

## **IGH Somatic Hypermutation Analysis, B-Cell Chronic Lymphocytic Leukemia (B-CLL), Varies**

**Test ID:** BCLL

**Explanation:** On the effective date, the specimen requirements will be clarified and reportable fields will be added to allow for discrete results reporting.

Current Specimen Requirements	New Specimen Requirements
<p><b>Submit only 1 of the following specimens:</b></p> <p><b>Specimen Type:</b> Whole blood  <b>Container/Tube:</b>  <b>Preferred:</b> Lavender top (EDTA)  <b>Acceptable:</b> Yellow top (ACD)  <b>Specimen Volume:</b> 4 mL  <b>Collection Instructions:</b>            1. Invert several times to mix blood.            2. Send whole blood specimen in original tube. <b>Do not aliquot.</b>            3. Label specimen as blood.  <b>Specimen Stability:</b> Refrigerated/Ambient</p> <p><b>Specimen Type:</b> Bone marrow  <b>Container/Tube:</b>  <b>Preferred:</b> Lavender top (EDTA)  <b>Acceptable:</b> Yellow top (ACD)  <b>Specimen Volume:</b> 2 mL  <b>Collection Instructions:</b>            1. Invert several times to mix bone marrow.            2. Send bone marrow specimen in original tube.  <b>Do not aliquot.</b>            3. Label specimen as bone marrow.  <b>Specimen Stability:</b> Refrigerated/Ambient</p> <p><b>Specimen Type:</b> Extracted DNA from blood or bone marrow</p>	<p><b>Submit only 1 of the following specimens:</b></p> <p><b>Specimen Type:</b> Whole blood  <b>Container/Tube:</b>  <b>Preferred:</b> Lavender top (EDTA)  <b>Acceptable:</b> Yellow top (ACD)  <b>Specimen Volume:</b> 4 mL  <b>Collection Instructions:</b>            1. Invert several times to mix blood.            2. Send whole blood specimen in original tube. <b>Do not aliquot.</b>            3. Label specimen as whole blood.  <b>Specimen Stability:</b> Refrigerated (preferred) 7 days/Ambient 7 days  <b>Additional Information:</b> To ensure minimum volume and concentration of DNA are met, the requested volume must be submitted. Testing may be canceled if DNA requirements are inadequate.</p> <p><b>Specimen Type:</b> Bone marrow  <b>Container/Tube:</b>  <b>Preferred:</b> Lavender top (EDTA)  <b>Acceptable:</b> Yellow top (ACD)  <b>Specimen Volume:</b> 2 mL  <b>Collection Instructions:</b>            1. Invert several times to mix bone marrow.            2. Send bone marrow specimen in original tube.  <b>Do not aliquot.</b>            3. Label specimen as bone marrow.  <b>Specimen Stability:</b> Ambient (preferred) 7 days/Refrigerate 7 days  <b>Additional Information:</b> To ensure minimum volume and concentration of DNA are met, the requested volume must be submitted. Testing may be canceled if DNA requirements are inadequate.</p> <p><b>Specimen Type:</b> Extracted DNA from whole blood or bone marrow</p>

**Container/Tube:** 1.5- to 2-mL screw-top tube

**Specimen Volume:** Entire specimen

**Collection Instructions:**

1. Label specimen as extracted DNA and indicate specimen source (blood or bone marrow).
2. The required volume of DNA is 50 mcL at a concentration of 20 ng/mcL.
3. Include volume and concentration on tube.

**Specimen Stability:** Frozen (preferred)/Refrigerated

**Container/Tube:** 1.5- to 2-mL screw-top tube

**Specimen Volume:** Entire specimen

**Collection Instructions:**

1. DNA must be extracted from blood or bone marrow within 7 days of collection.
2. Label specimen as extracted DNA and source of specimen
3. Provide volume and concentration of the DNA

**Specimen Stability Information:** Frozen (preferred)/Refrigerate/Ambient

**Additional Information:**

1. Specimens are preferred to be received within 1 year after DNA extraction.
2. DNA must be extracted in a CLIA-certified laboratory or equivalent and must be extracted from a specimen type listed as acceptable for this test (including applicable anticoagulants). We cannot guarantee that all extraction methods are compatible with this test. If testing fails, one repeat will be attempted, and if unsuccessful, the test will be reported as failed and a charge will be applied.

**Current Specimen Stability**

Specimen Type	Temperature	Time
Varies	Varies	7 days

**New Specimen Stability**

Specimen Type	Temperature	Time
Varies	Varies	

**Current Result Codes**

Result ID	Reporting Name
39465	BCLL Result
MP005	Specimen Type
19674	Final Diagnosis

**New Result Codes**

Result ID	Reporting Name
622044	Final Interpretation
39465	BCLL Result
MP005	Specimen Type
622055	Primer Set
622045	Primary V-gene
623097	Primary J-gene
622046	Primary Mutation Status %
622047	Primary Mutation Status
622048	Primary Rearrangement Status
622053	Primary Subset
622049	Secondary V-gene
623098	Secondary J-gene
622050	Secondary Mutation Status %
622051	Secondary Mutation Status
622052	Secondary Rearrangement Status
622054	Secondary Subset
19674	Final Diagnosis

**Questions**

Contact Melissa Lonzo, Laboratory Resource Coordinator at 800-533-1710.