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

Physician: Example,

Patient: LUNG, eu neg

DOB	
Sex:	Unknown
Patient Identifiers:	58861
Visit Number (FIN):	59261
Collection Date:	4/17/2024 11:58

Lung Cancer Mutation Panel

ARUP test code 3017230

Lung Mut Int	Not Detected

Lung Cancer Mutation Panel

No BRAF, EGFR, ERBB2, KRAS or MET variant was detected. This result does not rule out the possibility of a mutation below the detectable limit of the assay.

This result has been reviewed and approved by [redacted]

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, 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	24-108-108109	4/17/2024 11:58:00 AM	4/17/2024 12:11:13 PM	4/29/2024 4:50:00 PM
Block ID	24-108-108109	4/17/2024 11:58:00 AM	4/17/2024 12:11:13 PM	4/29/2024 4:50:00 PM

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

END OF CHART

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