FlexISH® MYC/IGH TriCheck™ Probe

CE IVD

Background

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.

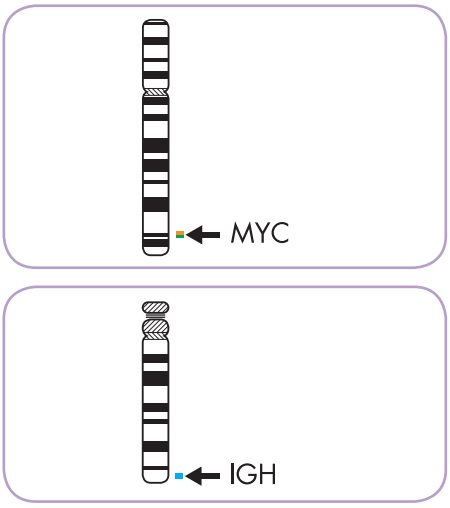
Probe Description

The FlexISH® MYC/IGH TriCheck™ Probe is composed of:

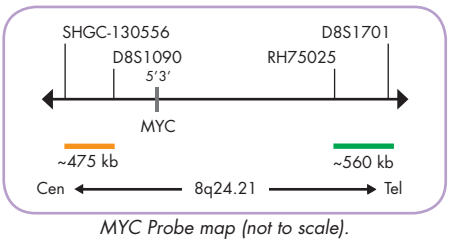
- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~10.0 ng/µl), which target sequences mapping in 8q24.21** (chr8:130,373,051-130,930,673) distal to the MYC breakpoint region.
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~2.5 ng/µl), which target sequences mapping in 8q24.21** (chr8:127,888,765-128,363,281) proximal to the MYC breakpoint region.
- ZyBlue (excitation 418 nm/emission 467 nm) labeled polynucleotides (~70 ng/µl), which target sequences mapping in 14q32.33** (chr14:105,462,169-106,995,000) harboring the IGH locus.
- Formamide based hybridization buffer

Results

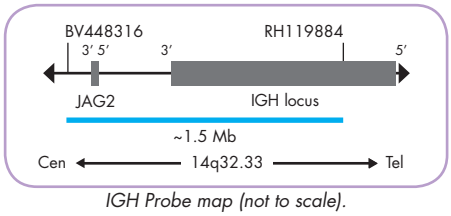
In an interphase nucleus without rearrangements of the MYC/IGH loci, two green/orange fusion signals and two blue signals are expected.
A MYC-IGH fusion is indicated by one separate green signal and one separate orange signal, both co-localizing with blue signals. A MYC translocation without involvement of IGH is indicated by separated orange and green signals without co-localization of the separated signals with blue signals.



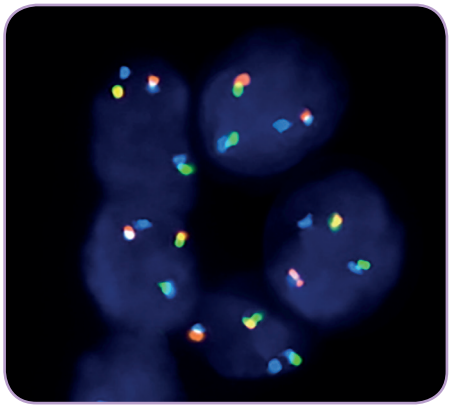
Ideograms of chromosomes 8 (above) and 14 (below) indicating the hybridization locations.



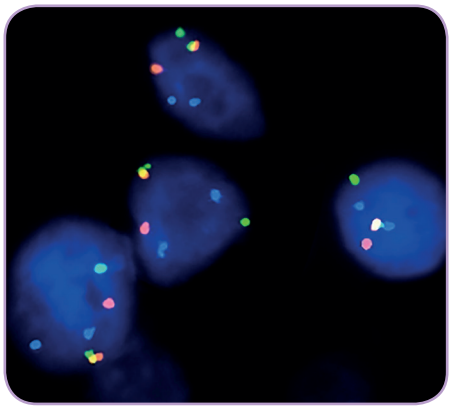
MYC Probe map (not to scale).



IGH Probe map (not to scale).



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.

Prod. No.	Product	Label	Tests* (Volume)
Z-2293-50	FlexISH MYC/IGH TriCheck Probe CE IVD	●/●/●	5 (50 µl)
Related Products			
Z-2182-5	FlexISH-Tissue Implementation Kit CE IVD Incl. Heat Pretreatment Solution Citric, 150 ml; Pepsin Solution, 1 ml; 5x FlexISH Wash Buffer, 150 ml; DAPI/DuraTect-Solution, 0.2 ml		5

** Using 10 µl probe solution per test. IVD 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*