FOUNDATIONONE® CDx

Our comprehensive genomic profiling revolves around your patient

FoundationOne®CDx is the first FDA-approved tissue-based comprehensive genomic profiling test. It provides guideline-recommended genomic results and has Medicare coverage for qualifying patients across all solid tumors.

Clear Treatment Options with One Test

- **Targeted Therapy:** Proven to help predict patient benefit across multiple targeted therapies in multiple cancer indications with over 20 companion diagnostic (CDx) claims
- **Immunotherapy**: Helps inform immunotherapy decisions by including genomic signatures such as microsatellite instability (MSI) and tumor mutational burden (TMB)
- **Simplified Report**: CDx results and associated therapies are highlighted upfront
- **Coverage**: National coverage for qualifying Medicare and Medicare Advantage patients across all solid tumors[1]

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**

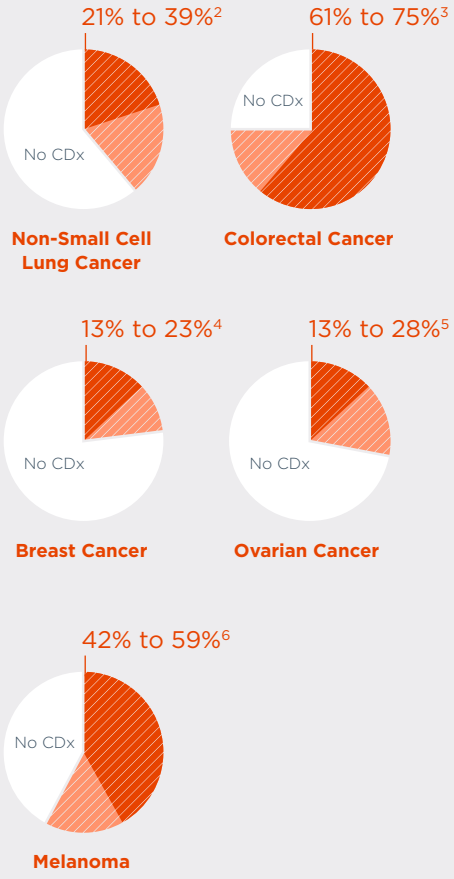
Comprehensive Approach to Find More Patients

- **Non-Small Cell Lung Cancer** (NSCLC): Single gene testing or limited panels have been shown to miss up to 35% of *ALK* fusions[7] and 21% of *EGFR* mutations (41% of these missed *EGFR* mutations are common alterations targetable by an FDA-approved therapy in the applicable patient's tumor type).[8]
- **Colorectal Cancer** (CRC): Of the 6.4% of patients that harbor potentially resistant *KRAS* mutations outside of codons 12 and 13, 88% may not be identified by focused PCR-based testing methods as having such a *KRAS* mutation.[9]
- **Prostate**: By testing for all mutations, regardless of germline or somatic*, FoundationOne CDx can identify more than twice as many men who may benefit from PARP inhibitor therapy than conventional germline-only testing.[10]
- **Breast**: Analyze guideline recommended *BRCA1/2,* and *PIK3CA*, as well as additional clinically-relevant genes such as *NTRK3*, *ESR1*, and *AKT1.*

*FoundationOne CDx detects both somatic and germline alterations but does not differentiate between the two on reports.

Clinically Actionable Results

Published Incidences at Diagnosis of CDx Findings



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)
	MET exon 14 skipping-associated indels or single nucleotide variants	Tabrecta™ (capmatinib)
Melanoma	*BRAF* V600E	Tafinlar® (dabrafenib) or Zelboraf® (vemurafenib)
	BRAF 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)
Cholangiocarcinoma	*FGFR2* fusions and select rearrangements	Pemazyre™ (pemigatinib)
Prostate Cancer	Homologous Recombination Repair *(HRR) gene (BRCA1, BRCA2, ATM, BARD1, BRIP1, CDK12, CHEK1, CHEK2, FANCL, PALB2, RAD51B, RAD51C, RAD51D and RAD54L)* alterations	Lynparza® (olaparib)
Solid Tumors	TMB ≥ 10 mutations per megabase	Keytruda® (pembrolizumab)

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; 22535154, Colombino et al., 2012; 22614978, Long et al., 2011; 21343559. **7.** Ali SM, et al. Comprehensive genomic profiling identifies a subset of crizotinib-responsive ALK-rearranged non-small cell lung cancer not detected by FISH. The Oncologist. 2016 Jun;21(6):762-770. **8.** Suh J, et al. Hybrid Capture-Based Comprehensive Genomic Profiling Identifies Lung Cancer Patients with Well-Characterized Sensitizing Epidermal Growth Factor Receptor Point Mutations That Were Not Detected by Standard of Care Testing. 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.** J Chung et al *Prospective Comprehensive Genomic Profiling of Primary and Metastatic Prostate Tumors*, JCO Precision Oncology, May 2019.

FoundationOne®CDx is a next-generation sequencing based in vitro diagnostic test for advanced cancer patients with solid tumors and is for prescription use only. The test analyzes 324 genes as well as genomic signatures including microsatellite instability (MSI) and tumor mutational burden (TMB) and is a companion diagnostic to identify patients who may benefit from treatment with specific therapies in accordance with the approved 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 test 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 the complete label, including companion diagnostic indications and important risk information, please visit *www.F1CDxLabel.com*

FOUNDATION MEDICINE®

www.foundationmedicine.com | Tel. 888.988.3639 | Fax 617.418.2290 | US-FDX-2000039