FLUXION

DATA SHEET

Spotlight 59™ Oncology Panel

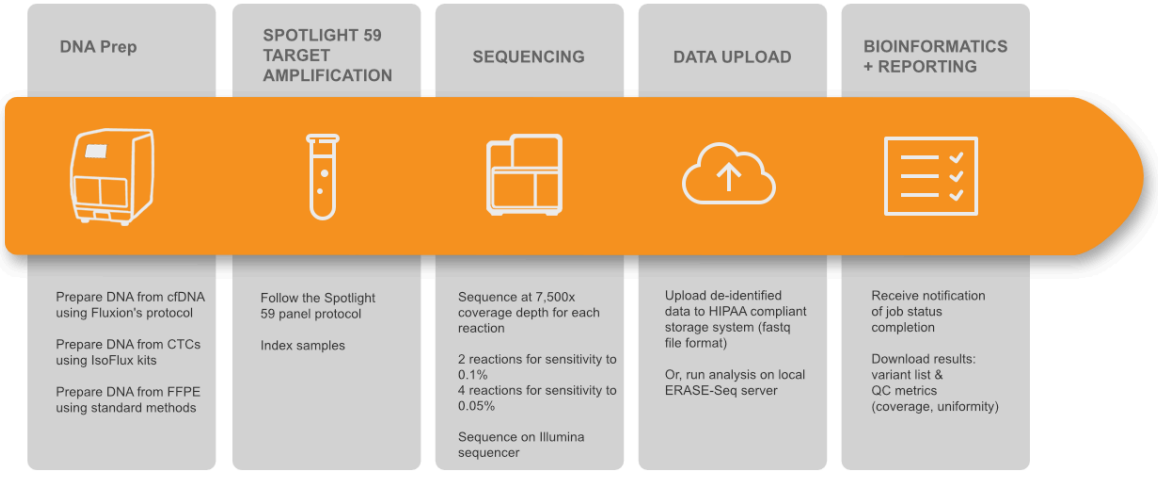
All-in-one liquid biopsy solution for ultra-sensitive variant detection from cfDNA

Designed specifically for detection of somatic mutations from liquid biopsy samples, the Spotlight 59 Oncology Panel is a turnkey solution for Illumina sequencers, offering ultra-sensitive variant detection from low input quantities of DNA. The high sensitivity of Spotlight 59 makes it ideal for cfDNA, CTCs, and other challenging sample types. Combined with ERASE-Seq, Fluxion's statistically powered variant caller, Spotlight 59 delivers >90% sensitivity and <0.1 false positives at 0.1% allele frequency. Compatible with cfDNA and CTCs from Fluxion's IsoFlux Liquid Biopsy System, Spotlight 59 creates a complete sample-to-answer assay for high sensitivity mutation detection of solid tumor cancers from blood samples.

Features

- >90% sensitivity and <0.1 false positives per sample at 0.05-0.1% allele frequency
- Turnkey solution for library generation in a single kit, including sequencing adapters and sample barcodes
- Ready-to-sequence libraries in just 2 hours
- Starting input quantities as low 20 ng total DNA
- Average amplicon size of 140 bp for compatibility with cfDNA and FFPE
- ERASE-Seq cloud-based variant calling included with kit purchase
- Custom configurations available to target specific variants
- No MIDs (molecular IDs) required; increases sensitivity, reduces bias and assay complexity
- No primer trimming required

The Spotlight 59 Oncology Panel offers comprehensive and hotspot coverage of 59 clinically-relevant oncology-related genes, using a 277-amplicon design to generate multiplex libraries compatible with Illumina sequencing platforms. Spotlight 59 is powered by ERASE-Seq, Fluxion's statistically powered variant caller that is available free of charge to Spotlight users. ERASE-Seq utilizes statistical analysis to compare sequencing results to a detailed background model and technical replicates. This approach eliminates both random errors and systemic biases inherent in all sequencing workflows. ERASE-Seq delivers superior detection sensitivity to 0.1% allele frequency and below, with a false positive rate 10-100X lower than leading molecular barcode approaches.



