ZytoDot® 2C SPEC BCL2 Break Apart Probe

ZytoDot [®]2^C Products for CISH analysis

Background

The ZytoDot® 2C SPEC BCL2 Break Apart Probe (PD53) 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 by chromogenic in situ hybridization (CISH). The probe is intended to be used in combination with the ZytoDot ® 2C CISH Implementation Kit (Prod. No. C-3044-10/-40). 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.

Probe Description

The Zyto*Dot* [®] 2C SPEC BCL2 Break Apart Probe is composed of:

- Digoxigenin-labeled polynucleotides (~0.50 ng/µl), which target sequences mapping in 18q21.33** (chr18:60,415,418-60,589,273) proximal to the BCL2 breakpoint region.
- Dinitrophenyl-labeled polynucleotides (~0.75 ng/µl), which target sequences mapping in 18q21.33** (chr18:60,994,528-61,507,691) distal to the BCL2 breakpoint region.
- · Formamide based hybridization buffer

Ideogram of chromosome 18 indicating the hybridization locations.

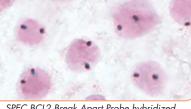
← 18q21.33 → SPEC BCL2 Probe map (not to scale).

Cen

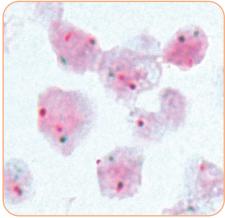
Results

In an interphase nucleus of a normal cell lacking a translocation involving the 18q21.33 band, using the Zyto*Dot* [®] 2C CISH Implementation Kit, two red/green fusion signals are expected representing two normal (non-rearranged) 18q21.33 loci. A signal pattern consisting of one red/green fusion signal, one red signal, and a separate green signal indicates one normal 18q21.33 locus and one 18q21.33 locus affected by a translocation.

IVD



SPEC BCL2 Break Apart Probe hybridized to normal interphase cells as indicated by two red/green fusion signals per nucleus.



Example of an aberrant signal pattern: Lymphoma tissue section with translocation affecting the 18q21.33 locus as indicated by one red/green fusion (non-rearranged) signal, one red signal, and one separate green signal

		ie rea signal, and one sep	sarale green signal.
Prod. No.	Product	Label	Tests* (Volume)
C-3073-100	Zyto <i>Dot</i> 2C SPEC BCL2 Break Apart Probe C € 0124 IVD	DIG/DNP	10 (100 µl)
Related Prod	ucts		
C-3044-10	Zyto <i>Dot</i> 2C CISH Implementation Kit C € IVD		10
	Incl. Heat Pretreatment Solution EDTA, 150 ml; Pepsin Solution, 1 ml; Wash Buffer SSC, 210 ml; 20x Wash Buffer TBS, 50 ml; Anti-DIG/DNP-Mix, 1 ml; HRP/AP-Polymer-W AP-Red Solution A, 0.1 ml; AP-Red Solution B, 4 ml; HRP-Green Solution A, 0.2 ml; HRP-Green Solution B, 4 ml; Nuclear Blue Solution, 4 ml; Mounting Solution (alcoholir),		

* Using 10 µl probe solution per test. [VD] 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

ZYTOVISION Molecular diagnostics simplified DE039-1-25

