CLL FISH Testing

Why use CLL FISH testing for your patient?

Fluorescence in situ hybridization (FISH) testing is utilized to detect genetic changes associated with the diagnosis and prognosis of patients with chronic lymphocytic leukemia (CLL). CLL FISH testing is beneficial to perform with classic cytogenetic testing (also performed at Sterling Pathology) for initial diagnosis, but FISH may be performed solely for continual monitoring of disease for the following reasons:

- Important diagnostic and prognostic indicators[1]
- Detects deletions of chromosomes 6q, 11q22.3/ATM, 13q14.3/DLEU1,2 and 17p13.1/TP53 gene regions
- Detects trisomy 12, monosomy 13 and translocation (11:14)
- Improved detection rate of typical, non-random CLL abnormalities 75% versus 16% by classic cytogenetics[2]
- 48 hour turnaround time
- Improved information in a timely manner allows for more informed and productive treatment options

In addition to FISH for CLL:

- Molecular testing for mutations in the IgHV gene is complementary to FISH analysis in cases with a diagnosis of CLL. The results of molecular testing provides information about the patient's prognosis.

Specimen Requirements

- Bone marrow or peripheral blood

1 Nelson, Beverly, Rohit Gupta, Gordon Dewald, Sarah Paternoster, Steven Rosen, and LoAnn Peterson. "Chronic Lymphocytic Leukemia FISH Panel: Impact on Diagnosis." *American Journal of Clinical Pathology* 128.2 (2007): 323-32.

2 Goorha, Salil, Martha J. Glenn, Elizabeth Drozd-Borysiuk, and Zhong Chen. "A Set of Commercially Available Fluorescent In-situ Hybridization Probes Efficiently Detects Cytogenetic Abnormalities in Patients with Chronic Lymphocytic Leukemia." *Genetics in Medicine* 6.1 (2004): 48-53.

Company Overview

Sterling Pathology provides the latest testing technologies specializing in the monitoring and diagnosis of hematopoietic diseases. Sterling Pathology is dedicated to providing the best diagnostic hematopathology services to meet the needs of our hematology and oncology physicians and their patients. We offer a continuum of diagnostic, prognostic, and predictive testing services in anatomic morphology, molecular genetics, cytogenetics, flow cytometry, FISH, and immunohistochemistry.

Expertise

- Board-Certified pathologists with hematopathology subspecialty expertise
- Board-Certified geneticists with cytogenetic subspecialty expertise
- Access to hematopathologist and geneticist for peer-to-peer telephone consultations
- Academic clinical case review

Service

- Unmatched industry-leading turn-around time
- Personalized service from your local Account Executives
- Dedicated customer service care team

Quality

- CAP-accredited, CLIA and state licensed testing facility
- Expanded comprehensive test menu through strategic alliances
- Dedicated logistic staff to manage specimen transport

Report Delivery

- Standardized reporting with full-color photomicrographs
- Reports available via mail, facsimile, remote print, or EMR interface
- WebPortal with 24/7 access to patient reports

Third Party Billing

- Sterling Pathology will bill Medicare, Medicaid and all private insurance providers
- Sterling Pathology will bill all secondary and supplementary insurance providers

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CLL (Chronic Lymphocytic Leukemia) – By FISH Analysis

Genetic regions analyzed: 6q deletion, 11q22/ATM, 13q14.3/DLEU1,2 and 17p13.1/p53 gene deletions, trisomy 12, monosomy 13 and t(11;14)

Testing for genetic abnormalities in CLL cases will further classify disease state and help guide treatment options.

Components/ Chromosome	Loci	Gene	Probe Color	Assay Type	Normal Pattern	Abnormal Patterns	Abnormality Identified
6	6q21	SEC63	G	Spot Count	2R2G	2R1G	SEC63 gene deletion
	6q23.2	MYB	R	Spot Count		1R2G	MYB gene deletion
						1R1G	Whole arm deletion of 6q
11	11q22.3	ATM	G	Spot Count	2R2G	2R1G	ATM deletion
17	17p13.1	p53	R	Spot Count		1R2G	p53 gene deletion
12	12p11.1-q11.1	CEN 12	G	Spot Count	2R2G2A	2R3G2A	Trisomy 12
13	13q14.3	DLEU1&2	R	Spot Count		1R2G2A	DLEU gene deletion (D13S319 region)
	13q34	LAMP1	A	Spot Count		0R2G2A	Homozygous DLEU deletion
						1R2G1A	Monosomy 13 or whole arm deletion
						2R2G1A	LAMP1 deletion
11	11q13	CCND1	R	Fusion	2R2G	1R1G2F	t(11;14)
14	14q32	IgH	G			1R1G1F	atypical t(11;14)
14						2R3G	IgH gene rearrangement (but not to CCND1), or trisomy 14

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