

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

Physician: Doctor, Example

Patient: Patient, Example

DOB: 3/31/1961
Sex: Female
Patient Identifiers: 01234567890ABCD, 012345
Visit Number (FIN): 01234567890ABCD
Collection Date: 01/01/2017 12:34

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 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: This list contains regions where the average sequencing depth (number of times a particular position is sequenced) for 20% or more of the region is below our stringent cutoff of 300. Sensitivity for detection of low allelic frequency mutations may be reduced in areas with low depth of coverage. The sequencing reads from these regions were manually reviewed. If high quality variants are detected in these regions they will be listed above in Tier 1 or Tier 2. 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 multi-gene 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

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

Unless otherwise indicated, testing performed at:

malignancies.
GENES TESTED: ATM, BCL2, BIRC3*, BRAF, BTG1, BTK, CARD11, CD79B, CXCR4, DDX3X, FBXW7, IKZF3, KRAS, MAP2K1, MED12, MGA, MYD88, NOTCH1, NRAS, PLCG2, POT1, 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.

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. 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)
Multi-nucleotide 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 US 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

Access ARUP Enhanced Report using the link below:

-Direct access:

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ARUP LABORATORIES | 800-522-2787 | aruplab.com
500 Chipeta Way, Salt Lake City, UT 84108-1221
Jonathan R. Genzen, MD, PhD, Laboratory Director

Patient: Patient, Example
ARUP Accession: 21-091-110583
Patient Identifiers: 01234567890ABCD, 012345
Visit Number (FIN): 01234567890ABCD
Page 2 of 3 | Printed: 7/20/2022 7:13:52 AM

VERIFIED/REPORTED DATES

Procedure	Accession	Collected	Received	Verified/Reported
Chronic Lymphocytic Leukemia Specimen	21-091-110583	4/1/2021 12:21:00 PM	4/1/2021 12:22:31 PM	4/7/2021 10:48:00 AM
Chronic Lymphocytic Leukemia Interp	21-091-110583	4/1/2021 12:21:00 PM	4/1/2021 12:22:31 PM	4/7/2021 10:48:00 AM
EER, CLL Panel by NGS	21-091-110583	4/1/2021 12:21:00 PM	4/1/2021 12:22:31 PM	4/7/2021 10:48:00 AM

END OF CHART

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Page 3 of 3 | Printed: 7/20/2022 7:13:52 AM