FOUNDATIONONE® LIQUID CDx

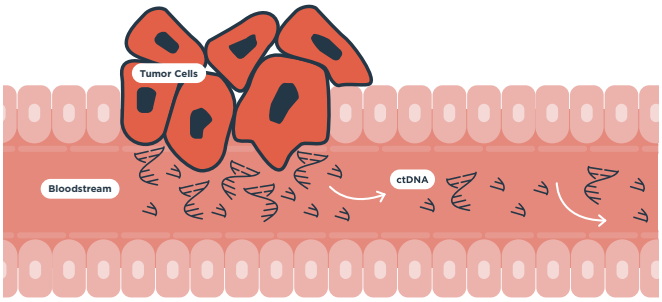
When it comes to ctDNA Liquid Test Tumor Fraction Matters.

Why is Tumor Fraction valuable for your patients?

Tumor Fraction(TF) is a biomarker measuring ctDNA level in a blood sample.

TF is a key determinant of liquid biopsy testing performance and can be used to prioritize confirmatory tissue testing for patients with negative result and low tumor fraction[1].

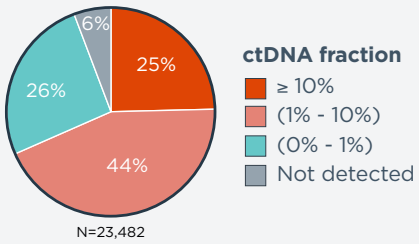
FoundationOne Liquid CDx reports Tumor Fraction as a percentage when Tumor Fraction is 1% or greater.



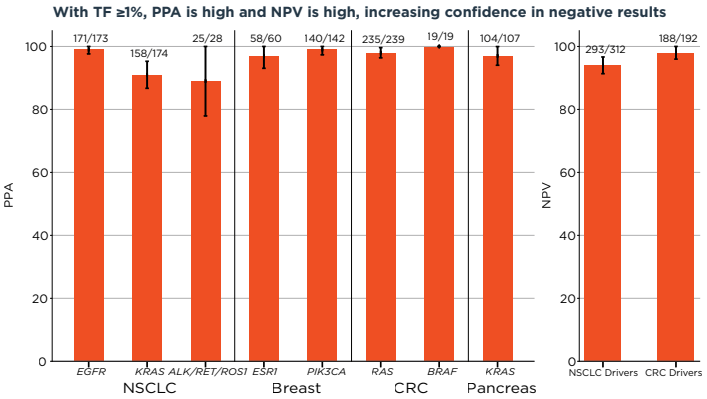
Specimens with elevated Tumor Fraction have substantial ctDNA content, and thus higher sensitivity for identifying genomic alterations. **Such specimens are at lower risk of false negative results.**

TF High	TF Low	TF CBD
TF ≥1% TF reported as a numerical value	TF <1% TF reported as <1% as lower than 1% of ctDNA TF was detected	TF Cannot Be Determined Reported when the biomarker QC metrics are not met
Clinical Implication[2]		
Low probability of detecting additional mutations or rearrangements on tissue testing	Benefit from confirmatory tissue testing to detect other alterations	Benefit from confirmatory tissue testing to detect other alterations

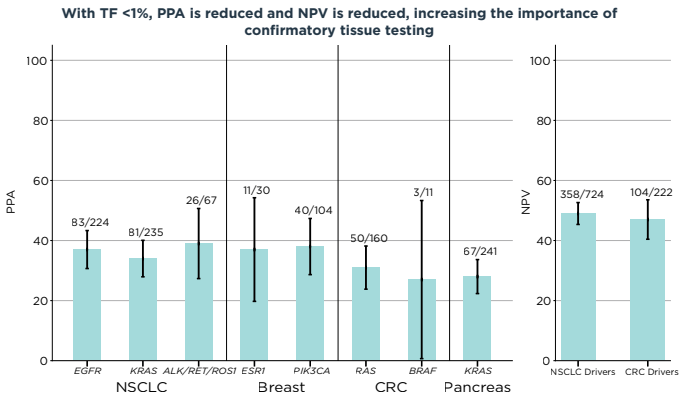
TF is varied by cancer types.
69% of patients despite of tumor type presenting with TF of >1% based on data from ≤23,000 liquid samples[1].



When ctDNA TF on FoundationOne Liquid CDx ≥1%, sensitivity is similar to that of FoundationOne CDx[3].



