FlexISH® MYC/IGH TriCheck™ Probe

Intended Purpose

The FlexISH MYC/IGH TriCheck Probe (PL247) is intended to be used for the qualitative detection of human MYC rearrangements with and without participation of the human IGH locus in formalin-fixed, paraffin-embedded specimens by fluorescence *in situ* hybridization (FISH). The probe is intended to be used in combination with the FlexISH-Tissue Implementation Kit (Prod. No. Z-2182-5/-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 FlexISH MYC/IGH TriCheck 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 (~2,5 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).
- ZyBlue (excitation 418 nm/emission 467 nm) labeled polynucleotides (~70,0 ng/µl), which target sequences mapping in 14q32.33* (chr14:105,462,169-106,995,000) harboring the IGH locus. (see Fig. 1).
- Formamide based hybridization buffer

* according to Human Genome Assembly GRCh37/hg19

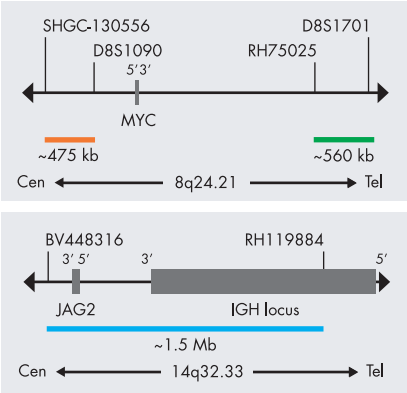
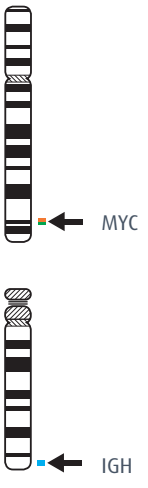


Fig. 1: Top: MYC Probe map; Bottom: IGH Probe map (not to scale)

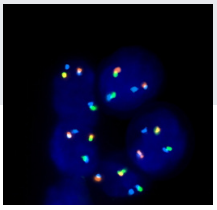


Ideograms of chromosome 8 and 14 indicating the hybridization locations

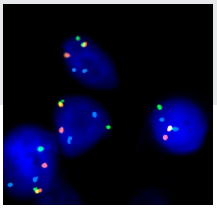
Results

Normal situation: In interphases of normal cells or cells without MYC rearrangements, two green/orange fusion signals appear when using an appropriate dual bandpass filter set and two blue signals appear when using an appropriate single bandpass filter set. When using an appropriate triple color bandpass filter set, two green/orange fusion signals and two blue signals can be observed.

Aberrant situation: A rearrangement of the MYC gene region not involving the IGH locus is indicated by a green/orange fusion signal, separated single green and orange signals and two blue signals. A MYC rearrangement involving the IGH locus is indicated by one green/orange fusion signal, one separate blue signal and one green/blue fusion signal as well as one orange/blue fusion signal. In a cell with a rearrangement of the IGH locus not involving the MYC gene or a trisomy of chromosome 14, two green/orange fusion signals and three blue signals can be observed.



Example of an aberrant signal pattern: Non-Hodgkin lymphoma tissue section with t(8;14) as indicated by one separate green and one separate orange signal, and one additional blue signal.



Example of an aberrant signal pattern: Non-Hodgkin lymphoma tissue section with translocation of the MYC gene without IGH involvement as indicated by one separate green and one separate orange signal, without an additional blue signal.

Labels	Chromosome	Reg. Status	Tests	Order No.
●|●|●	8, 14	CE/IVD	5 (50 µl)	**Z-2293-50**