ARUP® LABORATORIES

800-522-2787 | aruplab.com
500 Chipeta Way, Salt Lake City, UT 84108-1221
Jonathan R. Genzen, MD, PhD, Chief Medical Officer

Client: ARUP Example Report Only
500 Chipeta Way
Salt Lake City, UT 84108
UNITED STATES

Physician: Example,

Patient: LUNG, eu pos

DOB

Sex:	Unknown
Patient Identifiers:	58864
Visit Number (FIN):	59264
Collection Date:	4/17/2024 11:59

Lung Cancer Mutation Panel
ARUP test code 3017230

Lung Mut Int

Detected

Lung Cancer Mutation Panel

A mutation in the EGFR gene exon 19 was detected:
c.2237_2255delinsT, p.Glu746_Ser752delinsVal (NM_005228.4).

This result has been reviewed and approved by ▇▇▇▇▇▇▇

BACKGROUND INFORMATION: Lung Cancer Mutation Panel

CHARACTERISTICS: This assay is an amplicon enrichment-based
massively parallel sequencing assay targeting hotspot variants
in genes critical for the diagnostic, prognostic, and
therapeutic assessment of various solid tumors. The amplicon
primer pool is designed to interrogate different DNA variant
classes including single nucleotide variants (SNVs), multiple
nucleotide variants (MNVs), and small insertions and deletions
(1-25 base pairs [bp]) within a limited set of highly clinically
relevant gene loci for the identification of actionable somatic
variants in FFPE tissue from solid tumors.

GENES TESTED: The following regions are evaluated to detect
hotspot SNVs, MNVs, small insertions, and small deletions,
unless otherwise indicated: BRAF (NM_004333) exon 15*; EGFR
(NM_005228) exons 18, 19, 20, 21; ERBB2 (NM_004448) exons 8*,
19, 20*; KRAS (NM_004985) exons 2*, 3*, 4*; MET (NM_001127500)
exons 14, 15*, intron 14*.
*Indicated regions are partially covered for hotspots only and
not reported in full. More information about the targeted
regions of this test is included in the Additional Technical
Information available in the Laboratory Test Directory.

METHODOLOGY: Genomic DNA was isolated from a
microscopically-guided dissection of FFPE tumor tissue and then
enriched for the targeted regions of the tested genes. The
variant status of the targeted genes was determined by massively
parallel sequencing. The hg19 (GRCh37) reference sequence was
used as a reference for identifying genetic variants. Clinically
significant variants and variants of uncertain significance
within the preferred transcripts are reported.

LIMITATIONS: This test will not detect variants in areas outside
the targeted genomic regions or below the limit of detection.
More information about the targeted regions of this test is
included in the Additional Technical Information available in
the Laboratory Test Directory. Copy number alterations (losses
or amplifications), translocations, microsatellite instability,

H=High, L=Low, *=Abnormal, C=Critical

Unless otherwise indicated, testing performed at:

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Patient: LUNG, eu pos
ARUP Accession: 24-108-108167
Patient Identifiers: 58864
Visit Number (FIN): 59264
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tumor mutational burden, deep intronic variants, and insertions/deletions larger than 25 bp will not be detected. Since this is a DNA-based assay, RNA variants will not be detected. This test evaluates for variants in tumor tissue only and cannot distinguish between somatic and germline variants. Therefore, if a hereditary/familial cancer is of clinical concern, additional clinical evaluation and genetic counseling should be considered prior to additional testing. In some cases, variants may not be identified due to technical limitations related to the presence of known pseudogenes, GC-rich regions, repetitive or homologous regions, low mappability regions, and/or variants located in regions overlapping amplicon primers. Tissue samples yielding between 1ng and 5ng total DNA input may yield suboptimal results and will be accepted for testing with a client-approved disclaimer. Additional clinical evaluation should be considered for complete genetic analysis, including detection of translocations or gene rearrangements. Interrogation of the many variants known to cause METex14 skipping is largely limited to canonical variants. For comprehensive evaluation of variants resulting in METex14 skipping, RNA-based assays should be considered. Benign or likely benign variants in the preferred transcript are not reported. Variant allele frequency (VAF) is not reported.

LIMIT OF DETECTION (LOD): The LOD for this assay is 10 percent VAF for all variant classes detected by the assay. For variants near the assay LOD, positive percent agreement (PPA) was found to be greater than 90 percent for all variant classes.

ANALYTICAL ACCURACY/SENSITIVITY (PPA): The PPA estimates for the respective variant classes (with 95 percent credibility region) are listed below. Genes included on this test are a subset of a larger methods-based validation from which the PPA values are derived.
Single nucleotide variants (SNVs): 98.4 percent (95.1-99.7 percent)
Deletions (1-25bp): 96.6 percent (89.6-99.3 percent)
Insertions/duplications (1-25bp): 96.8 percent (90.2-99.3 percent)
Multiple nucleotide variants (MNVs): 98.2 percent (91.8-99.8 percent)

CLINICAL DISCLAIMER: Results of this test must always be interpreted within the context of clinical findings and other relevant data and should not be used alone for a diagnosis of malignancy, determination of prognosis, or recommendation of therapy. This test is not intended to detect minimal residual disease.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the U.S. Food and Drug Administration. This test was performed in a CLIA-certified laboratory and is intended for clinical purposes.

Block ID	1

VERIFIED/REPORTED DATES

Procedure	Accession	Collected	Received	Verified/Reported
Lung Mut Int	24-108-108167	4/17/2024 11:59:00 AM	4/17/2024 12:11:48 PM	4/29/2024 5:05:00 PM
Block ID	24-108-108167	4/17/2024 11:59:00 AM	4/17/2024 12:11:48 PM	4/29/2024 5:05:00 PM

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END OF CHART

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