

The Oncolife logo, which consists of a circular icon containing a DNA double helix, followed by the word "Oncolife" in a large, bold, blue sans-serif font.

**Comprehensive Genomic Panel**

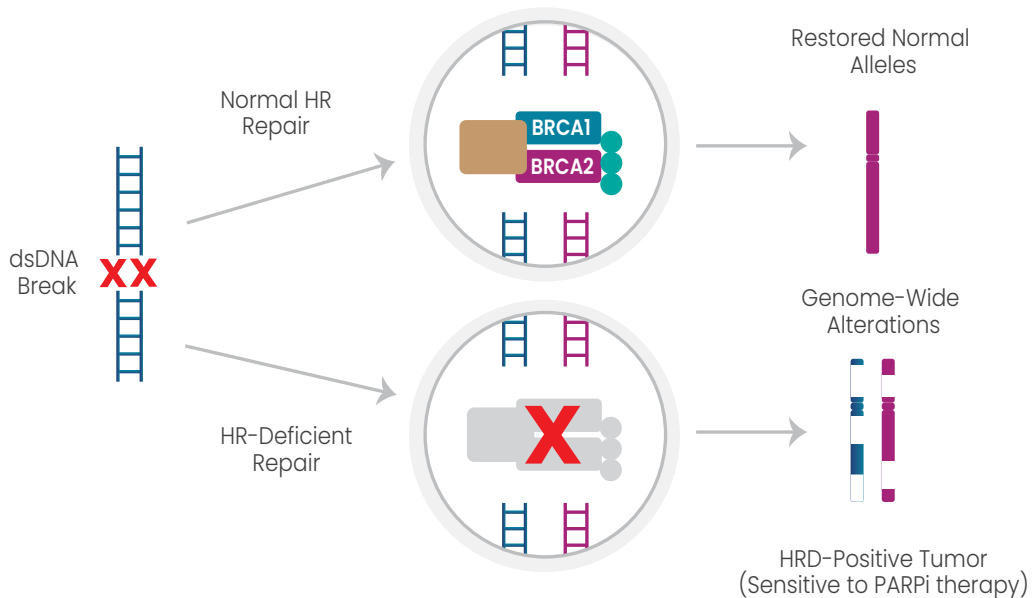
**517** **GENES + HRD/GIM**

Comprehensive Study of Early, Advanced and Metastatic Ovarian, Prostate, Pancreatic, Breast Cancer by Next Generation Sequencing

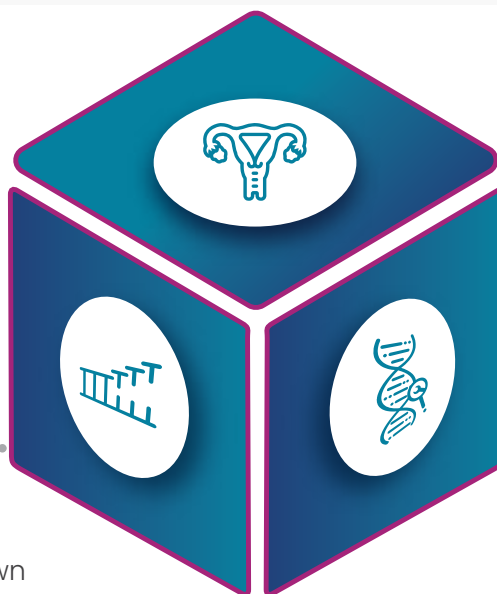
# EPIDEMIOLOGY

**Ovarian Carcinomas** has been steadily increasing over the past 10 years in many countries, which accounts for an estimated 295,414 new cases and 184,799 deaths worldwide in recent times.

