Test Definition: CSP53

TP53 Gene Somatic Mutation Pre-Analysis Cell Sorting, Varies (Non-Orderable)

Overview

Useful For

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

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: Whole blood
Container/Tube: Lavender top (EDTA) or yellow top (ACD)
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 Minimum Volume

1 mL

Reject Due To

Gross hemolysis	Reject
Fully clotted	Reject

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 mutation 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 mutation 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.

Not applicable

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

1. 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
2. Lehmann S, Oqawa S, Raynaud SD, et al. Molecular allelokaryotyping of early-stage, untreated chronic lymphocytic leukemia. Cancer. 2008;112(6):1296-1305
3. 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

4. Zent CS, Call TG, Hogan WJ, et al. Update on risk-stratified management for chronic lymphocytic leukemia. Leuk Lymphoma. 2006;47(9):1738-1746
5. 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. doi:10.1038/s41408-022-00756-9
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 Saturday

Report Available
7 days

Specimen Retention Time
DNA: 3 months

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Main Campus

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.

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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