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FoundationOne CDx i FoundationOne Liquid CDx analiziraju po 15+ klinički relevantnih biomarkera u uznapredovalom karcinomu prostate, uključujući sve koje preporučuju ESMO smjernice.¹⁻⁶



Otkrijte odgovarajuće terapijske opcije za svoje pacijente s uznapredovalim karcinomom prostate

Prestao je odgovarati na hormonsku terapiju. Postoji li mogućnost primjene ciljane terapije?

Njegov ljekar je znao kada uraditi CGP:

- Pri dijagnozi metastatske bolesti
- Pri progresiji u kastraciono-rezistentnu bolest
- Razmotriti kod regionalne bolesti i daljnje progresije

Terapija odobrena od EMA-e i preporučena smjericama		FoundationOne® CDx ⁵	CE-IVD testovi
			FoundationOne® Liquid CDx ⁶
Specifično za prostatu	Lynparza® (olaparib)	Alteracije BRCA1/2	Alteracije BRCA1/2
	Lynparza® (olaparib) + abiraterone	Alteracije BRCA1/2	Alteracije BRCA1/2
	Zejula™ (niraparib)	Alteracije BRCA1/2	Alteracije BRCA1/2
Tumor-agnostički	Keytruda® (pembrolizumab)	MSI-High	MSI [†]
	Rozlytrek® (entrectinib), Vitakvi® (larotrectinib), Augtyro™ (repotrectinib)	Fuzije NTRK1/2/3 [†]	Fuzije NTRK1/2/3 [†]
	Retsevmo® (selpercatinib)	Fuzije RET [†]	Fuzije RET [†]

EMA = European Medicines Agency

[†] MSI status will be reported for FoundationOne Liquid CDx samples determined to have high microsatellite instability.

[‡] Not included in Prostate Guidelines, but can still provide clinical utility and are pan-tumor FDA-approved therapies.

Jeste li znali?

SPOP

Novi biomarker, mutiran u do 14% karcinoma prostate^{6,7}

PTEN, TP53, RB1

Prepoznaju agresivni karcinom prostate koji može imati korist od kabazitaksela + karboplatina

HRDsig⁸

Može identificirati pacijente osjetljive na PARP inhibitore (PARPi) i hemoterapiju na bazi platine

Biopsija tkiva: FoundationOne®CDx		Tečna biopsija: FoundationOne®Liquid CDx	
Svi solidni tumori	• CE-IVD • DNA (324 gena) • Tumorsko mutacijsko opterećenje, mikrosatelitska nestabilnost i pan-tumorski HRD potpis (HRDsig)⁸ • Mogućnost prelaska na tečnu biopsiju	• CE-IVD • DNA (324 gena)^{††} • Tumorsko mutacijsko opterećenje iz krvi, visoka mikrosatelitska nestabilnost i tumorska frakcija ctDNA^{††} • Mogućnost prelaska na testiranje tkiva	
	Vrijeme izrade nalaza: 8,8 dana**	Vrijeme izrade nalaza: 8 dana**	

Svi gore navedeni FoundationOne proizvodi imaju CE-IVD odobrenje.

Nisu svi CGP testovi jednaki

Kakav je test koji koristite?

- Naši CGP testovi iz tkiva i krvi otkrivaju sve biomarkere koje smjernice preporučuju za uznapredovali karcinom prostate, uključujući HRR gene poput BRCA1/2.¹⁻⁶
- Ne propustite nijednog pacijenta: validirana detekcija i izvještavanje o gubitku BRCA1/2 u tkivu i krvi. Ova promjena, prisutna u 1 od 30 pacijenata s mCRPC-om, povezana je s kliničkom koristi od PARP inhibitora.⁹

FOUNDATIONONE® LIQUID CDx

- ✓ Jedinstveno prikazuje tumorsku frakciju ctDNA s definiranim pragom za kliničke odluke i veću pouzdanost negativnih nalaza
- ✓ Kod pacijenata s PSA >5 ng/mL vjerovatnija je visoka tumorska frakcija ctDNA, koja može usmjeriti daljnje liječenje¹¹
- ✓ Tumorska frakcija ctDNA pomaže procijeniti potrebu za dopunskim testiranjem tkiva za teže uočljive alteracije, poput gubitka BRCA¹¹
- ✓ Otkrivanje novonastalih mutacija rezistencije bez ponovne biopsije

