ZytoLight® SPEC ALK Dual Color Break Apart Probe

CE IVD

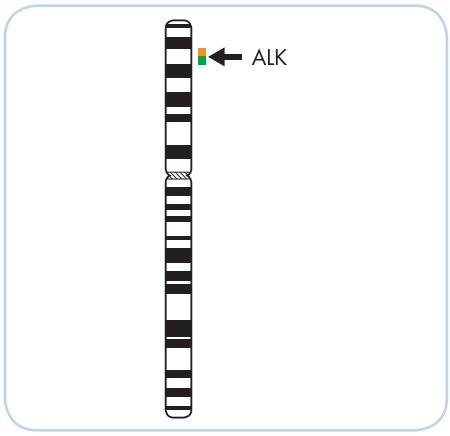
Background

The ZytoLight® SPEC ALK Dual Color Break Apart Probe (PL81) is intended to be used for the qualitative detection of translocations involving the human ALK gene at 2p23.1-p23.2 in formalin-fixed, paraffin-embedded specimens, such as non-small cell lung cancer (NSCLC), by fluorescence *in situ* hybridization (FISH).
The probe is intended to be used in combination with the ZytoLight® FISH-Tissue Implementation Kit (Prod. No. Z-2028-5/-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 NSCLC and therapeutic measures should not be initiated based on the test result alone.

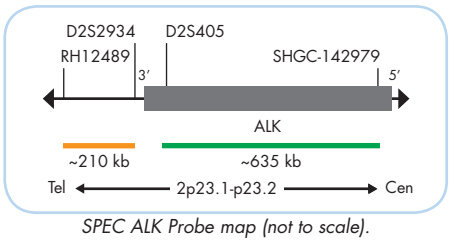
Probe Description

The ZytoLight® SPEC ALK Dual Color Break Apart Probe is composed of:

- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~10 ng/µl), which target sequences mapping in 2p23.1-p23.2** (chr2:29,460,144-30,095,822) proximal to the ALK breakpoint region.
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~4.5 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



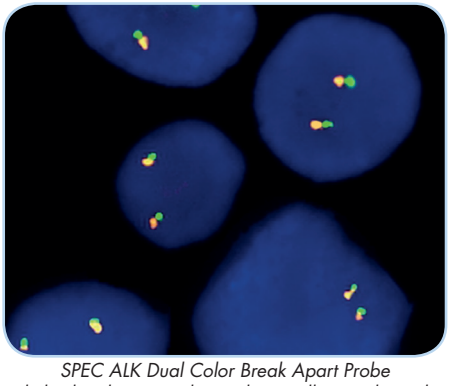
Ideogram of chromosome 2 indicating the hybridization locations.



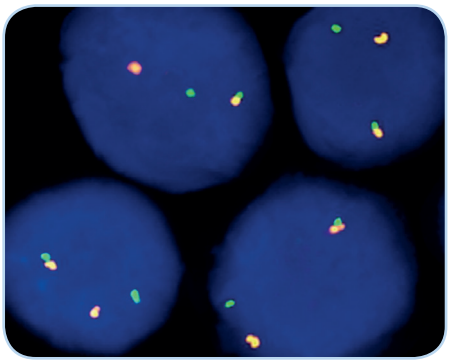
SPEC ALK Probe map (not to scale).

Results

In an interphase nucleus of a normal cell lacking a translocation involving the 2p23.1-p23.2 band, two orange/green fusion signals are expected representing two normal (non-rearranged) 2p23.1-p23.2 loci. A signal pattern consisting of one orange/green fusion signal, one orange signal, and a separate green signal indicates one normal 2p23.1-p23.2 locus and one 2p23.1-p23.2 locus affected by a translocation or inversion.
EML4-ALK inversion with deletion of 5'-ALK sequences is indicated by one or multiple isolated orange signals.



SPEC ALK Dual Color Break Apart Probe hybridized to normal interphase cells as indicated by two orange/green fusion signals per nucleus.



NSCLC tissue section with translocation affecting the 2p23 locus as indicated by one orange/green fusion (non-rearranged) signal, one orange signal, and one separate green signal.

Prod. No.	Product	Label	Tests* (Volume)
Z-2124-50	ZytoLight SPEC ALK Dual Color Break Apart Probe CE IVD	●/●	5 (50 µl)
Z-2124-200	ZytoLight SPEC ALK Dual Color Break Apart Probe CE IVD	●/●	20 (200 µl)
Related Products			
Z-2028-5	ZytoLight FISH-Tissue Implementation Kit CE IVD Incl. Heat Pretreatment Solution Citric, 150 ml; Pepsin Solution, 1 ml; Wash Buffer SSC, 210 ml; 25x Wash Buffer A, 50 ml; DAPI/DuraTect-Solution, 0.2 ml		5
Z-2028-20	ZytoLight FISH-Tissue Implementation Kit CE IVD Incl. Heat Pretreatment Solution Citric, 500 ml; Pepsin Solution, 4 ml; Wash Buffer SSC, 560 ml; 25x Wash Buffer A, 100 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*