

## CLL Prognostic Panels

Test Code	Panel	Specimen Requirements				Description
		Tube	Specimen	Quantity	Minimum	
17239 or 17239X	<b>CLL Prognostic Panel, Comprehensive</b> – Chromosome Analysis, CLL/LPD (Karyotype) – B-Cell CLL FISH (11q, 17p, 13q, Trisomy 12) – IgV <sub>H</sub> Gene Mutation – ZAP70 – CD38 – Beta 2 Microglobulin	Collect <b>ALL 3</b> types of the following tubes:				This comprehensive panel is considered the most complete set of tests currently used for predicting prognosis in patients with CLL.
		Sodium heparin (green-top)	whole blood	33.0 mL	13.0 mL	
		EDTA (lavender-top)	whole blood	3.0 mL	1.0 mL	
		No additive (red-top)	serum	1.0 mL	0.5 mL	
<b>Note:</b> At room temperature						
17312 or 17312X	<b>CLL Prognostic Panel, Comprehensive w/o Karyotype</b> – B-Cell CLL FISH (11q, 17p, 13q, Trisomy 12) – IgV <sub>H</sub> Gene Mutation – ZAP70 – CD38 – Beta 2 Microglobulin	Collect <b>ALL 3</b> types of the following tubes:				This panel of tests is comprehensive and includes all the tests considered necessary for prognosis, except for karyotyping. The included Fluorescent in situ hybridization (FISH) studies cover most of the important cytogenetic abnormalities. Other abnormalities, such as translocations or deletions, can be detected by karyotyping, but the cytogenetic studies of B-cell malignancies may yield few or no representative metaphases of B-cells in culture, with the possibility of false-negative results.
		Sodium heparin (green-top)	whole blood	13.0 mL	3.0 mL	
		EDTA (lavender-top)	whole blood	3.0 mL	1.0 mL	
		No additive (red-top)	serum	1.0 mL	0.5 mL	
<b>Note:</b> At room temperature						
17240 or 17240X	<b>CLL Prognostic Panel, Limited</b> – B-Cell CLL FISH (11q, 17p, 13q, Trisomy 12) – IgV <sub>H</sub> Gene Mutation – ZAP70	Collect <b>BOTH</b> types of the following tubes:				This panel of tests contains most of the essential tests not offered in the typical laboratory.
		Sodium heparin (green-top)	whole blood	8.0 mL	2.0 mL	
		EDTA (lavender-top)	whole blood	3.0 mL	1.0 mL	
<b>Note:</b> At room temperature						
17290 or 17290X	<b>CLL Prognostic Panel, Monitoring</b> – B-Cell CLL FISH (11q, 17p, 13q, Trisomy 12) – ZAP70 – CD38 – Beta 2 Microglobulin	Collect <b>ALL 3</b> types of the following tubes:				Additional molecular abnormalities may appear in patients with CLL at a later stage of their disease. Consequently, this panel contains prognostic tests where results may change in the course of the disease and thus can predict progression. This panel is appropriate for monitoring patients with CLL.
		Sodium heparin (green-top)	whole blood	8.0 mL	2.0 mL	
		EDTA (lavender-top)	whole blood	3.0 mL	1.0 mL	
		No additive (red-top)	serum	1.0 mL	0.5 mL	
<b>Note:</b> At room temperature						

# Individual Prognostic Tests

Test Code	Test Name	Specimen Requirements			Description
		Volume	Tube	Temperature	
14601 or 14601X	Chromosome Analysis, CLL/LPD (Karyotype)	10-20 mL whole blood (3 mL min) 1-3 mL bone marrow	Sodium heparin (green-top)	Room temperature preferred Refrigerated acceptable	Examination of chromosomes in dividing cells. Advantage: The specimen can be screened for multiple cytogenetic abnormalities and is best to detect a larger number of chromosome abnormalities. Disadvantage: The cytogenetic studies of B-cell malignancies may yield few or no representative metaphases of B-cells in culture, with the possibility of false-negative results.
15787 or 15787X	FISH, B-Cell CLL Panel*	3-5 mL whole blood 1-3 mL bone marrow	Sodium heparin (green-top)	Room temperature preferred Refrigerated acceptable	Probes include 11q, 17p, 13q and Trisomy 12. FISH has two advantages over conventional chromosome analysis: 1., allows for the detection of specific chromosome abnormalities in non dividing cells that might be missed by metaphase analysis. 2., it can detect very small loss of chromosome material beyond the resolution of banding analysis. The 17p and 11q aberrations have been linked to shorter treatment-free intervals and shorter survival time, whereas a 13q deletion has a more favorable outcome. Trisomy 12 has been associated with an intermediate-to-unfavorable prognosis.
15480 or 15480X	IgV <sub>H</sub> Gene Mutation Status*	3 mL whole blood (1 mL min)	EDTA (lavender-top) Heparin (green-top) ACD (yellow-top)	Room temperature or refrigerated	Mutated result indicates > 3% deviation from the germline sequence. Patients with immunoglobulin heavy-chain variable region (IgV <sub>H</sub> ) mutations tend to have a more favorable prognosis with longer overall survival than patients with an unmutated gene status.
		<b>Note:</b> Sequencing may not be possible for specimens with < 10% clonal B-cells			
16000 or 16000X	ZAP70*	5 mL whole blood (1 mL min) 2 mL bone marrow (1 mL min)	Sodium heparin (green-top) EDTA (lavender-top) ACD (yellow-top)	Room temperature	The most established predictor of disease progression is lack of mutation in the IgV <sub>H</sub> in neoplastic cells. However, because IgV <sub>H</sub> mutation testing is not widely available, zeta-associated protein (ZAP70) has served as a surrogate marker. In CLL B-cells, elevated ZAP70 results predict an aggressive disease course. Negative results predict a more indolent disease course.
37400 or 37400X	Cell Surface Marker, CD38*	5 mL whole blood (1 mL min) 2 mL bone marrow (1 mL min)	Sodium heparin (green-top)	Room temperature	CD38 is a membrane protein that marks cellular activation and maturation and has signaling activity. CD38 expression is associated with neoplastic cells showing atypical morphology, diffuse bone marrow infiltration, high peripheral blood lymphocytosis and less favorable overall prognosis. CD38 may vary over time and is now viewed as an independent prognostic marker of outcome with its own clinical value.
		<b>Note:</b> Specify marker CD38 on requisition			
19521P	Beta 2 Microglobulin, Serum	1 mL serum (0.5 mL min)	No additive (red-top)	Room temperature preferred Refrigerated or frozen acceptable	Studies show that beta 2 microglobulin (B2M) is an independent predictor of progression-free survival in patients with CLL and IC. High values of this serum protein are indicative of a poorer prognosis than if values are low.
		<b>Note:</b> Overnight fasting is preferred			

\* This test was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary. Performance characteristics refer to the analytical performance of the test.