

## Overview

### Useful For

Determination of B-cell content and confirmation the presence of a clonal B-cell population evaluating chronic lymphocytic leukemia patients prior to *TP53* variant analysis

### Method Name

Only orderable as a reflex. For more information see P53CA / Hematologic Neoplasms, *TP53* Somatic Mutation, DNA Sequencing Exons 4-9, Varies.

Flow Cytometric Cell Selection

### NY State Available

Yes

## Specimen

### Specimen Type

Varies

### Specimen Required

Only orderable as a reflex. For more information see P53CA / Hematologic Neoplasms, *TP53* Somatic Mutation, DNA Sequencing Exons 4-9, Varies.

**Specimen Type:** Blood

**Container/Tube:** Lavender top (EDTA) or yellow top (ACD solution B)

**Specimen Volume:** 3 mL

#### Collection Instructions:

1. Invert several times to mix blood.
2. Send whole blood specimen in original tube. **Do not aliquot.**
3. Label specimen as blood.

**Specimen Stability Information:** Ambient/Refrigerate <10 days

### Specimen Minimum Volume

1 mL

### Reject Due To

Gross hemolysis	Reject
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Fully clotted	Reject
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**Specimen Stability Information**

Specimen Type	Temperature	Time	Special Container
Varies	Ambient (preferred)	10 days	
	Refrigerated	10 days	

**Clinical & Interpretive**
**Clinical Information**

Patients with chronic lymphocytic leukemia (CLL) have variable disease course influenced by a series of tumor biologic factors. The presence of chromosomal 17p- or *TP53* gene variation confers a very poor prognosis to a subset of CLL patients, both at time of initial diagnosis as well as at disease progression, or in the setting of therapeutic resistance. *TP53* gene variant status in CLL has emerged as the single most predictive tumor genetic abnormality associated with adverse outcome and poor response to standard immunochemotherapy; however, patients can be managed with alternative therapeutic options.

**Reference Values**

Only orderable as a reflex. For more information see P53CA / Hematologic Neoplasms, *TP53* Somatic Mutation, DNA Sequencing Exons 4-9, Varies.

**Interpretation**

Correlation with clinical, histopathologic and additional laboratory findings is required for final interpretation of these results. The final interpretation of results for clinical management of the patient is the responsibility of the managing physician.

**Cautions**

No significant cautionary statements

**Clinical Reference**

- Zenz T, Krober A, Scherer K, et al. Monoallelic TP53 inactivation is associated with poor prognosis in chronic lymphocytic leukemia: results from a detailed genetic characterization with long-term follow-up. *Blood*. 2008;112(8):3322-3329
- Lehmann S, Oqawa S, Raynaud SD, et al. Molecular allelokaryotyping of early-stage, untreated chronic lymphocytic leukemia. *Cancer*. 2008;112(6):1296-1305
- Rossi D, Cerri M, Deambrogi C, et al. The prognostic value of TP53 mutations in chronic lymphocytic leukemia is independent of Del17p13: implications for overall survival and chemorefractoriness. *Clin Cancer Res*. 2009;15(3):995-1004
- Zent CS, Call TG, Hogan WJ, et al. Update on risk-stratified management for chronic lymphocytic leukemia. *Leuk Lymphoma*. 2006;47(9):1738-1746
- Hampel PJ, Parikh SA. Chronic lymphocytic leukemia treatment algorithm 2022 [published correction appears in *Blood Cancer J*. 2022 Dec 22;12(12):172]. *Blood Cancer J*. 2022;12(11):161. Published 2022 Nov 29.

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6. Trbusek M, Smardova J, Malcikova J, et al. Missense mutations located in structural p53 DNA-binding motifs are associated with extremely poor survival in chronic lymphocytic leukemia. *J Clin Oncol.* 2011;29(19):2703-2708

7. Halldorsdottir AM, Lundin A, Murray F, et al. Impact of TP53 mutation and 17p deletion in mantle cell lymphoma. *Leukemia.* 2011;25(12):1904-1908

8. Young KH, Leroy K, Moller MB, et al. Structural profiles of TP53 gene mutations predict clinical outcome in diffuse large B-cell lymphoma: an international collaborative study. *Blood.* 2008;112(8):3088-3098

## Performance

### Method Description

Peripheral blood specimens from chronic lymphocytic leukemia patients are analyzed by fluorescent activated cell sorting and enrichment to determine B-cell content and confirm the presence of a clonal B-cell population. (Instruction manual: BD FACSMelody Cell Sorter User's Guide. Revision 3. BD Biosciences; 03/2020)

### PDF Report

No

### Day(s) Performed

Specimens processed: Monday through Sunday

Results reported: Monday through Friday

### Report Available

7 days

### Specimen Retention Time

DNA: 3 months

### Performing Laboratory Location

Rochester

## Fees & Codes

### Fees

- Authorized users can sign in to [Test Prices](#) for detailed fee information.
- Clients without access to Test Prices can contact [Customer Service](#) 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact [Customer Service](#).

### Test Classification

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

**CPT Code Information**

88184-Flow cytometry, first cell surface, cytoplasmic or nuclear marker

88185 x 4-Each additional marker

**LOINC® Information**

Test ID	Test Order Name	Order LOINC® Value
CSP53	TP53 Pre-Analysis Cell Sorting, V	No LOINC Needed

Result ID	Test Result Name	Result LOINC® Value
607678	TP53 Pre-Analysis Cell Sort	No LOINC Needed
607687	Final Diagnosis	22637-3