

# Our comprehensive genomic profiling revolves around your patient

The first and only FDA-approved broad companion diagnostic for all solid tumors, FoundationOne®CDx helps identify innovative treatments for your advanced cancer patients from our proven portfolio of tests and services.



### Clear Treatment Options with One Test

- Targeted Therapy: Direct path to 19 companion diagnostic therapies across 5 cancer indications, and clinical trial matching across all solid tumors
- Immunotherapy: Helps inform immunotherapy decisions by including genomic signatures such as microsatellite instability (MSI) and tumor mutational burden (TMB)
- **Simplified Report**: All results are provided in a simplified report, with companion diagnostic results and associated therapies highlighted upfront
- Coverage: National coverage for qualifying Medicare and Medicare Advantage patients across all solid tumors<sup>1</sup>



# Convenient, Broad Companion Diagnostic

- **Spare Tissue**: Results from a single tissue sample identify multiple biomarkers to save time and tissue compared with sequential single-gene testing
- **Get Results Fast**: Turnaround time of less than 2 weeks from when we receive the tissue sample
- Stay Up to Date: Comprehensive platform that can be updated regularly as more genes and genomic signatures are indicated for use with FDA-approved therapies
- **Save Time**: Online ordering and status tracking available for your care team at **www.foundationmedicine.com/f1cdx**

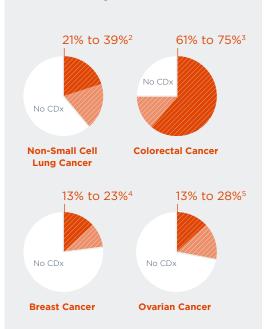


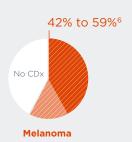
# Comprehensive Approach to Find More Patients

The approach used by FoundationOne CDx has been shown by our FoundationOne® assay to identify more patients, compared with traditional single-gene testing methods, who test positive for the following genomic alterations in several cancer types:



Clinically Actionable Results
Published Incidences at Diagnosis
of CDx Findings





- Non-Small Cell Lung Cancer (NSCLC): Up to 35% and 21% more patients identified with *ALK* fusions and *EGFR* alterations, respectively, compared with traditional FISH and PCR-based methods.
- Colorectal Cancer (CRC): Up to 88% more patients with resistant KRAS alterations than focused PCR-based test methods.<sup>9</sup>
- Prostate: Our test goes beyond standard of care to test for therapeutically relevant alterations in genes such as AR and genes of emerging clinical significance: ALK, ROS1, and NTRK
- Breast: Analyze guideline recommended *ERBB2* (HER2), *BRCA1*, and *BRCA2*, as well as additional clinically-relevant genes such as *PIK3CA*, *NTRK1*, *NTRK2*, and *NTRK3*



## **Companion Diagnostic Indications**

INDICATIONS	BIOMARKER	FDA-APPROVED THERAPY*
Non-Small Cell Lung Cancer (NSCLC)	EGFR exon 19 deletions and EGFR exon 21 L858R alterations	Gilotrif® (afatinib), Iressa® (gefitinib), Tagrisso® (osimertinib) or Tarceva® (erlotinib)
	EGFR exon 20 T790M alterations	Tagrisso* (osimertinib)
	ALK rearrangements	Alecensa® (alectinib), Xalkori® (crizotinib), or Zykadia® (ceritinib)
	BRAF V600E	Tafinlar® (dabrafenib) in combination with Mekinist® (trametinib)
Melanoma	BRAF V600E	Tafinlar* (dabrafenib) or Zelboraf* (vemurafenib)
	<i>BRAF</i> V600E or V600K	Mekinist* (trametinib) or Cotellic* (cobimetinib) in combination with Zelboraf* (vemurafenib)
Breast Cancer	ERBB2 (HER2) amplification	Herceptin* (trastuzumab), Kadcyla* (ado-trastuzumab emtansine), or Perjeta* (pertuzumab)
	PIK3CA alterations	Piqray® (alpelisib)
Colorectal Cancer (CRC)	KRAS wild-type (absence of mutations in codons 12 and 13)	Erbitux® (cetuximab)
	KRAS wild-type (absence of mutations in exons 2, 3 and 4) and NRAS wild-type (absence of mutations in exons 2, 3 and 4)	Vectibix* (panitumumab)
Ovarian Cancer	BRCA1/2 alterations	Lynparza* (olaparib) or Rubraca* (rucaparib)

