FLUXION

DATA SHEET

Spotlight TP53™ Liquid Biopsy Panel

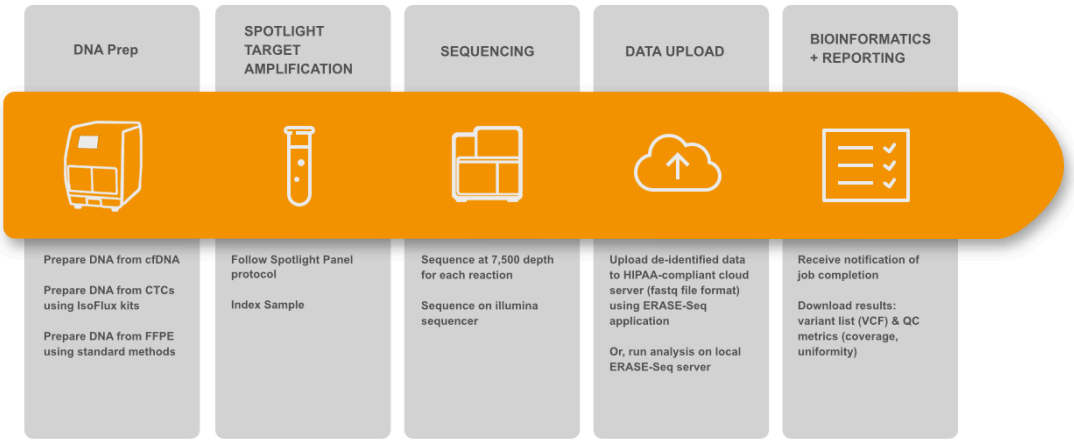
Comprehensive coverage of all coding regions of TP53

The Spotlight TP53 liquid biopsy NGS panel contains 21 amplicons with an average size of 140 bp that provides comprehensive coverage of all coding regions of TP53. The Spotlight TP53 Panel is compatible with short DNA fragments from cfDNA and FFPE samples. This product is a complete kit that includes all elements necessary for generating ready-to-sequence libraries, including primer pairs and indexed sequencing adapters. Combined with ERASE-Seq, Fluxion's statistically powered variant caller, Spotlight TP53 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 TP53 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 UMIs (molecular IDs) required; increases sensitivity, reduces bias and assay complexity

Spotlight TP53 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 TP53 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 (7,500X per reaction, 2 reactions). Fluxion's ERASE-Seq bioinformatics solution is accessed via secure upload to a HIPAA-compliant cloud-based server. Statistical comparison to a well-characterized reference model specific to the Spotlight TP53 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 is included for Spotlight customers.

Product Specifications

Feature	Specification
Input DNA Required	20 ng (2-reaction kit)
Starting Sample	cfDNA, CTC, FFPE
Library Prep Time Required	2 hours
Number of Amplicons	21
Amplicon Size	106-154 bp (average 140 bp)
Total Target Size	1.8 kb
On Target Percentage	> 95%
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 per sample

Ordering Information

Description	Part Number
24-sample Spotlight TP53 Panel, including primer pool, library kit, and adapter kit; 0.1% AF sensitivity, 20 ng input, 2 reaction tubes per sample, ERASE-Seq data analysis	910-0131

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

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RevC, P/N 634-0097