

ZytoLight® SPEC BCR/ABL1 Dual Color Dual Fusion Probe



Background

The ZytoLight® SPEC BCR/ABL1 Dual Color Dual Fusion Probe (PL68) is intended to be used for the qualitative detection of the translocation t(9;22)(q34.1;q11.2) involving the human BCR and ABL1 genes in cytologic specimens, such as chronic myeloid leukemia (CML), by fluorescence *in situ* hybridization (FISH). The probe is intended to be used in combination with the ZytoLight® FISH-Cytology Implementation Kit (Prod. No. Z-2099-20). The product is intended for professional use only. All tests using the product should be performed in a certified, licensed anatomic pathology laboratory under the supervision of a pathologist/human geneticist by qualified personnel. The probe is intended to be used as an aid to the differential diagnosis of CML and therapeutic measures should not be initiated based on the test result alone.

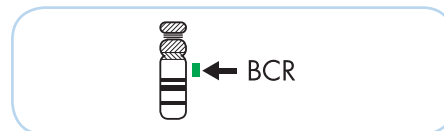
Probe Description

The ZytoLight® SPEC BCR/ABL1 Dual Color Dual Fusion Probe is composed of:

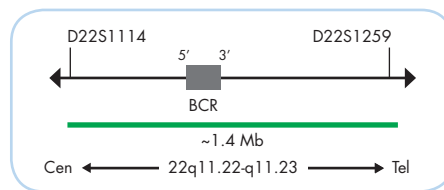
- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~12 ng/μl), which target sequences mapping in 22q11.22-q11.23** (chr22:23,000,029-24,431,064) harboring the BCR gene region.
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~6 ng/μl), which target sequences mapping in 9q34.11-q34.13** (chr9:133,223,081-134,103,849) harboring the ABL1 gene region.
- Formamide based hybridization buffer

Results

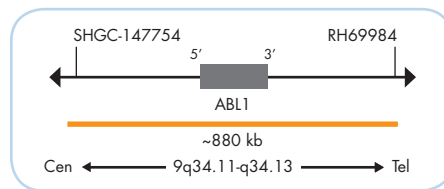
In a normal interphase nucleus, two orange and two green signals are expected. A reciprocal translocation involving two breakpoints splits the two signals and generates a fusion signal on each of the chromosomes involved. The chromosomal regions which are not translocated are indicated by the single orange respectively green signal.



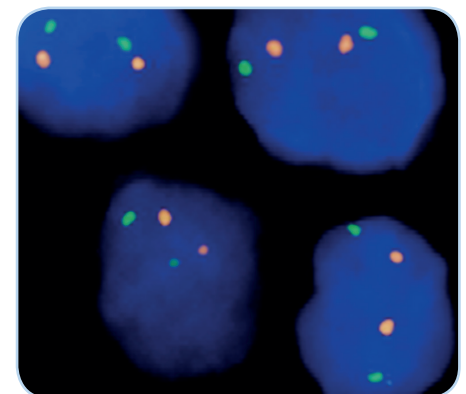
Ideograms of chromosomes 22 (above) and 9 (below) indicating the hybridization locations.



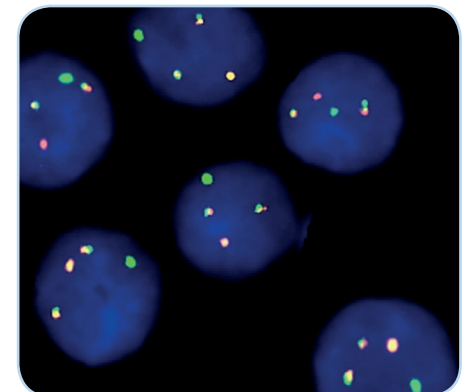
SPEC BCR Probe map (not to scale).



SPEC ABL1 Probe map (not to scale).



SPEC BCR/ABL1 Dual Color Dual Fusion Probe hybridized to normal interphase cells as indicated by two orange and two green signals in each nucleus.



Bone marrow specimen with translocation affecting the BCR/ABL1 loci as indicated by one separate orange signal, one separate green signal and two orange/green fusion signals.

Prod. No.	Product	Label	Tests* (Volume)
Z-2111-50	ZytoLight SPEC BCR/ABL1 Dual Color Dual Fusion Probe CE IVD	●/●	5 (50 μl)
Z-2111-200	ZytoLight SPEC BCR/ABL1 Dual Color Dual Fusion Probe CE IVD	●/●	20 (200 μl)
Related Products			
Z-2099-20	ZytoLight FISH-Cytology Implementation Kit CE IVD Incl. Cytology Pepsin Solution, 4 ml; 20x Wash Buffer TBS, 50 ml; 10x MgCl ₂ , 50 ml; 10x PBS, 50 ml; Cytology Stringency Wash Buffer SSC, 500 ml; Cytology Wash Buffer SSC, 500 ml; DAPI/DuraTect-Solution, 0.8 ml		20

* Using 10 μl probe solution per test. IVD labeled products are only available in certain countries. All other countries research use only! Please contact your local dealer for more information.

**According to Human Genome Assembly GRCh37/hg19