Client: ARUP Example Report Only
500 Chipeta Way
Salt Lake City, UT 84108
UNITED STATES

Physician: EXAMPLE, PHYSICIAN

Patient: Example, Report

DOB	4/26/2023
Sex:	Male
Patient Identifiers:	48328
Visit Number (FIN):	48681
Collection Date:	4/26/2023 07:32

Chronic Lymphocytic Leukemia Mutation Panel by Next Generation Sequencing

ARUP test code 3001858

Chronic Lymphocytic Leukemia Specimen	Whole Blood
Chronic Lymphocytic Leukemia Interp	See Note

See Note
CLL Panel by NGS
Submitted diagnosis or diagnosis under consideration for variant interpretation: Chronic lymphocytic leukemia (CLL)
TIER 1: Variants of Known Clinical Significance in Hematologic Malignancies
None found
TIER 2: 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.
NOTCH1(NM_017617.3) exon 1

BACKGROUND INFORMATION: Chronic Lymphocytic Leukemia (CLL) Mutation Panel by Next Generation Sequencing
CHARACTERISTICS: Chronic lymphocytic leukemia (CLL) is a hematopoietic disorder characterized by monoclonal B-cell proliferation. Recent studies have identified recurrently mutated genes with diagnostic and/or prognostic impact in CLL and other lymphoid malignancies. The presence of certain mutations may inform clinical management. This multigene panel by massively parallel sequencing (next generation sequencing) is a more cost-effective approach when compared to the cost of multiple single-gene tests. This test can be used to complement the morphologic and cytogenetic workup of CLL and other lymphoid malignancies.

GENES TESTED: ATM; BCL2; BIRC3*; BRAF; BTG1; BTK; CARD11; CD79B; CXCR4; DDX3X; FBXW7; IKZF3; KRAS; MAP2K1; MED12; MGA; MYD88; NOTCH1; NRAS; PLCG2; POT1; RNASEH2A; RNASEH2B; RPS15*; SAMHD1; SF3B1; TP53; XPO1; ZMYM3
*One or more exons of the preferred transcript were not covered by sequencing for the indicated gene; see limitations section below.

METHODOLOGY: Genomic DNA was isolated from peripheral blood or bone marrow then enriched for the targeted exonic regions of the

tested genes. The variant status of the targeted genes 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 called in 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 genes 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.
The following regions were not sequenced due to technical limitations of the assay:
BIRC3 (NM_001165) exon 5
RPS15 (NM_001018) exon 3

LIMIT OF DETECTION (LOD): 5 percent variant allele fraction (VAF) for single nucleotide variants (SNV) and small variants less than 24 base pairs (bp). Variants greater than 24bp may be detected at LOD, but the analytical sensitivity may be reduced.

ANALYTICAL SENSITIVITY: 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): 96.9 percent (95.1-98.1 percent)
Insertions/duplications (1-24bp): 98.1 percent (95.5-99.3 percent)
Insertions/duplications (greater than 24bp): greater than 99 percent (92.9-100.0 percent)
Deletions (1-24bp): 96.7 percent (92.8-98.7 percent)
Deletions (greater than 24bp): 90 percent (79.5-96.1 percent)
Multinucleotide variants (MNVs): 97 percent (93.0-99.0 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 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.

EER, CLL Panel by NGS

See Note

Authorized individuals can access the ARUP Enhanced Report using the following link:

VERIFIED/REPORTED DATES

Procedure	Accession	Collected	Received	Verified/Reported
Chronic Lymphocytic Leukemia Specimen	23-116-100737	4/26/2023 7:32:00 AM	4/26/2023 7:36:58 AM	4/26/2023 9:33 00 AM

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

Chronic Lymphocytic Leukemia Interp	23-116-100737	4/26/2023 7:32:00 AM	4/26/2023 7:36:58 AM	4/26/2023 9:33 00 AM
EER, CLL Panel by NGS	23-116-100737	4/26/2023 7:32:00 AM	4/26/2023 7:36:58 AM	4/26/2023 9:33 00 AM

END OF CHART

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