## ZytoDot® 2C SPEC BCL2 Break Apart Probe

### Intended Purpose

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.

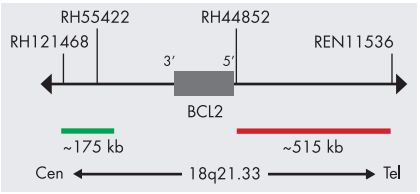
The probe is intended to be used as an aid to the differential diagnosis of various cancers and therapeutic measures should not be initiated based on the test result alone.

### Probe Description

The ZytoDot 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 (see Fig. 1).
- 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 (see Fig. 1).
- Formamide based hybridization buffer

* according to Human Genome Assembly GRCh37/hg19



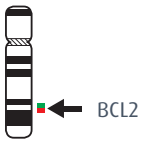
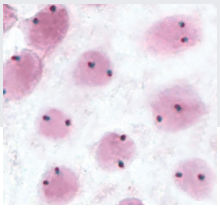




Fig. 1: SPEC BCL2 Probe map (not to scale); Right: Ideogram of chromosome 18 indicating the hybridization locations

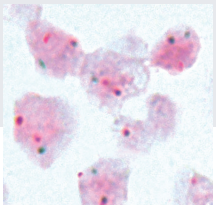
### Results

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

**Aberrant situation:** One BCL2 gene region affected by a translocation is indicated by one separate distinct dot-shaped green signal and one separate distinct dot-shaped red signal.



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.

| Labels | Chromosome | Reg. Status | Tests | Order No. |
|---|---|---|---|---|
| DIG/DNP | 18 | CE/IVD | 10 (100 µl) | **C-3073-100** |

## ZytoDot® 2C SPEC EWSR1 Break Apart Probe

### Intended Purpose

The ZytoDot 2C SPEC EWSR1 Break Apart Probe (PD24) is intended to be used for the qualitative detection of translocations involving the human EWSR1 gene at 22q12.2 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 ZytoDot 2C SPEC EWSR1 Break Apart Probe is composed of:

- Digoxigenin-labeled polynucleotides (~0.50 ng/µl), which target sequences mapping in 22q12.2* (chr22:29,779,841-30,057,928) distal to the EWSR1 breakpoint region (see Fig. 1).
- Dinitrophenyl-labeled polynucleotides (~0,75 ng/µl), which target sequences mapping in 22q12.1-22q12.2* (chr22:29,413,831-29,673,440) proximal to the EWSR1 breakpoint region (see Fig. 1).
- Formamide based hybridization buffer

* according to Human Genome Assembly GRCh37/hg19

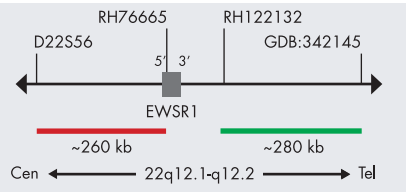
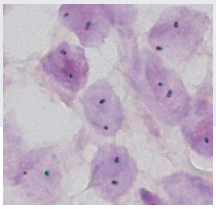


Fig. 1: SPEC EWSR1 Probe map (not to scale); Right: Ideogram of chromosome 22 indicating the hybridization locations

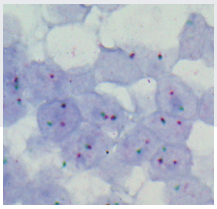
### Results

**Normal situation:** In interphases of normal cells or cells without a translocation involving the EWSR1 gene region, two red/green fusion signals appear.

**Aberrant situation:** One EWSR1 gene region affected by a translocation is indicated by one separate distinct dot-shaped green signal and one separate distinct dot-shaped red signal.



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



Example of an aberrant signal pattern: Ewing sarcoma tissue section with translocation affecting the 22q12.1-q12.2 locus as indicated by one non-rearranged red/green fusion signal, one red signal, and one separate green signal.

| Labels | Chromosome | Reg. Status | Tests | Order No. |
|---|---|---|---|---|
| DIG/DNP | 22 | CE/IVD | 10 (100 µl) | **C-3043-100** |