ZytoLight® SPEC EWSR1 Dual Color Break Apart Probe

Intended Purpose

The ZytoLight SPEC EWSR1 Dual Color Break Apart Probe (PL55) is intended to be used for the qualitative detection of translocations involving the human EWSR1 gene at 22q12.2 in formalin-fixed, paraffin-embedded specimens, such as Ewing sarcoma, 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 Ewing sarcoma and therapeutic measures should not be initiated based on the test result alone.

Probe Description

The ZytoLight SPEC EWSR1 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 22q12.2* (chr22:29,779,841-30.179,900) distal to the EWSR1 breakpoint region (see Fig. 1).
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~4,5 ng/µl), which target sequences mapping in 22q12.1-q12.2* (chr22:29,191,431-29,673,440) proximal to the EWSR1 breakpoint region (see Fig. 1).
- Formamide based hybridization buffer

* according to Human Genome Assembly GRCh37/hg19

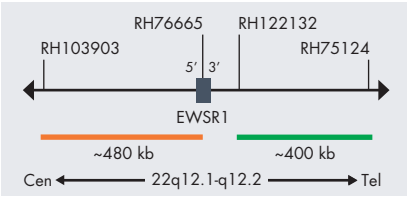
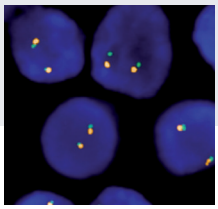


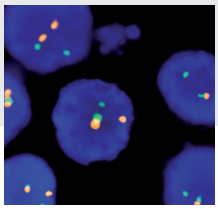
Fig. 1: SPEC EWSR1 Probe map (not to scale); Right: Ideogram of chromosome 22 indicating the hybridization locations

Results

Normal situation: In interphases of normal cells or cells without a translocation involving the EWSR1 gene region, two green/orange fusion signals appear.
Aberrant situation: One EWSR1 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.



Ewing sarcoma tissue section with translocation affecting the 22q12.1-q12.2 locus as indicated by one non-rearranged orange/green fusion signal, one orange signal, and one separate green signal.

Labels	Chromosome	Reg. Status	Tests	Order No.
●|●	22	CE/IVD	5 (50 µl)	**Z-2096-50**
			20 (200 µl)	**Z-2096-200**

ZytoLight® SPEC EWSR1/FLI1 TriCheck™ Probe

Intended Purpose

The ZytoLight SPEC EWSR1/FLI1 TriCheck Probe (PL141) is intended to be used for the qualitative detection of rearrangements involving the human EWSR1 gene at 22q12.2 and the human FLI1 gene at 11q24.3 in formalin-fixed, paraffin-embedded specimens, such as Ewing sarcoma, 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 Ewing sarcoma and therapeutic measures should not be initiated based on the test result alone.

Probe Description

The ZytoLight SPEC EWSR1/FLI1 TriCheck Probe is composed of:

- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~10,0 ng/µl), which target sequences mapping in 22q12.2* (chr22:29,779,841-30.179,900) distal to the EWSR1 breakpoint region (see Fig. 1).
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~4,5 ng/µl), which target sequences mapping in 22q12.1-q12.2* (chr22:29,191,431-29,673,440) proximal to the EWSR1 breakpoint region (see Fig. 1).
- ZyBlue (excitation 418 nm/emission 467 nm) labeled polynucleotides (~37,0 ng/µl), which target sequences mapping in 11q24.3* (chr11:128,707,454-129,346,602) distal to the FLI1 breakpoint region (see Fig. 1).
- Formamide based hybridization buffer

* according to Human Genome Assembly GRCh37/hg19

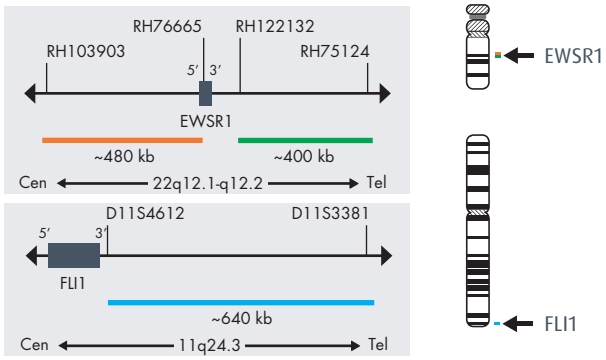
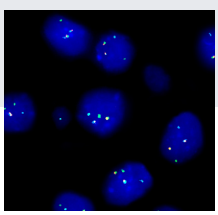


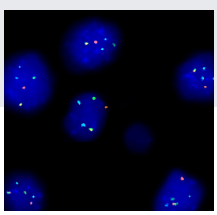
Fig. 1: Top: SPEC EWSR1 Probe map; Bottom: SPEC FLI1 Probe map (not to scale); Right: Ideograms of chromosome 22 and 11 indicating the hybridization locations

Results

Normal situation: In interphases of normal cells or cells without FLI1-EWSR1 rearrangement, two green/orange fusion signals and two blue signals are expected.
Aberrant situation: A FLI1-EWSR1 fusion is indicated by one separate orange signal co-localizing with one blue signal and one separate green signal. An EWSR1 translocation without involvement of FLI1 is indicated by the split of one green/orange fusion signal without co-localization of the separated orange signal with one blue signal.



Ewing sarcoma tissue section with FLI1-EWSR1 fusion as indicated by orange/blue fusion signals.



Ewing sarcoma tissue section with a non-FLI1 EWSR1 rearrangement as indicated by the lack of co-localization of the separated orange signal with one blue signal.

Labels	Chromosome	Reg. Status	Tests	Order No.
●|●|●	11, 22	CE/IVD	5 (50 µl)	**Z-2183-50**