*Liquid Biopsy Research Summary*

# Foundation Medicine's ctDNA Tumor Fraction Informs Interpretation of Driver-Negative Liquid Biopsies[1]

Rolfo CD, et al. Journal of Clinical Oncology 41, no. 16_suppl (June 01, 2023) 9076-9076. DOI: 10.1200/JCO.2023.41.16_suppl.9076

***A study investigating whether algorithmic quantification of ctDNA in a LBx sample can increase confidence in negative LBx results, reducing need for confirmatory tissue biopsy testing.***

## Liquid biopsy sensitivity to detect genomic alterations varies based on the amount of circulating tumor DNA (ctDNA) in the blood.[1-3]

Foundation Medicine's ctDNA tumor fraction quantifies ctDNA level to inform clinical decision making.

## BACKGROUND

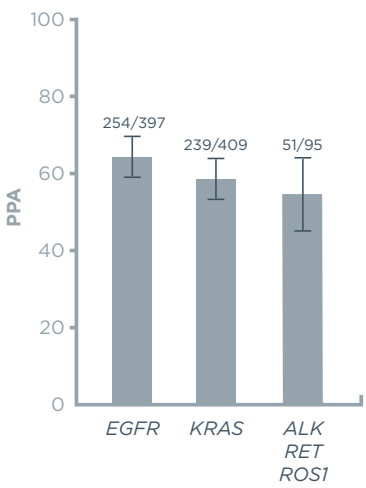
- Professional guidelines recommend genomic testing in multiple cancer types; however, many patients receive limited or no biomarker testing[1,2]
- Liquid biopsy (LBx) is a pragmatic and accessible option for comprehensive genomic profiling (CGP) that detects actionable alterations to inform treatment decisions and promote guideline-adherent care[2]
- Professional guidelines recommend reflex to tissue biopsy when liquid biopsy is negative[2]
- Foundation Medicine's ctDNA tumor fraction is a biomarker measuring ctDNA level in a sample; this study evaluated the relationship between ctDNA tumor fraction and biomarker detection[1,3]

## METHOD

- Samples from patients with advanced non-small cell lung cancer (aNSCLC) that received both FoundationOne CDx and FoundationOne Liquid CDx testing were analyzed[1]
- Eligible patients had tissue collected prior to liquid biopsy, with a median of 306 days between collection dates[1]
- ctDNA level was quantified using Foundation Medicine's ctDNA tumor fraction[1]
- Positive percent agreement (PPA) between FoundationOne Liquid CDx FoundationOne CDx in detection of oncogenic driver alterations was calculated.[1]

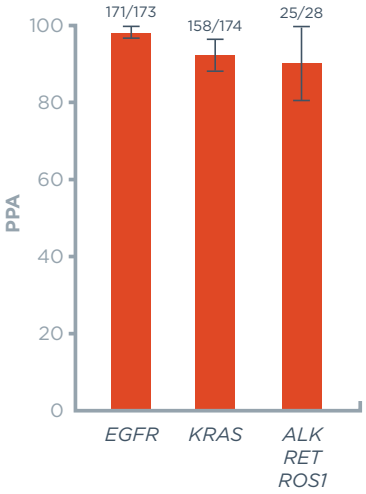
## NSCLC

### Overall Population



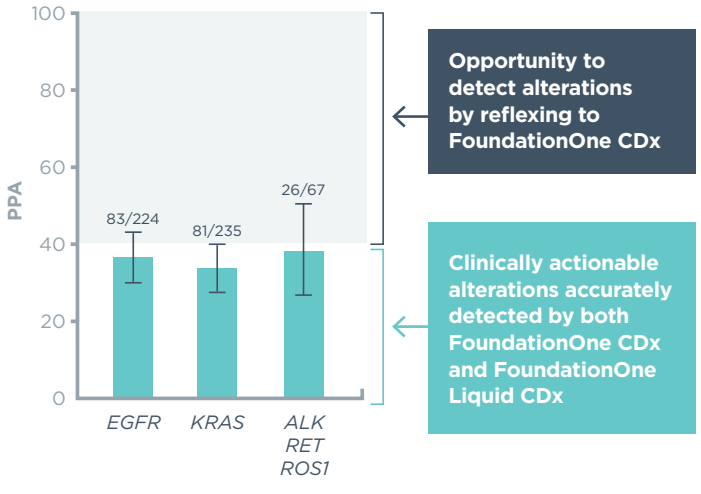

### ctDNA tumor fraction ≥1%

PPA is high, increasing confidence in negative FoundationOne Liquid CDx results




### ctDNA tumor fraction <1%

PPA is reduced, increasing the importance of confirmatory tissue testing with FoundationOne CDx

