OncoStrands®

ESSENTIAL | EXTENDED | COMPREHENSIVE

Key Biomarkers per Cancer Type
(All covered through various OncoStrands© panels)
associated with FDA-approved targeted therapy[1]

OncoStrands© is Technology-Agnostic:
- Ultilising various NGS technologies (Illumina, Thermo Fisher, Covaris, Twist Biosciences, IDT, etc.).
- Available to choose from both off-the-shelf and/or in-house developed & extensively validated panels including our trademarked OncoStrands© Essential, Extended & Comprehensive assays, ranging from 50 to over 520 genes[2].

Extensive & Unique Combination of Tumour Profiling Tests, screening for:
- DNA & RNA alterations; variants (SNVs, Indels, CNVs), fusion genes and splice sites.
- Genomics signatures including Tumour Mutational Burder (TMB), Microsatellite Instability (MSI) and Homologous Recombination Deficiency (HRD) phenotypes.

Report Includes:
- Contents as per the latest AMP & CAP guidelines
- Recommended clinical matching[1] with biomarkers, & clinical trials as per FDA, EMA, NCCN, ESMO, etc.

All Solid Tumours (pan-cancer biomarkers)

Tumour mutational burden (TMB)
Microsatellite instability (MSI)
Pembrolizumab

NTRK fusions (NTRK1, NTRK2, NTRK3)
Entrectinib & Larotrectinib

Lung, Non-Small Cell Lung Cancer (NSCLC)

AKT1, ALK, BRAF, DDR2, EGFR, ERBB2, FGFR1, FGFR3, KRAS, MAP2K1, MET, NRAS, PIK3CA, PTEN, ROS1, RET, STK11, TP53

ALK, RET, ROS1 rearrangements
Crizotinib, Alectinib, Brigatinib, Lorlatinib, Ceritinib, Pralsetinib, Selpercatinib & Entrectinib

BRAF V600E
Dabrafenib + Trametinib

EGFR (exons 19, 20 & 21 alterations/mutations)
Erlotinib, Gefitinib, Afatinib, Amivantamab, Dacominitib & Osimertinib, Erlotinib + Ramucirumab

MET exon 14 skipping
Capmatinib, Tepotinib

KRAS G12C
Sotorasib

Melanoma

BRAF, CTNNB1, GNA11, GNAQ, KIT, MAP2K1, NF1, NRAS, PDGFRA, PIK3CA, PTEN, TP53

BRAF V600E
Dabrafenib, Vemurafenib

BRAF V600K
Dabrafenib + Trametinib, Encorafenib + Binimetinib, Vemurafenib + Cobimetinib, Trametinib

Colon, Colorectal Cancer

AKT1, BRAF, HRAS, KRAS, MET, MLH1, MSH2, MSH6, NRAS, PIK3CA, PMS2, PTEN, SMAD4, TP53

BRAF V600E
Encorafenib + Cetuximab

KRAS and/or NRAS exon 2,3, 4 mutations
Cetuximab & Panitumumab

MSI-H
Ipilimumab + Nivolumab, Nivolumab

Gastric, Gastrointestinal Stromal Tumour (GIST)

BRAF, KIT, KRAS, MET, MLH1, PDGFRA, TP53

PDGFRA exon 18 mutations
Avapritinib

KIT exon 9, 11, 13, 14, 17 mutations
Imatinib, Sunitinib, Regorafenib, Ripretinib

Prostate Cancer

AR, ATM, BRAF, CD274, FGFR2, MLH1, MSH2, PMS2, PTEN

AR alterations/mutations
Abiraterone, Apalutamide, Bicalutamide, Enzalutamide & Darolutamide

BRCA1, BRCA2
Olaparib, Rucaparib

Other HRR mutations (ATM, BARD1, BRIP1, CDK12, CHEK1/2, FANCA, FANCL, PALB2, RAD51B/C/D, RAD54L, etc.)
Olaparib

Thyroid Cancer

ALK, BRAF, HRAS, KRAS, NRAS, RET, TERT, CDKN2A

Breast Cancer

AKT1, AR, BRCA1, BRCA2, ERBB2, FGFR1, FGFR2, PALB2, PIK3CA, PTEN

BRCA1, BRCA2
Olaparib & Talazoparib

ESR1 (for HR+ and/or HER2+)
Exemestane, Letrozole, Anastrozole, Tamoxifen, Fulvestrant

