

# ONE PROVEN PORTFOLIO OF TESTS & SERVICES. THAT'S OUR FOUNDATION.



## Most experience with comprehensive genomic profiling<sup>1</sup>

450+

peer-reviewed publications on the current and potential utility of comprehensive genomic profiling<sup>1</sup>

400K+

patients tested with comprehensive genomic profiling in a clinical setting<sup>1</sup>



Tissue- AND blood-based **FDA-approved** comprehensive genomic profiling testing for all solid tumors with FoundationOne®CDx and FoundationOne®Liquid CDx



All Foundation Medicine comprehensive genomic profiling tests are run in **CAP accredited** and **CLIA certified** labs.



### Understanding results:

- Medical Case Consulting by a team of oncologists and pathologists to discuss results
- Molecular Tumor Boards for eligible institutions to educate on the actionability of comprehensive genomic profiling



### Workflow integration:

- Digital Experience for ordering, tracking and reporting
- EMR interfacing



### Clinical trial matching:

- Notify physicians of enrollment opportunities for NCI-match trial arms
- Precision Enrollment program identifies patients with rare or specific biomarkers and matches them with sponsor trials using the FoundationSmartTrials™ engine



### Financial Assistance and Coverage:

- Medicare covers all Foundation Medicine tests for qualifying patients who meet clinical criteria.<sup>2</sup>
- FoundationOne CDx and FoundationOne Liquid CDx are covered by TRICARE for qualifying patients.<sup>3</sup>
- Foundation Medicine's testing experience has shown that:
  - 79% of patients have \$0 financial responsibility for testing<sup>4</sup>
  - 86% of patients have a financial responsibility of \$100 or less for testing<sup>5</sup>
- We offer a financial program based on need for those patients that may still have out of pocket costs.



SEE OUR PROVEN PORTFOLIO OF TESTS ON THE BACK

# Our Proven Portfolio



## FOUNDATIONONE® CDx

- FDA-approved tissue-based comprehensive genomic profiling test for all solid tumors
- Companion Diagnostic (CDx) Claims for 23 targeted therapies
- Option to reflex to liquid

324 Genes (DNA), TMB + MSI + LOH\*

FFPE Tissue (10 USS or 1 Block† + 1 H&E Slide)

<2 weeks\*\*



## FOUNDATIONONE® LIQUID CDx

- FDA-approved blood-based comprehensive genomic profiling test for all solid tumors
- Companion Diagnostic (CDx) Claims for 4 targeted therapies
- Option for mobile phlebotomy
- Option to reflex to tissue

324 genes (DNA), Reports bTMB, MSI-H, and tumor fraction†

Peripheral Whole Blood (2 8.5mL Tubes)

<2 weeks\*\*



## FOUNDATIONONE® HEME

- A laboratory developed test for hematologic malignancies, sarcomas or solid tumors where known or novel gene fusion detection is desired

406 genes (DNA), 265 genes (RNA), TMB + MSI

FFPE Tissue, Bone Marrow Aspirate, Peripheral Whole Blood (16 USS + 1 H&E or 1 FFPE block or 2.5 mL Bone Marrow Aspirate or 1 filled EDTA Tube + 2.5 mL Paxgene Tube Peripheral Whole Blood)

2 weeks\*\*

## IHC

- FDA-approved CDx for 2 immunotherapies in specific solid tumors

PD-L1

FFPE Tissue (4 USS)

5 days\*\*

Learn more about our proven portfolio of tests and services at [www.foundationmedicine.com](http://www.foundationmedicine.com)

\* For ovarian cancer  
† Block is preferred  
\*\* From receipt of specimen

‡ 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.

1. Data on file, Foundation Medicine, Inc, 2020
2. For FoundationOne®CDx and FoundationOne®Liquid CDx, see "Decision for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced cancer - CAG-00450R." (See Appendix B). For FoundationOne®Heme, see the "Local Coverage Determination (LCD): MoDX: NEXT-GENERATION Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies (L38047)".
3. TRICARE Policy Manual 6010.60-M, Chapter 6, Section 3.1Genetic Testing and Counseling, 2.2 Genetic tests that have received United States (U.S.) Food and Drug Administration (FDA) medical device 510(k) clearance or premarket approval that are medically necessary for the diagnosis and treatment of an illness or injury and have demonstrated clinical utility are a TRICARE benefit.
4. Based on settled claims from 1/1/19 to 3/31/20 for all tests offered by Foundation Medicine and reported during that time before considering any financial assistance. 61% of commercially insured and 90% of Medicare and Medicare Advantage patients paid \$0 for Foundation Medicine testing.
5. Based on settled claims from 1/1/19 to 3/31/20 for all tests offered by Foundation Medicine and reported during that time before considering any financial assistance. 65% of commercially insured and 97% of Medicare and Medicare Advantage patients had or qualified for a payment of \$100 or less for Foundation Medicine testing.

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 <http://foundationoneheme.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.FICDXLabel.com](http://www.FICDXLabel.com) and [www.FILCDxLabel.com](http://www.FILCDxLabel.com).