Integrated ONCOLOGY
LabCorp Specialty Testing Group

Resolution ctDx Lung™ Assay

ctDNA LIQUID BIOPSY NGS ASSAY

Provides clinicians with information that can drive treatment decisions in patients with NSCLC

The Resolution ctDx Lung assay includes actionable genes for targeted FDA-approved therapies or therapies in clinical trials.

BENEFITS

- An assay that only focuses on genes implicated in lung cancer
- Liquid biopsies can offer a complete picture of tumor heterogeneity
- Useful when tissue biopsies are limited or unobtainable from the patient
- Non-invasive method with testing performed on a blood sample
- Faster turn-around time compared to tissue NGS profiling[1]

CLINICAL DATA

Clinical Response Rate Data

In a prospective clinical study, the Resolution ctDx Lung assay demonstrated the following performance[1]:

- Somatic mutations detected in **64%** (135/210) of patients
- **97%** (34/35) of patients who received plasma-directed therapy had a clinical and radiological response to the matched targeted therapy
- **46%** (96/210) of patients had an oncogenic driver alteration detected, including actionable mutations in *EGFR*, *ALK*, *MET*, *BRAF*, *ROS1*, and *RET*.
- **90%** (60/67) positive concordance between plasma and tissue NGS testing. Sub-analysis demonstrated **96%** (49/51) positive concordance within NCCN® oncogenic recognized driver alterations in lung cancer.

Resolution ctDx Lung assay out-performs in detecting gene fusions

A comparison study was performed between two ctDNA assays, Resolution ctDx Lung and Guardant360®, to determine concordance from reports of actionable gene fusions in NSCLC[2].

- In tumor positive *ALK*, *ROS1*, or *RET* fusions samples, the following number of fusions were detected in the corresponding plasma samples:

Test	Fusions Detected (compared to tissue)[2]	Allele Frequency Range[3]
Resolution ctDx Lung	81.3% (13/16)	0.17-62.8%
Guardant360	43.8% (7/16)	0.3-8.2%

- For cases detected by both assays, Resolution ctDx Lung identified the mutations at a median of a 7% higher allele frequency demonstrating an increase in overall sensitivity.[2]
- For 6 patients in which a fusion was detected only by the Resolution ctDx Lung assay, the average time to treatment discontinuation was 15.2 months (range of 3-34 months).[3]

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GENE LIST

The Resolution ctDx Lung™ assay targets actionable, somatic SNVs, indels, fusions, and copy number variants in 23 genes in NSCLC.[4]

Gene	SNV/Indel	Fusions	CNV
AKT1	●		
ALK	●	●	
B2M	●		●
BRAF	●		
EGFR	●	●	●
ERBB2 (HER2)	●		●
FGFR1			●
FGFR2	●	●	
FGFR3		●	
KEAP1	●		
KRAS	●		●
MAP2K1 (MEK1)	●		
MET	●		●
MYC			●
NRAS	●		
NTRK1		●	●
PIK3CA	●		●
PTEN			●
RET	●	●	
RICTOR			●
ROS1	●	●	
STK11	●		●
TP53	●		●

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3. Resolution Bioscience. (2019, June 17). Resolution Liquid Biopsy *Assay Detects More Complex Variants than Guardant360 in Retrospective Lung Cancer Comparison Study* [Press Release]. Available at: https://www.businesswire.com/news/home/20190617005175/en. Accessed February 11, 2020.
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