FOUNDATIONONE® CDx

- ✓ Uključuje HRDsig, validirani biomarker za klasifikaciju HRD statusa različitih tumora
- ✓ Klinički validirano tumorsko mutacijsko opterećenje (TMB)
- ✓ Pouzdana detekcija fuzija iz DNA
- ✓ Dostupan kao dopunski test ako je tumorska frakcija ctDNA niska, a nalaz FoundationOne®Liquid CDx negativan



IZVRŠNA KORISNIČKA PODRŠKA

- ✓ Namjenski tim za tehničku, naučnu i medicinsku podršku korisnicima
- ✓ Jednostavno online naručivanje i praćenje slučajeva uz digitalne nalaze u različitim formatima (PDF, CSD)
- ✓ Dodatne usluge: razmjena podataka i kolegijalna podrška u tumačenju nalaza[#]

Jedinstven CGP portfolio s ujednačenim kvalitetom testiranja tkiva i krvi



Razmotrite tečnu biopsiju ako je uzorak tkiva star, iscrpljen, teško dostupan ili premalen, ili kada tumor postane otporan na terapiju. Preporučuje se i kada je brži nalaz klinički važan.¹²



Razmotrite testiranje tkiva kada je lako dostupno ili kada je tumorska frakcija ctDNA u nalazu tečne biopsije ispod 1%.



Odaberite Foundation Medicine rješenja za jasan, detaljan, sveobuhvatan i validiran CGP nalaz, koji se redovno isporučuje za 8 dana.^{**}



Naručivanje Foundation Medicine testova putem GenoLaba: www.genolab.ba/konsultacije

CGP = Comprehensive genomic profiling
CSD = clinically structured data

FoundationOne®CDx and FoundationOne®Liquid CDx are qualitative next-generation sequencing based *in vitro* diagnostic tests for advanced cancer patients with solid tumors and are for prescription use only. FoundationOne®CDx utilizes FFPE tissue and analyzes 324 genes as well as genomic signatures. FoundationOne®Liquid CDx analyzes 324 genes utilizing circulating cell-free DNA and is FDA-approved to report short variants in 311 genes. The tests are companion diagnostics to identify patients who may benefit from treatment with specific therapies in accordance with the 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 tests 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 testing with FoundationOne®CDx when archival tissue is not available which may pose a risk. Patients who are tested with FoundationOne®Liquid CDx and 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 important risk information, please visit <https://www.foundationmedicine.com/qa/online/foundationmedicine/en/foundationmedicine?keycode=286605475>.

¹ Based on somatic testing guidelines in advanced prostate cancer, including 19 HRR genes, MSI/MSI-H, plus 7 clinically relevant biomarkers (TMB, MSH2, MSH6, PMS2, PTEN, RB1, TP53).

² Homologous Recombination Deficiency Signature (HRDsig) is reported as a laboratory professional service that has not been reviewed or approved by the FDA, and is included on our FoundationOne CDx Professional Service page as "HRDsig Positive", "HRDsig Negative" or "Cannot Be Determined".

³ ctDNA tumor fraction is reported as a laboratory professional service which has not been reviewed or approved by the FDA. Foundation Medicine's ctDNA tumor fraction is a determination of the amount of circulating tumor DNA as a fraction of total cell free DNA in a blood sample that accounts for aneuploidy, variant allele frequency, fragment length information, clonal hematopoiesis predictions and known tumor-associated alterations.

⁴ Part of Foundation One offering. Not available in every country. Please refer to your Roche-Foundation Medicine representative to know more about Foundation One and specific terms and conditions of the service offering in your country.

⁵ Data on file, Foundation Medicine, Inc., 2024. Median TAT from sample receipt to report. International markets.

⁶ 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.

⁷ bTMB, MSI-H status, and tumor fraction are reported as a laboratory professional service which is not reviewed or approved by the FDA.

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