

FoundationOne® CDx otkriva mogućnosti CGP testiranja tkiva

FoundationOne® CDx analizira sve gene koje preporučuju smjernice i pomaže proširiti terapijske opcije za pacijente s uznapredovalim karcinomom.^{1,2}

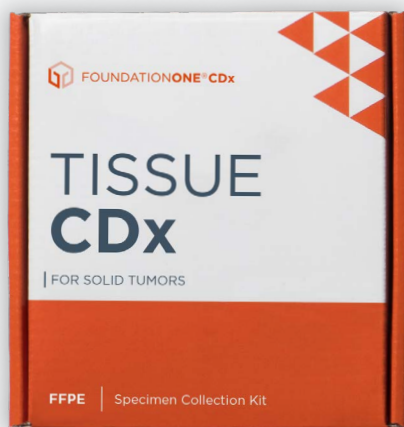


FoundationOne CDx,
CGP test solidnih tumora
s CE-IVD odobrenjem

35+ CDx indikacija
odobrenih od FDA-e

Indikacije prateće dijagnostike (CDx) za NSCLC, karcinom dojke, prostate, kolorektuma i jajnika, melanom, holangiokarcinom i druge solidne tumore

Uz CDx indikacije za pojedinačne tipove tumora, dostupne su i **4 pan-tumorske** CDx indikacije za solidne tumore.



FoundationOne CDx otkriva različite biomarkere fuzija, uključujući ALK, ROS1, FGFR2, RET i NTRK1/2/3.³

*Dodatne usluge kao podrška
FoundationOne CDx testiranju*

Uključuje rezultate genomskih potpisa:

- Tumorsko mutacijsko opterećenje (TMB)
- Mikrosatelitska nestabilnost (MSI)
- Potpis deficita homologne rekombinacije (HRDsig)*

**IHC testiranje dostupno je kao dopuna narudžbi
FoundationOne CDx testa†**

Dako PD-L1 22C3 pharmDx

Ventana PD-L1 SP142

Dako PD-L1 28-8 pharmDx

Ventana PD-L1 SP263

* HRDsig is reported as a laboratory professional service which has not been reviewed or approved by the FDA.

† This service may not be available in all countries. Please consult your local Roche-FMI representative for information regarding the availability of this service in your country and the specific conditions for its implementation.

FoundationOne CDx se izdvaja

	FoundationOne CDx
Broj gena povezanih s karcinomom u panelu	324
Odobren od FDA-e	✓
CE-IVD odobrenje	✓
CDx indikacije odobrene od FDA-e	35+
	5 CDx indikacija za fuzije ✓ TMB CDx ✓ MSI-H CDx
Male varijante (supstitucije i indeli)	309
Amplifikacije i/ili gubici broja kopija	309
Rearanžmani	324 gena

Razmotrite testiranje tkiva kada je ono lako dostupno i/ili je to vaš preferirani klinički pristup.

Foundation Medicine nastoji **maksimalno iskoristiti uzorke pacijenata uz Precision Enrichment[†]**:

- Stopa obogaćivanja povećana s 30% na 50%
- Broj uzoraka koji bi bili nedostadni (QNS) smanjen je za 66,7%; ti uzorci mogli su biti obrađeni i imati izdat nalaz
- 90–91% slučajeva sa statusom Pass/Qualified
- Uspješnost sekvenciranja: 97,9% (medijan)⁵

Otkrijte ove terapijski relevantne biomarkere

FoundationOne CDx analizira biomarkere preporučene smjericama, uključujući:



PROSTATA

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



NSCLC

ALK NTRK1
BRAF NTRK2
EGFR NTRK3
ERBB2 RET
KRAS ROS1
MET



DOJKA

AKT1 NTRK1
BRCA1 NTRK2
BRCA2 NTRK3
ESR1 PIK3CA
MSI PTEN
RET TMB
ERBB2 (HER2)



KOLOREKTUM

BRAF NTRK3
ERBB2 MSI
KRAS RET
NRAS POLE
NTRK1 POLD1
NTRK2

Medijan izrade nalaza:

8,8 dana[†]

Nisu svi CGP testovi jednaki.

Naručite FoundationOne CDx putem GenoLaba.

www.genolab.ba/konsultacije



FoundationOne®CDx is a qualitative next-generation sequencing based *in vitro* diagnostic test for advanced cancer patients with solid tumors and is for prescription use only. The test analyzes 324 genes as well as genomic signatures including microsatellite instability (MSI) and tumor mutational burden (TMB) and is a companion diagnostic to identify patients who may benefit from treatment with specific therapies 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. Some patients may require a biopsy. For the complete label, including companion diagnostic indications and important risk information, please visit <https://www.foundationmedicine.qarad.eifu.online/foundationmedicine/en/foundationmedicine?keycode=286605475>.

[†] U.S. data on file, Foundation Medicine Inc., 2023. Median Turnaround time, specimen receipt to report.

1. ASCO Guidelines <https://society.asco.org/practice-patients/guidelines> (Accessed on October 2024). 2. ESMO Updated Guidelines M.F. Mosele, et al. (2024) Ann Oncol (35) <https://doi.org/10.1016/j.annonc.2024.04.005>. 3. U.S. Food & Drug Administration. List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools). Updated October 6, 2023. Accessed October 16, 2023. Data on File, Foundation Medicine, Inc., 2024. 4. Lin et al. Precision needle-punch tumor enrichment from paraffin blocks improves the detection of clinically actionable genomic alterations and biomarkers. Front. Oncol. 19 February 2024 14:1328512. doi: 10.3389/fonc.2024.1328512 5. Alexander BM, Douglas PS, Marron TU, et al. Real-world pan-tumor comprehensive genomic profiling sample adequacy and success rates in tissue and liquid specimens. The Oncologist. Published online October 13, 2024. doi:10.1093/oncolo/oyae258

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