ZytoLight® SPEC BRAF Dual Color Break Apart Probe

Intended Purpose

The ZytoLight SPEC BRAF Dual Color Break Apart Probe (PL147) is intended to be used for the qualitative detection of translocations involving the human BRAF gene at 7q34 in formalin-fixed, paraffin-embedded specimens by fluorescence *in situ* hybridization (FISH). The probe is intended to be used in combination with the ZytoLight 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 ZytoLight SPEC BRAF 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 7q34* (chr7:140.535,100-141,233,856) distal to the BRAF breakpoint region (see Fig. 1).
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~4,5 ng/µl), which target sequences mapping in 7q34* (chr7:139,972,721-140,469,362) proximal to the BRAF breakpoint region (see Fig. 1).
- Formamide based hybridization buffer

* according to Human Genome Assembly GRCh37/hg19

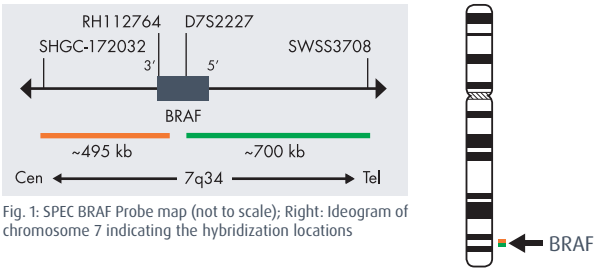
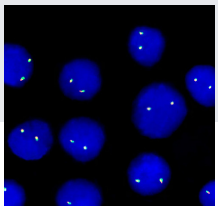


Fig. 1: SPEC BRAF Probe map (not to scale); Right: Ideogram of chromosome 7 indicating the hybridization locations

Results

Normal situation: In interphases of normal cells or cells without a translocation involving the BRAF gene region, two green/orange fusion signals appear.
Aberrant situation: One BRAF gene region affected by a translocation is indicated by one separate green signal and one separate orange signal. A deletion of 5′ BRAF sequences resulting in a FAM131B-BRAF fusion is indicated by the loss of one green signal.



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

Labels	Chromosome	Reg. Status	Tests	Order No.
●| ●	7	CE/IVD	20 (200 µl)	**Z-2189-200**

ZytoLight® SPEC BRAF/CEN 7 Dual Color Probe

Intended Purpose

The ZytoLight SPEC BRAF/CEN 7 Dual Color Probe (PL149) is intended to be used for the qualitative detection of amplifications involving the human BRAF gene as well as the detection of chromosome 7 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 ZytoLight 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 ZytoLight SPEC BRAF/CEN 7 Dual Color Probe is composed of:

- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~10 ng/µl), which target sequences mapping in 7q34* (chr7:140,266,210-140,792,511) harboring the BRAF gene region (see Fig. 1).
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~1,5 ng/µl), which target sequences mapping in 7p11.1-q11.1 specific for the alpha satellite centromeric region D7Z1 of chromosome 7.
- Formamide based hybridization buffer

* according to Human Genome Assembly GRCh37/hg19

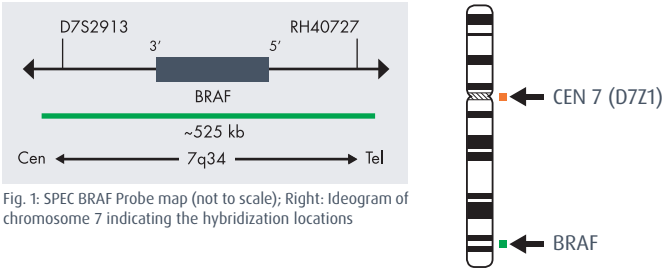
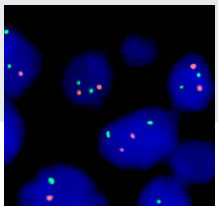


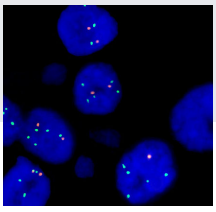
Fig. 1: SPEC BRAF Probe map (not to scale); Right: Ideogram of chromosome 7 indicating the hybridization locations

Results

Normal situation: In interphases of normal cells or cells without an amplification involving the BRAF gene region, two green and two orange signals appear.
Aberrant situation: In cells with an amplification of the BRAF gene region, an increased number of green signals or green signal clusters will be observed.



Normal interphase cells, BRAF (green), CEN 7 (orange).



Example of an aberrant signal pattern: NSCLC tissue section with amplification of the BRAF gene (green).

Labels	Chromosome	Reg. Status	Tests	Order No.
●| ●	7	CE/IVD	20 (200 µl)	**Z-2191-200**