



**300+ Genes
1 Blood Draw
Now FDA-Approved**

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 to provide fast, convenient access to comprehensive results that can 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 RUBYRACA® (rucaparib)¹



Proven Quality

To receive our FDA approval and demonstrate evidence of our high-quality testing, we ran over

7,500 validation samples

covering over **30,000 unique genomic variants** across more than **30 cancer indications.**



Proven Portfolio

Only Foundation Medicine offers an

FDA-approved portfolio

of tissue- and blood-based comprehensive genomic profiling tests for all solid tumors — **with Medicare coverage for qualifying patients.**[†]

* FoundationOne Liquid CDx is FDA-approved to report substitutions and indels in 311 genes, including rearrangements and copy number losses only in *BRCA1/2*. Comprehensive results across all 324 genes, including bTMB, MSI-H status, and tumor fraction are reported in the professional services section of the report.

† Medicare and Medicare Advantage members have coverage in accordance with the Centers for Medicare and Medicaid Services (CMS) national coverage determination (NCD) criteria.

Includes Clinically Relevant Genes and Biomarkers

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



NSCLC

ALK	NTRK2
BRAF	NTRK3
EGFR	RET
ERBB2	ROS1
KRAS	bTMB
MET	
NTRK1	



PROSTATE

ATM	FANCL
BARD1	NTRK1
BRCA1*	NTRK2
BRCA2*	NTRK3
BRIPI	PALB2
CDK12	RAD51B
CHEK1	RAD51D
CHEK2	RAD54L
FANCA	MSI-H



BREAST

BRCA1	NTRK2
BRCA2	NTRK3
ERBB2	PIK3CA
ESR1	MSI-H
NTRK1	



COLORECTAL

BRAF	NTRK1
ERBB2	NTRK2
KRAS	NTRK3
NRAS	MSI-H

FoundationOne Liquid CDx is an FDA-approved companion diagnostic for 3 therapies in NSCLC and 1 in prostate cancer.

* Only select intronic or non-coding regions of BRCA1/2.

Sample Report

FOUNDATIONONE LIQUID CDx PATIENT: Sample, Jane TUMOR TYPE: Prostate cancer (NOS) REPORT DATE: 01 June 2020 ORDERED TEST # ORD-XXXXXXX-XX

PATIENT SEX: Male AGE: 65 YEARS OLD
PHYSICIAN NAME: Not Given
SPECIMEN TYPE: Not Given

Companion Diagnostic (CDx) Associated Findings

GENOMIC FINDINGS DETECTED	FDA-APPROVED THERAPEUTIC OPTIONS
BRCA2 V1532fs*2	Rucaparib* (rucaparib)

Other Short Variants Identified

Results reported in this section are not prescriptive or conclusive for labeled use of any specific therapeutic product. See professional services section for information on the alterations listed in this section as well as any additional detected copy number alterations, gene rearrangements, or biomarkers.

OTHER BIOMARKERS WITH POTENTIAL CLINICAL SIGNIFICANCE

TP53 C242G

Please refer to appendix for Explanation of Clinical Significance Classification and for variants of unknown significance (VUS).

ABOUT THE TEST: FoundationOne®Liquid CDx is a next generation sequencing (NGS) assay that identifies clinically relevant genomic alterations in circulating tumor DNA.

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Interpretive comment on this page and subsequent pages is provided as a professional service, and is not reviewed or approved by the FDA.

Biomarker Findings

Blood Tumor Mutational Burden - 5 Mutations
Microsatellite status - Cannot be Determined
Tumor Fraction - 13%

Genomic Findings

For a complete list of the genes assayed, please refer to the Appendix.
BRCA2 V1532fs*2
TP53 C242G

4 Therapies with Clinical Benefit 10 Clinical Trials
0 Therapies with Lack of Response

BIOMARKER FINDINGS	THERAPY AND CLINICAL TRIAL IMPLICATIONS
Blood Tumor Mutational Burden - 5 Mutations	No therapies or clinical trials. See Biomarker Findings section.
Microsatellite status - Cannot be Determined	Unable to determine Microsatellite status due to insufficient evidence of genomic instability.
Tumor Fraction - 13%	Tumor fraction is an estimate of the percentage of circulating-tumor DNA (ctDNA) present in a cell-free DNA (cfDNA) sample based on observed allelic frequency.
GENOMIC FINDINGS	THERAPIES WITH CLINICAL BENEFIT (IN PATIENT'S TUMOR TYPE)
BRCA2 = V1532fs*2	Olaparib <input checked="" type="checkbox"/> Niraparib <input type="checkbox"/> Rucaparib <input type="checkbox"/> Talazoparib <input type="checkbox"/>
10 Trials <small>see p. 11</small>	<input type="checkbox"/> NCCN Category

The content provided is a professional service by Foundation Medicine, Inc. and has been reviewed in accordance with FDA.

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.

Rucaparib® is a registered trademark of Clovis Oncology

References

1. Foundation Medicine. FoundationOne Liquid CDx Technical Information. www.FILCDxLabel.com. Accessed August 2020.

