ZytoLight® SPEC BCR/ABL1 Dual Color Dual Fusion Probe

Intended Purpose

The Zyto*Light* SPEC BCR/ABL1 Dual Color Dual Fusion Probe (PL68) is intended to be used for the qualitative detection of the translocation t(9;22)(q34.1;q11.2) involving the human BCR and ABL1 genes in cytologic specimens, such as chronic myeloid leukemia (CML), by fluorescence *in situ* hybridization (FISH). The probe is intended to be used in combination with the Zyto*Light* FISH-Cytology Implementation Kit (Prod. No. 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 CML and therapeutic measures should not be initiated based on the test result alone.

Probe Description

The Zyto*Light* SPEC BCR/ABL1 Dual Color Dual Fusion Probe is composed of:

- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~12,0 ng/µl), which target sequences mapping in 22q11.22-q11.23* (chr22:23,000,029-24,431,064) harboring the BCR gene region (see Fig. 1).
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~6 ng/µl), which target sequences mapping in 9q34.11-q34.13* (chr9:133,223,081-134,103,849) harboring the ABL1 gene region (see Fig. 1).
- Formamide based hybridization buffer

* according to Human Genome Assembly GRCh37/hg19

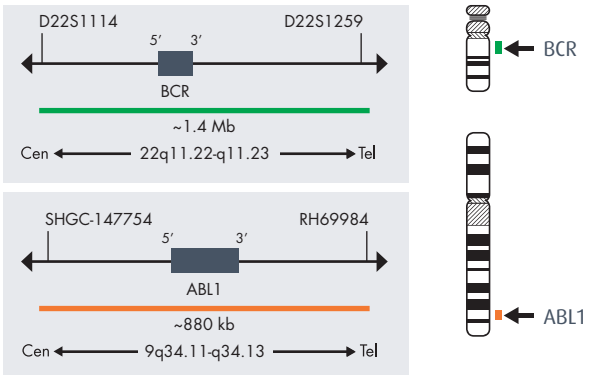
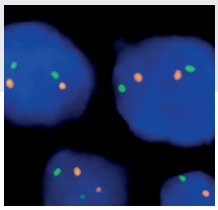


Fig. 1: Top: SPEC BCR Probe map; Bottom: SPEC ABL1 Probe map (not to scale); Right: Ideograms of chromosome 22 and 9 indicating the hybridization locations

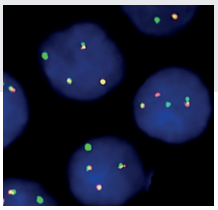
Results

Normal situation: In interphases of normal cells or cells without a translocation involving the respective gene regions, two separate green and orange signals appear.

Aberrant situation: A gene fusion is indicated by one separate orange signal, one separate green signal, and two orange/green fusion signals.



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



Bone marrow specimen with translocation affecting the BCR/ABL1 loci as indicated by one separate orange signal, one separate green signal and two orange/green fusion signals.

Labels	Chromosome	Reg. Status	Tests	Order No.
●|●	9, 22	CE/IVD	5 (50 µl)	**Z-2111-50**
			20 (200 µl)	**Z-2111-200**

ZytoLight® SPEC RET Dual Color Break Apart Probe

Intended Purpose

The Zyto*Light* SPEC RET Dual Color Break Apart Probe (PL105) is intended to be used for the qualitative detection of translocations involving the human RET gene at 10q11.21 in formalin-fixed, paraffin-embedded specimens, such as non-small cell lung cancer (NSCLC) or papillary thyroid carcinoma (PTC), by fluorescence *in situ* hybridization (FISH). The probe is intended to be used in combination with the Zyto*Light* 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 NSCLC or PTC and therapeutic measures should not be initiated based on the test result alone.

Probe Description

The Zyto*Light* SPEC RET 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 10q11.21* (chr10:43,626,274-43,902,346) distal to the RET breakpoint region (see Fig. 1).
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~4,5 ng/µl), which target sequences mapping in 10q11.21* (chr10:43,340,888-43,510.171) proximal to the RET breakpoint region (see Fig. 1).
- Formamide based hybridization buffer

* according to Human Genome Assembly GRCh37/hg19

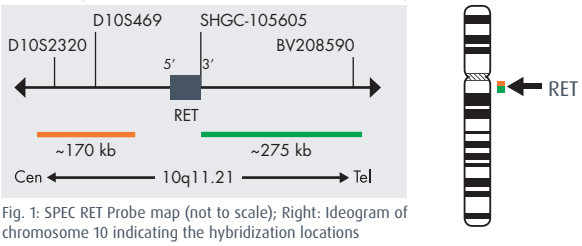
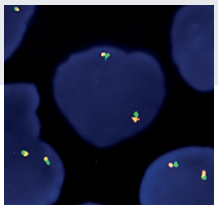


Fig. 1: SPEC RET Probe map (not to scale); Right: Ideogram of chromosome 10 indicating the hybridization locations

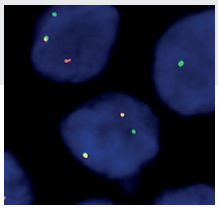
Results

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

Aberrant situation: One RET gene region affected by a translocation is indicated by one separate green signal and one separate orange signal. Isolated green signals are the result of deletions proximal to the RET breakpoint region. Inversions involving genes in close proximity such as CCDC6 might not be observable due to just subtle signal separation.



Hybridized to normal interphase cells as indicated by two orange/green fusion signals per nucleus.



Paraffin-embedded human thyroid tumor cell line (TPC-1) with translocation affecting the 10q11.21 locus as indicated by one orange/green fusion (non-rearranged) signal, one orange signal, and one separate green signal.

Labels	Chromosome	Reg. Status	Tests	Order No.
●|●	10	CE/IVD	5 (50 µl)	**Z-2148-50**
			20 (200 µl)	**Z-2148-200**