FDA-Approved Content

Report Section 1

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

2. All Other Biomarkers
   All other biomarkers, including tumor mutational burden (TMB) and microsatellite instability (MSI), without companion diagnostic claims
Tumor Mutational Burden - TMB-Intermediate (6 Muts/Mb)

Microsatellite status - MS-Stable

Genomic Findings

For a complete list of the genes assayed, please refer to the Appendix.

- **EGFR** L858R
- **PIK3CA** E545K - subclonal™
- **MDM4** amplification - equivocal™
- **CDKN2A/B** loss
- **IKBKE** amplification - equivocal™
- **MTAP** loss
- **PIK3CA** amplification - equivocal™
- **RB1** splice site 576+1G>T

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

†† See About the Test in appendix for details.

**BIOMARKER FINDINGS**

- **Tumor Mutational Burden** - TMB-Intermediate (6 Muts/Mb)
- **Microsatellite status** - MS-Stable

**GENOMIC FINDINGS**

- **EGFR** - L858R
- **PIK3CA** - E545K - subclonal™

**THERAPIES WITH CLINICAL BENEFIT**

16 Therapies with Clinical Benefit
28 Clinical Trials
0 Therapies with Lack of Response

**Therapies with Clinical Benefit**

- Atezolizumab
- Durvalumab
- Nivolumab
- Pembrolizumab

**Therapies with Clinical Benefit in Other Tumor Types**

- Avelumab
- Cemiplimab-rwlc

**Therapies with Clinical Benefit in Patient’s Tumor Type**

- Afatinib
- Dacomitinib
- Erlotinib
- Gefitinib
- Osimertinib

- None

- Everolimus

**Therapies with Clinical Benefit in Other Tumor Types**

- Cetuximab
- Lapatinib
- Panitumumab

** 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

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FoundationOne®CDx is a next-generation sequencing based in vitro diagnostic device for detection of substitutions, insertions and deletions 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.