

# ZytoDot® 2C SPEC ALK Break Apart Probe



## Background

The ZytoDot® 2C SPEC ALK Break Apart Probe (PD35) is intended to be used for the qualitative detection of translocations involving the human ALK gene at 2p23.2 in formalin-fixed, paraffin-embedded specimens, such as non-small cell lung cancer (NSCLC), 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).

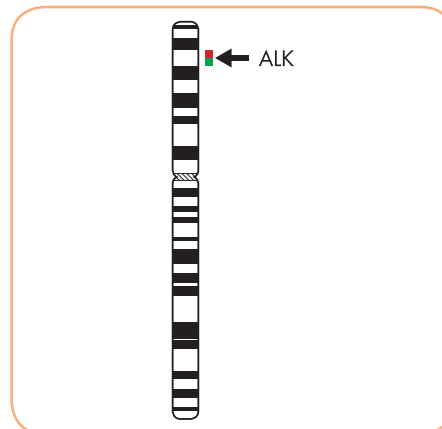
The product is intended for professional use only. All tests using the product should be performed in a certified, licensed anatomic pathology laboratory under the supervision of a pathologist/human geneticist by qualified personnel.

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

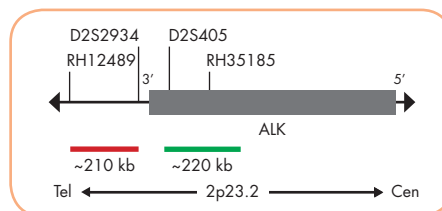
## Probe Description

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

- Digoxigenin-labeled polynucleotides (~0.50 ng/μl), which target sequences mapping in 2p23.2\*\* (chr2:29,460,144-29,681,581) proximal to the ALK breakpoint region.
- Dinitrophenyl-labeled polynucleotides (~0.75 ng/μl), which target sequences mapping in 2p23.2\*\* (chr2:29,174,204-29,383,335) distal to the ALK breakpoint region.
- Formamide based hybridization buffer



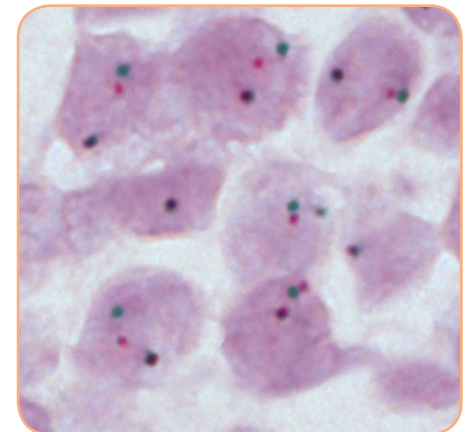
Ideogram of chromosome 2 indicating the hybridization locations.



SPEC ALK Probe map (not to scale).

## Results

In an interphase nucleus of a normal cell lacking a translocation involving the 2p23.2 band, using the ZytoDot® 2C CISH Implementation Kit, two red/green fusion signals are expected representing two normal (non-rearranged) 2p23.2 loci. A signal pattern consisting of one red/green fusion signal, one red signal, and a separate green signal indicates one normal 2p23.2 locus and one 2p23.2 locus affected by a translocation or inversion. EML4-ALK inversion with deletion of 5'-ALK sequences is indicated by one or multiple isolated red signals.



Lung carcinoma tissue section with translocation affecting the 2p23.2 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-3055-100	ZytoDot 2C SPEC ALK Break Apart Probe CE IVD	DIG/DNP	10 (100 μl)
C-3055-400	ZytoDot 2C SPEC ALK Break Apart Probe CE IVD	DIG/DNP	40 (400 μl)
<b>Related Products</b>			
C-3044-10	ZytoDot 2C CISH Implementation Kit CE IVD 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-Mix, 1 ml; 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 (alcoholic), 1 ml		10
C-3044-40	ZytoDot 2C CISH Implementation Kit CE IVD 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		40

\* 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