ZytoLight® SPEC MDM2/CEN 12 Dual Color Probe

Intended Purpose

The ZytoLight SPEC MDM2/CEN 12 Dual Color Probe (PL18) is intended to be used for the qualitative detection of amplifications involving the human MDM2 gene as well as the detection of chromosome 12 alpha satellites in formalin-fixed, paraffin-embedded specimens, such as atypical lipomatous tumor/well differentiated liposarcoma (ALT/WDLPS) and dedifferentiated liposarcoma (DDLPS), 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 ALT/WDLPS and DDLPS and therapeutic measures should not be initiated based on the test result alone.

Probe Description

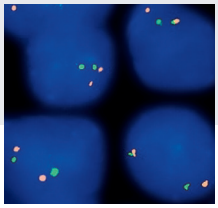
The ZytoLight SPEC MDM2/CEN 12 Dual Color Probe is composed of:

- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~10 ng/µl), which target sequences mapping in 12q15* (chr12:69,071,802-69,565,421) harboring the MDM2 gene region (see Fig. 1).
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~1.5 ng/µl), which target sequences mapping in 12p11.1-q11 specific for the alpha satellite centromeric region D12Z3 of chromosome 12.
- Formamide based hybridization buffer

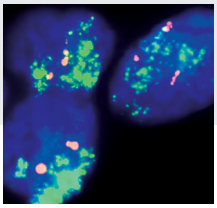
* according to Human Genome Assembly GRCh37/hg19

Results

Normal situation: In interphases of normal cells or cells without an amplification involving the MDM2 gene region, two green signals and two orange signals appear.
Aberrant situation: In cells with an amplification of the MDM2 gene region an increased number of green signals or green signal clusters will be observed.



Normal interphase cells, MDM2 (green), CEN 12 (orange).



Liposarcoma tissue section with amplification of the MDM2 gene (green), CEN 12 (orange).

Labels	Chromosome	Reg. Status	Tests	Order No.
●|●	12	CE/IVD	5 (50 µl)	**Z-2013-50**
			20 (200 µl)	**Z-2013-200**

ZytoLight® SPEC FOXO1 Dual Color Break Apart Probe

Intended Purpose

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.

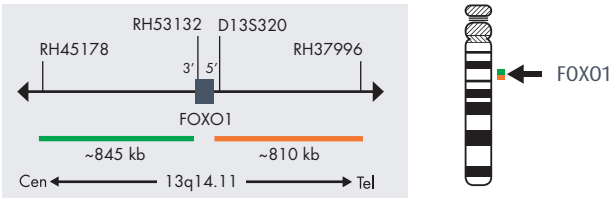
The probe is intended to be used as an aid to the differential diagnosis of ARMS and therapeutic measures should not be initiated based on the test result alone.

Probe Description

The ZytoLight SPEC FOXO1 Dual Color Break Apart Probe is composed of:

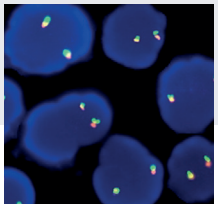
- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~10 ng/µl), which target sequences mapping in 13q14.11* (chr13:40,285,558-41,132,595) proximal to the FOXO1 breakpoint region (see Fig. 1).
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~4,5 ng/µl), which target sequences mapping in 13q14.11* (chr13:41,246,917-42,054,781) distal to the FOXO1 breakpoint region (see Fig. 1).
- Formamide based hybridization buffer

* according to Human Genome Assembly GRCh37/hg19

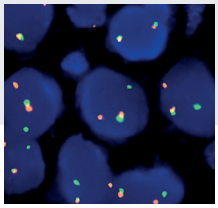


Results

Normal situation: In interphases of normal cells or cells without a translocation involving the FOXO1 gene region, two green/orange fusion signals appear.
Aberrant situation: One FOXO1 gene region affected by a translocation is indicated by one separate green signal and one separate orange signal.



Hybridized to normal interphase cells as indicated by two orange/green fusion signals per nucleus.



Labels	Chromosome	Reg. Status	Tests	Order No.
●|●	13	CE/IVD	5 (50 µl)	**Z-2139-50**