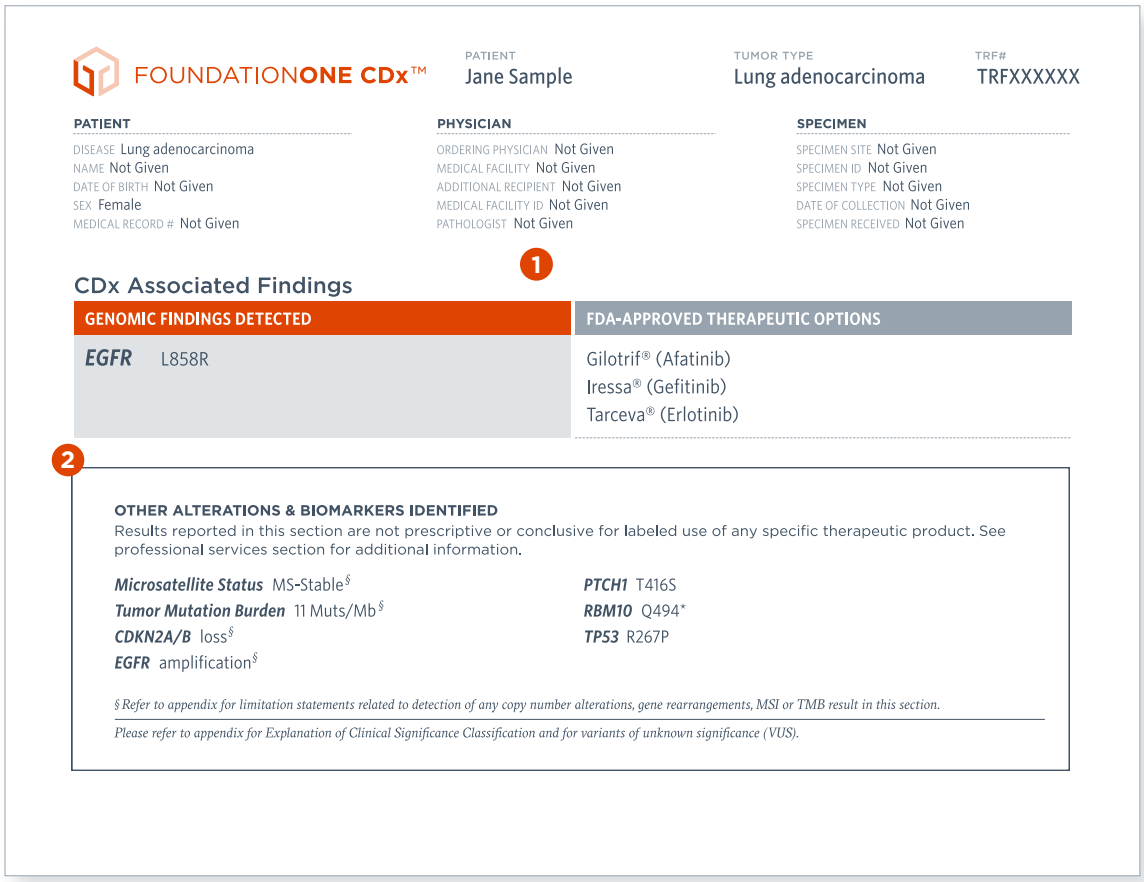
FOUNDATIONONE CDx™

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

FDA-Approved Content

Report Section 1



FOUNDATIONONE CDx™

PATIENT Jane Sample

TUMOR TYPE Lung adenocarcinoma

TRF# TRFXXXXXX

PATIENT
DISEASE Lung adenocarcinoma
NAME Not Given
DATE OF BIRTH Not Given
SEX Female
MEDICAL RECORD # Not Given

PHYSICIAN
ORDERING PHYSICIAN Not Given
MEDICAL FACILITY Not Given
ADDITIONAL RECIPIENT Not Given
MEDICAL FACILITY ID Not Given
PATHOLOGIST Not Given

SPECIMEN
SPECIMEN SITE Not Given
SPECIMEN ID Not Given
SPECIMEN TYPE Not Given
DATE OF COLLECTION Not Given
SPECIMEN RECEIVED Not Given

1

CDx Associated Findings

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 Mutation Burden 11 Muts/Mb§
CDKN2A/B loss§
EGFR amplification§
PTCH1 T416S
RBM10 Q494*
TP53 R267P

§ 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	TRF#
Jane Sample	Lung adenocarcinoma	TRFXXXXXX

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 Not Given
DATE OF BIRTH Not Given
SEX Female
MEDICAL RECORD # Not Given

PHYSICIAN

ORDERING PHYSICIAN Not Given
MEDICAL FACILITY Not Given
ADDITIONAL RECIPIENT Not Given
MEDICAL FACILITY ID Not Given
PATHOLOGIST Not Given

SPECIMEN

SPECIMEN SITE Not Given
SPECIMEN ID Not Given
SPECIMEN TYPE Not Given
DATE OF COLLECTION Not Given
SPECIMEN RECEIVED Not Given

Biomarker Findings

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

Genomic Findings

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

EGFR amplification, L858R
PTCH1 T416S
CDKN2A/B loss
RBM10 Q494*
TP53 R267P

6 Disease relevant genes with no reportable alterations : ***KRAS, ALK, BRAF, MET, RET, ERBB2, ROS1*** (1)

7 **Therapies with Clinical Benefit** in patient's tumor type
7 **Therapies with Clinical Benefit** in other tumor type
18 **Clinical Trials**

BIOMARKER FINDINGS	THERAPIES WITH CLINICAL BENEFIT (IN PATIENT'S TUMOR TYPE) (2)	THERAPIES WITH CLINICAL BENEFIT (IN OTHER TUMOR TYPE)
Tumor Mutation Burden - TMB-Intermediate (11 Muts/Mb)	Atezolizumab	Avelumab
	Nivolumab	Durvalumab
(3) 9 Trials see p. 14	Pembrolizumab	
Microsatellite status - MS-Stable	No therapies or clinical trials. see Biomarker Findings section	

GENOMIC FINDINGS	THERAPIES WITH CLINICAL BENEFIT (IN PATIENT'S TUMOR TYPE) (2)	THERAPIES WITH CLINICAL BENEFIT (IN OTHER TUMOR TYPE)
EGFR **-** amplification, L858R	Afatinib	Cetuximab
	Erlotinib	Lapatinib
	Gefitinib	Panitumumab
(3) 4 Trials see p. 15	Osimertinib	
PTCH1 **-** T416S	none	Sonidegib

(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*.

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