FlexISH® RET/KIF5B TriCheck™ Probe

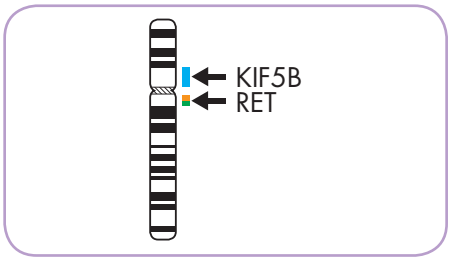
CE IVD

Background

The FlexISH® RET/KIF5B TriCheck™ Probe (PL226) is intended to be used for the qualitative detection of rearrangements involving the human RET gene in with and without participation of the human KIF5B gene 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.

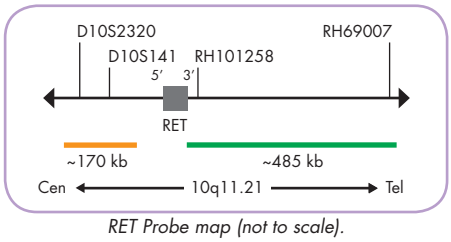


Ideogram of chromosome 10 indicating the hybridization locations.

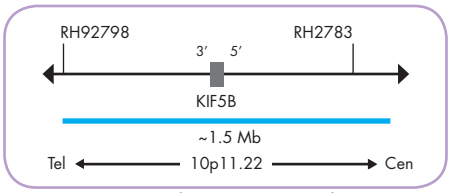
Probe Description

The FlexISH® RET/KIF5B TriCheck™ Probe is composed of:

- ZyOrange (excitation 547 nm/ emission at 572 nm) labeled polynucleotides (~2.5 ng/µl), which target sequences mapping in 10q11.21** (chr10:43,340,888-43,510,171) proximal to the RET breakpoint region.
- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~10 ng/µl), which target sequences mapping in 10q11.21** (chr10:43,626,274-44,112,146) distal to the RET breakpoint region.
- ZyBlue (excitation 418 nm/emission at 467 nm) labeled polynucleotides (~70 ng/µl), which target sequences mapping in 10p11.22** (chr10:31,640,467-33,085,804) harboring the KIF5B gene region.
- Formamide based hybridization buffer



RET Probe map (not to scale).



KIF5B Probe map (not to scale).

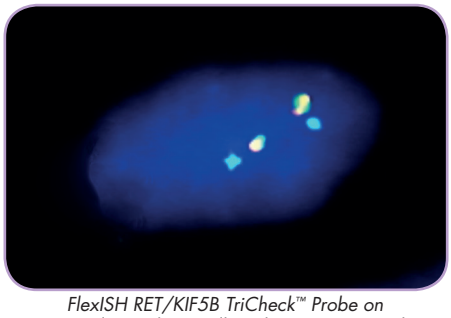
Results

In an interphase nucleus without rearrangements of the KIF5B/RET locus, two green/orange fusion signals and two blue signals are expected.

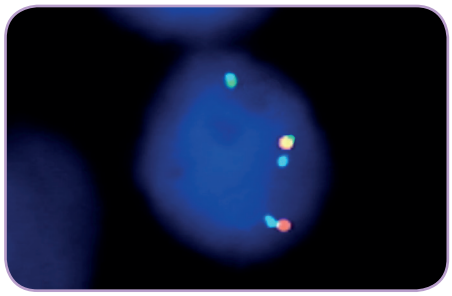
A KIF5B-RET inversion is indicated by one separate green signal, one separate orange signal, and an additional blue signal.

A RET translocation is indicated by separated orange and green signals without an additional blue signal.

KIF5B-RET inversion with deletion of the 5′-RET sequences is indicated by loss of one orange signal and co-localization of the isolated green signal with a blue signal.



FlexISH RET/KIF5B TriCheck™ Probe on normal interphase cells with non-rearranged RET loci (two green/orange fusion signals), and non-rearranged KIF5B loci (two blue signals).



Example of an aberrant signal pattern: NSCLC tissue section with a KIF5B-RET inversion as indicated by one green, one separated orange, and an additional blue signal.

Specimen kindly provided by Dr. Schildhaus, Essen, Germany.

Prod. No.	Product	Label	Tests* (Volume)
Z-2269-50	FlexISH RET/KIF5B TriCheck Probe CE IVD	●/●/●	5 (50 µl)
Z-2269-200	FlexISH RET/KIF5B TriCheck Probe CE IVD	●/●/●	20 (200 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
Z-2182-20	FlexISH-Tissue Implementation Kit CE IVD Incl. Heat Pretreatment Solution Citric, 500 ml; Pepsin Solution, 4 ml; 5x FlexISH Wash Buffer, 500 ml; DAPI/DuraTect-Solution, 0.8 ml		20

** 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*