ZytoLight® SPEC NECTIN4/1p12 Dual Color Probe

CE 0124
IVD

Background

The ZytoLight® SPEC NECTIN4/1p12 Dual Color Probe (PL291) is intended to be used for the qualitative detection of amplifications involving the human NECTIN4 gene as well as the detection of chromosome 1p12 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).

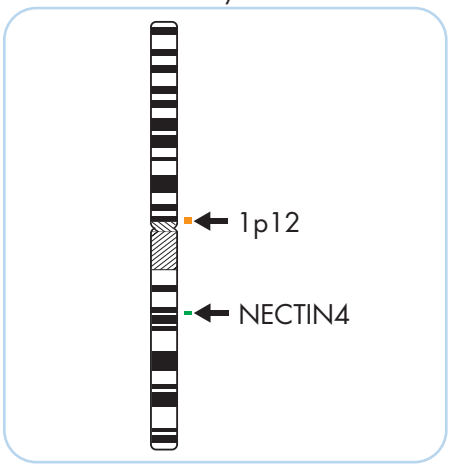
The product is intended for professional use only. All tests using the product should be performed in a certified, licensed anatomic pathology laboratory under the supervision of a pathologist/human geneticist by qualified personnel.

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.

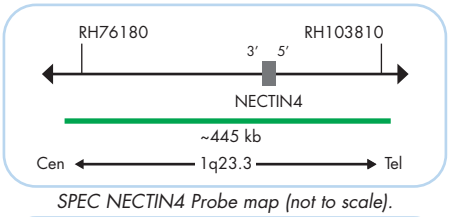
Probe Description

The ZytoLight® SPEC NECTIN4/1p12 Dual Color Probe is composed of:

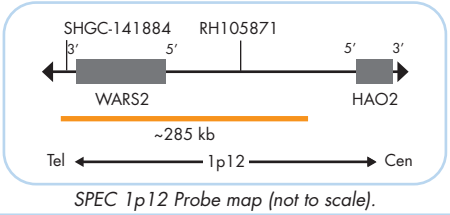
- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~10 ng/µl), which target sequences mapping in 1q23.3** (Chr1:160,773,463-161,218,427) harboring the NECTIN4 gene region.
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~4.5 ng/µl), which target sequences mapping in 1p12** (Chr1:119,537,102-119,823,147).
- Formamide based hybridization buffer



Ideogram of chromosome 1 indicating the hybridization locations.



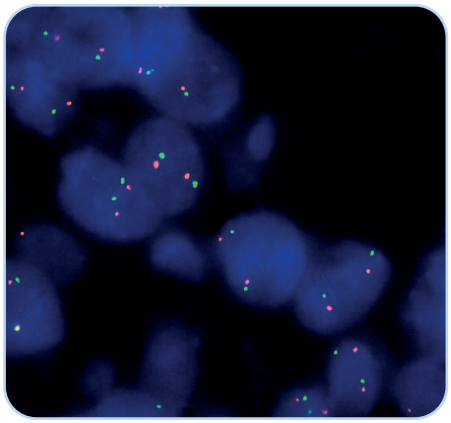
SPEC NECTIN4 Probe map (not to scale).



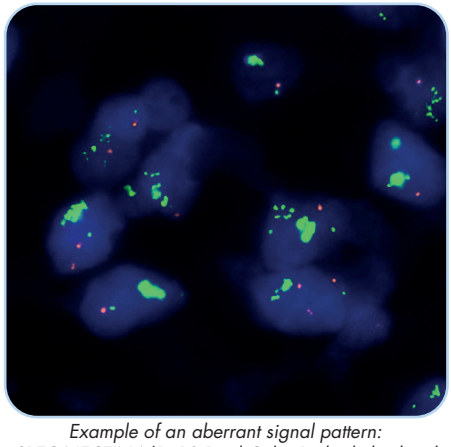
SPEC 1p12 Probe map (not to scale).

Results

In a normal interphase nucleus, two green and two orange signals are expected. In a cell with amplification of the NECTIN4 gene locus, multiple copies of the green signal or green signal clusters will be observed.



SPEC NECTIN4/1p12 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: SPEC NECTIN4/1p12 Dual Color Probe hybridized to urothelial carcinoma tissue section with amplification of the NECTIN4 gene as indicated by green signal clusters.

Prod. No.	Product	Label	Tests* (Volume)
Z-2331-50	ZytoLight SPEC NECTIN4/1p12 Dual Color Probe CE 0124 IVD	●/●	5 (50 µl)
Z-2331-200	ZytoLight SPEC NECTIN4/1p12 Dual Color 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*