<sup>\*</sup> Tarceva" is the registered trademark of OSI Pharmaceuticals, LLC. Zelboraf\*, Herceptin\*, Perjeta\*, Kadcyla\*, and Cotellic\* are registered trademarks of Genentech, Inc. Gilotrif\* is a registered trademark of Boehringer Ingelheim International GmbH. Incesa\*, Lynparza, and Tagrisso\* are registered trademarks of the AstraZeneca group of companies. Xalkori\* is a registered trademark of Pfizer Inc. Zykadia\*, Tafinlar\*, Pigray\* and Mekinist\* are registered trademarks of Novartis AG Corporation Switzerland. Erbitux\* is a registered trademark of ImClone LLC, a wholly owned subsidiary of Eli Lilly and Company. Alecensa\* is a registered trademark of Chugai Seiyaku Kabushiki Kaisha. Vectibix\* is a registered trademark of Immunex Corporation. Rubraca\* is a registered trademark of Clovis Oncology, Inc.

#### **About Foundation Medicine**

Foundation Medicine is a world-leading molecular information company offering a portfolio of tests and services to deliver convenient access to precision medicine today and the advancements of cancer care tomorrow for physicians and their patients. For more information, please visit foundationmedicine.com

#### **TO LEARN MORE:**

Visit www.foundationmedicine.com/f1cdx

#### TO ORDER:

Create an account to order online at www.foundationmedicine.com/signup

#### References

1. Medicare and Medicare Advantage members have coverage of FoundationOne CDx in accordance with the Centers for Medicare and Medicaid Services (CMS) national coverage determination (NCD) criteria. 2. VanderLaan et al., 2018; 29413057, Kris et al., 2014; 24846037, D'Angelo et al., 2011; 21482987, Esteban et al., 2015; 25766256, Han et al., 2017; 29110846. Barlesi et al., 2016; 26777916, Hata et al., 2013; 24105277, Tanaka et al., 2017; 28978102, Sequist et al., 2011; 21430269, Oxnard et al., 2011; 21135146, Paik et al., 2011; 21483012.

3. Roth et al., 2010; 20008640, Amado et al., 2008; 18316791, Douillard et al., 2013; 24024839, Heinemann et al., 2014; 25088940, Price et al., 2015; 25742472, De Roock et al., 2010; 20619739, Vaughn et al., 2011; 21305640, Peeters et al., 2013; 23325582.

4. Cancer Genome Atlas Network et al., 2012; 23000897, Owens et al., 2004; 15140287, Chmielecki et al., 2014; 25480824, Bartlett et al., 2001; 11745673.

5. Yang et al., 2011; 21990299, Cancer Genome Atlas Research Network., 2011; 21720365, Zhang et al., 2011; 21324516, Pennington et al., 2013; 24240112.

6. Greaves et al., 2013; 23273605, Hodis et al., 2012; 22817889, Menzies et al., 2012; 22515154, Colombino et al., 2012; 22614978, Long et al., 2011; 213435599.

7. Ali et al Oncologist. 2016 Jun; 21(6):762-70. doi:10.1634/theoncologist.2015-0497. Epub 2016 May 31.

8. Suh J, et al. The Oncologist. 2018; 23:776-781.

9. Rankin A, Klempner SJ, Erlich R, et al. Broad Detection of Alterations Predicted to Confer Lack of Benefit From *EGFR* Antibodies or Sensitivity to Targeted Therapy in Advanced Colorectal Cancer. *The Oncologist.* 2016.

10. Boussemart et al. Hybrid-capture based genomic profiling identifies *BRAF* V600 and non-V600 alterations in melanoma samples negative by prior testing. ESMO 2017.

FoundationOne®CDx is a next-generation sequencing based in vitro test intended for use by healthcare professionals for advanced cancer patients with solid tumors. The test analyzes 324 genes as well as genomic signatures including microsatellite instability (MSI) and tumor mutational burden (TMB) and is FDA-approved as a companion diagnostic to identify patients who may benefit from treatment with a specific list of therapies (listed in Table 1 in the Technical Information at http://www.foundationmedicine. com/flcdx) in accordance with the approved therapeutic product labeling. Additional genomic findings, other than those listed in Table 1, may be reported and are not prescriptive or conclusive for labeled use of any specific therapeutic product. Use of the test does not guarantee a patient will be matched to a treatment or clinical trial option, or that all relevant alterations will be detected. Some patients may require a biopsy. For the complete label, including important risk information, please visit http://www.foundationmedicine.com/flcdx.

