

BCR/ABL Testing

Why use BCR/ABL FISH testing for your patient?

BCR/ABL fluorescence in situ hybridization (FISH) testing is utilized to diagnose patients with chronic myeloid leukemia (CML) and acute lymphocytic leukemia (ALL), and to monitor disease remission and residual disease. BCR/ABL 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^{2,3} for the following reasons:

- Increased sensitivity¹
- Able to monitor residual disease
- Cost effective²
- 48 hour turnaround time
- Only requires peripheral blood and not an invasive bone marrow to monitor disease

After BCR/ABL FISH testing

If positively diagnosed using FISH testing, it is recommended that a molecular BCR/ABL test is run on the sample to determine the level of positivity by PCR and produce additional relevant results for treatment (also performed at Sterling Pathology).

Specimen Requirements

- Bone marrow aspirate or biopsy for initial diagnosis if concurrent cytogenetics testing is to be performed
- Peripheral blood for continual monitoring of disease remission/progression

1 Sessions, J. "Chronic Myeloid Leukemia in 2007." *American Journal of Health-System Pharmacy* 64.24 Suppl 15 (2007): S4-S9.

2 A., Pelz, Kroning H., Franke A., Wieacker P., and Stumm M. "High Reliability and Sensitivity of the BCR/ABL1 D-FISH Test for the Detection of BCR/ABL Rearrangements." *Annals of Hematology* 81.3 (2002): 147-53.

3 Dewald, G. W., W. A. Wyatt, A. L. Juneau, R. O. Carlson, A. R. Zinsmeister, S. M. Jalal, J. L. Spurbeck, and R. T. Silver. "Highly Sensitive Fluorescence In Situ Hybridization Method to Detect Double BCR/ABL Fusion and Monitor Response to Therapy in Chronic Myeloid Leukemia." [Http://bloodjournal.hematologylibrary.org](http://bloodjournal.hematologylibrary.org). American Society of Hematology, 1 May 2009. Web. 3 Dec. 2013.

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 report

Third Party Billing

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

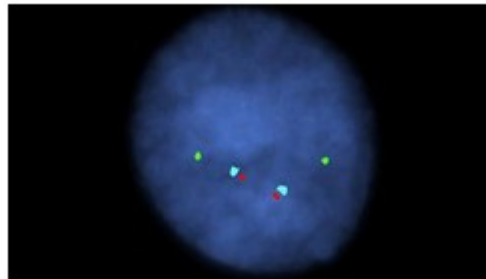
BCR/ABL FISH Testing

BCR/ABL/ASS triple color, dual fusion probes (Abbott Laboratories) for the detection of Chronic Myeloid Leukemia (CML) and Acute Lymphoblastic Leukemia (ALL). Loci: 9q34 (ABL/ASS) and 22q11.2 (BCR).

This test detects the BCR/ABL gene rearrangement resulting from a t(9;22) - Philadelphia chromosome, along with the variant that includes an ASS gene deletion on chromosome 9q34.

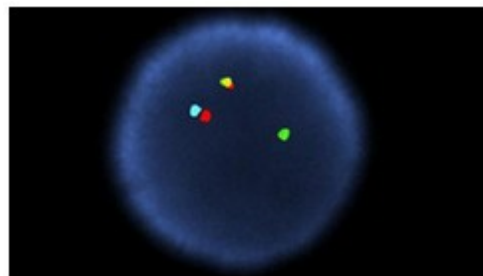
Probe Name	Probe Location	Fluorophore
Vysis LSI ASS-ABL	9q34	SpectrumOrange
Vysis LSI BCR	22q11.2	SpectrumGreen
Vysis LSI ASS-ABL	9q34	SpectrumAqua

Normal signal pattern



Nucleus showing the two aqua/orange and two green signal pattern.

Abnormal signal pattern



Nucleus showing the one aqua/orange, one green, and one orange/green fusion (yellow) signal pattern.

Markers: Probes 9q34 and 22q11.2 (see Above)