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**FoundationOne CDx i
FoundationOne Liquid CDx
obuhvaćaju po 12+ klinički
relevantnih biomarkera kod
uznapredovalog CRC-a,
uključujući sve koje
preporučuju ESMO smjernice.^{1,6-7}**



Proširite mogućnosti liječenja kolorektalnog karcinoma (CRC)

Ciljana terapija je prestala djelovati.
Postoji li djelotvorna alternativa?

Njegov liječnik je znao kada testirati:

- Pri postavljanju dijagnoze metastatskog adenokarcinoma
- Pri dijagnozi lokalno neresektabilne bolesti ili kada operacija nije medicinski moguća
- Pri metastatskoj progresiji nakon liječenja ranog stadija bolesti (resektabilne ili neresektabilne)
- Pri recidivu, posebno nakon ciljane terapije

Terapije odobrene od EMA-e i preporučene smjernicama ¹		CE-IVD testovi
		FoundationOne®CDx ⁶ + FoundationOne®Liquid CDx ⁷
Specifično za CRC	Braftovi® (encorafenib) + Erbitux® (cetuximab)	BRAF V600E
	Vectibix® (panitumumab), Erbitux® (cetuximab)	KRAS/NRAS divlji tip
	Opdivo® (nivolumab) + Yervoy® (ipilimumab)	MSI-H, MSI [*]
Neovisno o tipu tumora	Keytruda® (pembrolizumab)	MSI-H, MSI [*]
	Rozlytrek®* (entrectinib), Vitakvi® (larotrectinib), Augtyro™ (repotrectinib)	Fuzije NTRK1/2/3 [†]
	Retsevmo® (selpercatinib)	Fuzije RET

EMA = European Medicines Agency
[†] When considering eligibility for Rozlytrek® based on the detection of *NTRK1/2/3* fusions, testing using plasma specimens is only appropriate for patients for whom tumor tissue is not available for testing.
^{*} MSI status will be reported for FoundationOne Liquid CDx samples determined to have high microsatellite instability.

Jeste li znali?

POLE/POLD1¹

- Smjernice ih sada preporučuju za sve pacijente s metastatskim CRC-om.¹
- Mogu prepoznati kandidate za inhibitore imunoloških kontrolnih tačaka koje samo MSI/dMMR testiranje može propustiti.

HRDsig¹⁸

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

	Biopsija tkiva: FoundationOne®CDx ⁶	Tečna biopsija: FoundationOne®Liquid CDx ⁷
Svi solidni tumori	• CE-IVD • DNA (324 gena) - tehnologija hibridnog hvatanja s visokim protokom • Tumorsko mutacijsko opterećenje, mikrosatelitska nestabilnost i pan-tumorski HRD potpis (HRDsig)[†] • Mogućnost prelaska na tečnu biopsiju	• CE-IVD • DNA (324 gena) - tehnologija hibridnog hvatanja s visokim protokom[†] • Tumorsko mutacijsko opterećenje iz krvi, visoka mikrosatelitska nestabilnost i tumorska frakcija ctDNA⁸ • Mogućnost prelaska na testiranje tkiva
	Vrijeme do nalaza: 8,8 dana ⁹	Vrijeme do nalaza: 8 dana ⁹

CGP testovi se razlikuju po mogućnostima

Kako se vaš test poredi s drugima?

FoundationOne CDx i FoundationOne Liquid CDx:

• Otkrivaju sve klinički relevantne biomarkere u CRC-u, uključujući RAS (KRAS i NRAS) i BRAF, kao i nove biomarkere poput FGFR.^{1-2,6-7}

• Otkrivaju POLE/POLD1.⁶⁻⁷

• Prikazuju somatske alteracije, uz jasno označene potencijalne germinalne alteracije.^{**6-7}

FOUNDATIONONE® CDx

✓ Klinički validirano tumorsko mutacijsko opterećenje (TMB) i visoka mikrosatelitska nestabilnost (MSI-H)

