ZytoLight® SPEC CKS1B/CDKN2C Dual Color Probe

CE IVD

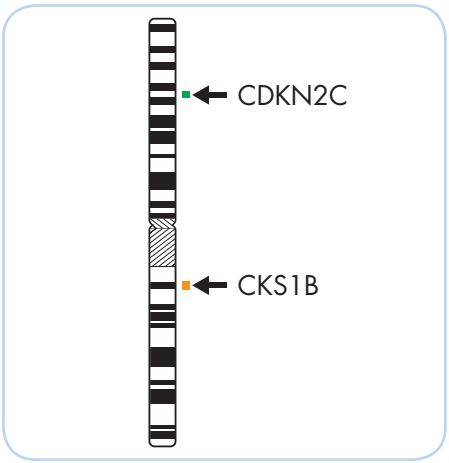
Background

The ZytoLight® SPEC CKS1B/CDKN2C Dual Color Probe (PL232) is intended to be used for the qualitative detection of amplifications/gains involving the human CKS1B gene at 1q21.3-q22 and deletions involving the human CDKN2C gene at 1p32.3 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.

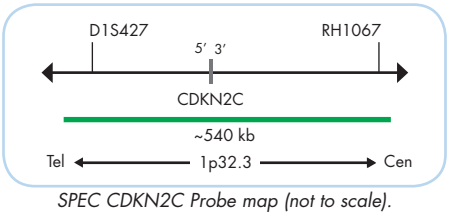
Probe Description

The ZytoLight® SPEC CKS1B/CDKN2C Dual Color Probe is composed of:

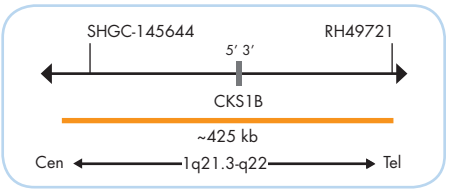
- ZyOrange (excitation 547 nm/ emission at 572 nm) labeled polynucleotides (~4.5 ng/µl), which target sequences mapping in 1q21.3-q22** (chr1:154,722,168-155,144,639) harboring the CKS1B gene.
- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~10.0 ng/µl), which target sequences mapping in 1p32.3** (chr1:51,196,272-51,737,475) harboring the CDKN2C gene.
- Formamide based hybridization buffer



Ideogram of chromosome 1 indicating the hybridization locations.



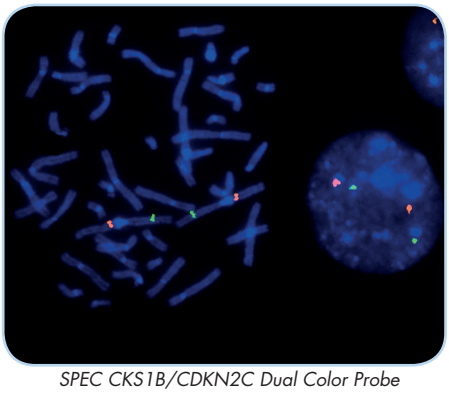
SPEC CDKN2C Probe map (not to scale).



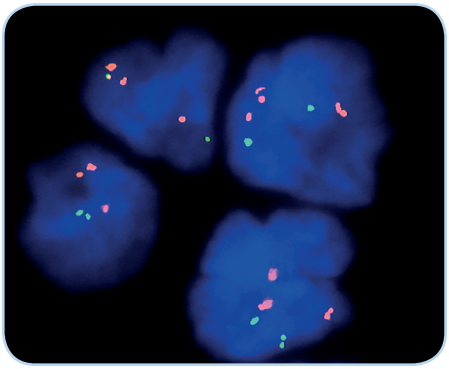
SPEC CKS1B Probe map (not to scale).

Results

In a normal interphase nucleus, two orange and two green signals are expected.
In a cell with a gain/amplification of the CKS1B gene locus, multiple copies of the orange signal or orange signal clusters will be observed.
In a cell with deletion of the CDKN2C gene locus one or no copy of the green signal will be observed. Deletions affecting only parts of the CDKN2C locus might result in a normal signal pattern with green signals of reduced size.



SPEC CKS1B/CDKN2C Dual Color Probe 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 of a pediatric ALL case with amplification affecting the CKS1B locus as indicated by three or more orange signals.

Material kindly provided by Paediatric Oncology/ Haematology, Charieté – Universitätsmedizin Berlin.

Prod. No.	Product	Label	Tests* (Volume)
Z-2276-50	ZytoLight SPEC CKS1B/CDKN2C 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*