



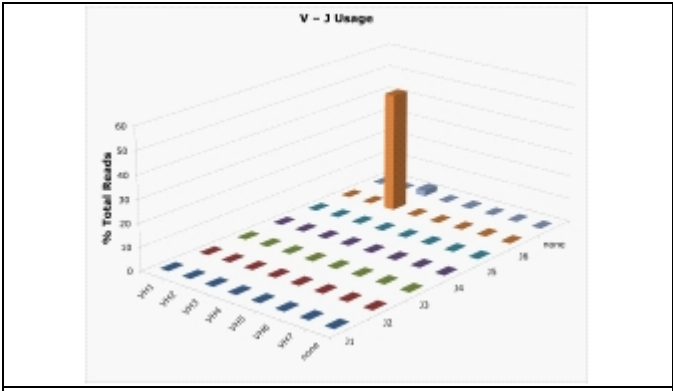
TEST DESCRIPTION	IgVH Mutational Status by NGS
TEST CODE	M IgVH
REPORT TYPE	Final

PATIENT	TEST REPORT_3-21, I GVH	MPLN #	1004160179	Test Facility	
DOB	01/01/1900	COLLECTED	10/04/2016, 00:00		67 Moose Lane, Tok, AK
SSN #		ORDERED	10/04/2016, 11:19		
PATIENT ID		RECEIVED	10/04/2016, 11:19	ORDERING	DR. JONATHAN L KLEIN
SPEC ID		REPORT	10/04/2016, 11:44	COPY TO	

MOLECULAR TEST RESULTS

RESULT	IgVH Somatic Hypermutation NEGATIVE
	IGHV3-21 DETECTED
COMMENT	Reference range [<97% homology to reference IGH = hypermutated, 97-98% = borderline, >98% = non-hypermutated] Patient clonal reads showed 100% sequence homology to most closely matched germline <i>IGH</i> reference sequences. Negative IgVH somatic hypermutation status is an unfavorable prognostic indicator in chronic lymphocytic leukemia / small lymphocytic lymphoma (CLL/SLL). IGHV3-21 gene utilization has also been reported to represent an adverse prognostic indicator independently associated with poor outcomes in CLL/SLL (Blood Rev. 2010 May; 24(3): 135–141.)

HISTORY	CLL
SPECIMEN	Peripheral blood
METHODOLOGY	<i>IGH</i> framework 1 V-J amplicon libraries are prepared using Invivoscribe primers, PGM adapters, and patient sample DNA. Pooled libraries are sequenced on the Ion Torrent PGM™ instrument, and generated FASTQ files are analyzed by LymphoTrack® PGM® Software (Version 2.0). ≥ 4-fold difference between first and third most abundant <i>IGH</i> sequences defines clonal read data (Am J Clin Pathol. 2014 Mar;141(3):348-59), and IgVH SHM status is resulted in accordance with recommended College of American Pathologists reporting guidelines (Arch Pathol Lab Med. 2016 Apr 15).
CPT CODES	81263



Clonal B-cell VDJ Utilization Profile: VH3-21-J6

Molecular Pathology Laboratory Network, Inc. is certified by CLIA for high complexity clinical testing. Analyte specific reagents (ASR) are used in this study. Federally required statement: This test was developed and its performance characteristics determined by Molecular Pathology Laboratory Network, Inc. It has not been cleared or approved for specific uses by the U.S. Food and Drug Administration. However, the FDA has determined that such approval and clearance are not necessary.

Electronically signed by: Bevan Tandon, M.D. 10/04/2016, 11:44

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