Unfortunately, the majority of patients are diagnosed as advanced stage **III-IV at the time of preliminary diagnosis.**



The data from **The Cancer Genome Atlas (TCGA)** have showed that approximately **50%** of High-grade Serous Ovarian Carcinoma patients have HRD



Recently, clinical trials have shown that maintenance therapy with **Poly (ADP-ribose) polymerase (PARP)** inhibitors can improve **Progression Free Survival**

Patients with **BRCA1/2 mutation and/or homologous recombination deficiency (HRD)** are **most benefitted**

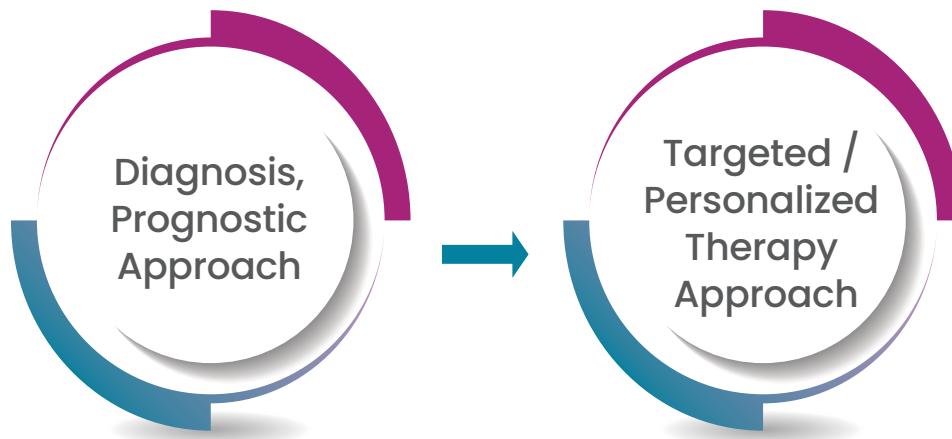


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For PAOLA-1 and PRIMA, homologous recombination deficiency was defined as BRCA1/2 mutation or an genomic instability score (GIS)  $\geq 42$ . For VELIA, homologous recombination deficiency was defined as BRCA1/2 mutation or a GIS  $\geq 33$ .

## Need for the Hour

A Comprehensive Gene Panel determining the status of HRD/GIM by evaluating TMB, MSI, LOH in Ovarian Cancers



## INTRODUCING

Oncolife Comprehensive Genomic Panel (517 genes + HRD/GIM)

## Key Highlights

(517 genes + HRD/GIM)

- Covers 500+ unique genes for single gene and multigene biomarker insights.
- Detection of complex biomarkers associated with immunotherapies such as TMB & MSI.

### Single-Gene Biomarkers

- Single-nucleotide variants (SNVs)
- Insertions and deletions (indels)
- Novel and known fusions
- Splice variants, and copy number variants (CNVs)
- Including copy number gains and losses across 517 genes



### Multi-Gene Biomarkers

- Study potential responses to immunotherapy with measurement of tumor mutational burden (TMB)
- Predisposition to genetic hypermutability by comparing microsatellite instability (MSI) regions



Homologous recombination deficiency (HRD) research 46 homologous recombination repair (HRR) genes, including BRCA large gene rearrangements, and assess genomic scarring with the genomic instability metric (GIM)

## Genes Covered

### 46 HRR pathway genes covered by the Oncolife Comprehensive Panel

ABRAXAS1	ATM	ATR	BAP1	BARD1	BLM	BRCA1	BRCA2	BRIP1	CDK12	CHEK1	CHEK2
FANCA	FANCC	FANCD2	FANCE	FANCF	FANCG	FANCI	FANCL	FANCM	MRE11	NBN	PALB2
PARP1	PARP2	PARP3	POLD1	POLE	PPP2R2A	PTEN	RAD50	RAD51	RAD51B	RAD51C	RAD51D
RAD52	RAD54L	RNASEH2A	RNASEH2B	RNASEH2C	RPA1	SLX4	TP53	XRCC2	XRCC3		

- Team of Molecular Pathologist and Molecular Scientists collaboratively evaluating, annotating, interpreting the variant of interest.
- **AMC/ACMG/ASCO/CAP/NCCN/EMA/ESMO** guidelines followed.  
Tumor content > 20%, to enable take a proper quality and concentration of DNA and RNA.



