FlexISH® BCL2/BCL6 DistinguISH™ Probe

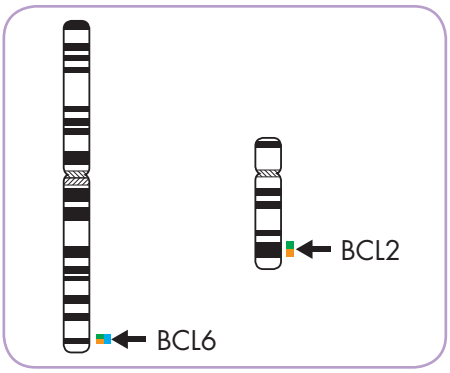
CE
IVD

Background

The FlexISH® BCL2/BCL6 DistinguISH™ Probe (PL238) is intended to be used for the qualitative detection of translocations involving the human BCL2 gene at 18q21.33 and the human BCL6 gene at 3q27.3 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 FlexISH®-Tissue Implementation Kit (Prod. No. Z-2182-5/-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 B-cell lymphoma and therapeutic measures should not be initiated based on the test result alone.



Ideograms of chromosomes 3 (left) and 18 (right) indicating the hybridization locations.

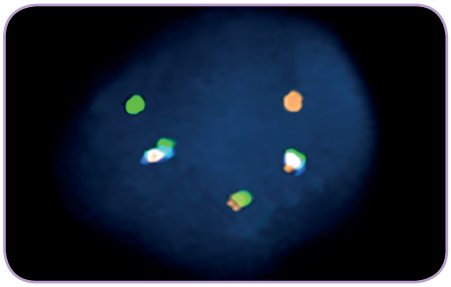
Probe Description

The FlexISH® BCL2/BCL6 DistinguISH™ Probe is composed of:

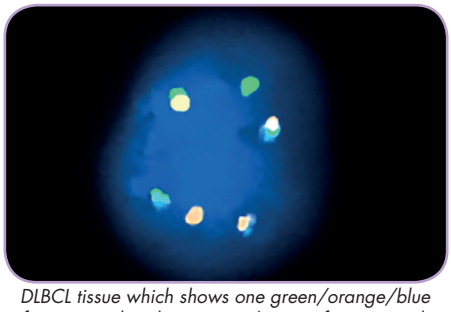
- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~10.0 ng/µl), which target sequences mapping in 18q21.33** (chr18:60,046,152-60,779,138) proximal to the BCL2 breakpoint region and in 3q27.3** (chr3:186,578,337-187,403,834) proximal to the BCL6 breakpoint region
- ZyOrange (excitation 547 nm/emission at 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 and in 3q27.3-q28** (chr3:187,744,962-188,411,425) distal to the BCL6 breakpoint region
- ZyBlue (excitation 418 nm/emission 467 nm) labeled polynucleotides, (~70.0 ng/µl), which target sequences mapping in 3q27.3** (chr3:186,578,337-187,403,834) proximal to the BCL6 breakpoint region co-localizing with the green-labeled BCL6 polynucleotides and in 3q27.3-q28** (chr3:187,744,962-188,411,425) distal to the BCL6 breakpoint region co-localizing with the orange-labeled BCL6 polynucleotides
- Formamide based hybridization buffer

Results

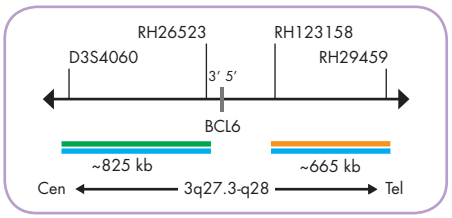
In an interphase nucleus without BCL2 or BCL6 rearrangements, two BCL2 specific green/orange fusion signals and two BCL6 specific green/orange/blue fusion signals are expected. A BCL2 rearrangement is indicated by one separate green and one separate orange signal, both not co-localizing with blue signals. A BCL6 rearrangement is indicated by one separate green and one separate orange signal, both co-localizing with blue signals.



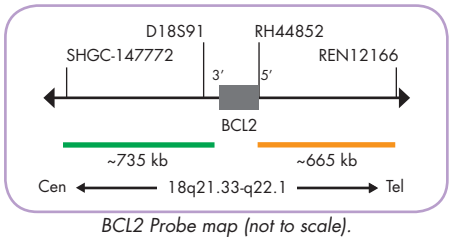
Lymphoma tissue which shows two green/orange/blue fusion signals and one green/orange fusion signal. BCL2 rearrangement is indicated by one separate green and one separate orange signal, both not co-localizing with blue signals.
Specimen kindly provided by Dr. Rontogianni, Athens, Greece.



DLBCL tissue which shows one green/orange/blue fusion signal and one green/orange fusion signal. BCL6 rearrangement is indicated by one separate green and one separate orange signal, both co-localizing with blue signals. Additionally, one separate orange and one separate green signal indicate a further BCL2 positivity, confirming a BCL2/BCL6 co-rearrangement.



BCL6 Probe map (not to scale).



BCL2 Probe map (not to scale).

Prod. No.	Product	Label	Tests* (Volume)
Z-2283-50	FlexISH BCL2/BCL6 DistinguISH Probe CE IVD	●/●/●	5 (50 µl)
Z-2283-200	FlexISH BCL2/BCL6 DistinguISH Probe CE IVD	●/●/●	20 (200 µl)
Related Products			
Z-2182-5	FlexISH-Tissue Implementation Kit CE IVD Incl. Heat Pretreatment Solution Citric, 150 ml; Pepsin Solution, 1 ml; 5x FlexISH Wash Buffer, 150 ml; DAPI/DuraTect-Solution, 0.2 ml		5
Z-2182-20	FlexISH-Tissue Implementation Kit CE IVD Incl. Heat Pretreatment Solution Citric, 500 ml; Pepsin Solution, 4 ml; 5x FlexISH Wash Buffer, 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*