

# ZytoDot® 2C SPEC MYC Break Apart Probe

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IVD

## Background

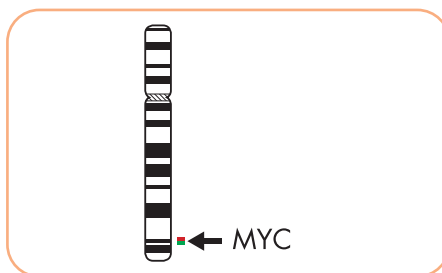
The ZytoDot® 2C SPEC MYC Break Apart Probe (PD46) is intended to be used for the qualitative detection of translocations involving the human MYC gene at 8q24.21 in formalin-fixed, paraffin-embedded specimens by chromogenic *in situ* hybridization (CISH). The probe is intended to be used in combination 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.

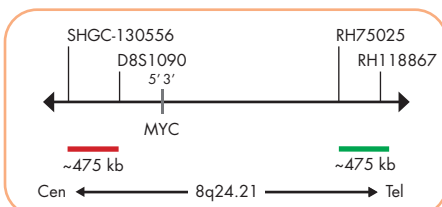
## Probe Description

The ZytoDot® 2C SPEC MYC Break Apart Probe is composed of:

- Digoxigenin-labeled polynucleotides (~0.50 ng/μl), which target sequences mapping in 8q24.21\*\* (chr8:130,373,051-130,847,951) distal to the MYC breakpoint region.
- Dinitrophenyl-labeled polynucleotides (~0.75 ng/μl), which target sequences mapping in 8q24.21\*\* (chr8:127,888,765-128,363,281) proximal to the MYC breakpoint region.
- Formamide based hybridization buffer



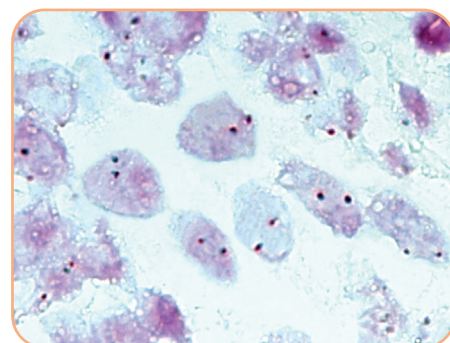
Ideogram of chromosome 8 indicating the hybridization locations.



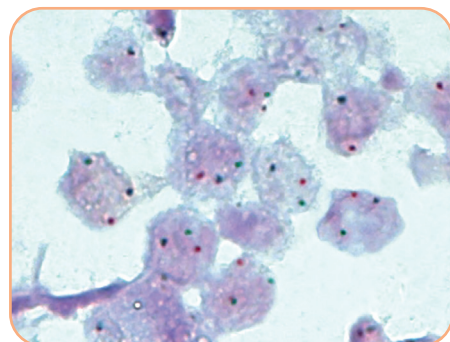
SPEC MYC Probe map (not to scale).

## Results

In an interphase nucleus of a normal cell lacking a translocation involving the 8q24.21 band, using the ZytoDot® 2C CISH Implementation Kit, two red/green fusion signals are expected representing two normal (non-rearranged) 8q24.21 loci. A signal pattern consisting of one red/green fusion signal, one red signal, and a separate green signal indicates one normal 8q24.21 locus and one 8q24.21 locus affected by a translocation. Alternative break points particularly observed in variant MYC translocations t(8;22) and t(2;8) might result in different signal patterns.



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



Example of an aberrant signal pattern: Non-Hodgkin lymphoma tissue section with translocation affecting the 8q24.21 locus as indicated by one red/green fusion (non-rearranged) signal, one red signal, and one separate green signal.

Prod. No.	Product	Label	Tests* (Volume)
C-3066-400	ZytoDot 2C SPEC MYC Break Apart Probe CE 0124 IVD	DIG/DNP	40 (400 μl)
<b>Related Products</b>			
C-3044-40	ZytoDot 2C CISH Implementation Kit CE IVD		40
Incl. Heat Pretreatment Solution EDTA, 500 ml; Pepsin Solution, 4 ml; Wash Buffer SSC, 560 ml; 20x Wash Buffer TBS, 2x 50 ml; Anti-DIG/DNP-Mix, 4 ml; HRP/AP-Polymer-Mix, 4 ml; AP-Red Solution A, 0.4 ml; AP-Red Solution B, 15 ml; HRP-Green Solution A, 0.8 ml; HRP-Green Solution B, 15 ml; Nuclear Blue Solution, 20 ml; Mounting Solution (alcoholic), 4 ml			

\* 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