DataSheet

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OncoScan™ FFPE Assay Kit

Genome-wide copy number in 48 hours

Copy number analysis in solid tumors is rapidly gaining importance in cancer diagnosis, prognosis, and therapy selection[1]. OncoScan™ FFPE Assay Kit is capable of determining highly accurate copy number changes and allelic imbalances, including loss of heterozygosity (LOH) in solid tumors from limited amounts of highly modified and degraded FFPE-derived DNA.

The OncoScan™ assay utilizes the Molecular Inversion Probe (MIP) technology, a proven technology for identifying copy number alterations, loss of heterozygosity (LOH), and detecting somatic mutations. This assay has been shown to perform well with highly degraded DNA, such as that derived from FFPE-preserved tumor samples of various ages and with low inputs of DNA starting material, making the assay a natural choice in cancer clinical research.

MIP probes are used to capture the alleles of over 220,000 SNPs at carefully selected genomic locations, evenly distributed across the genome and with increased density within ~900 cancer genes.

OncoScan FFPE Assay Kit offers:

- **Low sample input, fast results** – from only 80 ng of FFPE-derived DNA to results in 48 hours
- **One assay, multiple data views** – whole-genome copy number, loss of heterozygosity (LOH) at ≤10 Mb across the genome, and detection of key somatic mutations
- Detection of copy number changes found in as low as 25% of aberrant cells with **a linear copy number range of 50+ copies**
- High-resolution (50–125 kb) copy number detection in priority cancer genes
- **Rapid analysis** – visualization of copy number data for hundreds of samples in minutes
- Detection of frequently tested **somatic mutations** at ~20% sensitivity

The OncoScan FFPE assay algorithms have been especially developed to address two major challenges associated with solid tumor copy number analysis: first, establishing the expected normal copy number state for a given locus, and second, accounting for "normal cell contamination" present in most samples, which affects copy number estimates.

To address the first issue, a universal reference dataset has been created of ~400 normal and normal adjacent tissue (NAT) FFPE samples from over 20 sources covering a broad range of geographic locations, collection sites, block ages, cancer tissue types as well as gender. These were chosen to capture the diversity of FFPE samples for which the normal copy number at each locus was assessed.

Secondly, the TuScan algorithm was developed based on a modification of ASCAT[2] to determine if a consistent percentage of aberrant cells (%AC) and ploidy are present at each copy number change. When successful, the algorithm reports the linear integer copy number in the cancer portion only, effectively subtracting the normal component, thereby enabling a comparison between tumor samples with different contributions of normal cell contamination. For highly heterogeneous samples or where there is a very low percentage presence of aberrant cells, the algorithm reports the fractional, average linear copy number of all cells within the sample.

OncoScan FFPE assay genetic coverage

The MIP probes were carefully selected and empirically tested to provide the best performance across the genome with a higher density of SNP probes in cancer and cancer-related genes.

The genes covered at the highest probe density were selected through collaboration with leading scientists from Stand Up to Cancer® consortium (SU2C); other target genes were selected following input from Cancer Genomics Consortium and Cancer Gene census lists from the Wellcome Trust Sanger Institute.

Genetic content	Resolution	Median probe density (kb/probe)
Cancer gene coverage		
232 genes (of highest clinical relevance)	50 kb	2.5
644 genes	50–110 kb	5.0
15 genes	110–125 kb	5.6
Whole-genome coverage		
90% of genome (outside of cancer genes)	300–310 kb	16
97% of genome (outside of cancer genes)	380 kb	19

The MIP probes have been designed to detect SNPs with the highest minor allele frequency (MAF) and were selected to obtain maximum information about allelic imbalances resulting from copy number changes.

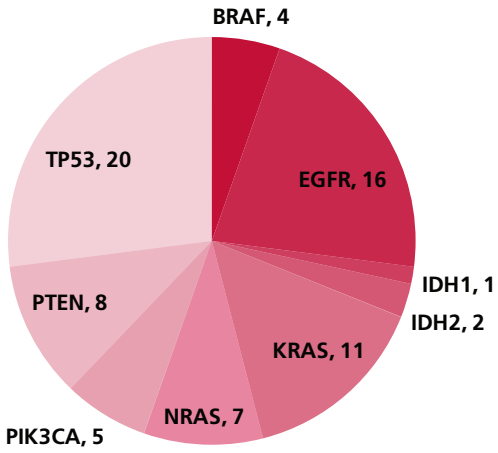
The somatic mutation panel covers 74 mutations in nine genes (BRAF, KRAS, EGFR, IDH1, IDH2, PTEN, PIK3CA, NRAS, TP53), and concordance with orthogonal methods has been demonstrated for multiple somatic mutations. A software tool is provided for visualization of the mutant call versus the reference (wild type).

References

1 Ciriello G., *et al*. Emerging landscape of oncogenic signatures across human cancers. *Nature Genetics* **45**(10):1127–1133 (2013).

2 Van Loo P., *et al*. Allele-specific copy number analysis of tumors. *PNAS* **107**(39):16910–16915 (2010).

Figure 1A: Number of somatic mutations by gene detected by the OncoScan FFPE assay.



OncoScan™ FFPE Assay Kit contents

Part number	Product name	Description
902293	OncoScan™ FFPE Assay Kit (OncoScan™ Reagent Kit + 48 OncoScan™ Arrays)	Sufficient for 24 samples
902305	OncoScan™ Training Kit (OncoScan Reagent Kit + 36 OncoScan Arrays)	Sufficient for 18 samples

OncoScan™ Reagent Kit components

Module	Storage	Part number[1]
OncoScan™ Somatic Mutation Probe Mix 1.0	–20°C	902272
▪ Somatic Mutation Probe Mix 1.0		▪ 902247
OncoScan™ Copy Number Probe Mix 1.0 & Controls	–20°C	▪ 902268
▪ Positive Control (12 ng/µL)		▪ 902249
▪ Negative Control		▪ 902250
▪ Copy Number Probe Mix 1.0		▪ 902248
▪ Buffer A		▪ 902246
OncoScan™ Gap Fill and 1st Stage PCR	–20°C	902269
▪ Buffer A		▪ 902246
▪ Gap Fill Enzyme Mix		▪ 902252
▪ SAP, Recombinant (1 U/µL)		▪ 902251
▪ dNTP Mix (A/T)		▪ 902254
▪ dNTP Mix (G/C)		▪ 902255
▪ Nuclease-Free Water		▪ 902253
▪ Exo Mix		▪ 902256
▪ Cleavage Buffer		▪ 902257
▪ Cleavage Enzyme (2 U/µL)		▪ 902258
▪ PCR Mix		▪ 902259
▪ Taq Polymerase (5 U/µL)		▪ 902260

Module	Storage	Part number[1]
OncoScan™ 2nd Stage PCR and Post PCR Processing	–20°C	902270
▪ PCR Mix		▪ 902259
▪ Taq Polymerase (5 U/µL)		▪ 902260
▪ Buffer B		▪ 902261
▪ HaeIII Enzyme (10 U/µL)		▪ 902262
▪ Exo I Enzyme (20 U/µL)		▪ 902263
▪ Nuclease-Free Water		▪ 902253
▪ Hybridization Mix		▪ 902264
OncoScan™ Stain Reagents	2–8°C	902271
▪ Stain 1		▪ 902265
▪ Stain 2		▪ 902266
▪ Array Holding Buffer		▪ 901733
Individual Bottles	Room temp	
▪ Wash A		▪ 901680
▪ Wash B		▪ 901681

[1]Part numbers are for identification purposes only. Individual kit components cannot be ordered separately.

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