InVisionFirst® LUNG

About InVisionFirst®-Lung

InVisionFirst®-Lung is a clinical diagnostic laboratory-developed test (LDT) validated for the accurate identification of genomic alterations in 37 genes that helps support the therapeutic decisions in patients diagnosed with advanced non-small cell lung cancer (NSCLC).

Using a proprietary enhanced tagged-amplicon Next Generation Sequencing (eTAm-Seq™) technology, this test can detect single nucleotide variants (SNVs), small insertions and deletions (InDels), copy number (CNVs), and structural variants (SV) such as fusions from plasma cell free DNA (cfDNA) with a detection range as low as 0.1% variant allele fraction with a mean read depth of 70,000.

InVisionFirst®-Lung at a glance

Run on two 10 mL blood collection tubes	37 gene panel including NSCLC markers	Turnaround time 7 calendar days	Results accessible through secure online portal

Indications for Use / Medicare Coverage[1]

At diagnosis*

> When results for EGFR SNVs and InDels; rearrangements in ALK, NTRK1, RET and ROS1; and SNVs for BRAF are not available;
AND

> When tissue-based comprehensive genomic profile (CGP) is infeasible [i.e., quantity not sufficient or tissue-based CGP or invasive biopsy is medically contraindicated].

Or

At progression*

> For patients progressing on or after chemotherapy or immunotherapy who have not been tested for EGFR SNVs and indels; rearrangements in ALK, NTRK1, RET and ROS1; and SNVs for BRAFs, and for whom tissue- based CGP is infeasible;
OR

> For patients progressing on EGFR tyrosine kinase inhibitors (TKIs).

InVisionFirst®-Lung analytical performance specifications for the 8 NSCLC actionable genes[1,2]

	Detection Range	*Variant Allele Fraction CNAR*	*Analytical Sensitivity*	*Analytical Specificity*
SNVs	≥0.10%	0.25% 0.06-0.08%	95.0% 93.0%	100%
Indels	≥0.10%	0.50% 0.10%	98.4% 83.0%	100%
Fusions	≥0.10%	0.50% 0.06%	96.2% 77.5%	100%
CNVs	≥1.25x	≥1.5x ≥1.25x	98.3% 86.0%	100%

CNAR: Copy Number Amplification Ratio

* If no genetic alteration is detected by InVisionFirst®-Lung or if circulating tumor DNA (ctDNA) is insufficient/not detected, tissue-based genotyping should be considered.

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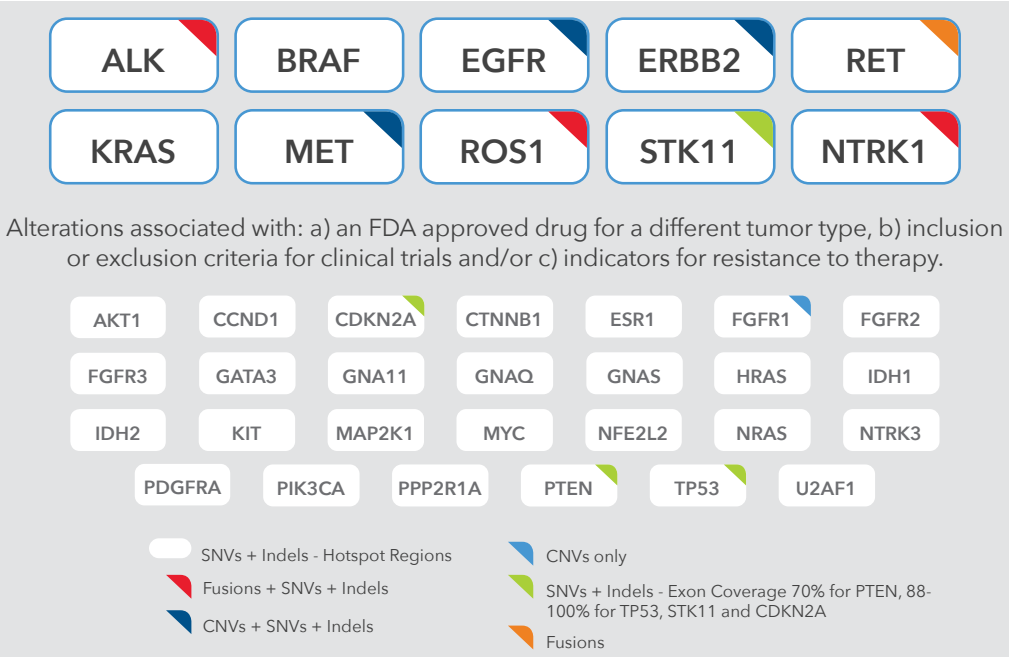
Gene Panel List

Includes well-established alterations associated with NSCLC [2]



Report

✓ The report includes genetic alterations and corresponding recommended therapeutics, such as assessment of predicted response to treatments and availability of currently enrolling clinical trials.

NSCLC driver alterations plasma vs tissue comparison[3]

	PPV	*NPV*	*Specificity*
EGFR (exons 18-21)	100.0%	96.7%	100.0%
ALK/ROS1 fusions	100.0%	99.0%	100.0%
BRAF V600E	100.0%	98.6%	100.0%
ERBB2 (HER2) exon 20 ins	100.0%	100.0%	100.0%
KRAS	98.0%	87.8%	98.9%
MET ex14del	100.0%	97.8%	100.0%
STK11	93.8%	93.9%	98.9%

98%
Concordance with tissue

98.9-100%
Specificity

26%
more actionable alterations detected compared to tissue

Note: The InVisionFirst®-Lung Assay is not intended for profiling for germline (i.e., inheritable) mutation testing.

References: 1. Inivata. (Centers for Medicare and Medicaid Services, https://www.cms.gov/medicare-coverage-database/, 2019). 2. Plagnol, V. *et al.PloS one* 13, e0193802, doi:10.1371/journal.pone.0193802(2018). 3. Pritchett, M.A. *et al. JCO Precision Oncology* 1-15, doi:10.1200/po.18.00299 (2019).

NEO GENOMICS

neogenomics.com client.services@neogenomics.com Toll Free 866.776.5907

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