OncoStrands™

Extended Panel (Tissue Biopsy)

OncoStrands™ Extended Panel (Tissue) tests for 108 selected cancer-relevant genes in a pan-cancer setting from formalin-fixed, paraffin embedded (FFPE) or cytology tumour material. The test was designed with poor quality FFPE samples in mind, and it provides high accuracy, sensitivity, and specificity for even heavily degraded FFPE tissue samples.

In contrast to hotspot panels, this hybrid capture next generation sequencing assay covers the full coding region of 103 out of 108 genes, screening for mutations, small indels, promoter mutations (*TERT* gene), and copy number variations (CNVs). The assay is particularly useful for advanced pancreatic, prostate, breast, hepatobiliary, colorectal, uterine, ovarian and fallopian tube tumours as most of the currently known DNA damage repair genes, including *BRCA1* and *BRCA2* are covered. It also provides an accurate microsatellite instability (MSI) value for each sample (close to 170 MSI loci have been included in the panel design compared to just 5 loci screened for in conventional tests).

The assay can detect biomarkers that are frequently mutated in various cancer types. This data, combined with cutting-edge curation and analysis solutions, enables not only the detection of biomarkers but also matching with key and emerging treatment guidelines, FDA-approved targeted therapies, and clinical trials. The assay provides an accurate MSI score, and even more value when combined with the 18 gene OncoStrands™ Essential RNA fusion panel.

This enables oncologists to select the most appropriate therapeutic approach, anticipate prognosis of the disease course, and fully personalize the disease management for each patient.

108 Pan-Cancer Gene DNA Targets
SNVs, CNVs, MSI
Full coding regions – 103 genes including *BRCA1/2*

Low (20%)* Tumour Content (TC) Required

Screens Key and Emerging Biomarkers for Multiple Tumour Types
Screens for FDA-approved therapies & NCCN recommended biomarkers

High Accuracy at ≥5% Limit of Detection
Customised assay chemistry validated* even for poor quality FFPE samples

10 Days Turnaround Time**

Bespoke Consultation with Molecular Pathologists

*Validated at 10% TC for SNVs and 20% TC for CNVs and MSI
**Comprehensive report available 10 working days from laboratory sample receipt and subject to sample acceptance criteria

Test Specifications & Validation Characteristics

Based on in-house validation of clinical samples and reference standards

Methodology	Next generation sequencing
Aberrations Covered	SNVs, indels, CNVs, MSI
Specimen Requirements	• FFPE tissue block OR minimum 10 unstained sections (each 5µm thick). Minimum tumour content of 20%. • Copy of histology report.

*Please refer to the Molecular Oncology Request Form for full specimen requirements.

Mutation Type	Accuracy	Sensitivity	Specificity	Limit of Detection
SNVs/indels	100%	100%	100%	≥5%
CNVs*	100%	99.0%	100%	N/A
MSI	**MSI** -percentage concordance with samples run on orthogonal tests = 100% (close to 170 MSI loci included for screening in the assay)			

*CNVs on targeted NGS platforms is an estimate based on prediction algorithm which considers multiple factors. The assay is validated for gene amplifications of ≥5 and homozygous deletions.

OncoStrands™ Extended Panel Full Gene List

AKT1, ALK, APC, AR, ARID1A, ATM, ATR, BAP1, BARD1, BRAF, BRCA1, BRCA2, BRIP1, CDH1, CD274, CDK4, CDK6, CDK12, CDKN2A, CDKN2B, CHEK1, CHEK2, CSF1R, CTNNB1, CYSLTR2, DDR2, EGFR, EPCAM, ERBB2, ERBB3, ERCC2, ESR1, EZH2, FANCA, FANCL, FBXW7, FGFR1, FGFR2, FGFR3, FOXL2, GNA11, GNAQ, GNAS, HDAC2, HNF1A, HRAS, H3F3A(hotspots only), *H3F3B*(hotspots only), *HIST1H3B*(hotspots only), *HIST1H3C*(hotspots only), *IDH1, IDH2, JAK2, KEAP1, KIT, KRAS, MAP2K1, MAP2K2, MET, MLH1, MRE11, MSH2, MSH6, MYC, MYCN, MTOR, MUTYH, NBN, NF1, NF2, NFE2L2, NOTCH1, NRAS, NTRK1, NTRK2, NTRK3, PALB2, PDGFRA, PDGFRB, PIK3CA, PMS2, POLD1, POLE, PPP2R1A, PPP2R2A, PTCH1, PTEN, PTPN11, RAD50, RAD51B, RAD51C, RAD51D, RAD54L, RAF1, RB1, RET, ROS1, SETD2, SF3B1, SMAD4, SMARCB1, SMO, SRC, STK11, TERT*(5' promoter only), *TP53, TSC1, TSC2, and VHL*

LifeStrands Empowering Lives with Genomics | DNA LAB

This Assay Screens For Genetic Alterations That Are Linked To Current FDA Approved Therapies*

