FOUNDATIONONE®LIQUID CDx

FoundationOne® Liquid CDx unlocks what liquid CGP can do

CE-IVD approved comprehensive genomic profiling (CGP) panel analyzes 300+ cancer-associated genes providing valuable insights for therapy selection and clinical trial enrollment for patients with advanced cancer.[1]

The only CGP liquid biopsy to report

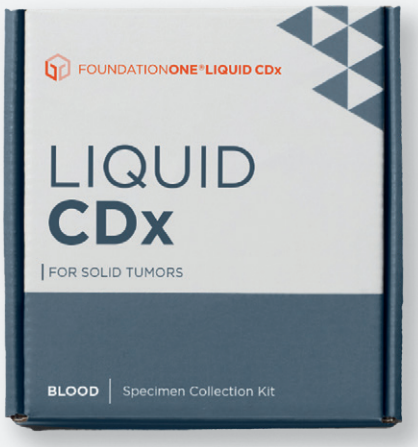
ctDNA tumor fraction

with a cutoff that guides decision-making*†[2]

Low ctDNA tumor fraction can help identify compromised sensitivity.[2]

With FoundationOne® Liquid CDx, you can have greater confidence in negative results when ctDNA tumor fraction is ≥1%.

When FoundationOne® Liquid CDx reports high (≥1%) ctDNA tumor fraction, results show **nearly 100% concordance** between FoundationOne® CDx and FoundationOne® Liquid CDx across tumor types. When ctDNA is low (<1%) reflexing to tissue might uncover additional findings.†[2]



FoundationOne® Liquid CDx is a **blood-based send-out CGP test** that reports:

Complex and Rare *NTRK 1, 2 & 3* Fusions

FoundationOne® Liquid CDx is proven to detect targetable fusion, including *ALK*, *ROS1*, and *NTRK1/2/3* across all solid tumors.[3]

ESR1 and *PIK3CA* Mutations

FoundationOne® Liquid CDx detects emerging biomarkers to identify breast cancer patients who may benefit from the latest treatment innovation.

bTMB and MSH-High

FoundationOne® Liquid CDx reports both bTMB and MSI-H* to optimize the use of immunotherapies.

CH Banner

Our CH Banner highlights variants that may represent Clonal Hematopoiesis of indeterminate potential (CHIP) when genomic findings from cfDNA may originate from non-tumor somatic alterations.[4]

* ctDNA tumor fraction, bTMB, and MSI-H are reported as laboratory professional services which have not been reviewed or approved by the FDA.
† Sensitivity is high for short variants and fusions when ctDNA tumor fraction is ≥1%.

FoundationOne® Liquid CDx Stands Out

	FoundationOne® Liquid CDx
Panel Size of Cancer-associated Genes	**300+ genes**
FDA-Approved	✓
CE-IVD Approved	✓
FDA CDx Indications	**10+**
ctDNA Tumor Fraction*†	✓
bTMB*	✓
MSI-High*	✓
Target Raw Coverage for Certain Clinically Relevant Genes	**10,000x-100,000x+**

Consider liquid testing when recommended by guidelines or when the tissue sample is old, depleted or difficult to retrieve; when cancer becomes treatment resistant; or for repeat testing when disease progresses.

Includes comprehensive assessment of the following complex biomarkers:

- Blood Tumor Mutational Burden (bTMB)*
- Microsatellite Instability - High (MSI-High)*

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Detect these clinically actionable biomarkers

FoundationOne® Liquid CDx analyzes guideline-recommended biomarkers including:

PROSTATE

ATM
ATR
BARD1
BRCA1
BRCA2
BRIP1
CDK12
CHEK1
CHEK2
FANCA
FANCL
MLH1
MRE11A
MSH2
MSH6
MSI-H
NBN
PALB2
bTMB
PMS2
PTEN
RAD51B
RAD51C
RAD51D
RAD54L
RB1
TP53
SPOP

NSCLC

ALK
BRAF
EGFR
ERBB2
KRAS
MET
NTRK1
NTRK2
NTRK3
RET
ROS1

BREAST

AKT1
BRCA1
BRCA2
ESR1
MSI-H
RET
ERBB2 (HER2)
NTRK1
NTRK2
NTRK3
PIK3CA
PTEN
bTMB

COLORECTAL

BRAF
ERBB2
KRAS
NRAS
NTRK1
NTRK2
NTRK3
MSI-H
RET
POLE
POLD1

9-day‡ turnaround time

‡ Data on file. Foundation Medicine, Inc., 2025. Refers to working days.

All CGP tests are not created equal.

Order FoundationOne® Liquid CDx today.

https://www.roche.de/diagnostik/produkte-loesungen/portfolios/foundation-medicine

FoundationOne®Liquid CDx is for prescription use only and is a qualitative next-generation sequencing based *in vitro* diagnostic test for advanced cancer patients with solid tumors. The test analyzes 324 genes utilizing circulating cell-free DNA and is FDA-approved to report short variants in 311 genes and as a companion diagnostic to identify patients who may benefit from treatment with specific therapies (listed in Table 1 of the Intended Use) in accordance with the approved 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 test does not guarantee a patient will be matched to a treatment. A negative result does not rule out the presence of an alteration.
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 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 complete risk information, please visit **https://www.foundationmedicine.qarad.eifu.online/foundationmedicine/en/foundationmedicine?keycode=286605475**.

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‡ Data on file. Foundation Medicine, Inc., 2024. Median TAT from sample receipt to report, International markets.

1. Data on File, Foundation Medicine, Inc., 2024. **2.** Rolfo CD, et al. Measurement of ctDNA Tumor Fraction Identifies Informative Negative Liquid Biopsy Results and Informs Value of Tissue Confirmation. Clin Cancer Res. 2024 Jun 3;30(11):2452-2460. doi: 10.1158/1078-0432.CCR-23-3321. **3.** Data on File, Foundation Medicine, Inc., data as of January 27, 2023. Full list of FDA approved diagnostics: Food and Drug Administration. List of Cleared or Approved Companion Diagnostics. Accessed February 13, 2024. https://www.fda.gov/medical-devices/in-vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-in-vitro-and-imaging-tools. **4.** Husain H, Madison RW, Haberberger J, et al. P2.14-01 Clinical Utility of Reflex to Tissue-based Comprehensive Genomic Profiling (CGP) After Negative Liquid Biopsy (LBx) in NSCLC. J Thorac Oncol. 2022;17:9 (S156-S157).

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