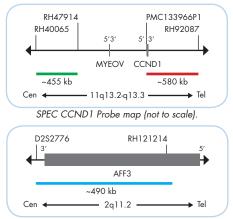
ZytoLight® SPEC CCND1 Break Apart/2q11/CEN 6 Quadruple Color Probe ()

Background

The ZytoLight [®] 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 ZytoLight [®] 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.



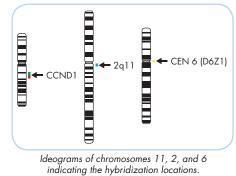
SPEC 2q11 Probe map (not to scale).

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Probe Description

The ZytoLight [®] SPEC CCND1 Break Apart/2q11/CEN 6 Quadruple Color Probe is composed of:

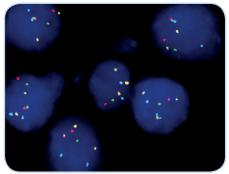
- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~10 ng/µl), which target sequences es mapping in 11q13.2-q13.3** (chr11:68,249,010-68,705,283) proximal to CCND1 breakpoint region.
- ZyRed (excitation at 580 nm/emission 599 nm) labeled polynucleotides (~4.5 ng/µl), which target sequences mapping in 11q13.3** (chr11:69,453,301-70,031,240) distal to the CCND1 breakpoint region.
- ZyBlue (excitation at 418 nm/emission 467 nm) labeled polynucleotides (~37 ng/µl), which target sequences mapping in 2q11.2** (chr2:100,132,806-100,621,725).
- ZyGold (excitation at 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



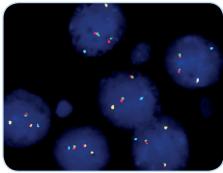
Results

In a normal interphase nucleus, two red/ green fusion signals, two blue, and two gold signals are expected. In a cell with translocation of the CCND1 gene locus, a signal pattern consisting of one red/ green fusion signal, one red, and a separate green signal indicates one normal CCND1 locus and one CCND1 locus 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.

IVD



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.

Molecular diagnostics simplified

FE079-1-23

Prod. No.	Product	Label	Tests* (Volume)
Z-2118-200	Zyto <i>Light</i> SPEC CCND1 Break Apart/2q11/CEN 6 Quadruple Color Probe C € [VD]	●/●/●/●	20 (200 µl)
Related Proc	lucts		
Z-2028-20	Zyto <i>Light</i> FISH-Tissue Implementation Kit C E [VD] Incl. Heat Pretreatment Solution Citric, 500 ml; Pepsin Solution, 4 ml; Wash Buffer SSC, 560 ml; 25x Wash Buffer A, 100 ml; DAPI/DuraTect-Solution, 0.8 ml		20
0 1 1	on per test. [VD] labeled products are only available in certain countries. All other countries research use only! Please contact your local dealer for more information nome Assembly GRCh37/hg19		

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