Client: Example Client ABC123
123 Test Drive
Salt Lake City, UT 84108
UNITED STATES

Physician: Doctor, Example

Patient: Patient, Example

DOB	12/31/1752
Sex:	Female
Patient Identifiers:	01234567890ABCD, 012345
Visit Number (FIN):	01234567890ABCD
Collection Date:	00/00/0000 00:00

Somatic TP53 Mutations in Formalin-Fixed, Paraffin-Embedded (FFPE) Tissue

ARUP test code 3017688

TP53 FFPE Interp: Not Detected

Somatic TP53 mutations in FFPE

No TP53 mutation 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: Somatic TP53 Mutations in Formalin-Fixed, Paraffin-Embedded (FFPE) Tissue

CHARACTERISTICS: Targeted massively parallel sequencing (also known as next generation sequencing) is used for the detection of mutations in all coding exons of TP53 in formalin-fixed, paraffin-embedded (FFPE) tissue from various tumors. TP53 mutation status is a prognostic marker in many different tumor types.

GENE(S) TESTED: TP53 (NM_000546.5) exons 2-11

METHODOLOGY: Genomic DNA is isolated from microscopically guided dissection of tumor tissue and then enriched for the targeted regions of TP53. The variant status of the targeted regions is determined by massively parallel sequencing. The hg19 (GRCh37) reference sequence is used as a reference for identifying genetic variants. Clinically significant variants and variants of uncertain significance within the preferred transcript are reported.

LIMITATIONS: This test will not detect variants in areas outside the targeted genomic regions or below the limit of detection. Variants in regions that are not included in the preferred transcript for TP53 (NM_000546.5) are not detected. Benign and likely benign variants are not reported. In some cases, large insertion/deletion variants, especially those greater than 60 base pairs (bp), may not be detected. Variant allele frequency (VAF) is not reported. This test is not intended to detect minimal residual disease. This test cannot distinguish between somatic and germline variants; therefore, if a hereditary/familial cancer syndrome is of clinical concern, consider additional clinical evaluation and genetic counseling before additional testing.

LIMIT OF DETECTION: 5 percent mutant allele for single nucleotide variants (SNV) and small- to medium-sized multinucleotide variants (MNV) (less than 60 bp). At least 10

percent tumor cells are required for testing.

ANALYTICAL SENSITIVITY (PPA): The positive percent agreement (PPA) estimate 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): 99 percent (97.4-99.9 percent)
Multinucleotide variants (MNVs): 93 percent (82.2-98.0 percent)
Small insertions/duplications (1-21bp): greater than 99 percent (95.6-100.0 percent)
Medium insertions/duplications (22-60bp): greater than 99 percent (82.9-100.0 percent)
Large insertions (61-64bp): greater than 99 percent (22.9-100.0 percent)
Small deletions (1-21bp): greater than 99 percent (97.6-100.0 percent)
Medium deletions (22-60bp): greater than 99 percent (71.2-99.2 percent)
Large deletions (61-13547bp): 64 percent (42.9-81.1 percent)

CLINICAL DISCLAIMER: Results of this test must always be interpreted within the clinical context and other relevant data and should not be used alone for a diagnosis of malignancy. 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	4567

VERIFIED/REPORTED DATES

Procedure	Accession	Collected	Received	Verified/Reported
TP53 FFPE Interp	25-225-101917	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Block ID	25-225-101917	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00

END OF CHART

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