ZytoLight® SPEC EGR1/D5S23,D5S721 Dual Color Probe

CE IVD

Background

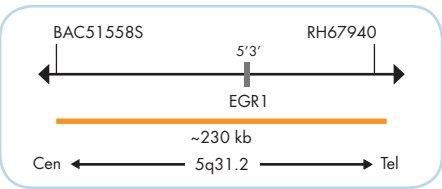
The ZytoLight® SPEC EGR1/D5S23, D5S721 Dual Color Probe (PL169) is intended to be used for the qualitative detection of deletions involving the human EGR1 gene as well as the detection of the human D5S23,D5S721 control region at 5p15.2-p15.31 in cytologic specimens by fluorescence *in situ* hybridization (FISH).
The probe is intended to be used in combination with the ZytoLight® 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

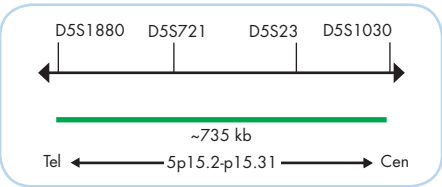
The ZytoLight® SPEC EGR1/D5S23,D5S721 Dual Color Probe is composed of:

- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~4.5 ng/µl), which target sequences mapping in 5q31.2** (chr5:137,667,079-137,897,109) harboring the EGR1 gene region.
- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~10 ng/µl), which target sequences mapping in 5p15.2-p15.31** (chr5:9,233,775-9,967,465) harboring the D5S23,D5S721 locus.
- Formamide based hybridization buffer

Ideogram of chromosome 5 indicating the hybridization locations.



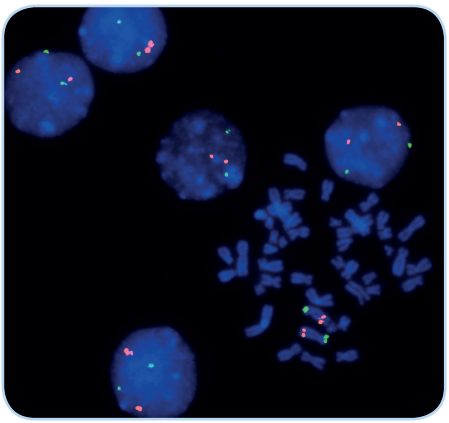
SPEC EGR1 Probe map (not to scale).



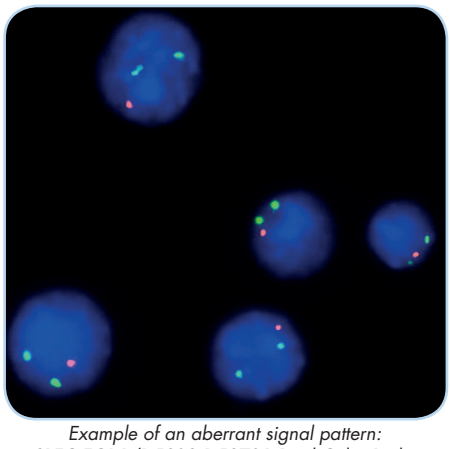
SPEC D5S23,D5S721 Probe map (not to scale).

Results

In a normal interphase nucleus, two orange and two green signals are expected. In a cell with deletion of the EGR1 gene locus, one or no copy of the orange signal will be observed.



SPEC EGR1/D5S23,D5S721 Dual Color Probe hybridized to normal interphase calls as indicated by two orange and two green signals and to metaphase chromosomes of a normal cell.



Example of an aberrant signal pattern: SPEC EGR1/D5S23,D5S721 Dual Color Probe hybridized to an AML specimen with deletion of the EGR1 gene as indicated by one orange and two green signals in each nucleus.

Prod. No.	Product	Label	Tests* (Volume)
Z-2211-50	ZytoLight SPEC EGR1/D5S23,D5S721 Dual Color Probe CE IVD	●/●	5 (50 µl)
Related Products			
Z-2099-20	ZytoLight FISH-Cytology Implementation Kit CE IVD Incl. Cytology Pepsin Solution, 4 ml; 20x Wash Buffer TBS, 50 ml; 10x $MgCl_2$, 50 ml; 10x PBS, 50 ml; Cytology Stringency Wash Buffer SSC, 500 ml; Cytology Wash Buffer SSC, 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*