# Scope of Oncolife Comprehensive Genomic Panel

(517 genes + HRD/GIM)

## List of DNA Genes

AICF | ABCB1 | ABL1 | ABL2 | ABRAXAS1 | ACSM2B | ACVRI | ACVR1B | ACVR2A | ADAMI8 | ADAMTS12 | ADAMTS2 | AKT1 | AKT2 | AKT3 | ALK | AMER1  
ANO4 | APC | AR | ARAF | ARHGAP35 | ARID1A | ARID1B | ARID2 | ARID5B | ARMC4 | ASXL1 | ASXL2 | ATM | ATR | ATRX | AURKA | AURKB  
AURKC | AXINI | AXIN2 | AXL | B2M | BAP1 | BARD1 | BCL2 | BCL2L1 | BCL6 | BCOR | BCR | BLM | BMP5 | BMPR2 | BRAF | BRCA1 | BRCA2 | BRINP3  
BRIPI | BTK | C6 | C8A | C8B | CACNA1D | CALR | CANX | CARD11 | CASP8 | CASR | CBF1 | CBL | CCND1 | CCND2 | CCND3 | CCNE1 | CD163 | CD274 | CD276  
CD79B | CDC73 | CDH1 | CDH10 | CDK12 | CDK4 | CDK6 | CDKN1A | CDKN1B | CDKN2A | CDKN2B | CDKN2C | CHD4 | CHEK1 | CHEK2 | CIC | CIITA | CNTN6  
CNTNAP4 | CNTNAP5 | COL11A1 | CREBBP | CSF1R | CSMD3 | CTCF | CTLA4 | CTNNA1 | CTNND2 | CUL1 | CUL3 | CUL4A | CUL4B | CYLD | CYP2C9 | CYP2D6 | CYSLTR2  
| DAXX | DCAF4L2 | DCCDC1 | DDR1 | DDR2 | DDX3X | DGCR8 | DICER1 | DNMT3A | DOCK3 | DPYD | DROSHA | DSC1 | DSC3 | E2F1 | EGFR | EIF1AX | ELF3 | EMSY |  
ENO1 | EP300 | EPAS1 | EPCAM | EPHA2 | ERAP1 | ERAP2 | ERBB2 | ERBB3 | ERBB4 | ERCC2 | ERCC4 | ERCC5 | ERFF1 | ESRI | ETV6 | EZH2 | FAMI35B | FANCA |  
FANCC | FANCD2 | FANCE | FANCF | FANCG | FANCI | FANCL | FANCM | FAS | FAT1 | FBXW7 | FGF19 | FGF23 | FGF3 | FGF4 | FGF7 | FGF9 | FGFRI | FGFRII | FGFRL1 | FGFRL2 | FGFRL3  
| FGFRL4 | FLT3 | FLT4 | FOXA1 | FOXL2 | FOXO1 | FUBP1 | FYN | GALNT1 | GATA2 | GATA3 | GLI1 | GLI3 | GNAI1 | GNAI3 | GNAQ | GNAS | GPR158 | GPS2 | GRID2 |  
HI-4 | H2BC5 | H3-3A | H3-3B | H3C2 | HCN1 | HDAC2 | HDAC9 | HIF1A | HLA-A | HLA-B | HLA-C | HNF1A | HRAS | ID3 | IDH1 | IDH2 | IGF1R | IKBKB | IL6ST |  
| IL7R | INPP4B | IRF4 | IRS4 | JAK1 | JAK2 | JAK3 | KCND2 | KCNH7 | KCNJ5 | KDM5C | KDM6A | KDR | KEAP1 | KEL | KIF3DL1 | KIT | KLF4 | KLF5 | | KLHL13 | KMT2A  
| KMT2B | KMT2C | KMT2D | KNSTRN | KRAS | KRTAP2-1 | KRTAP6-2 | LARP4B | LATS1 | LATS2 | LRRC7 | MAGOH | MAP2K1 | MAP2K2 | MAP2K4 | MAP2K7 | MAP3K1  
