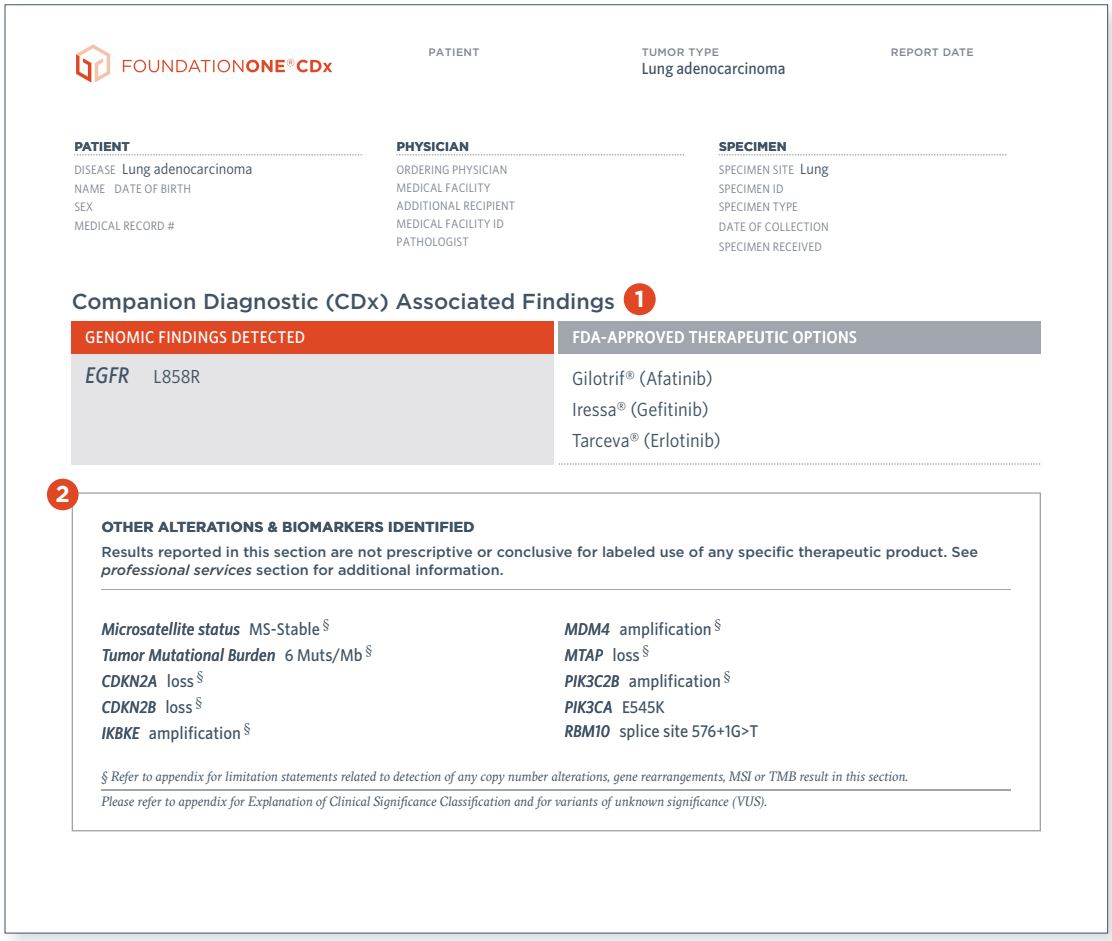
FOUNDATIONONE® CDx

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

FDA-Approved Content

Report Section 1



FOUNDATIONONE® CDx

PATIENT

TUMOR TYPE
Lung adenocarcinoma

REPORT DATE

PATIENT
DISEASE Lung adenocarcinoma
NAME DATE OF BIRTH
SEX
MEDICAL RECORD #

PHYSICIAN
ORDERING PHYSICIAN
MEDICAL FACILITY
ADDITIONAL RECIPIENT
MEDICAL FACILITY ID
PATHOLOGIST

SPECIMEN
SPECIMEN SITE Lung
SPECIMEN ID
SPECIMEN TYPE
DATE OF COLLECTION
SPECIMEN RECEIVED

Companion Diagnostic (CDx) Associated Findings 1

GENOMIC FINDINGS DETECTED	FDA-APPROVED THERAPEUTIC OPTIONS
EGFR L858R	Gilotrif® (Afatinib) Iressa® (Gefitinib) Tarceva® (Erlotinib)

2

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 Mutational Burden 6 Muts/Mb §
CDKN2A loss §
CDKN2B loss §
IKBKE amplification §
MDM4 amplification §
MTAP loss §
PIK3C2B amplification §
PIK3CA E545K
RBM10 splice site 576+1G>T

§ 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).

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

Professional Services

Report Section 2

FOUNDATIONONE®CDx

PATIENT | TUMOR TYPE: Lung adenocarcinoma | REPORT DATE | QRF#

ABOUT THE TEST FoundationOne®CDx is the first and only FDA-Approved comprehensive companion diagnostic for all solid tumors.

Interpretive content on this page and subsequent pages is provided as a professional service, and is not reviewed or approved by the FDA.

PATIENT
DISEASE Lung adenocarcinoma
NAME
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Biomarker Findings
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
PIK3C2B amplification - equivocal†
RBM10 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.

1

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

BIOMARKER FINDINGS	2 THERAPIES WITH CLINICAL BENEFIT (IN PATIENT'S TUMOR TYPE)	THERAPIES WITH CLINICAL BENEFIT (IN OTHER TUMOR TYPE)
Tumor Mutational Burden - TMB-Intermediate (6 Muts/Mb)	Atezolizumab	Avelumab
	Durvalumab	Cemiplimab-rwlc
	Nivolumab	
3 10 Trials *see p. 19*	Pembrolizumab	
Microsatellite status - MS-Stable	**No therapies or clinical trials.** see Biomarker Findings section	

GENOMIC FINDINGS	2 THERAPIES WITH CLINICAL BENEFIT (IN PATIENT'S TUMOR TYPE)	THERAPIES WITH CLINICAL BENEFIT (IN OTHER TUMOR TYPE)
EGFR - L858R	Afatinib	Cetuximab
	Dacomitinib	Lapatinib
	Erlotinib	Panitumumab
	Gefitinib	
3 10 Trials *see p. 22*	Osimertinib	
PIK3CA - E545K - subclonal	none	Everolimus

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

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

3 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 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*.

FOUNDATION MEDICINE®

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