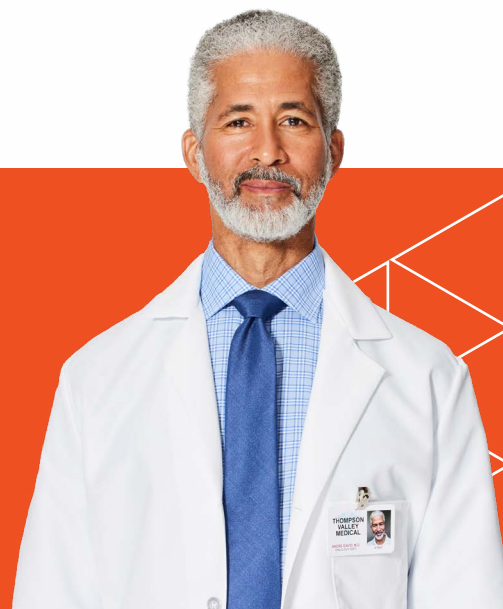


FoundationOne® Liquid CDx otvara mogućnosti tečnog CGP-a

Panel sveobuhvatnog genomskog profiliranja (CGP) s oznakom CE-IVD analizira više od 300 gena povezanih s rakom i pruža važne informacije za odabir terapije i uključivanje u kliničke studije kod pacijenata s uznapredovalim rakom.¹



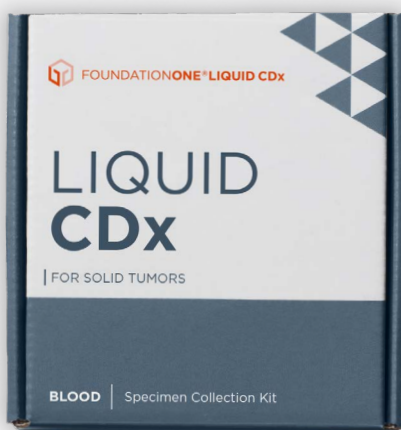
Jedina tečna biopsija za CGP koja prikazuje **tumorsku frakciju ctDNA**

s graničnom vrijednošću koja usmjerava odluke^{*†2}

Niska tumorska frakcija ctDNA može ukazati na smanjenu osjetljivost testa.²

Uz FoundationOne Liquid CDx možete imati veće povjerenje u negativan nalaz kada je tumorska frakcija ctDNA $\geq 1\%$.

Kada FoundationOne Liquid CDx pokaže visoku tumorsku frakciju ctDNA ($\geq 1\%$), nalazi pokazuju **gotovo 100% podudarnost** između FoundationOne CDx i FoundationOne Liquid CDx u različitim tipovima tumora. Pri niskoj frakciji ctDNA ($<1\%$), naknadno testiranje tkiva može otkriti dodatne nalaze.^{†2}



FoundationOne Liquid CDx je **CGP test iz krvi koji se šalje u referentni laboratorij** i prikazuje:

Složene i rijetke fuzije **NTRK1, 2 i 3**

FoundationOne Liquid CDx dokazano otkriva fuzije za koje postoji ciljana terapija, uključujući ALK, ROS1 i NTRK1/2/3, u svim solidnim tumorima.³

Mutacije **ESR1 i PIK3CA**

FoundationOne Liquid CDx otkriva nove biomarkere kako bi prepoznao pacijentice s rakom dojke koje mogu imati korist od najnovijih terapijskih dostignuća.

bTMB i MSI-H

FoundationOne Liquid CDx prikazuje bTMB i MSI-H^{*} radi optimalne primjene imunoterapije.

Oznaka klonalne hematopoeze (CH)

Oznaka CH ističe varijante koje mogu predstavljati klonalnu hematopoezu neodređenog potencijala (CHIP), kada genomski nalazi iz cfDNA mogu poticati od somatskih alteracija koje nisu tumorskog porijekla.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 $\geq 1\%$.

FoundationOne Liquid CDx se izdvaja

	FoundationOne Liquid CDx
Broj gena povezanih s rakom u panelu	300+ gena
FDA odobrenje	✓
Oznaka CE-IVD	✓
FDA indikacije prateće dijagnostike	10+
Tumorska frakcija ctDNA [†]	✓
bTMB [*]	✓
MSI-H [*]	✓
Ciljana dubina očitavanja za određene klinički relevantne gene	10.000x-100.000x+

Razmotrite tečnu biopsiju kada je preporučena smjernicama ili kada je uzorak tkiva star, iscrpljen ili teško dostupan; kada rak postane otporan na terapiju; ili za ponovno testiranje pri progresiji bolesti.

Obuhvata sveobuhvatnu procjenu sljedećih složenih biomarkera:

- Tumorsko mutacijsko opterećenje iz krvi (bTMB)^{*}
- Visoka mikrosatelitska nestabilnost (MSI-H)^{*}

^{*}ctDNA tumor fraction, bTMB, and MSI-H are reported as laboratory professional services which have not been reviewed or approved by the FDA.

Otkrijte ove klinički primjenjive biomarkere

FoundationOne Liquid CDx analizira biomarkere preporučene smjernicama, uključujući:



PROSTATA

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



NSCLC

ALK	NTRK1
BRAF	NTRK2
EGFR	NTRK3
ERBB2	RET
KRAS	ROS1
MET	



DOJKA

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



KOLOREKTALNI

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

**8 dana[†]
do nalaza**

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

CGP testovi se razlikuju po svojim mogućnostima.

Naručite FoundationOne Liquid CDx.

www.genolab.ba/konsultacije



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>.

^{*} 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 $\geq 1\%$.

[‡] 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. P214-01 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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