| MAP3K4 | MAPK1 | MAPK8 | MARCKS | MAX | MCL1 | MDM2 | MDM4 | MECOM | MED12 | MEF2B | MEN1 | MET | MGA | MITF | MLH1 | MLH3 | MPL | MRE11 | MSH2  
| MSH3 | MSH6 | MTAP | MTOR | MTUS2 | MUTYH | MYC | MYCL | MYCN | MYD88 | MYO10 | NBN | NCOR1 | NF1 | NF2 | NFE2L2 | NLRC5 | NOL4 | NOTCH1 |  
NOTCH2 | NOTCH3 | NOTCH4 | NRAS | NRXN1 | NSD2 | NT5C2 | NTRK1 | NTRK2 | NTRK3 | NUP93 | NYAP2 | OR10G8 | OR2G6 | OR2L13 | OR2L2 | OR2L8 | OR2M3  
| OR2T3 | OR2T33 | OR2T4 | OR2W3 | OR4A15 | OR4C15 | OR4C6 | OR4M1 | OR4M2 | OR5D18 | OR5F1 | OR5L1 | OR5L2 | OR6F1 | OR8H2 | OR8J2 | OR8U1 | ORC4  
| PAK5 | PALB2 | PARP1 | PARP2 | PARP3 | PARP4 | PAX5 | PBRM1 | PCBP1 | PCDH17 | PDCD1 | PDCD1LG2 | PDGFRA | PDGFRB | PDGFRA | PDGFRB | PDIA3 | PGD | PHF6  
| PIK3C2B | PIK3CA | PIK3CB | PIK3CD | PIK3CG | PIK3R1 | PIK3R2 | PIM1 | PLCG1 | PLXNC1 | PMS1 | PMS2 | POLD1 | POLE | POM121L1 | POT1 | PPIA2 | PPM1D |  
PPP2R1A | PPP2R2A | PPP6C | PRDM1 | PRDM9 | PRKACA | PRKARIA | PSMB10 | PSMB8 | PSMB9 | PTCH1 | PTEN | PTPN11 | PTPRD | PTPRT | PXDNL | RAC1 | RAD50 |  
RAD51 | RAD51B | RAD51C | RAD51D | RAD52 | RAD54L | RAF1 | RARA | RASA1 | RASA2 | RBL1 | RBM10 | RBP3 | RECQL4 | REG1A | REG1B | REG3A | REG3G | RET |  
RGS7 | RHEB | RHOA | RICTOR | RIT1 | RNASEH2A | RNASEH2B | RNASEH2C | RNF43 | ROS1 | RPA1 | RPL10 | RPL22 | RPL5 | RPS6KB1 | RPTOR | RPTOR | RUND3C3B  
| RUNX1 | RUNX1T1 | SDHA | SDHB | SDHC | SDHD | PTPRD | PTPRT | PXDNL | RAC1 | RAD50 | SETBP1 | SETD2 | SF3B1 | SH3BP2 | SIX1 | SIX2 | SLC15A2 | SLC8A1 |  
SLCO1B3 | SLX4 | SMAD2 | SMAD4 | SMARCA4 | SMARCB1 | SMC1A | SMO | SNCAIP | SOCS1 | SOS1 | SOX2 | SOX9 | SPEN | SPOP | SRC | SRSF2 | STAG2 | STAT1  
| STAT3 | STAT5B | STAT6 | STK11 | SUFU | SYT10 | SYT16 | TAF1 | TAP1 | TAP2 | TAPBP | TBX3 | TCF7L2 | TERT | TET2 | TGFBR1 | TGFBR2 | TMEM132D | TNFAIP3 |  
TNFRSF14 | TOP1 | TOP2A | TP53 | TP63 | TPMT | TPP2 | TPT1 | TRHDE | TRIM48 | TRIM51 | TRRAP | TSC1 | TSC2 | TSHR | U2AF1 | UGT1A1 | USP8 | USP9X | VHL |  
WAS | WT1 | XPO1 | XRCC2 | XRCC3 | YAP1 | YES1 | ZBTB20 | ZFX3 | ZIM3 | ZMYM3 | ZNF217 | ZNF429 | ZNF479 | ZNF536 | ZRSR2

