

ZytoLight® SPEC CCND1 Dual Color Break Apart Probe



Background

The ZytoLight® SPEC CCND1 Dual Color Break Apart Probe is designed to detect translocations involving the chromosomal region 11q13.3 harboring the CCND1 gene. The CCND1 gene (cyclin D1, a.k.a. PRAD1) encodes a regulatory subunit of cyclin-dependent kinases.

Translocations involving the chromosomal region t(11;14) (q13.3;q32.3) are considered to be characteristic for mantle cell lymphomas (MCL) but have also been identified in other lymphoproliferative disorders (LPDs), such as B-prolymphocytic leukemia, and, less frequently, in plasma cell myelomas, B-cell chronic lymphocytic leukemia, and in splenic lymphomas with villous lymphocytes (SLVL).

The t(11;14) rearrangement often leads to overexpression of the CCND1 protein. Determination of translocations involving the chromosomal region 11q13.3 can also help to distinguish MCL from other chronic lymphoproliferative disorders. Since the course of MCL is aggressive, and its response to chemotherapy is poor, differential diagnosis is clinically important.

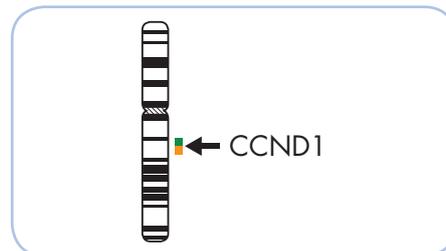
Additionally, it was also shown that a renal oncocytoma (RO) specific breakpoint is located in band 11q13.3, involving the CCND1 locus. The histologic features of RO may overlap with those of chromophobe renal cell carcinoma (ChRCC). Fluorescence *in situ* Hybridization (FISH) can be used as a diagnostic tool for differentiation of RO from ChRCC.

References

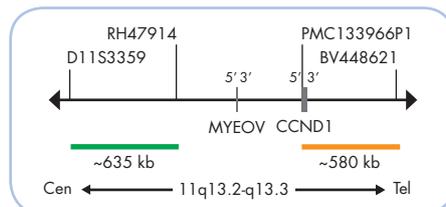
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Probe Description

The SPEC CCND1 Dual Color Break Apart Probe is a mixture of two direct labeled probes hybridizing to the 11q13.2-q13.3 band. The orange fluorochrome direct labeled probe hybridizes distal to and covers the CCND1 gene, while the green fluorochrome direct labeled probe hybridizes proximal to that gene.



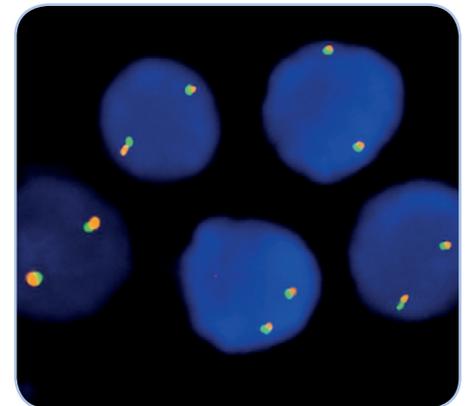
Ideogram of chromosome 11 indicating the hybridization locations.



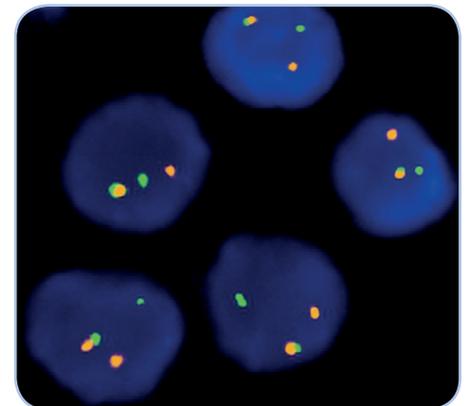
SPEC CCND1 Probe map (not to scale).

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.



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 indicating the translocation.

| Prod. No. | Product | Label | Tests* (Volume) |
|-------------------------|---|-------|-----------------|
| Z-2108-200 | ZytoLight SPEC CCND1 Dual Color Break Apart Probe CE IVD | ●/● | 20 (200 µl) |
| Related Products | | | |
| Z-2028-20 | ZytoLight FISH-Tissue Implementation Kit CE IVD Incl. Heat Pretreatment Solution Citric, 500 ml; Pepsin Solution, 4 ml; Wash Buffer SSC, 500 ml; 25x Wash Buffer A, 100 ml; DAPI/DuraTect-Solution, 0.8 ml | | 20 |
| 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.