

# Our Proven Portfolio



Facilitates a precision medicine approach for a broad spectrum of patients in a clinically relevant timeframe

	FoundationOne®CDx	FoundationOne®Liquid CDx*	FoundationOne®Heme	IHC
FDA-Approved	FDA-approved CDx for 23 targeted therapies	FDA-approved CDx for 4 targeted therapies	-	FDA-approved CDx for 2 immunotherapies
Target Tumor Types	All Solid Tumors	Liquid Biopsy (ctDNA) - All Solid Tumors	Hematologic Malignancies, Sarcomas (Soft Tissue + Bone)	Specific Solid Tumors
Number of Genes Analyzed	324 (DNA)	324 (DNA)*	406 (DNA) 265 (RNA)	-
Genomic Signatures/ Biomarkers	Tumor Mutational Burden (TMB) Microsatellite Instability (MSI)	Blood TMB (bTMB)* Microsatellite Instability (MSI*) <sup>‡</sup> Tumor Fraction*	Tumor Mutational Burden (TMB) Microsatellite Instability (MSI)	PD-L1
Specimen†	FFPE Tissue	Peripheral Whole Blood	FFPE Tissue Bone Marrow Aspirate Peripheral Whole Blood	FFPE Tissue
	10 USS or 1 Block‡ + 1 H&E slide	2 Tubes (8.5mL each) of Peripheral Whole Blood	16 USS + 1 H&E Slide or 1 FFPE block or 2.5 mL Bone Marrow Aspirate or 1 filled EDTA Tube + 2.5 mL Paxgene Tube Peripheral Whole Blood	4 USS
Report Features <sup>§</sup>	Point mutations, insertions/deletions, copy number alterations, select rearrangements	Point mutations, insertions/deletions, copy number alterations, select rearrangements	Point mutations, insertions/deletions, copy number alterations, rearrangements	Tumor Proportion Score (TPS) and/or Combined Positive Score (CPS) for approved/validated tumor types
Typical Turnaround Time <sup>  </sup>	< 2 weeks	< 2 weeks	2 weeks	5 days

Financial Assistance Program information is available at [aid.foundationmedicine.com](https://aid.foundationmedicine.com)

FFPE – Formalin-fixed, paraffin embedded tissue

USS – Unstained slides

\* FoundationOne Liquid CDx is FDA-approved to report substitutions and indels in 311 genes, including rearrangements and copy number losses only in *BRCA1/2*.

Comprehensive results across all 324 genes, including bTMB, MSI-H status, and tumor fraction are reported in the professional services section of the report.

<sup>‡</sup> MSI status will be reported for samples determined to have high microsatellite instability

<sup>†</sup> For full details, refer to specimen instructions at [www.foundationmedicine.com](https://www.foundationmedicine.com)

<sup>‡</sup> FFPE Block is preferred

<sup>§</sup> For FDA approved tests, reports contain FDA approved genomic results as well as additional information provided as a professional service that is not reviewed by the FDA.

<sup>||</sup> Based on typical turnaround time from receipt of specimen

## About Foundation Medicine

Foundation Medicine is a world-leading molecular insights company offering a portfolio of comprehensive genomic profiling tests and services designed to ensure you have access to quality genomic insights regardless of cancer or specimen type.

### TO LEARN MORE:

Visit [www.foundationmedicine.com](http://www.foundationmedicine.com)

### TO ORDER:

Contact Client Services at 888.988.3639 or [client.services@foundationmedicine.com](mailto:client.services@foundationmedicine.com)

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 [www.F1CDxLabel.com](http://www.F1CDxLabel.com) and [www.F1LCDxLabel.com](http://www.F1LCDxLabel.com).

FoundationOne Heme was developed and its performance characteristics determined by Foundation Medicine. It has not been cleared or approved by the U.S. Food and Drug Administration. For more information on this laboratory developed test please see the Technical Specifications at [www.foundationoneheme.com](http://www.foundationoneheme.com).



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