

ZytoLight® SPEC ALK/EML4 TriCheck™ Probe



Background

The ZytoLight® SPEC ALK/EML4 TriCheck™ Probe (PL74) is intended to be used for the qualitative detection of rearrangements involving the human ALK gene at 2p23.1-p23.2 and the human EML4 gene at 2p21 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/EML4 TriCheck™ Probe is composed of:

- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~10.0 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.
- ZyBlue (excitation 418 nm/emission 467 nm) labeled polynucleotides (~37.0 ng/µl), which target sequences mapping in 2p21** (chr2:41,573,525-43,349,624) harboring the EML4 gene region.
- Formamide based hybridization buffer

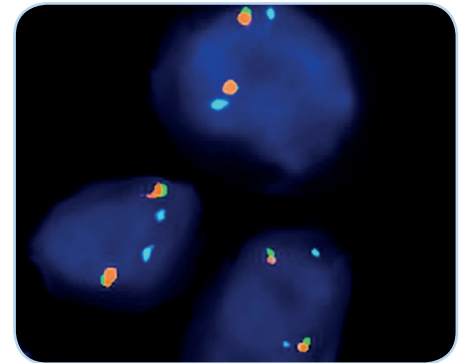
Results

In an interphase nucleus without rearrangement of the EML4-ALK locus, two orange/green fusion signals and two blue signals are expected.

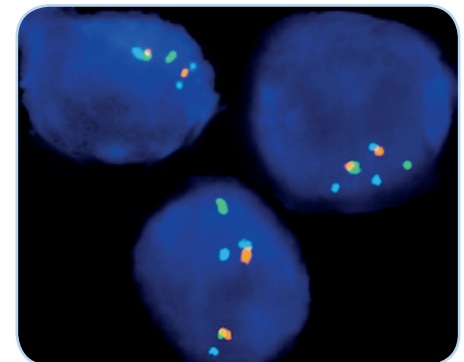
An EML4-ALK inversion is indicated by one separate green signal, one separate orange signal, and an additional blue signal.

An ALK translocation is indicated by separated orange and green signals without an additional blue signal.

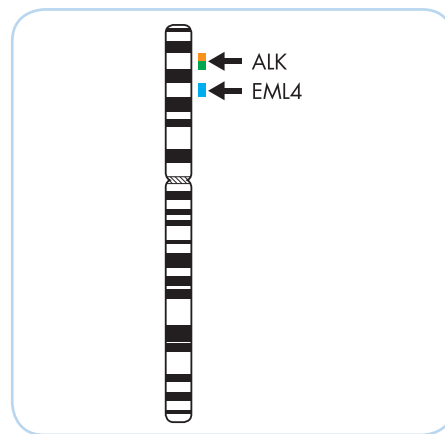
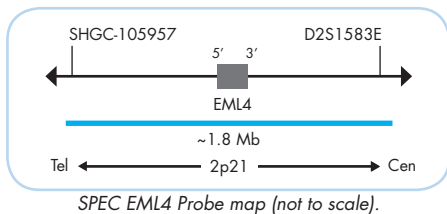
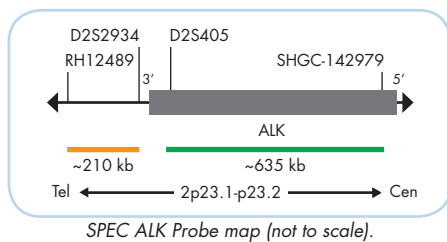
EML4-ALK inversion with deletion of 5'-ALK sequences is indicated by loss of one green signal and co-localization of the isolated orange signal with a blue signal.



SPEC ALK/EML4 TriCheck™ Probe on normal interphase cells with non-rearranged ALK loci (two orange/green fusion signals), and non-rearranged EML4 loci (two blue signals).



NSCLC tissue section with an EML4-ALK inversion as indicated by one green, one separated orange, and one additional blue signal.



Prod. No.	Product	Label	Tests* (Volume)
Z-2117-50	ZytoLight SPEC ALK/EML4 TriCheck Probe CE 0124 IVD	●/●/●	5 (50 µl)
Z-2117-200	ZytoLight SPEC ALK/EML4 TriCheck Probe CE 0124 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