When FoundationOne Liquid CDx results are negative and Tumor Fraction is low (<1%), additional tissue CGP may uncover actionable findings[3].



ctDNA: circulating tumor DNA **LBx:** liquid biopsy test **PPA:** positive percent agreement **NPV:** negative predictive value

Be Confident with your Treatment Decision based on FoundationOne Liquid CDx

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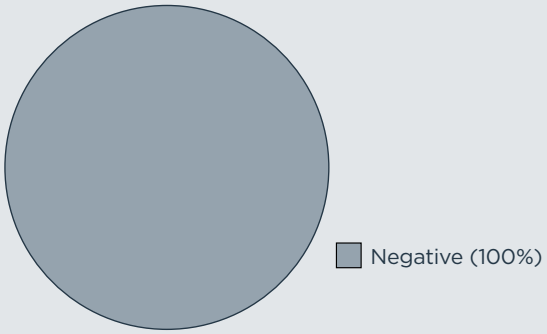
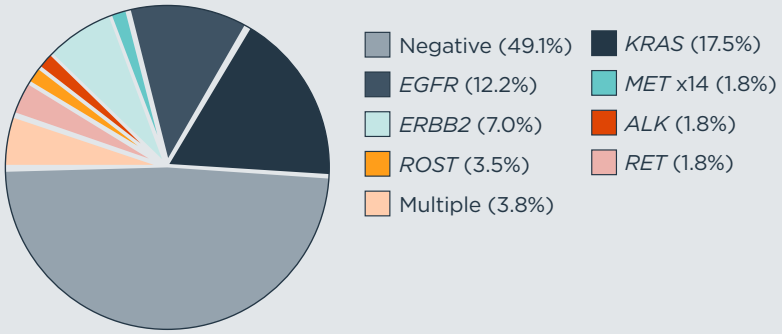
Are negative liquid biopsy results reliable or uninformative?

ctDNA tumor fraction informs the relative benefit from reflex to tissue biopsy CGP. In advanced NSCLC, tissue biopsy after negative FoundationOne Liquid CDx with TF ≥1% does not identify new driver alterations, these patients might have avoided reflex to confirmatory tissue biopsy test[3].

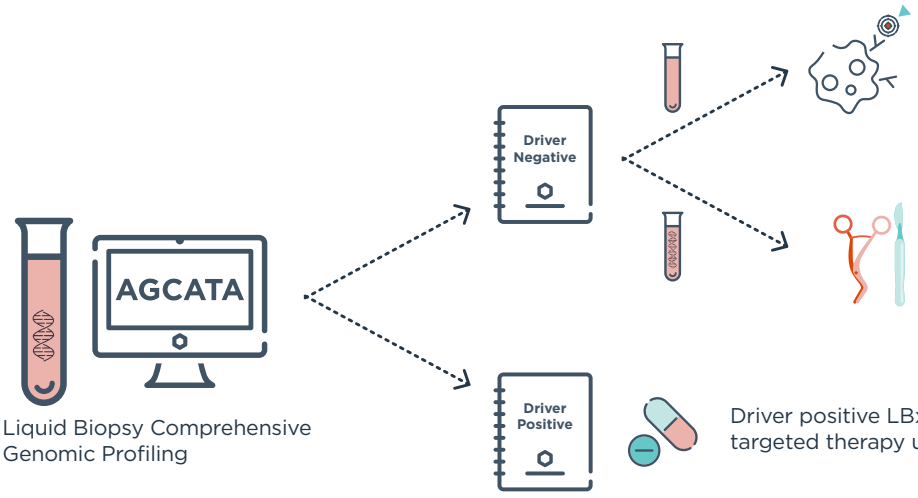
Result of reflex tissue biopsy test for negative FoundationOne Liquid CDx test with TF ≥1%
n=24



Result of reflex tissue biopsy test for negative FoundationOne Liquid CDx test with TF<1%
n=57



ctDNA Tumor Fraction on FoundationOne®Liquid CDx Builds Confidence in Driver-Negative Reports[3]



Informative Negative
Patients with driver negative LBx CGP with **high tumor fraction** can be treated with first line standard of care therapies without reflex to tissue biopsy.

Indeterminate Negative
Patients with driver negative LBx CGP with **low tumor fraction** may benefit from reflex tissue CGP, where driver alterations are frequently detected.

Driver positive LBx can guide targeted therapy use.

NSCLC: non small cell lung cancer **LBx:** Liquid biopsy test **TF:** tumor fraction **ctDNA:** circulating tumor DNA **CGP:** comprehensive genomic profiling

More About FoundationOne Liquid CDx

FoundationOne Liquid CDx is the broadest FDA-approved liquid-based comprehensive genomic profiling test, analyzing over 300 genes, analyzes bTMB, MSI-H status, and ctDNA tumor fraction to help identify patients who may benefit from treatment with specific targeted therapies in multiple cancer indications.

To learn more about FoundationOne Liquid CDx go to
https://www.rochefoundationmedicine.com/home/services/liquid.html

To place an order
https://www.rochefoundationmedicine.com/home/choose-your-country.html

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1. Husain H, Pavlick DC, Fendler BJ, et al. Tumor Fraction Correlates With Detection of Actionable Variants Across > 23,000 Circulating Tumor DNA Samples. *JCO Precis Oncol*. 2022;6:e2200261. doi:10.1200/PO.22.00261
2. FoundationOne Liquid CDx Sample Report
3. Rolfo CD, Madison R, Pasquina LW et al, Abstract 9076, Utility of ctDNA tumor fraction to inform negative liquid biopsy (LBx) results and need for tissue reflex in advanced non-small cell lung cancer (aNSCLC). 2023 ASCO Annual Meeting. https://ascopubs.org/doi/abs/10.1200/JCO.2023.41.16_suppl.9076 [Access October 18, 2023]

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