

12

Foundation Medicine CGP testovi iz tkiva i krvi obuhvataju po 12+ klinički relevantnih biomarkera kod uznapredovalog karcinoma dojke, uključujući sve koje preporučuju ESMO smjernice.^{1-2, 5-6}



Otkrijte odgovarajuće terapijske opcije za svoje pacijentice s karcinomom dojke

Metastatska HR-pozitivna, HER2-negativna bolest progredirala je tokom endokrine terapije uz CDK4/6 inhibitor. Šta dalje?

Njen ljekar je znao kada uraditi profiliranje:

- Pri dijagnozi metastatske bolesti
- Pri daljnjoj progresiji
- Pri lokalnom ili regionalnom neresektabilnom recidivu

Terapija odobrena od EMA-e i preporučena smjernicama ¹		CE-IVD testovi
		FoundationOne®CDx ⁵ + FoundationOne®Liquid CDx ⁶
Specifično za dojku	Lynparza® (olaparib), Talzena® (talazoparib)	Alteracije BRCA1/2*
	Kadcyla® (trastuzumab emtansine), Enhertu® (trastuzumab deruxtecan), Tyverb® (lapatinib), Herceptin® (trastuzumab) + lapatinib, Tyverb® (lapatinib) + anastrozole, Tyverb® (lapatinib) + letrozole, Herceptin® (trastuzumab), Nerlynx® (neratinib), Herceptin® (trastuzumab) + pertuzumab, Herceptin® (trastuzumab) + tucatinib, Herceptin® (trastuzumab) + anastrozole, Herceptin® (trastuzumab) + letrozole	Amplifikacija ERBB2
	Orserdu® (elacestrant)	Mutacije ESR1
	Piqray® (alpelisib) + fulvestrant	Mutacije PIK3CA
	Truqap® (capivasertib) + fulvestrant	AKT1 E17K, mutacije PIK3CA, alteracije PTEN
Tumor-agnostički	Keytruda® (pembrolizumab)	MSI-High, MSI†
	Rozlytrek® (entrectinib), Vitrakvi® (larotrectinib), Augtyro™ (repotrectinib)	Fuzije NTRK1/2/3
	Retsevmo® (selpercatinib)	Fuzije RET

EMA = European Medicines Agency

* Identifies somatic + germline, potential germline flagged for genetic testing.

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

Jeste li znali?

PTEN:¹

Gubitak PTEN ima terapijski značaj u do 5,6% HR-pozitivnih karcinoma dojke.¹

PIK3CA:²

Nova terapijska meta kod otpornosti na anti-HER2 terapiju, kao i kod otpornosti na endokrinu terapiju.²

HRDsig:^{5,7}

Može identifikirati pacijentice osjetljive na PARP inhibitore (PARPi) i hemoterapiju na bazi platine.

Nisu svi CGP testovi jednaki

Kakav je test koji koristite?

• Naš portfolio otkriva sve somatske biomarkere preporučene smjernicama za uznapredovali karcinom dojke, uključujući ESR1, AKT1, PIK3CA i PTEN. Gubitak PTEN nalazi se u do 5,6% HR-pozitivnih karcinoma dojke.^{11, 5-6}

• Dva panela, ujednačeni rezultati

FOUNDATIONONE® LIQUID CDx

- ✓ Prikazuje tumorsku frakciju ctDNA za veću pouzdanost negativnih nalaza^{#3}
- ✓ Mogućnost otkrivanja mutacija rezistencije bez ponovne biopsije

FOUNDATIONONE® CDx

- ✓ Klinički validirano tumorsko mutacijsko opterećenje (TMB)
- ✓ Dostupan kao dopunski test ako je tumorska frakcija ctDNA niska, a nalaz FoundationOne Liquid CDx negativan
- ✓ Uključuje HRDsig, validirani biomarker za klasifikaciju HRD statusa različitih tumora^{§8}



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.⁵⁻⁶



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.⁴



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.[†]

Naručite Foundation Medicine test: <https://www.rochefoundationmedicine.com/#/en/international/ordering-support>



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/en/foundationmedicine?keycode=286605475>.

