ZytoLight® SPEC GATA2/MECOM Dual Color Dual Fusion Probe

Intended Purpose

The Zyto*Light* SPEC GATA2/MECOM Dual Color Dual Fusion Probe (PL242) is intended to be used for the qualitative detection of the translocation t(3;3)(q21.3;q26.2) as well as the inversion inv(3)(q21.3q26.2) involving the human GATA2 and MECOM genes in cytologic specimens 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 various cancers and therapeutic measures should not be initiated based on the test result alone.

Probe Description

The Zyto*Light* SPEC GATA2/MECOM Dual Color Dual Fusion Probe is composed of:

- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~6,0 ng/µl), which target sequences mapping in 3q21.3* (chr3:127,902,316-128,564,215) harboring the GATA2 gene region (see Fig. 1).
- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~12,0 ng/µl), which target sequences mapping in 3q26.2* (chr3:168,249,484-169,743,447) harboring the MECOM gene region (see Fig. 1).
- Formamide based hybridization buffer

* according to Human Genome Assembly GRCh37/hg19

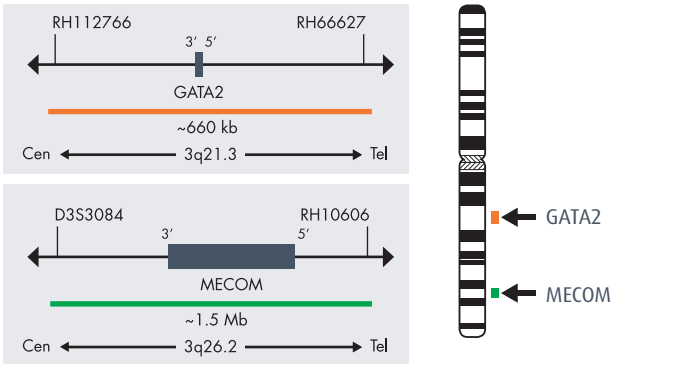
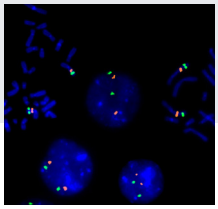


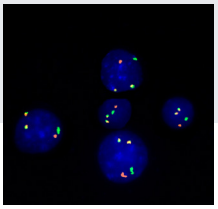
Fig. 1: Top: SPEC GATA2 Probe map; Bottom: SPEC MECOM Probe map (not to scale); Right: Ideogram of chromosome 3 indicating the hybridization locations

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. Three green signals and two orange signals are the result of a translocation affecting the MECOM gene region without the involvement of the GATA2 locus.



Hybridized to normal interphase cells as indicated by two orange and two green signals and to metaphase chromosomes of a normal cell.



Example of an aberrant signal pattern: Bone marrow smear with rearrangement affecting the GATA2/MECOM 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.
●|●	3	CE/IVD	5 (50 µl)	**Z-2287-50**

ZytoLight® SPEC PIK3CA/CEN 3 Dual Color Probe

Intended Purpose

The Zyto*Light* SPEC PIK3CA/CEN 3 Dual Color Probe (PL97) is intended to be used for the qualitative detection of amplifications involving the human PIK3CA gene as well as the detection of chromosome 3 alpha satellites in formalin-fixed, paraffin-embedded specimens 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 various cancers and therapeutic measures should not be initiated based on the test result alone.

Probe Description

The Zyto*Light* SPEC PIK3CA/CEN 3 Dual Color Probe is composed of:

- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~10 ng/µl), which target sequences mapping in 3q26.32-q26.33* (chr3:178,535,986-179,293,464) harboring the PIK3CA gene region (see Fig. 1).
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~1,5 ng/µl), which target sequences mapping in 3p11.1-q11.1 specific for the alpha satellite centromeric region D3Z1 of chromosome 3.
- Formamide based hybridization buffer

* according to Human Genome Assembly GRCh37/hg19

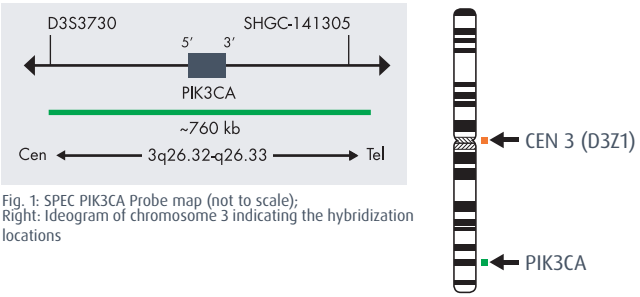
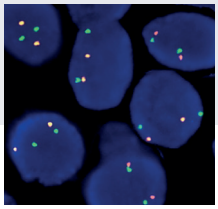


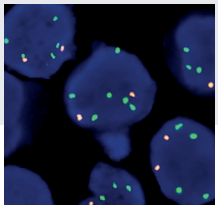
Fig. 1: SPEC PIK3CA Probe map (not to scale); Right: Ideogram of chromosome 3 indicating the hybridization locations

Results

Normal situation: In interphases of normal cells or cells without an amplification involving the PIK3CA gene region, two green and two orange signals appear.
Aberrant situation: In cells with an amplification of the PIK3CA 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.



Example of an aberrant signal pattern: Human breast cancer cell line with amplification of the PIK3CA gene as indicated by multiple green signals in each nucleus.

Labels	Chromosome	Reg. Status	Tests	Order No.
●|●	3	CE/IVD	20 (200 µl)	**Z-2140-200**