Tumour Type	Genetic Alterations/Biomarker	FDA-Approved Targeted Therapies (OR Contraindications)
FDA-Approved Treatments For Specific Genetic Alterations In Specific Tumour Types		
Non-small-cell lung cancer (NSCLC)	*BRAF* V600E	Dabrafenib + Trametinib
Melanoma		Dabrafenib, Vemurafenib
		Dabrafenib + Trametinib, Encorafenib + Binimetinib, Vemurafenib + Cobimetinib, Trametinib
Anaplastic thyroid cancer		Dabrafenib + Trametinib
Colorectal cancer		Encorafenib + Cetuximab
Melanoma	*BRAF* V600K	Dabrafenib + Trametinib, Encorafenib + Binimetinib, Vemurafenib + Cobimetinib, Trametinib
Ovarian cancer, fallopian tube cancer, peritoneal cancer	Deleterious or suspected deleterious germline or somatic mutations in *BRCA1* and/or *BRCA2*	Olaparib, Rucaparib, Niraparib
Prostate cancer		Olaparib, Rucaparib
Ovarian cancer, pancreatic adenocarcinoma	Deleterious or suspected deleterious germline mutations in *BRCA1* and/or *BRCA2*	Olaparib
HER-2 negative breast cancer		Olaparib, Talazoparib
Prostate cancer	Deleterious or suspected deleterious germline or somatic mutations in *ATM, BARD1, BRIP1, CDK12, CHEK1, CHEK2, FANCL, PALB2, RAD51B, D51C, RAD51D,* and *RAD54L*	Olaparib
NSCLC	*EGFR* exon 19 deletions, L858R	Afatinib, Dacomitinib, Erlotinib, Gefitinib, Osimertinib
	EGFR exon 20 insertions	Amivantamab
	EGFR non-resistant mutations other than exon 19 deletions and L858R	Afatinib
	EGFR T790M	Osimertinib
Breast cancer	*ERBB2* amplification	Ado-Trastuzumab Emtansine, Capecitabine + Trastuzumab + Tucatinib, Neratinib, Pertuzumab + Trastuzumab, Trastuzumab, Trastuzumab Deruxtecan
Oesophageal cancer		Trastuzumab
Gastric cancer, gastroesophageal junction cancer		Trastuzumab Deruxtecan
Bladder cancer	*FGFR3* oncogenic mutations	Erdafitinib
NSCLC	*KRAS* G12C	Sotarasib
NSCLC	*MET* exon 14 skipping	Capmatinib, Tepotinib
Colorectal cancer	MSI-H	Ipilimumab + Nivolumab, Nivolumab
Endometrial cancer		Dostarlimab
Gastrointestinal stromal tumour (GIST)	*PDGFRA* exon 18 mutations	Avapritinib
HR+ HER2- breast cancer	Oncogenic mutations in *PIK3CA*	Fulvestrat + Alpelisib
Medullary thyroid cancer	Oncogenic mutations in *RET*	Pralsetinib, Selpercatinib
FDA-Approved Treatments For Specific Biomarkers In Tumour Type-agnostic Indications		
Pan-cancer (solid tumours)	MSI-H	Pembrolizumab
FDA-Approved Treatments That Are Not Biomarker-linked In Solid Tumours Characterised By Specified Genetic Alterations		
Neurofibroma	Oncogenic mutations in *NF1*	Selumetinib
Epithelioid sarcoma	*SMARB1* deletions	Tazemetostat
Subependymal giant cell astrocytoma (SEGA)	Oncogenic mutations in *TSC1/TSC2*	Everolimus
GIST	*KIT* exon 9, 11, 13, 14, 17 mutations	Imatinib, Sunitinib (post progression on Imatinib), Regorafenib (post progression on Imatinib and Sunitinib), Ripretinib (post progression on ≥3 kinase inhibitors including Imatinib)
FDA-Listed Genetic Alterations Contraindicated For Specific Treatments		
Colorectal cancer	*KRAS* and/or *NRAS* exon 2, 3, and 4 mutations	Contraindicated for Panitumumab, Cetuximab
Pan-cancer (solid tumours)	*NTRK1* and *NTRK3* known acquired resistance mutations (e.g., *NTRK1* G595R and G667C; *NTRK3* F617L, G623R, and G696A)	Contraindicated for Entrectinib, Larotrectinib
FDA-Approved Combination Treatments With Nontargeted Therapies For Specific Genetic Alterations		
Melanoma	*BRAF* V600	Atezolizumab + Cobimetinib + Vemurafenib
Fallopian tube, ovarian, primary peritoneal carcinoma	Deleterious germline or somatic mutations in *BRCA1* and/or *BRCA2*	Bevacizumab + Olaparib
NSCLC	*EGFR* exon 19 deletions, L858R	Erlotinib + Ramucirumab
Esophagogastric cancer	*ERBB2* amplification	Trastuzumab + Cisplatin + Capecitabine or Fluorouracil

*Modified from www.ascopubs.org, current as of June 2022

Reports Include

- Contents as per the latest AMP and CAP guidelines
- Recommended clinical matching with biomarkers, and clinical trials as per FDA, EMA, NCCN, ESMO, etc.

Services Include

- Quality control for tissue adequacy performed by staff pathologist
- Tests run in house by qualified scientific and clinical staff under an accredited environment
- Complimentary consultation on various aspects of testing (e.g., appropriate test options based on tumour type, tissue availability etc.) provided by qualified staff molecular pathologist

Additional Services

- IHC- MMR, PDL-1, *ALK*, *ROS1*
- Range of Oncostrands™ (oncosomatic) and hereditary panels

About Us

At LifeStrands Genomics laboratories we believe that everyone should have access to better healthcare through the advancement of clinical genomics. Within our accredited laboratories, our dedicated team of medical professionals and scientists work together to deliver high-quality and reliable genomic solutions to clinicians, patients & researchers.

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