✓ Dostupan za naknadno testiranje kada je tumorska frakcija ctDNA u FoundationOne®Liquid CDx nalazu niska, a nalaz negativan[§]

✓ Pouzdana detekcija fuzija iz DNA

FOUNDATIONONE® LIQUID CDx

✓ Jedinstveno prikazuje tumorsku frakciju ctDNA s definiranom graničnom vrijednošću koja usmjerava kliničke odluke i povećava povjerenje u negativne nalaze[§]

✓ Prvi FDA-odobren CDx test iz krvi za pacijente s metastatskim kolorektalnim karcinomom (mCRC)⁴

✓ Otkriva mutacije rezistencije bez ponovne biopsije

✓ Pouzdana detekcija fuzija iz DNA



IZVRŠNA PODRŠKA KORISNICIMA

- ✓ Namjenski tim za tehničku, naučnu i medicinsku podršku korisnicima
- ✓ Jednostavno online naručivanje i praćenje slučajeva, uz digitalne nalaze dostupne u različitim formatima (PDF, CSD)
- ✓ Dodatne usluge, uključujući razmjenu podataka i kolegijalnu podršku za tumačenje nalaza[#]

Jedinstven CGP portfolio s ujednačenim kvalitetom testiranja tkiva i krvi.⁶⁻⁷



Razmotrite tečnu biopsiju kada je uzorak tkiva star, iscrpljen, teško dostupan ili premalen, ili kada rak postane otporan na terapiju. Preporučuje se i kada je brži nalaz klinički važan.⁵



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.¹

Naručite Foundation Medicine test: www.genolab.ba/konsultacije



CGP = Comprehensive genomic profiling
CSD = Clinically structured data

^{*} Foundation Medicine detects both somatic and germline alterations but does not differentiate between the two on reports. Germline banner alerts you to potential germline alterations.

[†] 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.

[‡] 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.

[§] 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".

^{||} Data on file. Foundation Medicine, Inc., 2024. Median TAT from sample receipt to report. International markets.

[¶] 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.

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 being considered for therapy based on detection of *NTRK1/2/3* and *ROS1* fusions should only be tested if tissue is unavailable. 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.qarad.elfu.online/foundationmedicine/en/foundationmedicine?keycode=286605475>.

Eributux® is a registered trademark of ImClone, LLC. Vectibix® is a registered trademark of Amgen. Braftovi® is a registered trademark of Array BioPharma, Inc. Tukysa® is a registered trademark of Seagen Inc. Opdivo® is a registered trademark of Bristol Myers Squibb Company. Keytruda® is a registered trademark of Merck. Rozyltrek® is a registered trademark of Genentech, Inc. Vitrakvi® is a registered trademark of Bayer. Retevmo® is a registered trademark of Eli Lilly and Company.

1. A. Cervantes, et al (2023). Metastatic colorectal cancer: ESMO Clinical Practice Guideline for diagnosis, treatment and follow-up; Ann Oncol. 34(1): 10-32. <https://doi.org/10.1016/j.annonc.2022.10.003>. 2. Ratti M, Orlandi E, Hahne JC, et al. Targeting FGFR Pathways in Gastrointestinal Cancers: New Frontiers of Treatment. Biomedicines. Sep 27 2023;11(10). 3. Data on File, Foundation Medicine, Inc., 2024. 4. Data on File, Foundation Medicine, Inc., 2023. Based on approved CDx indications for liquid biopsy tests as of June 2023. 5. Pascual, J., et al. (2022) Ann Oncol 33(8):750-68. <https://doi.org/10.1016/j.annonc.2022.05.520>. 6. Foundation Medicine. FoundationOne®CDx FDA Label. Accessed January 18, 2024. https://www.accessdata.fda.gov/cdrh_docs/pdf/f9/P190032S010C.pdf. 7. Richardson et al. 2023;41(16_suppl):5583-5583. doi: https://doi.org/10.1200/jco.2023.41.16_suppl.5583.

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