The Spotlight 59 liquid biopsy workflow for ultra-accurate detection of rare variants starts with isolation of DNA from a blood sample. This is followed by targeted amplification and sequencing at 15,000X per sample (standard protocol). Fluxion's ERASE-Seq bioinformatics solution is accessed via secure upload to a HIPAA-compliant cloud-based server. Statistical comparison to a well-characterized normal control specific to the Spotlight 59 panel is performed, allowing accurate variant calling to 0.1% allele frequency and below. Variant calls are available for download within 24-48 hours. The analysis service is included for Spotlight 59 customers.

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Product Specifications

Feature	Specification
Input DNA Required	20 ng (2-reaction kit) or 40 ng (4-reaction kit)
Starting Sample	cfDNA, CTC, FFPE
Library Prep Time Required	2 hours
Number of Amplicons	277
Amplicon Size	Average 140 bp
Number of Genes Covered	59
Total Target Size	25.75 kb
On Target Percentage	> 90%
Coverage Uniformity at > 20% of Mean	> 90%
Sensitivity (for base substitutions)	>90% at 0.1-0.2% allele frequency, 2-reaction kit >90% at 0.05-0.1% allele frequency, 4-reaction kit
Specificity	<0.1 false positives per sample
Validated Sequencers	MiSeq, MiniSeq, HiSeq, NextSeq, Iseq, NovaSeq
Average Sequencing Depth	15,000X (2-reaction kit); 30,000X (4-reaction kit)

Genes Represented

Genes represented in the Spotlight 59 Oncology Panel and Number of Amplicons

ABL1	5	*DDR2*	1	*FLT3*	4	*IDH2*	2	*MSH6*	4	*RET*	6
AKT1	2	*DNMT3A*	1	*FOXL2*	1	*JAK2*	2	*NOTCH1*	3	*STK11*	5
ALK	2	*EGFR*	9	*GNA11*	2	*JAK3*	3	*NPM1*	1	*SMAD4*	10
APC	9	*ERBB2*	4	*GNAQ*	2	*KDR*	9	*NRAS*	3	*SMARCB1*	4
ATM	19	*ERBB4*	8	*GNAS*	2	*KIT*	14	*PDGFRA*	4	*SMO*	5
BRAF	2	*EZH2*	1	*H3F3A*	2	*KRAS*	3	*PIK3CA*	11	*SRC*	1
CDH1	3	*FBXW7*	6	*HIST1H3B*	4	*MAP2K1*	5	*PIK3R1*	8	*TP53*	21
CDKN2A	2	*FGFR1*	2	*HNF1A*	4	*MET*	6	*PTEN*	14	*TSC1*	1
CSF1R	2	*FGFR2*	4	*HRAS*	2	*MLH1*	1	*PTPN11*	2	*VHL*	3
CTNNB1	1	*FGFR3*	6	*IDH1*	1	*MPL*	1	*RB1*	12		

The Spotlight 59 Oncology Panel includes both clinically relevant hotspot loci and regions of contiguous coverage, depending on the allele distribution across each target gene. The table depicts the genes represented, followed by the number of amplicons for each gene.

Contiguous, overlapping coverage is included for APC, ATM, EGFR, FBXW7, FGFR3, H3F3A, HNF1A, KIT, MSH6, PIK3CA, PTEN, SMAD4, and TP53.

Comprehensive coding exon coverage is included for TP53.

Ordering Information

Description	Part Number
48-sample Spotlight 59 Oncology Panel, including primer pool, library kit, and adapter kit; 0.1% AF sensitivity, 20 ng input, 2 reaction tubes per sample	910-0118
24-sample Spotlight 59 Oncology Panel, including primer pool, library kit, and adapter kit; 0.05% AF sensitivity, 40 ng input, 4 reaction tubes per sample	910-0113

The Spotlight 59 Oncology Panel is powered by Swift Biosciences Accel-Amplicon™ technology

For research use only. Not for use in diagnostic procedures.

Swift BIOSCIENCES™

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