---|---|---|
| *ATM* | *BRCA2* | *CHEK1* | *PALB2* | *RAD51C* |
| *BARD1* | *BRIP1* | *CHEK2* | *PPP2R2A* | *RAD51D* |
| *BRCA1* | *CDK12* | *FANCL* | *RAD51B* | *RAD54L* |

## Case Study on HRR Track

**Test Performed:** HRR Track and HRR somatic mutation panel
**56-year-old Male** Prostatic acinar adenocarcinoma, grade 5

| Genomic alteration | Nucleotide change | Depth / VAF | AMP Classification^ | Interpretation | Treatment Recommendation |
|---|---|---|---|---|---|
| *BRCA2* p.Gly3153 AlafsTer10 | c.9458del (ENST00000 380152.8) | 2720X / 46% | Tier 1 | Deleterious | Confers sensitivity to PARP inhibitors |

HRR track Liquid Biopsy test identified pathogenic mutation in *BRCA2* gene at 46% VAF which can be useful for treatment decisions.

HRR somatic mutation panel on Tissue Biopsy also detected same mutation at 65.6%. Germline confirmation is under process

## 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*) |