FoundationOne® CDx
FoundationOne® Liquid

COMPLEMENTARY TESTING OPTIONS FOR PATIENTS WITH SOLID TUMORS
FoundationOne CDx is the next evolution of FoundationOne®, with FDA approval, Medicare coverage and comprehensive results to help inform treatment decisions

First FDA-Approved Comprehensive Genomic Profiling (CGP) Test for patients with all solid tumors, including 324 genes and multiple companion diagnostic indications

National Coverage for qualifying Medicare & Medicare Advantage patients across all solid tumors

Robust Performance: Analytically validated across four main classes of genomic alterations, ensuring high quality results on 70 genes to better inform treatment decisions

Streamlined Report: Simplified report including longitudinal comparison with prior Foundation Medicine test results and a dynamic visual of mutant allele frequency (MAF) changes

FoundationOne Liquid is our next-generation liquid biopsy test for solid tumors, now including microsatellite instability (MSI-H) detection that can help inform immunotherapy selection

1. MSI status will be reported for samples determined to have high microsatellite instability. 2. 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. 3. Internal data on file as of September 2018.

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Clinically Relevant Results: Range of Published Incidences at Diagnosis of Companion Diagnostic (CDx) Associated Alterations Across 5 Common Cancers1-5

**CRC**
- 61–75% of Patients
  - KRAS or NRAS Wildtype
  - 61% - 75%
  - KRAS or NRAS Wildtype
  - 61% - 75%

**Melanoma**
- 42–59% of Patients
  - BRAF V600E or V600K
  - 42% - 59%

**NSCLC**
- 21–39% of Patients
  - EGFR CDx Alterations*
    - 15% - 28%
  - ALK Rearrangements
    - 5% - 8%
  - BRAF V600E Alterations
    - 1% - 2%

**Ovarian**
- 13–28% of Patients
  - BRCA1 or BRCA2
    - 13% - 28%
  - BRCA1 or BRCA2
    - 13% - 28%

**Breast**
- 13–23% of Patients
  - ERBB2 (HER2) amplifications

*Exon 19 Deletions, Exon 21 L858R, or Exon 20 T790M

FoundationOne CDx is intended for use as a companion diagnostic for 17 targeted therapies (see slide 15). FoundationOne Liquid is not intended for use as a companion diagnostic.

1 (CRC). Roth et al., 2010; 20088640, Amado et al., 2008; 18316791, Doudard 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, 2 (Melanoma). Greaves et al., 2013; 2327605, Hodis et al., 2012; 22817889, Mensies et al., 2012; 23535154, Colombino et al., 2012; 22049978, Long et al., 2011; 21343559. 3 (NSCLC). 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. 4 (Ovarian). Yang et al., 2011; 21990299, Cancer Genome Atlas Research Network., 2011; 21720365, Zhang et al., 2011; 21324516, Pennington et al., 2013; 24240112. 5 (Breast). Cancer Genome Atlas Network et al., 2012; 23000897, Owens et al., 2004; 15140287, Chmielecki et al., 2014; 25480824, Bartlett et al., 2001; 11745673. © 2018 Foundation Medicine
Help Inform Immunotherapy Decisions

Patients across all cancer types may test positive for one of three key biomarkers that can help inform immunotherapy decisions:

1. Data based on Foundation Medicine experience.
2. PD-L1 by immunohistochemistry (IHC) can be ordered as a supplemental test and may inform eligibility for several immunotherapies across different cancer types.

14% of patients who test negative for PD-L1 by IHC have MSI-High or TMB-High status, which may help inform immunotherapy decisions.

FoundationOne CDx provides results on TMB and MSI with every test.

FoundationOne Liquid reports MSI-High status for solid tumor patients.

TMB: Tumor Mutational Burden
MSI: Microsatellite Instability
PD-L1: By Immunohistochemistry (IHC)

1. Data based on Foundation Medicine experience.
2. PD-L1 by immunohistochemistry (IHC) can be ordered as a supplemental test and may inform eligibility for several immunotherapies across different cancer types.
When to consider using a liquid biopsy?

- When your patient has inadequate or inaccessible tissue for testing with FoundationOne CDx.
- When you suspect your patient may have progressed on targeted therapy.
- When you need faster access to genomic information and cannot wait for a tissue biopsy.

Complementary Testing Options

- FoundationOne® CDx
- FoundationOne® Liquid

When tissue biopsy is not ideal, a simple blood draw can deliver reliable answers.
**FoundationOne Liquid has added HRD genes, MSI-H**

FoundationOne Liquid’s gene list demonstrates clinical utility across multiple tumor types.

