ZytoMation® BCL2 Dual Color Break Apart FISH Probe

Intended Purpose

The Zyto*Mation* BCL2 Dual Color Break Apart FISH Probe (PL260) is intended to be used for the qualitative detection of translocations involving the human BCL2 gene at 18q21.33 in formalin-fixed, paraffin-embedded specimens, such as B-cell lymphoma, by fluorescence *in situ* hybridization (FISH). The probe is intended to be used in combination with the Bond FISH Kit (DS9636) on the automated Bond-MAX or Bond III system by Leica Biosystems.

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 B-cell lymphoma and therapeutic measures should not be initiated based on the test result alone.

Probe Description

The Zyto*Mation* BCL2 Dual Color Break Apart FISH Probe is composed of:

- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~6,0 ng/µl), which target sequences mapping in 18q21.33* (chr18:60,046,152-60.589,273) proximal to the BCL2 breakpoint region (see Fig. 1).
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~2,5 ng/µl), which target sequences mapping in 18q21.33-q22.1* (chr18:60,994,528-61,658,503) distal to the BCL2 breakpoint region (see Fig. 1).
- Formamide based hybridization buffer

* according to Human Genome Assembly GRCh37/hg19

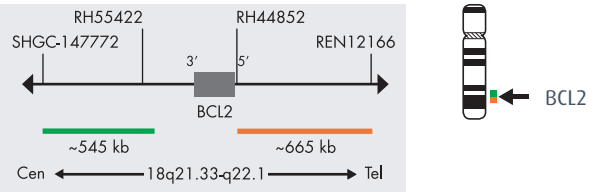
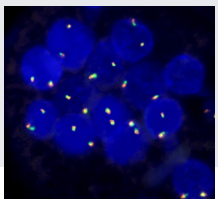


Fig. 1: BCL2 Probe map (not to scale); Right: Ideogram of chromosome 18 indicating the hybridization locations

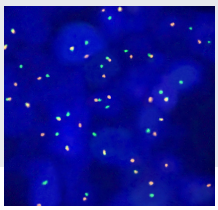
Results

Normal situation: In interphases of normal cells or cells without a translocation involving the BCL2 gene region, two green/orange fusion signals appear.

Aberrant situation: One BCL2 gene region affected by a translocation is indicated by one separate green signal and one separate orange signal.



Hybridized to normal interphase cells as indicated by two orange/green fusion signals per nucleus.



Follicular lymphoma tissue section with translocation of the BCL2 gene as indicated by one non-rearranged orange/green fusion signal, one orange and one separate green signal.

Labels	Chromosome	Reg. Status	Tests	Order No.
●|●	18	CE/IVD	Up to 20 (5.1 ml)	**Z-2306-5.1ML**