

300+ Genes 2 Tubes of Blood 1 FDA-Approved Liquid Biopsy Test



DEMONSTRATED CLINICAL OUTCOMES DATA

Companion diagnostic claims across multiple targeted therapies and cancer indications

FoundationOne®Liquid CDx helps guide treatment strategies for advanced cancer patients by analyzing 300+ genes from just two tubes of blood — making it the most comprehensive FDA-approved liquid biopsy on the market.



Comprehensive Panel Analyzes

324 genes*

from two tubes of blood, providing comprehensive results typically within 10 days† to help inform treatment strategies.

Includes results from genomic signatures:

- Blood Tumor Mutational Burden (bTMB)†
- Microsatellite Instability High (MSI-H)†
- Tumor Fraction†



Improved Outcomes

In the TRITON2 Clinical Trial

46% Objective Response Rate

for advanced prostate cancer patients who tested positive for *BRCA1/2* alterations and treated with RUBRACA® (rucaparib).¹



Actionable Insights

67% of patients

received a FoundationOne Liquid CDx report with a recommended therapy in their tumor type, a recommended therapy in another tumor type, or a clinical trial option³.



Coverage and Patient Access:

- Qualifying Original Medicare beneficiaries have no out-of-pocket costs for FoundationOne Liquid CDx.²
- 84% of patients have \$0 financial responsibility for Foundation Medicine testing.³
- As part of our FoundationAccess™ program, for each comprehensive genomic profiling test ordered, we complete a benefits investigation and reach out to all patients whom we expect may have out-of-pocket costs.

* FoundationOne®Liquid CDx is FDA-approved to report substitutions and indels in 311 genes, including rearrangements in *ALK* and *BRCA1/2* and copy number alterations in *BRCA1/2* and *ERBB2* (HER2). Comprehensive results across all 324 genes are reported as a laboratory professional service which is not reviewed or approved by the FDA.

† From receipt of specimen and complete order.

‡ bTMB, MSI-H status, and tumor fraction are reported as a laboratory professional service which is not reviewed or approved by the FDA.

Includes Clinically Relevant Genes and Biomarkers

For full list of 324 genes, visit foundationmedicine.com/FILCDx



NSCLC

ALK
BRAF
EGFR
ERBB2
KRAS
MET
NTRK1

NTRK2
NTRK3
RET
ROS1
bTMB



PROSTATE

ATM
BARD1
BRCA1
BRCA2
BRIPI
CDK12
CHEK1
CHEK2
FANCA

FANCL
NTRK1
NTRK2
NTRK3
PALB2
RAD51B
RAD51D
RAD54L
MSI-H



BREAST

BRCA1
BRCA2
ERBB2
ESR1
NTRK1

NTRK2
NTRK3
PIK3CA
MSI-H



COLORECTAL

BRAF
ERBB2
KRAS
NRAS

NTRK1
NTRK2
NTRK3
MSI-H

Companion Diagnostic Indications

TUMOR TYPES	BIOMARKER(S) DETECTED	THERAPY
Non-Small Cell Lung Cancer (NSCLC)	<i>EGFR</i> exon 19 deletions and <i>EGFR</i> exon 21 L858R substitution	IRESSA® (gefitinib), TAGRISSO® (osimertinib) or TARCEVA® (erlotinib)
	<i>ALK</i> rearrangements	ALECENSA® (alectinib)
	<i>MET</i> single nucleotide variants (SNVs) and indels that lead to <i>MET</i> exon 14 skipping	TABRECTA® (capmatinib)
Breast Cancer	<i>PIK3CA</i> mutations C420R, E542K, E545A, E545D [1635G>T only], E545G, E545K, Q546E, Q546R; and H1047L, H1047R, and H1047Y	PIQRAY® (alpelisib)
Ovarian Cancer	<i>BRCA1/2</i> alterations	RUBRACA® (rucaparib)
Prostate Cancer	<i>BRCA1</i> , <i>BRCA2</i> , <i>ATM</i> alterations	LYNPARZA® (olaparib)
	<i>BRCA1</i> , <i>BRCA2</i> alterations	RUBRACA® (rucaparib)

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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. Patients who are negative for 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 www.FILCDxLabel.com.

References

1. Foundation Medicine. FoundationOne Liquid CDx Technical Information. www.FILCDxLabel.com. Accessed August 2021.
2. Medicare and Medicare Advantage members have coverage in accordance with the Centers for Medicare and Medicaid Services (CMS) national coverage determination (NCD) criteria.
3. Based on US clinical tests reported between September 1, 2020 and June 1, 2021. Data current as of July, 2021. Only one sample per patient included. For patients who received multiple tests, the most recent test result was used.