Enhertu® (fam-trastuzumab deruxtecan-nxki) is a registered trademark of Daiichi Sankyo Company, Limited. Tykerb® (lapatinib) is a registered trademark of Novartis Pharmaceuticals Corporation. Margenza® (margetuximab-cmkb) is a registered trademark of MacroGenics, Inc. Nerlynx® (neratinib) is a registered trademark of Puma Biotechnology, Inc. Orserdu® (elacestrant) is a registered trademark of the Menarini Group. Lynparza® (olaparib) is a registered trademark of the AstraZeneca group of companies. Talzenna® (talazoparib) is a registered trademark of Pfizer, Inc. Keytruda® (pembrolizumab) is a registered trademark of Merck & Co., Inc. Herceptin®, Kadcyla®, Perjeta® are registered trademarks of Genentech, Inc. Piqray® is a registered trademark of Novartis AG. Truqap™ and Faslodex® are trademarks of the AstraZeneca group of companies. Jemperli® (dostarlimab-gxly) is a registered trademark of GlaxoSmith Kline. Rozlytrek® (entrectinib) is a registered trademark of Genentech Inc. Vitakvi® (larotrectinib) is a registered trademark of Bayer. Retevmo® (selpercatinib) is a registered trademark owned or licensed by Eli Lilly and Company, its subsidiaries, or affiliates. ITOVEBI™ (inavolisib) is a registered trademark of Genentech. palbociclib (Ibrance®) is a registered trademark of Pfizer.

- [§] Homologous Recombination Deficiency Signature (HRDsig) is reported as a laboratory professional service, and is included on our FoundationOne CDx Professional Service page as "HRDsig Positive", "HRDsign Negative" or "Cannot Be Determined".
- [†] Based on testing guidelines in advanced breast cancer. Does not include germline or IHC testing. PTEN loss detection requires high ctDNA tumor fraction when using a liquid biopsy.
- [‡] 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.
- ^{**} Part of Foundation More offering. Not available in every country. Please refer to your Roche-Foundation Medicine representative to know more about Foundation More and specific terms and conditions of the service offering in your country.
- ¹ Data on file. Foundation Medicine, Inc., 2024. Median Turnaround Time 8.8 days with FoundationOne CDx and 8 days with FoundationOne Liquid CDx, from sample receipt to report. International markets.

1. A. Gennari, F. André, C. H. Barrios, et al (2021), ESMO Clinical Practice Guideline for the diagnosis, staging and treatment of patients with metastatic breast cancer; Ann Oncol. 32(12): 1475-1495. <https://doi.org/10.1016/j.annonc.2021.09.019>. 2. Marra A, Chandarlapaty S, Modi S. Management of patients with advanced-stage HER2-positive breast cancer: current evidence and future perspectives. Nat Rev Clin Oncol. Jan 8 2024;doi:10.1038/s41571-023-00849-9. 3. Vasseur D, et al. Next-generation sequencing on circulating tumor DNA in advanced solid cancer: Swiss army knife for the molecular tumor board? A Review of the literature focused on FDA approved test. Cells. 2022; 11(12):1901. <https://doi.org/10.3390/cells11121901>. 4. Pascual, J., et al. (2022) Ann Oncol 33(8):750-68. <https://doi.org/10.1016/j.annonc.2022.05.520>. 5. Foundation Medicine. FoundationOne®CDx FDA Label. Accessed January 18, 2024. http://www.accessdata.fda.gov/cdrh_docs/pdf/f7/P170019S014C.pdf. 6. Foundation Medicine. FoundationOne®Liquid CDx FDA Label. Accessed October 1, 2024. https://www.accessdata.fda.gov/cdrh_docs/pdf/f9/P190032S010C.pdf. 7. Richardson D, et al. Clin Cancer Res. 2024;30(20):4644-4653. 8. Sokol ES, et al. JCO Precis Oncol. 2020;4:442-465.

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