

ZytoLight® SPEC ALK/2q11 Dual Color Probe



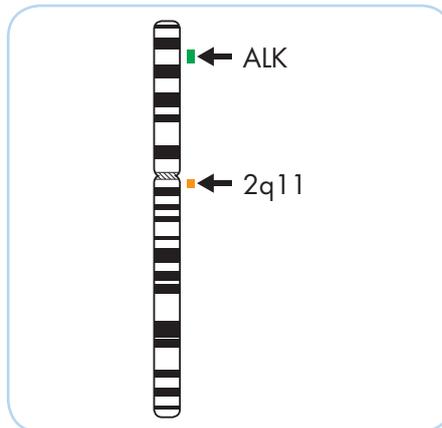
Background

The ZytoLight® SPEC ALK/2q11 Dual Color Probe (PL117) is intended to be used for the qualitative detection of amplifications involving the human ALK gene as well as the detection of chromosome 2q11 specific sequences in formalin-fixed, paraffin-embedded specimens 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 various cancers and therapeutic measures should not be initiated based on the test result alone.

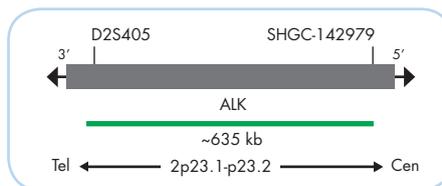
Probe Description

The ZytoLight® SPEC ALK/2q11 Dual Color Probe is composed of:

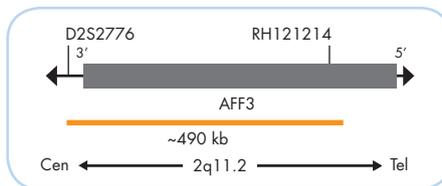
- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~10 ng/μl), which target sequences mapping in 2p23.1-p23.2** (chr2:29,460,144-30,095,822) harboring the ALK gene region.
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~4.5 ng/μl), which target sequences mapping in 2q11.2** (chr2:100,132,806-100,621,725).
- Formamide based hybridization buffer



Ideogram of chromosome 2 indicating the hybridization locations.



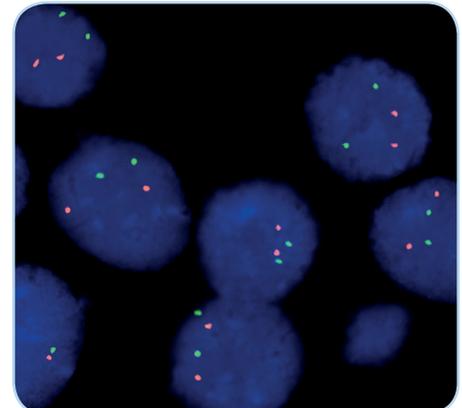
SPEC ALK Probe map (not to scale).



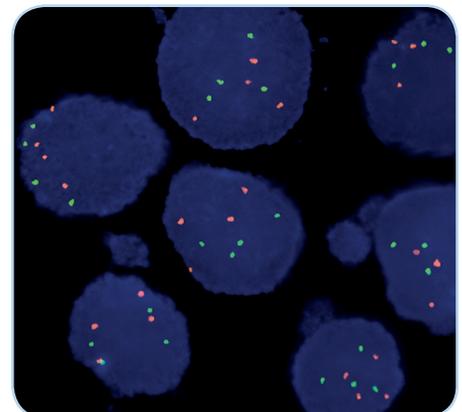
SPEC 2q11 Probe map (not to scale).

Results

In a normal interphase nucleus, two orange and two green signals are expected. In a cell with amplification of the ALK gene locus, multiple copies of the green signal or green signal clusters will be observed.



SPEC ALK/2q11 Dual Color Probe hybridized to normal interphase cells as indicated by two orange and two green signals in each nucleus.



Example of an aberrant signal pattern: Neuroblastoma tissue section with tetrasomy of chromosome 2 as indicated by four orange (2q11) and four green (ALK) signals in each nucleus.

| Prod. No. | Product | Label | Tests* (Volume) |
|--|---|-------|-----------------|
| Z-2161-200 | ZytoLight SPEC ALK/2q11 Dual Color Probe CE IVD | ●/● | 20 (200 μl) |
| Related Products | | | |
| Z-2028-20 | ZytoLight FISH-Tissue Implementation Kit CE IVD | | 20 |
| 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 | | | |

* 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