Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT W
WX0000003826 F 12/05/1988 34 Y

Referral Testing

Collected: 09/01/2023 10:18 Received: 09/01/2023 10:18

Test Name	Result	Flag	Ref-Ranges	Units	Site
TP53 Somatic Mutation, Prognostic					
Specimen Type	WB LAV				QCRL
Block Number	NA				QCRL
P53 Mutation, Leumeta	**POSITIVE**	**AB**	NEGATIVE		QCRL

Test Performed at:
Quest Diagnostics Nichols Institute
33608 Ortega Highway
San Juan Capistrano, CA 92675-2042 I Maramica MD, PhD, MBA

Exon 4	.	QCRL
Exon 5	.	QCRL
Exon 6	.	QCRL
Exon 7	.	QCRL
Exon 8	.	QCRL
Exon 9	.	QCRL
Interpretation	DETECTED	QCRL

TP53 mutation, (c.526T>C (p.Cys176Arg), 81.6%) 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.

LAB: L - LOW, H - HIGH, AB - ABNORMAL, C - CRITICAL, . - NOT TESTED

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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.

Performing Site:
QCRL: QUEST DIAGNOSTICS REFERENCE LAB CAPISTRANO 33608 Ortega Highway San Juan Capistrano CA 92675

Reported Date: 2023.09.01 10:19 TP53