FOUNDATIONONE® LIQUID CDx

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 RUBRACA® (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.

FOR MORE DETAILED INFORMATION VISIT *foundationmedicine.com/F1LCDx*

Includes Clinically Relevant Genes and Biomarkers

For full list of 324 genes, visit foundationmedicine.com/F1LCDx

NSCLC

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

PROSTATE

ATM	*FANCL*
BARD1	*NTRK1*
BRCA1*	*NTRK2*
BRCA2*	*NTRK3*
BRIP1	*PALB2*
CDK12	*RAD51B*
CHEK1	*RAD51D*
CHEK2	*RAD54L*
FANCA	MSI-H

BREAST

BRCA1	*NTRK2*
BRCA2	*NTRK3*
ERBB2	*PIK3CA*
ESR1	MSI-H
NTRK1	

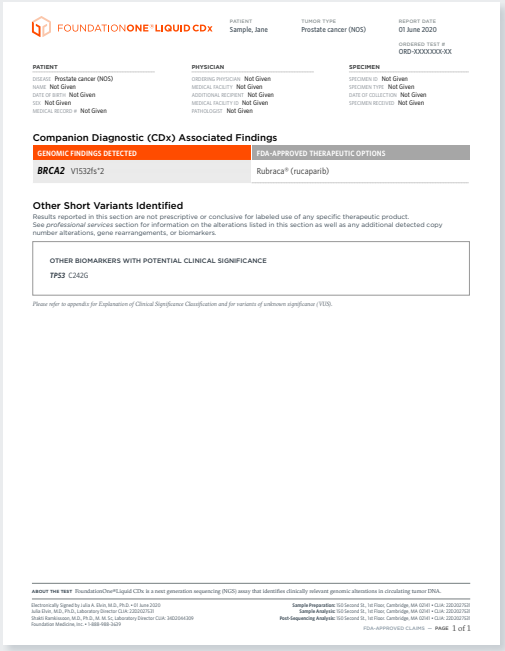
COLORECTAL

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
DISEASE Prostate cancer (NOS)
NAME Not Given
DATE OF BIRTH Not Given
SEX Not Given
MEDICAL RECORD # Not Given

PHYSICIAN
ORDERING PHYSICIAN Not Given
MEDICAL FACILITY Not Given
ADDITIONAL RECIPIENT Not Given
MEDICAL FACILITY ID Not Given
PATHOLOGIST Not Given

SPECIMEN
SPECIMEN ID Not Given
SPECIMEN TYPE Not Given
DATE OF COLLECTION Not Given
SPECIMEN RECEIVED Not Given

Companion Diagnostic (CDx) Associated Findings

GENOMIC FINDINGS DETECTED	FDA-APPROVED THERAPEUTIC OPTIONS
BRCA2 V1532fs*2	Rubraca® (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

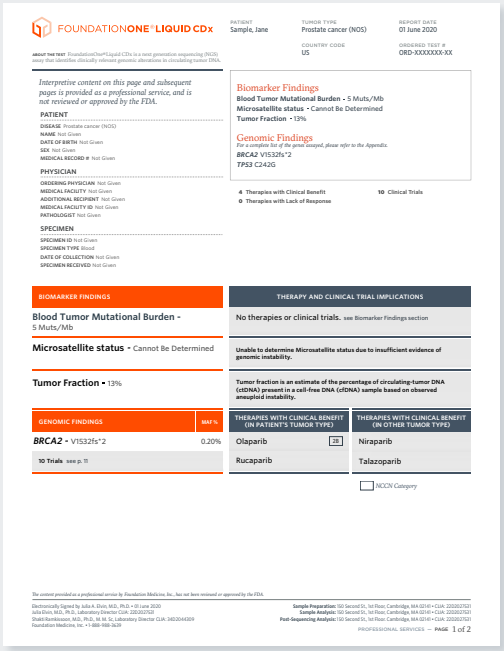
Please refer to appendix for Explanation of Clinical Significance Classification and for variants of unknown significance (VUS).

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

Electronically Signed by Julia A. Elvin, M.D., Ph.D. • 01 June 2020
Julia Elvin, M.D., Ph.D., Laboratory Director CLIA: 2101207521
Shakti Ramkissoon, M.D., Ph.D. (ASCP), M.Sc., Laboratory Director CLIA: 34D2064309
Foundation Medicine, Inc. • 1-888-988-3639

Sample Preparation: 150 Second St., 1st Floor, Cambridge, MA 02141 • CLIA: 2101207521
Sample Analysis: 150 Second St., 1st Floor, Cambridge, MA 02141 • CLIA: 2101207521
Post-Sequencing Analysis: 150 Second St., 1st Floor, Cambridge, MA 02141 • CLIA: 2101207521

FDA-APPROVED CLAIMS — PAGE 1 of 1



FOUNDATIONONE® LIQUID CDx

PATIENT Sample, Jane | TUMOR TYPE Prostate cancer (NOS) | COUNTRY CODE US | REPORT DATE 01 June 2020 | ORDERED TEST # ORD-XXXXXXX-XX

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

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

PATIENT
DISEASE Prostate cancer (NOS)
NAME Not Given
DATE OF BIRTH Not Given
SEX Not Given
MEDICAL RECORD # Not Given

PHYSICIAN
ORDERING PHYSICIAN Not Given
MEDICAL FACILITY Not Given
ADDITIONAL RECIPIENT Not Given
MEDICAL FACILITY ID Not Given
PATHOLOGIST Not Given

SPECIMEN
SPECIMEN ID Not Given
SPECIMEN TYPE Blood
DATE OF COLLECTION Not Given
SPECIMEN RECEIVED Not Given

Biomarker Findings
Blood Tumor Mutational Burden - 5 Muts/Mb
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
0 Therapies with Lack of Response
10 Clinical Trials

BIOMARKER FINDINGS	THERAPY AND CLINICAL TRIAL IMPLICATIONS
Blood Tumor Mutational Burden - 5 Muts/Mb	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 aneuploid instability.

GENOMIC FINDINGS	MAF %	THERAPIES WITH CLINICAL BENEFIT (IN PATIENT'S TUMOR TYPE)		THERAPIES WITH CLINICAL BENEFIT (IN OTHER TUMOR TYPE)
BRCA2 - V1532fs*2	0.20%	Olaparib	2B	Niraparib
10 Trials see p. 11		Rucaparib		Talazoparib

NCCN Category

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PROFESSIONAL SERVICES — PAGE 1 of 2

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.F1LCDxLabel.com.

Rubraca® is a registered trademark of Clovis Oncology

References

1. Foundation Medicine. FoundationOne Liquid CDx Technical Information. www.F1LCDxLabel.com. Accessed August 2020.

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