ERBB2 amplification
Ado-trastuzumab Emtansine, Capecitabine + Trastuzumab + Tucatinib, Neratinib, Pertuzumab + Trastuzumab, Trastuzumab-Deruxtecan, Trastuzumab

PIK3CA
Fulvestrant + Alpelisib

PTEN (for HER2-)
Everolimus

Pancreatic Cancer

AKT1, ATM, BRAF, BRCA1, BRCA2, KRAS, PALB2, PTEN, SMAD4, PALB2

BRCA1, BRCA2
Olaparib

Bladder Cancer

FGFR1, FGFR2, FGFR3, MSH5, PMS2, TSC1

FGFR fusions
Erdafinib

Sarcoma

ALK, APC, BRAF, CDK4, CTNNB1, ETV6, EWSR1, FOX01, GLI1, KJT, MDM2, MYOD1, NAB2, NF1, PAX3, PAX7, PDGFRA, PDGFRB, SDHB, SDHC, SMARCB1, TFE3, WT1

Ovarian, Fallopian Tube, Peritoneal Cancer

BRAF, BRCA1, BRCA2, KRAS, PDGFRA, FOXL2, TP53, HRD

BRCA1, BRCA2
Olaparib, Niraparib, Rucaparib, Bevacizumab + Olaparib

HRD+
Bevacizumab + Olaparib

Brain Cancer

BRAF, CDKN2A, CDKN2B, EGFR, IDH1, IDH2, TERT

Supplementary Tests
to assist better treatment decisions

Immunohistochemistry (IHC):
For the selection of immunotherapies
- PD-L1
- MMR

For TKI inhibitor treatments
- ALK
- ROS1

Promoter methylation (PCR-based):
- MLH1
- MGMT

[1]FDA-approved targeted therapy listed are not exhaustive. Recommended therapy details are part of the report contents for each patient.

[2]Listed biomarkers are available across all OncoStrands© assays. Full list of genes available upon request.

LifeStrands
Empowering lives with Genomics

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LifeStrands Genomics OncoStrands® Test Services

Broad-based genomic profiling utilising various NGS technologies to determine relevant genomic alterations (variants such as SNVs, indels, CNVs, fusion genes and splice sites) and signatures (TMB, MSI and HRD). Reporting content provides insights and actionable information based on the latest AMP & CAP guidelines and provides recommended clinical matchings with biomarkers and available clinical trials (FDA, EMA, NCCN, ESMO, etc.) for a variety of tumours.

OncoStrands® (genomic profiling for TISSUE Biopsy)			
Test Name	**Description**	**No. of Genes****	**TAT***
Essential Combined (DNA + Fusion)	NGS panel with 50 genes associated with different tumour types. This multi-biomarker panel enables the detection of some of the most common actionable targets seen in many cancer types including lung, colon, skin, urinary, bladder, stomach, thyroid and others.	50	7 – 10 days
Essential DNA		45	
Essential Fusion		18	
DNA 68	A 68-genes hybrid capture NGS panel with coverage of full coding regions of 68 key cancer-related genes (plus TERT promoter region), including BRCA1/2. Can be ordered in combination with 18 genes Essential RNA Fusion if screening for fusions is clinically important.	68	
DNA 68 + Essential Fusion		68 + 18 Fusion	
Extended	Hybrid capture DNA NGS panel with coverage of full coding regions, including BRCA1/2 and DNA damage repair genes. The assay also provides an accurate MSI score. Useful for tumours in the prostate, breast, ovary & fallopian tube, pancreas, biliary tract, uterus and colon. Can be ordered in combination with 18 genes Essential RNA Fusion if screening for fusions is clinically important.	109	
Extended + Essential Fusion		109 + 18 Fusion	
Comprehensive	Based on TSO 500 chemistry, the assay offers a comprehensive genomic analysis of 523 genes and targets SNVs, CNVs, fusions, splice variants, MSI and TMB. The assay provides coverage of NCCN biomarkers testing guidelines, genes associated with FDA-approved targeted therapies and clinical trials matching for a variety of tumours. Can be ordered with HRD for early to late-line PARPi treatment decisions for patients with ovarian cancer.	523	12 – 15 days
Comprehensive + HRD#		523 + HRD	
HRD#		BRCA1 & BRCA2 w/HRD	
Comprehensive Fusion	Comprehensive RNA fusion genomic analysis that covers hundreds of cancer-relevant fusion-associated genes, including novel fusions. Useful for rare, undifferentiated cancers, particularly for sarcomas.	501	

