ZytoLight® SPEC CKS1B/CDKN2C Dual Color Probe

Intended Purpose

The Zyto*Light* 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 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 CKS1B/CDKN2C Dual Color Probe is composed of:

- ZyOrange (excitation 547 nm/emission 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 region (see Fig. 1).
- 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 region (see Fig. 1).
- Formamide based hybridization buffer

* according to Human Genome Assembly GRCh37/hg19

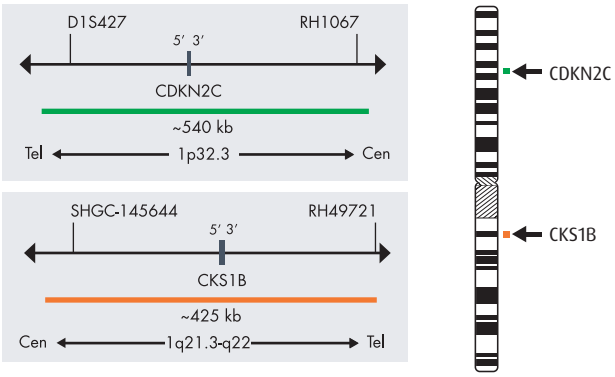
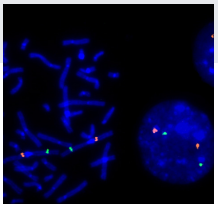


Fig. 1: Top: SPEC CDKN2C Probe map; Bottom: SPEC CKS1B Probe map (not to scale); Right: Ideogram of chromosome 1 indicating the hybridization locations

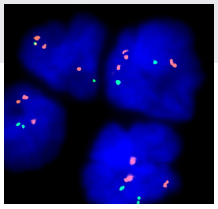
Results

Normal situation: In interphases of normal cells or cells without an amplification/gain involving the CKS1B gene region or a deletion involving the CDKN2C gene region, two orange signals and two green signals appear.

Aberrant situation: In cells with an amplification/gain of the CKS1B gene region, an increased number of orange signals will be observed. In cells with deletion affecting the CDKN2C gene region, a reduced number of green signals will be observed. Deletions affecting only parts of the CDKN2C gene region might result in a normal signal pattern with green signals of reduced size.



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.

Labels	Chromosome	Reg. Status	Tests	Order No.
	1	CE/IVD	5 (50 µl)	**Z-2276-50**
			20 (200 µl)	**Z-2276-200**

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