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 Whole Blood and Bone Marrow

ARUP test code 3017691

| | |
|---|---|
| TP53 WBBM Specimen | Whole Blood |
| TP53 WBBM Interp | See Note |

Somatic TP53 Mutations in WBBM

Indication for testing: Evaluate TP53 mutation status

Result:

Variants of Known Clinical Significance in Hematologic Malignancies

None found

Variants of Unknown Clinical Significance in Hematologic Malignancies

None found

This result has been reviewed and approved by [redacted]

Low coverage regions:
Listed below are regions where the average sequencing depth (number of times a particular nucleotide is sequenced) in at least 20% of the region-of-interest is less than our stringent cutoff of 300. Sensitivity for detection of low allelic frequency variants may be reduced in areas with reduced depth of coverage.
None

BACKGROUND INFORMATION: Somatic TP53 Mutations in Whole Blood and Bone Marrow

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 whole blood and bone marrow. TP53 mutation status is a prognostic marker in a variety of hematologic malignancies, including myeloid and lymphoid neoplasms.

GENES TESTED: TP53 (NM_000546), all coding exons

METHODOLOGY: Genomic DNA was isolated from peripheral blood or bone marrow and then enriched for the targeted coding regions of TP53. The variant status was determined by massively parallel sequencing. The hg19 (GRCh37) human genome assembly was used as

a reference for identifying genetic variants. Clinically significant variants and variants of uncertain significance within the preferred transcript are reported.

LIMITATIONS: Variants outside the targeted regions or below the limit of detection are not identified. Variants in regions that are not included in the preferred transcript for the targeted gene are not detected. In some cases, variants may not be identified due to technical limitations in the presence of pseudogenes or in repetitive or homologous regions. It is also possible some insertion/deletion variants may not be identified. Benign or likely benign variants in the preferred transcript are not reported but are available upon request. Interpretation of this test result may be impacted if this patient has had an undisclosed allogeneic bone marrow transplant or stem cell transplant. 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 (LOD): This test was validated using known true positive variants detected by orthogonal methods at as low as 5 percent variant allele frequency (VAF), including single nucleotide variants (SNVs), and insertions/duplications/deletions/complex variants (indels). Thus, this assay is expected to detect variants at 5 percent VAF, but variants with sufficient quality and read depth may be reported below 5 percent VAF.

ANALYTICAL SENSITIVITY: The positive percent agreement (PPA) estimates for the respective variant classes are listed below. The TP53 gene included on this test is a subset of a larger methods-based validation from which the following PPA values are derived.
Single nucleotide variants (SNVs): greater than 99 percent
Indels (insertions/duplications, deletions, complex variants): 98.5 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 or management of malignancy. Somatic TP53 mutations at low variant allele frequencies may be detected in clonal hematopoiesis of indeterminate potential (CHIP), clonal cytopenia of undetermined significance (CCUS), and therapy-related CCUS (t-CC). 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.

VERIFIED/REPORTED DATES

| Procedure | Accession | Collected | Received | Verified/Reported |
|---|---|---|---|---|
| TP53 WBBM Specimen | 25-225-101915 | 00/00/0000 00:00 | 00/00/0000 00:00 | 00/00/0000 00:00 |
| TP53 WBBM Interp | 25-225-101915 | 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