

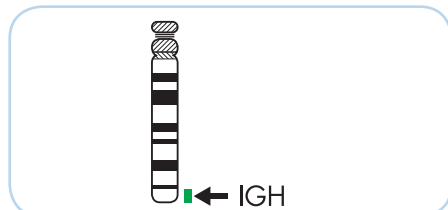
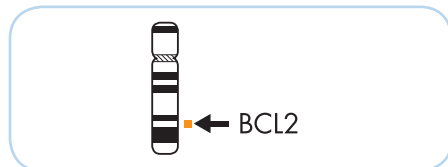
ZytoLight® SPEC BCL2/IGH Dual Color Dual Fusion Probe



Background

The ZytoLight® SPEC BCL2/IGH Dual Color Dual Fusion Probe (PL71) is intended to be used for the qualitative detection of the translocation t(14;18)(q32.3;q21.3) involving the human IGH and BCL2 genes in formalin-fixed, paraffin-embedded specimens by fluorescence *in situ* hybridization (FISH). The probe is intended to be used in combination with the ZytoLight® FISH-Tissue Implementation Kit (Prod. No. Z-2028-5/-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 various cancers and therapeutic measures should not be initiated based on the test result alone.

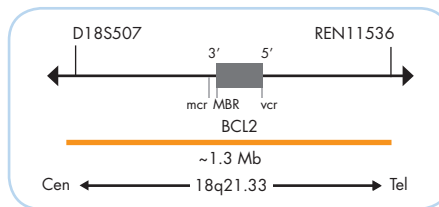


Ideograms of chromosomes 18 (above) and 14 (below) indicating the hybridization locations.

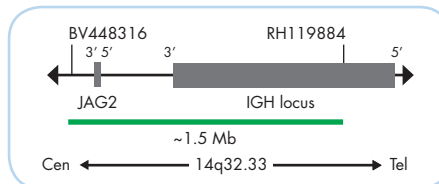
Probe Description

The ZytoLight® SPEC BCL2/IGH Dual Color Dual Fusion Probe is composed of:

- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~6 ng/µl), which target sequences mapping in 18q21.33** (chr18:60,180,078-61,507,691) harboring the BCL2 gene region.
- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~12 ng/µl), which target sequences mapping in 14q32.33** (chr14:105,462,169-106,995,000) harboring the IGH locus.
- Formamide based hybridization buffer



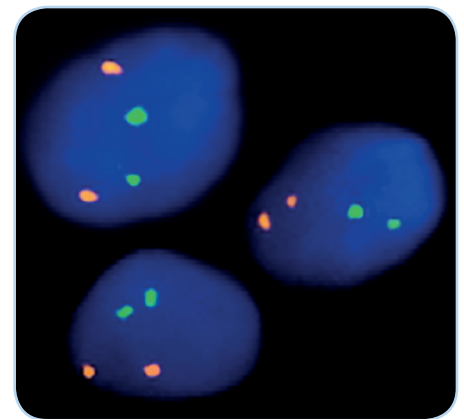
SPEC BCL2 Probe map (not to scale).



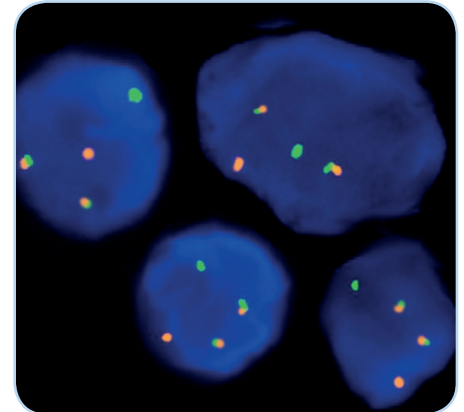
SPEC IGH Probe map (not to scale).

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 and green signal, respectively.



SPEC BCL2/IGH Dual Color Dual Fusion Probe hybridized to normal interphase cells as indicated by two orange and two green signals in each nucleus.



Example of an aberrant signal pattern: Bone marrow biopsy section with translocation affecting the BCL2/IGH 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-2114-50	ZytoLight® SPEC BCL2/IGH Dual Color Dual Fusion Probe CE IVD	●/●	5 (50 µl)
Z-2114-200	ZytoLight® SPEC BCL2/IGH Dual Color Dual Fusion Probe CE IVD	●/●	20 (200 µl)
Related Products			
Z-2028-5	ZytoLight® FISH-Tissue Implementation Kit CE IVD Incl. Heat Pretreatment Solution Citric, 150 ml; Pepsin Solution, 1 ml; Wash Buffer SSC, 210 ml; 25x Wash Buffer A, 50 ml; DAPI/DuraTest-Solution, 0.2 ml		5
Z-2028-20	ZytoLight® FISH-Tissue Implementation Kit CE IVD Incl. Heat Pretreatment Solution Citric, 500 ml; Pepsin Solution, 4 ml; Wash Buffer SSC, 560 ml; 25x Wash Buffer A, 100 ml; DAPI/DuraTest-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