FOUNDATIONONE®CDx FOUNDATIONONE®LIQUID CDx FOUNDATIONONE®HEME

INTERNATIONAL

One *proven portfolio*. That's our *foundation*.

Most **experience** with **comprehensive genomic profiling** (CGP)[1]

1,000+

Peer-reviewed publications on the current and potential utility of comprehensive genomic profiling[1]

1.5 M+

Foundation Medicine **reports delivered**[1]

- Tissue- AND blood-based **FDA-approved** comprehensive genomic profiling testing for all solid tumors with FoundationOne®CDx and FoundationOne®Liquid CDx.[5-6]
- Foundation Medicine comprehensive genomic profiling tests are run in **CAP accredited, CLIA** and **ISO certified** labs.[3]

UNDERSTANDING RESULTS

- Submit queries regarding patient results to our expert Medical Affairs team
- Get expert support in CGP report interpretation through P2P Advice, our web-based platform that connects you with peers for fast, reliable answers to your questions

WORKFLOW INTEGRATION

- Digital Experience for ordering, tracking and reporting
- Instant access via smartphone with MyFMI app

EXCELLENCE IN CUSTOMER CARE

- Dedicated customer care team for technical, scientific and medical support
- Seamless online experience to order and track your cases with digital reporting available in different format (PDF, JSON data, FoundationReport+ interactive report)
- Added-value services beyond our tests on education, data sharing and peer-to-peer report interpretation

A *unique CGP portfolio* with consistent quality *across tissue and liquid testing* options[5-6]

Consider liquid when a tissue sample is old, depleted, difficult to retrieve, too small, or when cancer becomes treatment resistant. Liquid is also recommended when faster results will be clinically important.[2]

Consider tissue when it is readily available and easy to retrieve or when ctDNA tumor fraction is below 1% in your liquid biopsy test result.[9]

Consider Foundation Medicine Solutions to get a clear, in-depth, comprehensive and validated CGP report, consistently delivered in 8 days.[†]

SEE OUR PROVEN PORTFOLIO OF TESTS ON THE BACK

Our *Proven* Portfolio

ALL SOLID TUMORS

TISSUE BIOPSY

FOUNDATIONONE®CDx

- FDA-approved companion diagnostic for +35 unique targeted therapies[4]
- DNA (324 genes)[5]
- TMB, MSI-H, pan-tumor HRDSig*
- FDA-approved CDx claims to detect ROS1, NTRK1/2/3, ALK, FGFR2 and RET fusions[4,5]
- 570+ pathologically distinct cancer types[8]
- Option to reflex to liquid

Median turnaround time of 8.8 days†

LIQUID BIOPSY

FOUNDATIONONE®LIQUID CDx

- FDA-approved companion diagnostic for +15 unique targeted therapies[4]
- DNA (324 genes)‡[6]
- bTMB, MSI, ctDNA Tumor Fraction§
- Robust DNA-based fusion detection with unique FDA-approved CDx claims for ALK, ROS1, NTRK1/2/3[6,10]
- Nearly 100% concordance to tissue biopsy for driver alterations when ctDNA TF ≥1%[9]
- Option to reflex to tissue

Median turnaround time of 8 days†

HEMATOLOGIC MALIGNANCIES AND SARCOMAS

FOUNDATIONONE®HEME

- DNA (406 genes) + RNA (265 genes) for hematologic malignancies, sarcomas, or solid tumors where RNA sequencing is desired[7]
- TMB, MSI
- FFPE Tissue

Median turnaround time of 20 days†

All FoundationOne products listed above are **CE-IVD approved.**[11-12]

IHC
Optional Tissue add-on for PD-L1

• Dako PD-L1 22C3 pharmDx • Dako PD-L1 28-8 pharmDx • Ventana PD-L1 SP142 • Ventana PD-L1 SP263

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

TMB: Tumor mutational burden, bTMB: blood tumor mutational burden, MSI: microsatellite instability

Order a Foundation Medicine test at *https://www.rochefoundationmedicine.com/#/en/international/ordering-support*

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

References
1. Data on file, Foundation Medicine, Inc, 2025 **2.** Pascual, J., et al. (2022) Ann Oncol 33(8):750-68. DOI: https://doi.org/10.1016/j.annonc.2022.05.520 **3.** Foundation Medicine CAP, CLIA and ISO Certificates available here https://www.foundationmedicine.com/resource/licenses (Accessed July 2025) **4.** Data on file, Foundation Medicine Inc., 2025. **5.** Foundation Medicine. FoundationOne®CDx FDA Label. Accessed June, 2024. https://www.accessdata.fda.gov/cdrh_docs/pdf17/P170019S014C.pdf. **6.** Foundation Medicine. FoundationOne®Liquid CDx FDA Label. Accessed June 2025. https://www.accessdata.fda.gov/cdrh_docs/pdf19/P190032S010C.pdf. **7.** FoundationOne® Heme. Technical specifications, available at: https://www.rochefoundationmedicine.com/#/en/international/foundationone-heme (Accessed June 2025) **8.** Data on file, Foundation Medicine Inc., 2024 **9.** 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. **10.** Data on file, Foundation Medicine, Inc. 2025 **11.** FoundationOne CDx Technical Specifications (Accessed July 2025) **12.** FoundationOne Liquid CDx Technical Specifications (Accessed July 2025)

FoundationOne®Heme is a laboratory developed test that was developed and its performance characteristics determined by Foundation Medicine. FoundationOne Heme has not been cleared or approved by the U.S. Food and Drug Administration. For more information on FoundationOne Heme, please see its Technical Specifications at *https://www.foundationmedicine.qarad.eifu.online/foundationmedicine/en/foundationmedicine?keycode=454269579*.

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 testingand 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.eifu.online/foundationmedicine/en/foundationmedicine?keycode=286605475.*

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