ZytoLight® Bladder Cancer Quadruple Color Probe

CE IVD

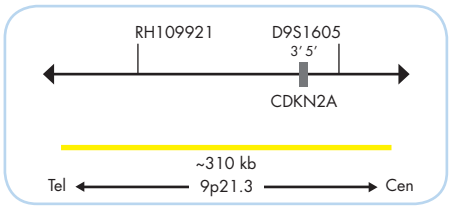
Background

The ZytoLight® Bladder Cancer Quadruple Color Probe is designed to detect CDKN2A (a.k.a. p16) deletions and aneuploidy of chromosomes 3, 7, and 17 in cytology specimens of tumors, e.g., in urine samples from patients with hematuria suspected of having bladder cancer (BC). Moreover, it has been shown that the detection of CDKN2A deletions and/or aneusomies of chromosomes 3, 7, and/or 17 may be used for the surveillance of patients with a history of bladder cancer to early detect possible tumor recurrence. BC represents the ninth most common cancer worldwide. About 430,000 new BC cases and 165,000 BC deaths occurred in 2012. Most of these tumors are non-invasive, well-differentiated, papillary tumors (pTa, low grade) and can be cured by endoscopic transurethral resection. However, up to 70% of pTa and superficially invasive (pT1) tumors recur and of these, 15-30% are characterized by tumor progression. Therefore, a long-term follow-up of patients with BC is necessary. The two standard methods used in the follow-up are either invasive (cystoscopy) or have a low sensitivity (cytology).
BC cells are characterized by typical cytogenetic changes. Homozygous deletion of the CDKN2A gene at 9p21.3 and polysomy of chromosomes 3, 7, and/or 17 are common abnormalities observed in urothelial cell carcinoma, all of which can be detected by FISH.
FISH on cells from urine has been shown to be highly sensitive and specific for detection of tumor cells in urine.

References
Antoni S, et al. (2017) Eur Urol 71: 96-108.
Dimashkieh H, et al. (2013) Cancer Cytopathol 121: 591-7.
Junker K, et al. (2006) Cytogenet Genome Res 114: 279-83.
Placer J, et al. (2002) Eur Urol 42: 547-52.
Sokolova IA, et al. (2000) J Mol Diagn 2: 116-23.

Probe Description

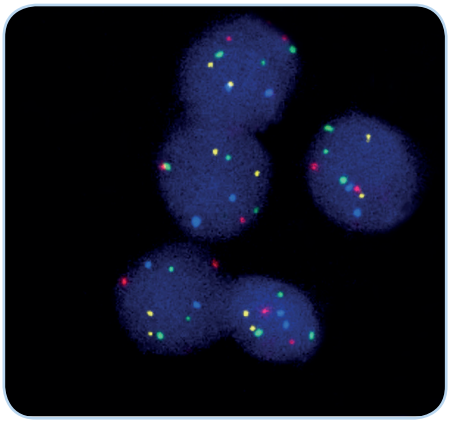
The Bladder Cancer Quadruple Color Probe is a mixture of a gold fluorochrome direct labeled SPEC CDKN2A probe specific for the CDKN2A gene at 9p21.3, a red fluorochrome direct labeled CEN 3 probe specific for the alpha satellite centromeric region of chromosome 3 (D3Z1), a green fluorochrome direct labeled CEN 7 probe specific for the alpha satellite centromeric region of chromosome 7 (D7Z1), and a blue fluorochrome direct labeled CEN 17 probe specific for the alpha satellite centromeric region of chromosome 17 (D17Z1).



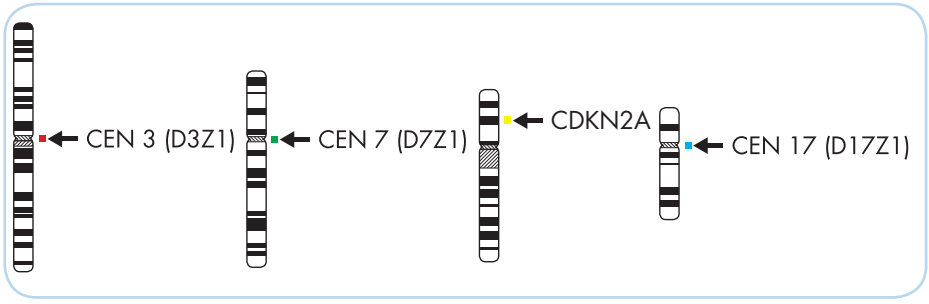
SPEC CDKN2A Probe map (not to scale).

Results

In a normal interphase nucleus, two gold, two red, two green, and two blue signals are expected. In a cell with deletion of the CDKN2A gene locus, a reduced number of gold signals will be observed. In cells with aneusomy of chromosomes 3, 7, or 17 more or less signals of the respective color will be visible.



Interphase tumor cells with trisomy of chromosome 7 as indicated by three green signals in each nucleus.



Ideograms of chromosomes 3, 7, 9, and 17 indicating the hybridization locations.

Prod. No.	Product	Label	Tests* (Volume)
Z-2305-50	ZytoLight Bladder Cancer Quadruple Color Probe CE IVD	●/●/●/●	5 (50 µl)
Z-2305-200	ZytoLight Bladder Cancer Quadruple Color Probe CE IVD	●/●/●/●	20 (200 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. CE IVD only available in certain countries. All other countries research use only! Please contact your local dealer for more information.*