ARUP LABORATORIES
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Jonathan R. Genzen, MD, PhD, Chief Medical Officer

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

Physician: Doctor, Example

Patient: Patient, Example

DOB	Unknown
Gender:	Male
Patient Identifiers:	01234567890ABCD, 012345
Visit Number (FIN):	01234567890ABCD
Collection Date:	00/00/0000 00:00

IGHV Mutation Analysis by Sequencing

ARUP test code 0040227

IGHV Mutation Analysis by Sequencing	Non Mutated

The specimen submitted for testing did not meet ARUP submission guidelines. Testing was performed on a specimen that did not meet validated specimen type requirements. Performance characteristics of this assay may be affected. Interpret results with caution. Please refer to the ARUP Laboratory Test Directory for information on specimen acceptability: http://www.aruplab.com/Specimen-Handling/index.jsp

This result has been reviewed and approved by [redacted]

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

INTERPRETIVE INFORMATION: IGHV Mutation Analysis by Sequencing

This test is designed to detect mutation status of the immunoglobulin heavy chain variable region (IGHV) gene in clonal B cell populations. CLL patients with non-mutated IGHV genes have a poorer clinical prognosis. In addition, cases of CLL expressing the IGHV 3-21 variable region gene segment have a poorer prognosis regardless of IGHV mutation status.

Methodology:
Patient RNA is isolated, reverse transcribed into cDNA, and amplified using VH leader and JH primers. Sequencing is then performed and results are compared against a database of all known variable region germline sequences. The closest matching germline VH gene segment and the percent of homology to it are reported. Homologies 98% and above are designated as non-mutated and those below 98% are designated as mutated. In addition, mutated cases with homologies between 97% to 97.9% are also flagged as borderline and may have an intermediate clinical course (Hamblin TJ et al., British Journal of Hematology 140:320-323, 2008).

Limitations:
CLL clones as low as 50% of total B cells can be analyzed by this test. Samples that do not yield an amplification product may either contain too few CLL cells or express VH genes with a high number of mutations that compromised PCR primer binding.

Results of this test must always be interpreted in the context of the patient's morphology and in conjunction with other relevant data. Results 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 US 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
IGHV Mutation Analysis by Sequencing	23-268-114398	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