New FDA-Approved Broad Companion Diagnostic (CDx) for Solid Tumors

FDA-Approved Content

Report Section 1

CDx Associated Findings

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

OTHER ALTERATIONS & BIOMARKERS IDENTIFIED

Results reported in this section are not prescriptive or conclusive for labeled use of any specific therapeutic product. See professional services section for additional information.

Microsatellite Status MS-Stable
Tumor Mutation Burden 11 Mut/Mb
CDKN2A/B loss
EGFR amplification

PTCH1 T416S
RBM10 Q494*
TP53 K267P

*Refer to appendix for limitation statements related to detection of any copy number alterations, gene rearrangements, MSI or TMB result in this section.

Please refer to appendix for Explanation of Clinical Significance Classification and for variants of unknown significance (VUS).

FDA-Approved Therapies

List of FDA-approved companion diagnostics to identify patients who may benefit from associated therapies

All Other Biomarkers

All other biomarkers, including tumor mutational burden (TMB) and microsatellite instability (MSi), without companion diagnostic claims
Professional Services

Report Section 2

Biomarker Findings
Microsatellite status - MS-Stable
Tumor Mutation Burden - TMB-Intermediate (11 Muts/Mb)

Genomic Findings
For a complete list of the genes tested, please refer to the appendix.

EGFR amplification, L858R
PTCH1 T416S
CDK4/2A 8loss
RBM10 Q494A
TP53 R267P

6 Disease relevant genes with no reportable alterations: KRAS, ALK, BRAF, MET, RET, ERBB2, ROS1

7 Therapies with Clinical Benefit in patient’s tumor type
10 Clinical Trials

7 Therapies with Clinical Benefit in other tumor type

Pertinent Negatives
Identifies important negative results that can be used for patient management

Therapies with Clinical Benefit
Interpretive content that can be used for patient management according to professional guidelines in oncology

Clinical Trials
Identifies trials based on patients’ unique genomic profile with page number for quick reference

TO LEARN MORE:
Visit www.foundationmedicine.com/f1cdx

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

FoundationOne CDx™ is a next-generation sequencing 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.