



1-800-533-1710

## IGH Somatic Hypermutation in B-CLL

BCLL

|                                                                                                                                                                              |                                 |                                 |               |                                                               |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|---------------------------------|---------------|---------------------------------------------------------------|
| PATIENT NAME<br><b>TESTING, BCLL_ABNORMAL</b>                                                                                                                                |                                 |                                 |               | ORDER NUMBER<br><b>Q612000304</b>                             |
| PATIENT ID<br>SA00180125                                                                                                                                                     | DATE OF BIRTH<br>01/01/2001     | AGE<br>25 Y                     | SEX<br>Female | REQUESTED BY<br>CLIENT CLIENT                                 |
| COLLECTED<br>5/12/2026, 12:00 AM                                                                                                                                             | RECEIVED<br>5/12/2026, 11:20 AM | REPORTED<br>5/12/2026, 11:33 AM |               |                                                               |
| The collected, received, and reported dates and times on the report are in the time zone of the performing location.<br>7028846<br>MCL RochesterCampus<br>Rochester MN 55901 |                                 |                                 |               | CLIENT ORDER NUMBER<br>SA00180125<br>CLIENT MRN<br>SA00180125 |

|                              |                                |
|------------------------------|--------------------------------|
| Final Interpretation         | Clonal rearrangement detected. |
| BCLL Result                  | see interpretation             |
| Specimen Type                | Peripheral blood               |
| Primer Set                   | LDR                            |
| Primary V-gene               | IGHV3-21*01                    |
| Primary J-gene               | IGHJ4*02                       |
| Primary Mutation Status %    | 5.2                            |
| Primary Mutation Status      | Mutated                        |
| Primary Rearrangement Status | Productive                     |
| Primary Subset               | 2                              |

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| INTERPRETATION                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Peripheral blood, IGH somatic hypermutation analysis:<br><br>A Mutated Productive IGHV3-21*01 rearrangement was identified (mutation level 5.2%).<br><br>A stereotyped clonal IGH gene rearrangement is identified, corresponding to stereotyped receptor subset #2. Subset #2 CLL patients have been associated with aggressive disease features. A substantial proportion of subset #2 cases harbor IGH V3-21 rearrangements and the majority show mutated IGH status (Stamatopoulos K et al., 2017, 27811850; Baliakas et al., 2015, 25634617).<br><br>Somatic hypermutation of the immunoglobulin heavy chain gene variable region (IGH-V) status is a recognized prognostic marker in chronic lymphocytic leukemia. Mutated CLL is defined by the presence of >2% IGH-V somatic mutation (or <98% identity to the closest germline sequence) and is independently associated with a relatively favorable prognosis. In contrast, unmutated IGH-V status, defined as <=2% somatic mutation (or >= 98% germline sequence identity) is associated with relatively adverse prognosis (Oscier D et al., 2002, 12149195; Agathangelidis A et al., 2022,35614318). Borderline mutation levels (1-3%) should be used with caution for prognostic purposes. Correlation for these results with clinical, pathologic, and other pertinent laboratory data is require for final interpretation.<br><br>Signing Pathologist: LAUREN SCHULTZ |
| METHOD                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |



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Method Summary - *IGH* V-region (IGHV) somatic mutation analysis: DNA is extracted and *IGH* gene rearrangements are amplified by PCR method using leader and/or FR1 forward primers. Next generation sequencing of the PCR product clonal *IGH* variable (IGHV) region is performed. Sequences of functional IGHV rearrangements are compared to a germline *IGH* sequence database to determine the closest IGHV gene exon and percent nucleobase identity. Mutated IGHV status is assigned when the analyzed clonal sequence is greater than 2% different from the germline reference and unmutated status is defined as 2% or less deviation from the reference.

## DISCLAIMER

This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

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