IMMUNOHISTOCHEMISTRY (supplementary to OncoStrands® Panels; optional add-on)			
Test Name	**Description**	**Clone**	**TAT***
PD-L1	Detection of PD-L1 protein on FFPE	SP263	5 – 7 days
ALK	Detection of ALK protein on FFPE	N/A	
ROS1	Detection of ROS1 protein on FFPE	N/A	
MMR	Detection of mismatch proteins (MLH1, PMS2, MSH2, MSH6) on FFPE	N/A	

**Full gene list is available upon request.
*TAT is reflected in working days, estimated upon sample receipt at our laboratory in Australia, Melbourne.
#HRD is reported in GIS, based on Myriad Genetics' proprietary algorithm and is available for Ovarian cancer ONLY.

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PCR-based methylation tests to inform and help predict patient outcomes, as well as serve as a guide for preventive measures, such as surveillance and risk reduction strategies, in individuals with an increased risk of developing cancer.

PROMOTER METHYLATION (PCR based)		
Test Name	**Description**	**TAT***
MLH1	Detection of methylation of the MLH1 gene promoter on FFPE, adjunct to MSI, MMR IHC, and for colon or endometrial tumours demonstrating MSI-H and loss of MLH1 protein expression.	5 – 7 days
MGMT	Detection of methylation of MGMT gene promoter on FFPE, for prognostic and predictive value for glioblastoma patients	

*TAT is reflected in working days, estimated upon sample receipt at our laboratory in Australia, Melbourne.

Specimen Requirements

Tissue Type & Selection – FFPE specimens, including cell blocks (core needle biopsies, fine-needle aspirates, and effusion cytologies) are accepted. Unfixed cytology specimens are NOT appropriate for genomic profiling. Decalcified and bleached tissues are NOT accepted. Chemo and radiotherapy-naïve cancer types are preferred. ONLY ovarian, fallopian tube and primary peritoneal cancer types are accepted for Comprehensive + HRD genomic profiling.

DNA/RNA is more stable in blocks than slides, therefore sending blocks is preferred, especially for Fusion panels, as RNA is known to degrade faster than DNA. For slides preparation, a minimum surface area of 5 x 5mm^2 is required. For smaller tissue area lesser than 5 x 5mm^2, additional five to ten (5 – 10) slides is required.

OncoStrands® NGS Panel	Sample Types Accepted	No. of FFPE Slides Required	Tumour Purity	Storage & Shipping Condition
Essential Combined **Essential DNA** **Essential Fusion**	Tissue/Cell block (preferred) OR **Unstained** FFPE slides on **uncoated** slides + 1 x H&E stained slide	10 x 5µm per panel	Minimum 10%	Room temperature (between 20 – 25°C), ship ambient within the same day if possible. DO NOT freeze, and keep away from direct sunlight.
DNA 68 **DNA 68 + Essential Fusion**				
Extended **Extended + Essential Fusion**		15 x 5 µm per panel	Minimum 20%	
Comprehensive **Comprehensive + HRD#** **Comprehensive Fusion**				

#HRD is reported in GIS, based on Myriad Genetics' proprietary algorithm and is available for Ovarian cancer ONLY.

Immunohistochemical Test	Sample Types Accepted	No. of FFPE Slides Required	Storage & Shipping Condition
PD-L1 (SP263)	Tissue/Cell block OR **Unstained** FFPE slides on **coated** slides + 1 x H&E stained slide	4 x 5µm per test	Room temperature (between 20 – 25°C), ship ambient within the same day if possible. DO NOT freeze, and keep away from direct sunlight.
ALK			
ROS1			
MMR (MLH, PMS2, MSH2, MSH6)		5 x 5µm	
Promoter Methylation Test	**Sample Types Accepted**	**No. of FFPE Slides Required**	
MLH1	Tissue/Cell block OR **Unstained** FFPE slides on **uncoated** slides + 1 x H&E stained slide	10 x 5µm (tumour) 10 x 5µm (normal tissue if available)	
MGMT		10 x 5µm	