## List of CNV-Genes

ABCB1 | ABL1 | ABL2 | ABRAXAS1 | ACVR1B | ACVR2A | ADAMTS12 | ADAMTS2 | AKT1 | AKT2 | AKT3 | ALK | AMER1 | APC | AR | ARAF | ARHGAP35  
ARID1A | ARID1B | ARID2 | ARID5B | ASXL1 | ASXL2 | ATM | ATR | ATRX | AURKA | AURKC | AXINI | AXIN2 | AXL | B2M | BAP1 | BARD1 | BCL2 | BCL2L1  
| BCL6 | BCOR | BLM | BMPR2 | BRAF | BRCA1 | BRCA2 | BRIPI | CARD11 | CASP8 | CBF1 | CBL | CCND1 | CCND2 | CCND3 | CCNE1 | CD274 |  
CD276 | CDC73 | CDH1 | CDH10 | CDK12 | CDK4 | CDK6 | CDKN1A | CDKN1B | CDKN2A | CDKN2B | CDKN2C | CHD4 | CHEK1 | CHEK2 | CIC |  
CREBBP | CSMD3 | CTCF | CTLA4 | CTNND2 | CUL3 | CUL4A | CUL4B | CYLD | CYP2C9 | DAXX | DDR1 | DDR2 | DDX3X | DICER1 | DNMT3A | DOCK3  
| DPYD | DSC1 | DSC3 | EGFR | EIF1AX | ELF3 | EMSY | ENO1 | EP300 | EPCAM | EPHA2 | ERAP1 | ERAP2 | ERBB2 | ERBB3 | ERBB4 | ERCC2 | ERCC4  
| ERFF1 | ESRI | ETV6 | EZH2 | FAMI35B | FANCA | FANCC | FANCD2 | FANCE | FANCF | FANCG | FANCI | FANCL | FANCM | FAT1 | FBXW7 | FGF19 |  
FGF23 | FGF3 | FGF4 | FGF9 | FGFRI | FGFRII | FGFRL1 | FGFRL2 | FGFRL3 | FGFRL4 | FLT3 | FLT4 | FOXA1 | FUBP1 | FYN | GATA2 | GATA3 | GLI3 | GNAI3 | GNAS | GPS2  
| H3-3A | H3-3B | HDAC2 | HDAC9 | HLA-A | HLA-B | HNF1A | IDH2 | IGF1R | IKBKB | IL7R | INPP4B | JAK1 | JAK2 | JAK3 | KDM5C | KDM6A | KDR |  
KEAP1 | KIT | KLF5 | KMT2A | KMT2B | KMT2C | KMT2D | KRAS | LARP4B | LATS1 | LATS2 | MAGOH | MAP2K1 | MAP2K4 | MAP2K7 | MAP3K1 | MAP3K4  
| MAPK1 | MAPK8 | MAX | MCL1 | MDM2 | MDM4 | MECOM | MEF2B | MEN1 | MET | MGA | MITF | MLH1 | MLH3 | MPL | MRE11 | MSH2 | MSH3 | MSH6  
| MTAP | MTOR | MUTYH | MYC | MYCL | MYCN | MYD88 | NBN | NCOR1 | NF1 | NF2 | NFE2L2 | NOTCH1 | NOTCH2 | NOTCH3 | NOTCH4 | NRAS |  
NTRK1 | NTRK3 | PALB2 | PARP1 | PARP2 | PARP3 | PARP4 | PBRM1 | PCBP1 | PDCD1 | PDCD1LG2 | PDGFRA | PDGFRB | PDIA3 | PGD | PHF6 | PIK3C2B  
| PIK3CA | PIK3CB | PIK3R1 | PIK3R2 | PIM1 | PLCG1 | PMS1 | PMS2 | POLD1 | POLE | POT1 | PPM1D | PPP2R1A | PPP2R2A | PPP6C | PRDM1 | PRDM9 |  
PRKACA | PRKARIA | PTCH1 | PTEN | PTPN11 | PTPRT | PXDNL | RAC1 | RAD50 | RAD51 | RAD51B | RAD51C | RAD51D | RAD52 | RAD54L | RAF1 | RARA  
| RASA1 | RASA2 | RBL1 | RBM10 | RECQL4 | RET | RHEB | RICTOR | RIT1 | RNASEH2A | RNASEH2B | RNF43 | ROS1 | RPA1 | RPS6KB1 | RPTOR | RUNX1 |  
SDHA | SDHB | SDHD | SETBP1 | SETD2 | SF3B1 | SLCO1B3 | SLX4 | SMAD2 | SMAD4 | SMARCA4 | SMARCB1 | SMC1A | SMO | SOX9 | SPEN | SPOP |  
SRC | STAG2 | STAT3 | STAT6 | STK11 | SUFU | TAP1 | TAP2 | TBX3 | TCF7L2 | TERT | TET2 | TGFBR2 | TNFAIP3 | TNFRSF14 | TOP1 | TP53 | TP63 | TPMT  
| TPP2 | TSC1 | TSC2 | U2AF1 | USP8 | USP9X | VHL | WT1 | XPO1 | XRCC2 | XRCC3 | YAP1 | YES1 | ZFX3 | ZMYM3 | ZNF217 | ZNF429 | ZRSR2