<table>
<thead>
<tr>
<th>ABL1</th>
<th>AKT1</th>
<th>ALK</th>
<th>APC</th>
<th>AR</th>
<th>ARAF</th>
<th>ATM</th>
<th>BRAF</th>
</tr>
</thead>
<tbody>
<tr>
<td>BRCA1</td>
<td>BRCA2</td>
<td>BTK</td>
<td>CCND1</td>
<td>CD274</td>
<td>CDH1</td>
<td>CDK4</td>
<td>CDK6</td>
</tr>
<tr>
<td>CDK12</td>
<td>CDKN2A</td>
<td>CHEK2</td>
<td>CRKL</td>
<td>CTNNB1</td>
<td>DDR2</td>
<td>EGFR</td>
<td>ERBB2</td>
</tr>
<tr>
<td>ERRFI1</td>
<td>ESR1</td>
<td>EZH2</td>
<td>FGFR1</td>
<td>FGFR2</td>
<td>FGFR3</td>
<td>FLT3</td>
<td>FOXL2</td>
</tr>
<tr>
<td>GNA11</td>
<td>GNAQ</td>
<td>GNAS</td>
<td>HRAS</td>
<td>IDH1</td>
<td>IDH2</td>
<td>JAK2</td>
<td>JAK3</td>
</tr>
<tr>
<td>KIT</td>
<td>KRAS</td>
<td>MAP2K1</td>
<td>MAP2K2</td>
<td>MDM2</td>
<td>MET</td>
<td>MPL</td>
<td>MTOR</td>
</tr>
<tr>
<td>MYC</td>
<td>MYCN</td>
<td>MYD88</td>
<td>NF1</td>
<td>NPM1</td>
<td>NRAS</td>
<td>PALB2</td>
<td>PDCD1LG2</td>
</tr>
<tr>
<td>PDGFA</td>
<td>PDGFRB</td>
<td>PIK3CA</td>
<td>PTEN</td>
<td>PTPN11</td>
<td>RAF1</td>
<td>RB1</td>
<td>RET</td>
</tr>
<tr>
<td>ROS1</td>
<td>SMO</td>
<td>STK11</td>
<td>TERT</td>
<td>TP53</td>
<td>VEGFA</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Key additional inclusions:**

*Microsatellite Instability Status (MSI-H)*

All 70 genes on FoundationOne Liquid are included on FoundationOne CDx (324 total genes).

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1. HRD stands for Homologous Recombination Deficiency (HRD). MSI status will be reported for samples determined to have high microsatellite instability.
Simplified, Clear Reporting

FoundationOne CDx results may include companion diagnostic (CDx) associated findings with a direct path to therapy

- FDA-approved CDx claims are shown with associated therapies and listed in alphabetical order by brand name (with generic name included) for quick recognition

<table>
<thead>
<tr>
<th>GENOMIC FINDINGS DETECTED</th>
<th>FDA-APPROVED THERAPEUTIC OPTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>EGFR L858R</td>
<td>Giotrif® (Afatinib)</td>
</tr>
<tr>
<td></td>
<td>Iressa® (Gefitinib)</td>
</tr>
<tr>
<td></td>
<td>Tarceva® (Erlotinib)</td>
</tr>
</tbody>
</table>

- All other genomic findings outside of our FDA-approved claims are shown here, with more information included in Professional Services

- Genomic signatures MSI and TMB are included with every test with results on Page 1 and interpretive content in Professional Services
Comprehensive Results to Help Inform Treatment Decisions

FoundationOne CDx and FoundationOne Liquid provide informative content that may help with treatment selection.

1. Therapies With Clinical Benefit (In Patient’s Tumor Type)
2. Therapies With Clinical Benefit (In Other Tumor Type)
3. Clinical Trials listed with simple page-number references
### Compare Prior Results with FoundationOne Liquid

Report includes comparison with prior Foundation Medicine test results and visual of mutant allele frequency (MAF) changes.

1. Foundation Medicine test type and reported date shown for each test
2. Biomarker and genomic findings listed and color-coded to refer to dynamic visual
3. Mutant allele frequency (MAF) percentage listed for each liquid biopsy
4. Change in MAF from previous liquid biopsy shown to help inform treatment decisions

<table>
<thead>
<tr>
<th>HISTORIC PATIENT FINDINGS</th>
<th>TEST 1</th>
<th>TEST 2</th>
<th>TEST 3</th>
<th>CHANGE FROM PREV.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tumor Mutational Burden</td>
<td>Cannot Be Determined</td>
<td>Not Tested</td>
<td>Not Tested</td>
<td>—</td>
</tr>
<tr>
<td>Microsatellite status</td>
<td>Cannot Be Determined</td>
<td>n/a</td>
<td>n/a</td>
<td>—</td>
</tr>
<tr>
<td><strong>EGFR</strong></td>
<td>2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>exon 19 deletion (L747_A750&gt;G)</td>
<td>detected</td>
<td>3 23.00%</td>
<td>0.20%</td>
<td>4 -22.8%</td>
</tr>
<tr>
<td><strong>TPS3</strong></td>
<td>2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C242G</td>
<td>detected</td>
<td>3 12.50%</td>
<td>0.30%</td>
<td>4 -12.40%</td>
</tr>
</tbody>
</table>

*Note: This comparison table refers only to genes and biomarkers assayed by prior FoundationOneLiquid or FoundationOne tests. Up to five previous tests may be shown.*
How to Order

Available to order now

Once the order form is submitted, we will complete the rest of the specimen retrieval process. We will contact the appropriate provider and send a Specimen Shipping Kit with instructions for specimen procurement and shipment.

