ZytoLight® SPEC FOXO1 Dual Color Break Apart Probe

Background

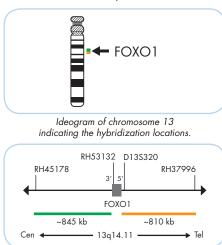
The ZytoLight [®] SPEC FOXO1 Dual Color Break Apart Probe (PL96) is intended to be used for the qualitative detection of translocations involving the human FOXO1 gene at 13q14.11 in formalin-fixed, paraffin-embedded specimens, such as alveolar rhabdomyosarcoma (ARMS), by fluorescence *in situ* hybridization (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 ARMS and therapeutic measures should not be initiated based on the test result alone.

Probe Description

The Zyto*Light* [®] SPEC FOXO1 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 13q14.11** (chr13:40,285,558-41,132,595) proximal to the FOXO1 breakpoint region.
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~4.5 ng/µl), which target sequences mapping in 13q14.11** (chr13:41,246,917-42,054,781) distal to the FOXO1 breakpoint region.
- · Formamide based hybridization buffer



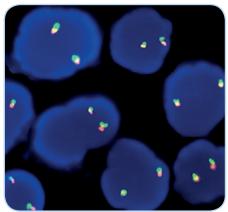
SPEC FOXO1 Probe map (not to scale).

Results

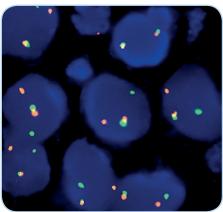
In an interphase nucleus lacking a translocation involving the 13q14.11 band, two orange/green fusion signals are expected representing two normal (non-rearranged) 13q14.11 loci. A signal pattern consisting of one orange/green fusion signal, one orange signal, and a separate green signal indicates one normal 13q14.11 locus and one 13q14.11 locus affected by a translocation.

CE

IVD



SPEC FOXO1 Dual Color Break Apart Probe hybridized to normal interphase cells as indicated by two orange/green fusion signals per nucleus.



Rhabdomyosarcoma tissue section with translocation affecting the 13q14.11 locus harboring FOXO1 as indicated by one orange/green fusion signal (non-rearranged), one orange signal, and one separate green signal.

FE059-1-23

Prod. No.	Product	Label	Tests* (Volume)
Z-2139-50	Zyto <i>Light</i> SPEC FOXO1 Dual Color Break Apart Probe ⊂ € IVD	●/●	5 (50 µl)
Related Pro	ducts		
Z-2028-5	Zyto <i>Light</i> FISH-Tissue Implementation Kit C € IVD		5
	Incl. Heat Pretreatment Solution Citric, 150 ml; Pepsin Solution, 1ml; Wash Buffer SSC, 210 ml; 25x Wash Buffer A, 50 ml; DAPI/DuraTect-Solution, 0.2 ml		
lsing 10 µl probe solu	tion per test. 呕 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		ZY1	
ZutoVision GmbH - Fischkai 1 - 27572 Bremerhaven - Germany - www.zytovision.com		Moleculo	ar diagnostics simplified