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

Physician: Doctor, Example

Patient: Patient, Example

DOB	4/11/1956
Gender:	Female
Patient Identifiers:	01234567890ABCD, 012345
Visit Number (FIN):	01234567890ABCD
Collection Date:	00/00/0000 00:00

TP53 Somatic Mutation, Prognostic

ARUP test code 2013484

TP53 Somatic Mutation, Prognostic	See Note Performed By: Quest San Juan Capistrano Inc. 33608 Ortega Highway San Juan Capistrano, CA 92675
TP53 Exon 4 Mutation	See Note Performed By: Quest San Juan Capistrano Inc. 33608 Ortega Highway San Juan Capistrano, CA 92675
TP53 Exon 5 Mutation	See Note Performed By: Quest San Juan Capistrano Inc. 33608 Ortega Highway San Juan Capistrano, CA 92675
TP53 Exon 6 Mutation	See Note Performed By: Quest San Juan Capistrano Inc. 33608 Ortega Highway San Juan Capistrano, CA 92675
TP53 Exon 7 Mutation	See Note Performed By: Quest San Juan Capistrano Inc. 33608 Ortega Highway San Juan Capistrano, CA 92675
TP53 Exon 8 Mutation	See Note Performed By: Quest San Juan Capistrano Inc. 33608 Ortega Highway San Juan Capistrano, CA 92675

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

TP53 Exon 9 Mutation	See Note Performed By: Quest San Juan Capistrano Inc. 33608 Ortega Highway San Juan Capistrano, CA 92675

TP53 Somatic Mutation, Interpretation	See Note

Specimen Type: BLOOD
PARAFFIN BLOCK NUMBER: NOT GIVEN
Interpretation DETECTED

TP53 mutation, (c.468_472dup (p.R158Pfs*14), 40.8%) was detected. Mutations in this tumor suppressor gene are frequently seen in a variety of cancer types. In rare untreated or pretreated patients, TP53 mutation may be present in the germline and indicate a hereditary cancer syndrome, in which case genetic counseling is suggested.

Mutations in TP53 tumor suppressor gene occur in greater than 50% of adult human cancers. The TP53 gene mutations usually correlate with poor outcome and early recurrence in cancer. Testing was performed on P53 exon 2-11 which account for >90% mutations in TP53 gene. We cannot rule out the possibilities of mutation in other sites of the gene.

The total nucleic acid was extracted from patient's whole blood or bone marrow cells or paraffin embedded tissues. For paraffin embedded specimens, microscopic review and marking of the specimen was performed by a pathologist, and genomic DNA was extracted from macro-dissected paraffin-embedded tissue sections. Next-generation sequencing (NGS) was used to detect mutations in all coding exons of TP53 (exons 2-11). TP53, NM_000546.5 was used as reference. This assay does not detect large deletions in the p53 gene. For (17p-) please refer to FISH assay. The sensitivity of this sequencing assay is 5% of mutant alleles in the background of normal wildtype alleles. Insertions up to 30bp and deletions up to 48bp have been successfully detected by this assay.

This test was developed and its analytical performance characteristics have been determined by Quest Diagnostics Nichols Institute San Juan Capistrano. It has not been cleared or approved by FDA. This assay has been validated pursuant to the CLIA regulations and is used for clinical purposes.

Laboratory results and submitted clinical information reviewed by Bernard Joseph Ilagan, MD, MHA, FACMG, CGMBS.

(* = OUT OF RANGE)
Performed By: Quest San Juan Capistrano Inc.
33608 Ortega Highway
San Juan Capistrano, CA 92675

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

VERIFIED/REPORTED DATES

Procedure	Accession	Collected	Received	Verified/Reported
TP53 Somatic Mutation, Prognostic	24-313-101622	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
TP53 Exon 4 Mutation	24-313-101622	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
TP53 Exon 5 Mutation	24-313-101622	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
TP53 Exon 6 Mutation	24-313-101622	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
TP53 Exon 7 Mutation	24-313-101622	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
TP53 Exon 8 Mutation	24-313-101622	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
TP53 Exon 9 Mutation	24-313-101622	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
TP53 Somatic Mutation, Interpretation	24-313-101622	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00

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