## List of Fusion-Driver-Genes

AKT1 | AKT2 | AKT3 | ALK | AR | BRAF | BRCA1 | CDKN2A | EGFR | ERBB2 | ERBB4 | ERG | ESRI | ETV1 | ETV4 | ETV5 | FGFRI | FGFRII | FGFRL1 |  
MAP3K8 | MET | MTAP | MYB | MYBL1 | NOTCH1 | NOTCH2 | NOTCH3 | NRG1 | NTRK1 | NTRK2 | NTRK3 | NUTM1 | PIK3CA | PIK3CB | PPARG | PRKACA  
PRKACB | RAF1 | RARA | RELB | RET | ROS1 | RSPO2 | RSPO3 | STAT6 | TERT | TFE3

# Performance Characteristics of the assay

Reproducible and sensitive detection of variants across multiple cancer types

**100%**

Analytical Accuracy

**100%**

Analytical Precision

For SNVs, Indels **5%**

Analytical Sensitivity (LOD)

**100%**

Analytical Specificity

	Sensitivity	Specificity
SNVs	99.6%	97.6%
Indels	99.5%	98.1%
CNVs Gain, CNVs Loss	100% 93%	100% 100%
Gene Fusion	100%	100%

Mfine Diagnostics has validated the test and determined its performance characteristics in accordance with the CAP/ACMG and NABL guidelines. All investigations have their limitations which are imposed by the limits of sensitivity & specificity of individual assay procedures as well as the quality of the specimen received by the laboratory.

## Test Ordering Information

Test Code	Test Name	Components	Specimen Type	Method	TAT
ONCO0144	Oncolife Comprehensive Genomic Panel (517 genes+ HRD/GIM)	(517 genes+ HRD/GIM)	FFPE Tissue/Paraffin block Histopathology report must accompany the specimen	NGS	4 Weeks
ONCO0123	Oncolife HRD Reflex	Genetic mutation test for BRCA1/2 will be performed first. If outcome is negative, HRD test will follow	FFPE Tissue/Paraffin block Histopathology report must accompany the specimen		15 + 21 Days
ONCO0068	Oncolife HRR 15 gene Germline panel	ATM, BARD1, BRCA1, BRCA2, BRIP1, CDK12, CHEK1, CHEK2, FANCL, PALB2, PPP2R2A, RAD51B, RAD51C, RAD51D, RAD54L	3 ml EDTA vial - Peripheral blood		21 Days
ONCO0069	Oncolife HRR 15 gene Somatic panel	ATM, BARD1, BRCA1, BRCA2, BRIP1, CDK12, CHEK1, CHEK2, FANCL, PALB2, PPP2R2A, RAD51B, RAD51C, RAD51D, RAD54L	3 ml EDTA vial - Peripheral blood/ Bone Marrow and FFPE Tissue		21 Days
ONCO0067	Oncolife HRR 15 Gene (Germline+Somatic)	ATM, BARD1, BRCA1, BRCA2, BRIP1, CDK12, CHEK1, CHEK2, FANCL, PALB2, PPP2R2A, RAD51B, RAD51C, RAD51D, RAD54L	3 ml EDTA vial - Peripheral blood/ Bone Marrow and FFPE Tissue		21 Days

 [support@mfine.co](mailto:support@mfine.co)

 [www.mfine.co](http://www.mfine.co)