

ZytoLight® SPEC CCND1 Dual Color Break Apart Probe



Background

The ZytoLight® SPEC CCND1 Dual Color Break Apart Probe (PL65) is intended to be used for the qualitative detection of translocations involving the human CCND1 gene at 11q13.3 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).

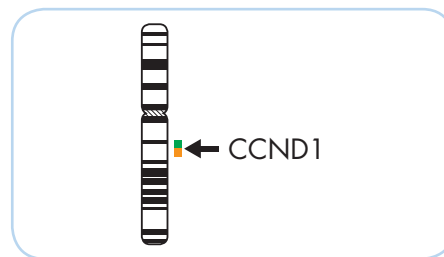
The product is intended for professional use only. All tests using the product should be performed in a certified, licensed anatomic pathology laboratory under the supervision of a pathologist/human geneticist by qualified personnel.

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.

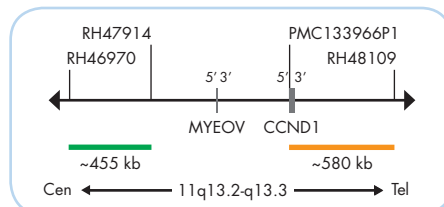
Probe Description

The ZytoLight® SPEC CCND1 Dual Color Break Apart 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 the CCND1 breakpoint region.
- ZyOrange (excitation 547 nm/emission 572 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.
- Formamide based hybridization buffer



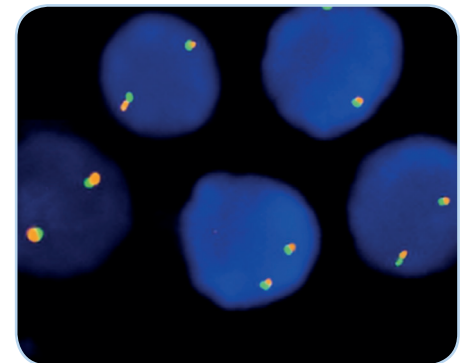
Ideogram of chromosome 11 indicating the hybridization locations.



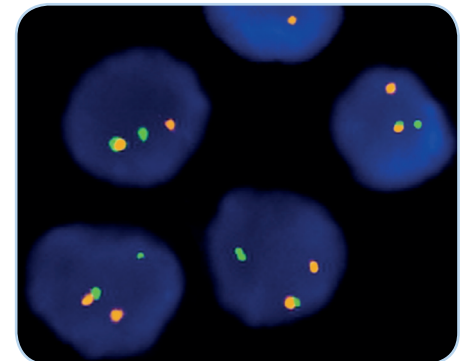
SPEC CCND1 Probe map (not to scale).

Results

In an interphase nucleus lacking a translocation involving the 11q13.2-q13.3 band, two orange/green fusion signals are expected representing two normal (non-rearranged) CCND1 loci. A signal pattern consisting of one orange/green fusion signal, one orange signal, and a separate green signal indicates one normal CCND1 locus and one CCND1 locus affected by an 11q13.2-q13.3 translocation.



SPEC CCND1 Dual Color Break Apart Probe hybridized to normal interphase cells as indicated by two orange/green fusion signals per nucleus.



Example of an aberrant signal pattern: Bone marrow biopsy section with translocation affecting the 11q13.2-q13.3 locus as indicated by one non-rearranged orange/green fusion signal, one orange signal, and one separate green signal.

Prod. No.	Product	Label	Tests* (Volume)
Z-2108-50	ZytoLight SPEC CCND1 Dual Color Break Apart Probe CE IVD	●/●	5 (50 μl)
Z-2108-200	ZytoLight SPEC CCND1 Dual Color Break Apart Probe CE IVD	●/●	20 (200 μl)
Related Products			
Z-2028-5	ZytoLight FISH-Tissue Implementation Kit CE IVD Incl. Heat Pretreatment Solution Citric, 150 ml; Pepsin Solution, 1 ml; Wash Buffer SSC, 210 ml; 25x Wash Buffer A, 50 ml; DAPI/DuroTect-Solution, 0.2 ml		5
Z-2028-20	ZytoLight FISH-Tissue Implementation Kit CE IVD Incl. Heat Pretreatment Solution Citric, 500 ml; Pepsin Solution, 4 ml; Wash Buffer SSC, 560 ml; 25x Wash Buffer A, 100 ml; DAPI/DuroTect-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