ZytoLight® SPEC MYC Dual Color Break Apart Probe

Intended Purpose

The ZytoLight SPEC MYC Dual Color Break Apart Probe (PL49) is intended to be used for the qualitative detection of translocations involving the human MYC gene at 8q24.21 in cytologic or formalin-fixed, paraffin-embedded specimens, such as diffuse large B-cell lymphoma (DLBCL) or Burkitt lymphoma (BL), by fluorescence *in situ* hybridization (FISH). The probe is intended to be used in combination with the ZytoLight FISH Implementation Kits (Prod. No. Z-2028-5/-20, or Z-2099-20).

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.

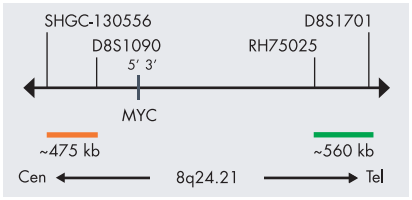
The probe is intended to be used as an aid to the differential diagnosis of DLBCL or BL and therapeutic measures should not be initiated based on the test result alone.

Probe Description

The ZytoLight SPEC MYC 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 8q24.21* (chr8:130,373,051-130,930,673) distal to the MYC breakpoint region (see Fig.1).
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~4.5 ng/µl), which target sequences mapping in 8q24.21* (chr8:127,888,765-128,363,281) proximal to the MYC breakpoint region (see Fig. 1).
- Formamide based hybridization buffer

* according to Human Genome Assembly GRCh37/hg19



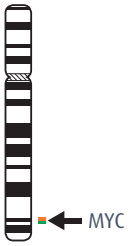
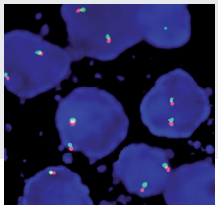


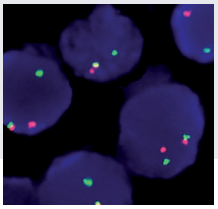
Fig. 1: SPEC MYC Probe map (not to scale); Right: Ideogram of chromosome 8 indicating the hybridization locations

Results

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



Burkitt lymphoma tissue section with translocation affecting the 8q24.21 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.
●|●	8	CE/IVD	5 (50 µl)	**Z-2090-50**
			20 (200 µl)	**Z-2090-200**

ZytoLight® SPEC MYC/CEN 8 Dual Color Probe

Intended Purpose

The ZytoLight SPEC MYC/CEN 8 Dual Color Probe (PL51) is intended to be used for the qualitative detection of amplifications involving the human MYC gene as well as the detection of chromosome 8 alpha satellites in formalin-fixed, paraffin-embedded specimens, such as breast cancer, 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.

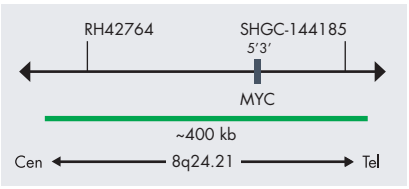
The probe is intended to be used as an aid to the differential diagnosis of breast cancer and therapeutic measures should not be initiated based on the test result alone.

Probe Description

The ZytoLight MYC/CEN 8 Dual Color Probe is composed of:

- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~10 ng/µl), which target sequences mapping in 8q24.21* (chr8:128,487,995-128,887,929) harboring the MYC gene region (see Fig. 1).
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~1,5 ng/µl), which target sequences mapping in 8p11.1-q11.1 specific for the alpha satellite centromeric region D8Z2 of chromosome 8.
- Formamide based hybridization buffer

* according to Human Genome Assembly GRCh37/hg19



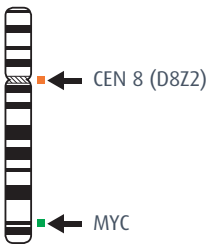
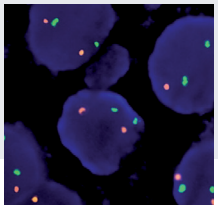


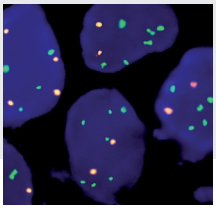
Fig. 1: SPEC MYC Probe map (not to scale);
Right: Ideogram of chromosome 8 indicating the hybridization locations

Results

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



Hybridized to normal interphase cells as indicated by two orange and two green signals in each nucleus.



Breast cancer tissue section with interphase cells showing partly polysomy 8 and partly amplification of the MYC gene locus.

Labels	Chromosome	Reg. Status	Tests	Order No.
●|●	8	CE/IVD	5 (50 µl)	**Z-2092-50**
			20 (200 µl)	**Z-2092-200**