ZytoLight® SPEC CCND1 Break Apart/2q11/CEN 6 Quadruple Color Probe

Intended Purpose

The Zyto*Light* SPEC CCND1 Break Apart/2q11/CEN 6 Quadruple Color Probe (PL75) is intended to be used for the qualitative detection of translocations involving the human CCND1 gene at 11q13.3 as well as for the detection of human chromosome 2q11 specific sequences as well as chromosome 6 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 Zyto*Light* 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 Zyto*Light* SPEC CCND1 Break Apart/2q11/CEN 6 Quadruple Color Probe is composed of:

- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~10 ng/µl), which target sequences mapping in 11q13.2-q13.3* (chr11:68,249,010-68,705,283) proximal to CCND1 breakpoint region (see Fig. 1).
- ZyRed (excitation 580 nm/emission 599 nm) labeled polynucleotides (~4,5 ng/µl), which target sequences mapping in 11q13.3* (chr11:69,453,301-70,031,240) distal to the CCND1 breakpoint region (see Fig. 1).
- ZyBlue (excitation 418 nm/emission 467 nm) labeled polynucleotides (~37,0 ng/µl), which target sequences mapping in 2q11.2* (chr2:100.132,806-100,621,725) (see Fig. 1).
- ZyGold (excitation 532 nm/emission 553 nm) labeled polynucleotides (~7 ng/µl), which target sequences mapping in 6p11.1-q11 specific for the alpha satellite centromeric region D6Z1 of chromosome 6.
- Formamide based hybridization buffer

* according to Human Genome Assembly GRCh37/hg19

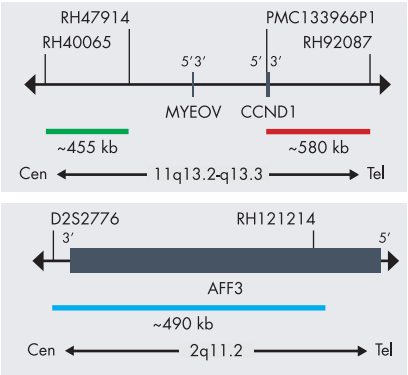
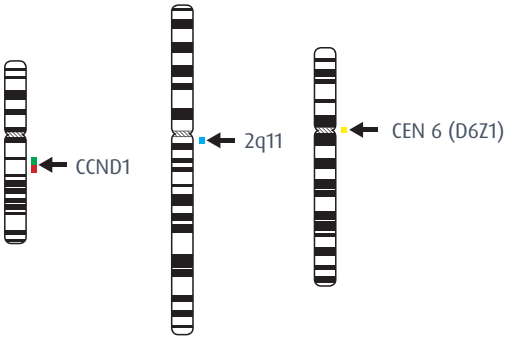


Fig. 1: Top: SPEC CCND1 Probe map; Bottom: SPEC 2q11 Probe map (not to scale)

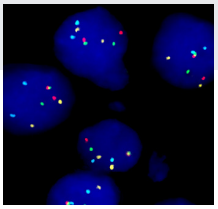


Ideograms of chromosome 11, 2 and 6 indicating the hybridization locations

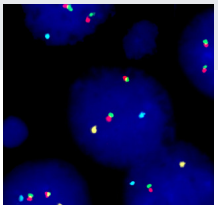
Results

Normal situation: In interphases of normal cells or cells without a translocation involving the CCND1 gene region, two red/green fusion signals, two blue and two gold signals appear.

Aberrant situation: In a cell with translocation of the CCND1 gene region, a signal pattern consisting of one red/green fusion signal, one red, and a separate green signal indicates one normal CCND1 gene region and one CCND1 gene region affected by an 11q13.3 translocation. In cells with aneusomy of chromosome 2 or 6, more or less signals of the respective color will be visible.



Example of an aberrant signal pattern: Renal cell carcinoma tissue section with translocation affecting the 11q13.3 locus as indicated by one non-rearranged red/green fusion signal, one red signal, and one separate green signal.



Example of an aberrant signal pattern: Renal cell carcinoma tissue section with monosomy of chromosome 2 and 6 as indicated by one blue and one gold signal in each nucleus.

Labels	Chromosome	Reg. Status	Tests	Order No.
	2, 6, 11	CE/IVD	20 (200 µl)	**Z-2118-200**