Want faster turnaround time? Create an account online! https://home.foundationmedicine.com/signup

Orders submitted online are reported faster than orders submitted by fax or email

• Can’t order online? Please send a completed test requisition form along with pathology report and insurance information by:
  • Email (client.services@foundationmedicine.com) or Fax (617-418-2290)

Questions? Call our Client Services team

• Phone: 888-988-3639
• Hours of Operation: Monday-Friday, 8am to 8pm ET
Online Ordering & Mobile Tracking

Order tests online to speed up the process vs. traditional paper and fax methods

- **Online Ordering:** New and improved online ordering highlights tests that align with patient’s clinical, specimen and insurance information¹
- **Order Tracking Online & NEW Mobile App:** Search by patient name, physician name, order number, or diagnosis to quickly get status updates

¹ Highlighted tests are not recommendations. Ordering physicians have the sole authority to select any of the tests deemed appropriate for their patient’s treatment. Patient names are for example use only.
National Coverage for Qualifying Medicare Patients

See full details of the Centers for Medicare and Medicaid Services (CMS) national coverage determination (NCD) at this link

Medicare and Medicare Advantage patients qualify for coverage when FoundationOne CDx is ordered by a treating physician and when all of the following requirements are met:

1. Patient has:
   a. either recurrent, relapsed, refractory, metastatic, or advanced stages III or IV cancer; and
   b. either not been previously tested using the same NGS test for the same primary diagnosis of cancer or repeat testing using the same NGS test only when a new primary cancer diagnosis is made by the treating physician; and
   c. decided to seek further cancer treatment (e.g., therapeutic chemotherapy).

2. The diagnostic laboratory test using NGS must have:
   a. FDA approval or clearance as a companion in vitro diagnostic; and
   b. an FDA-approved or cleared indication for use in that patient’s cancer; and
   c. results provided to the treating physician for management of the patient using a report template to specify treatment options.

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
# Our Comprehensive Product Portfolio

<table>
<thead>
<tr>
<th></th>
<th>FoundationOne®CDx</th>
<th>FoundationOne®Liquid</th>
<th>FoundationOne®Heme</th>
<th>IHC</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA-Approved</td>
<td><strong>FDA-approved</strong> CDx for 17 targeted therapies</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Target Tumor Types</td>
<td>All Solid Tumors</td>
<td>Liquid Biopsy (ctDNA) - All Solid Tumors</td>
<td>Hematologic Malignancies, Sarcomas (Soft Tissue + Bone)</td>
<td>Solid Tumors</td>
</tr>
<tr>
<td>Number of Genes Analyzed</td>
<td>324 (DNA)</td>
<td>70 (DNA)</td>
<td>406 (DNA) 265 (RNA)</td>
<td>-</td>
</tr>
<tr>
<td>Genomic Signatures / Biomarkers</td>
<td>TMB, MSI</td>
<td>MSI¹</td>
<td>TMB, MSI</td>
<td>PD-L1 (Dako 22C3 pharmDx™)</td>
</tr>
<tr>
<td>Specimen*</td>
<td>FFPE* Tissue</td>
<td>Peripheral Whole Blood</td>
<td>FFPE* Tissue, Bone Marrow Aspirate, or Peripheral Whole Blood</td>
<td>FFPE* Tissue</td>
</tr>
<tr>
<td>Report Features</td>
<td>Point mutations, insertions/deletions, copy number alterations, select rearrangements</td>
<td>Point mutations, insertions/deletions, copy number alterations, rearrangements</td>
<td>Point mutations, insertions/deletions, copy number alterations, rearrangements</td>
<td>Tumor Proportion Score (TPS), Combined Positive Score (CPS)</td>
</tr>
<tr>
<td>Typical Turnaround Time</td>
<td>&lt; 2 weeks‡</td>
<td>&lt; 2 weeks‡</td>
<td>2 weeks‡</td>
<td>5 days‡</td>
</tr>
</tbody>
</table>

Financial Assistance Program information is available at access.foundationmedicine.com

* FFPE – Formalin-fixed, paraffin embedded tissue
‡ Based on typical turnaround time from receipt of specimen
§ For full details, refer to specimen instructions at www.foundationmedicine.com

1. MSI status will be reported for specimens determined to have high microsatellite instability.
Financial Assistance, Expert Consultation & Clinical Trial Services

We have a range of services and programs to help patients and physicians

FoundationAccess

Our financial assistance program is available for eligible patients. Patients can apply online before, during or after testing is ordered at: access.foundationmedicine.com.

Ask An Expert

We have board-certified physicians available to provide clinical consultation regarding appropriateness of the testing ordered and to help interpret test results. Foundation Medicine does not dispense medical advice and all treatment decisions are to be made by the treating physician.

SmartTrials™ Precision Enrollment

We list clinical trials based on genomic alterations in our reports, and our Precision Enrollment program identifies patients with rare or specific biomarkers, such as NTRK fusions, and matches them with sponsor clinical trials.
Abbreviated Statement

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](http://www.foundationmedicine.com/f1cdx).
Thank you