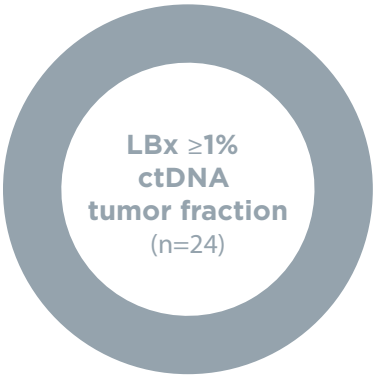


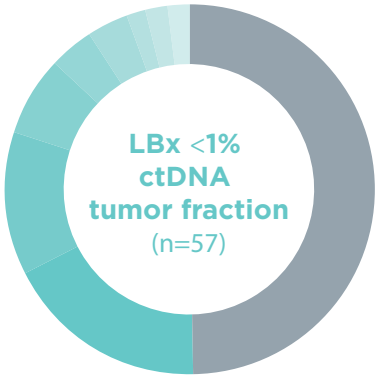

Positive percent agreement (PPA) between FoundationOne Liquid CDx FoundationOne CDx in detection of oncogenic driver alterations

# Foundation Medicine's ctDNA Tumor Fraction Introduces Confidence to Liquid Biopsy Results

No additional driver alterations were detected by FoundationOne®CDx in cases with **ctDNA tumor fraction ≥1%.**

Additional drivers were detected by FoundationOne®CDx in 51% of cases with **ctDNA tumor fraction <1%.**

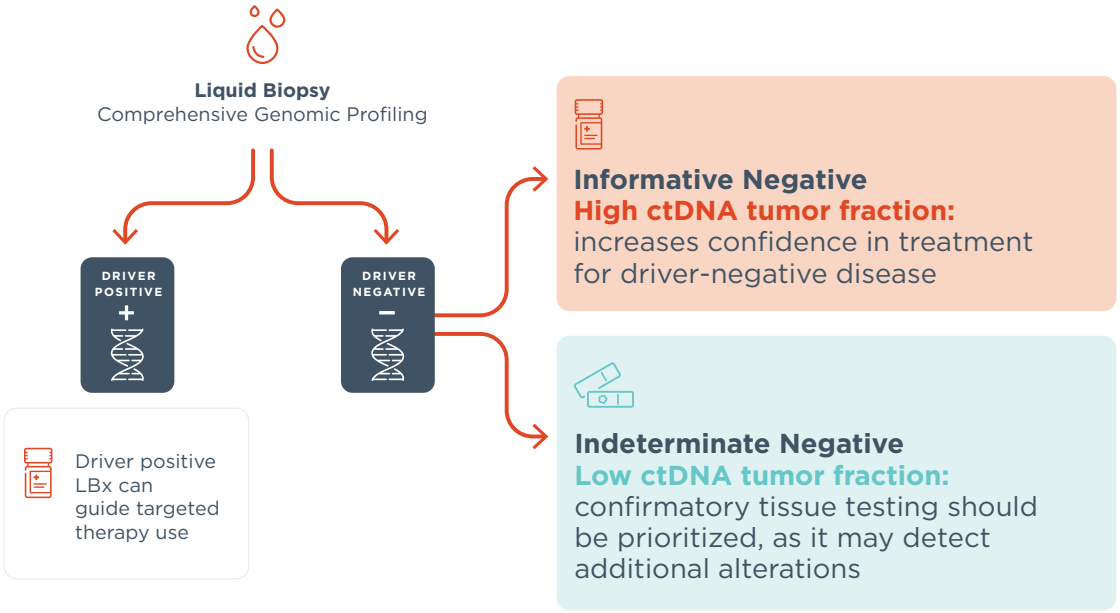



- Negative (49.1%)
- *KRAS* (17.5%)
- *EGFR* (12.2%)
- *ERBB2* (7.0%)
- *Multiple* (3.8%)
- *ROS1* (3.5%)
- MET x14 (1.8%)
- ALK (1.8%)
- *RET* (1.8%)

## Conclusion

## ctDNA tumor fraction Improves Confidence in Driver-Negative Liquid Biopsy Results[1]




FoundationOne®CDx and FoundationOne®Liquid CDx are qualitative next-generation sequencing based *in vitro* diagnostic tests for advanced cancer patientswith solid tumors and are for prescription use only. FoundationOne CDx utilizes FFPE tissue and analyzes 324 genes as well as genomic signatures. FoundationOne Liquid CDx analyzes 324 genes utilizing circulating cell-free DNA and is FDA-approved to report short variants in 311 genes. The tests are companion diagnostics to identify patients who may benefit from treatment with specific therapies in accordance with the therapeutic product labeling. Additional genomic findings may be reported and are not prescriptive or conclusive for labeled use of any specific therapeutic product. Use of the tests does not guarantee a patient will be matched to a treatment. A negative result does not rule out the presence of an alteration. Some patients may require a biopsy for testing with FoundationOne CDx when archival tissue is not available which may pose a risk. When considering eligibility for certain therapies for which FoundationOne Liquid CDx is a companion diagnostic, testing of plasma is only appropriate where tumor tissue is not available. Patients who are tested with FoundationOne Liquid CDx and are negative for other companion diagnostic mutations should be reflexed to tumor tissue testing and mutation status confirmed using an FDA-approved tumor tissue test, if feasible. For the complete label, including companion diagnostic indications and important risk information, please visit www.F1CDxLabel.com and www.F1LCDxLabel.com.

1. Rolfo CD, et al. Poster presented at ASCO 2023. Abstract 9076.
2. Rolfo C, et al. J Thoracic Oncol. 2021. 2021;16(10):1647-1662.
3. Husain H, et al. JCOPO. 2022. doi:10.1200/PO.22.00261.

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