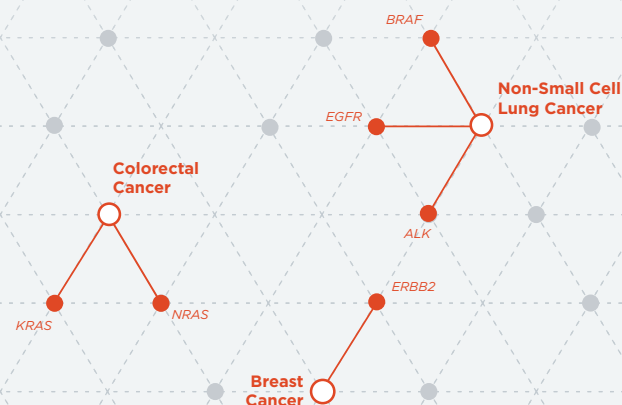




Transform genomic data into real-life results

FoundationOne CDx™ helps inform treatment decisions, with insights specific to each patient's cancer



New FDA-Approved Broad Companion Diagnostic for Solid Tumors



Clear Treatment Options with One Test

- **Simplified Report:** All results are provided in a simplified report, with companion diagnostic results and associated therapies highlighted upfront
- **Coverage:** National coverage for Medicare and Medicare Advantage patients across various solid tumor types is under review by the Centers for Medicare and Medicaid Services (CMS)¹
- **Options for Patients:** Identifies patients who may benefit from targeted therapies, as well as patients with important negative results that can be used for patient management
- **Immunotherapy:** Helps inform immunotherapy decisions by including genomic signatures such as microsatellite instability (MSI) and tumor mutational burden (TMB)

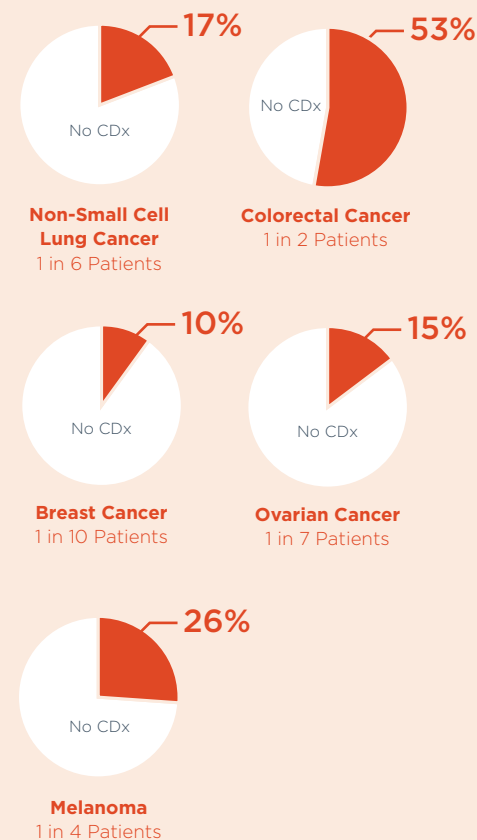


Convenient, Broad Companion Diagnostic

- **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/flcdx

Clinically Relevant Results

Projected Incidence of CDx Findings²





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:

- **Non-Small Cell Lung Cancer (NSCLC):** Up to 35%³ and 17%⁴ more patients identified with *ALK* fusions and *EGFR* alterations, respectively, compared with traditional FISH and PCR-based methods.
- **Colorectal Cancer (CRC):** Up to 12% more patients identified with resistant *KRAS* alterations compared with traditional PCR-based methods.⁵
- **Melanoma:** Up to 37% more patients identified with *BRAF* alterations compared with traditional PCR-based methods.⁶



Companion Diagnostic Indications

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

* Tarceva® is the registered trademark of OSI Pharmaceuticals, LLC. Zelboraf®, Herceptin®, Perjeta®, Kadcyła®, and Cotellic® are registered trademarks of Genentech, Inc. Gilotrif® is a registered trademark of Boehringer Ingelheim International GmbH. Iressa® and Tagrisso® are registered trademarks of the AstraZeneca group of companies. Xalkori® is a registered trademark of Pfizer Inc. Zykadia®, Tafinlar®, and Mekinist® are registered trademarks of Novartis AG Corporation Switzerland. Erbix® 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 insights company offering a suite of testing and support services to connect physicians and their patients to the latest cancer treatment approaches and making precision medicine a reality for thousands. For more information, please visit foundationmedicine.com or follow us on Twitter (@FoundationATCG).

TO LEARN MORE:

Visit www.foundationmedicine.com/f1cdx

TO ORDER:

Available to order in early 2018

References

1. As part of the joint FDA and Centers for Medicare and Medicaid Services (CMS) parallel review process, CMS has issued a proposed coverage memorandum. A final national coverage determination (NCD) is expected to be posted in 2018. At that time, Medicare and Medicare Advantage members will have coverage of FoundationOne CDx in accordance with the NCD criteria. 2. Projections based on data from Foundation Medicine's database as of August 2017. 3. Ali et al *Oncologist*. 2016 Jun;21(6):762-70. doi:10.1634/theoncologist.2015-0497. Epub 2016 May 31. 4. Schrock et al DOI: 10.1158/1078-0432.CCR-15-1668. 5. Rankin A, Klemptner 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. 6. 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* diagnostic device for detection of substitutions, insertion and deletion alterations, and copy number alterations in 324 genes and select gene rearrangements, as well as genomic signatures including microsatellite instability (MSI) and tumor mutational burden (TMB) using DNA isolated from formalin-fixed, paraffin-embedded (FFPE) tumor tissue specimens. For the complete intended use statement, including companion diagnostic indications, please see the FoundationOne CDx Technical Information, www.foundationmedicine.com/f1cdx.

