ZytoLight® SPEC CCND1/IGH Dual Color Dual Fusion Probe

CE IVD

Background

The ZytoLight® SPEC CCND1/IGH Dual Color Dual Fusion Probe (PL82) is intended to be used for the qualitative detection of the translocation t(11;14)(q13.3;q32.3) in cytologic or formalin-fixed, paraffin-embedded specimens by fluorescence *in situ* hybridization (FISH). The probe is intended to be used in combination with ZytoLight® FISH Implementation Kits (Prod. No. Z-2028-5/-20, or Z-2099-20).
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.

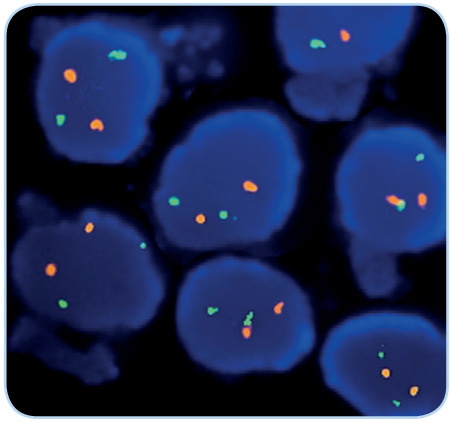
Probe Description

The ZytoLight® SPEC CCND1/IGH Dual Color Dual Fusion Probe is composed of:

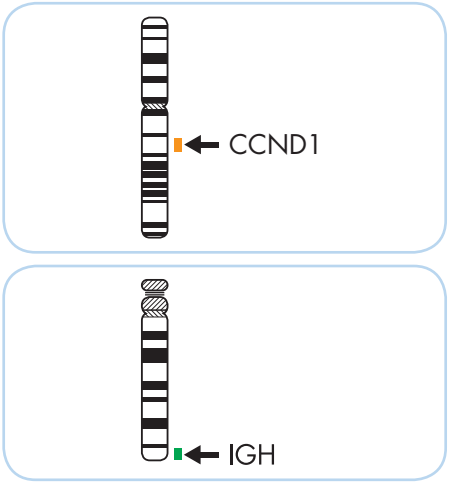
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~6.0 ng/µl), which target sequences mapping in 11q13.3** (chr11:68,522,105-70,031,240) harboring the CCND1 gene region.
- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~12.0 ng/µl), which target sequences mapping in 14q32.33** (chr14:105,462,169-106,995,000) harboring the IGH locus.
- Formamide based hybridization buffer

Results

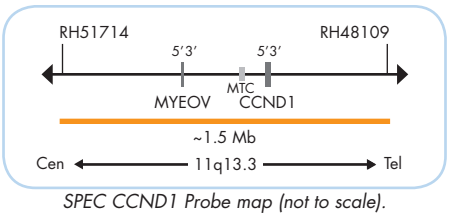
In a normal interphase nucleus, two orange and two green signals are expected. A reciprocal CCND1/IGH translocation leads to two orange/green fusion signals indicating both rearranged chromosomes. Additionally, the non-rearranged chromosomes are indicated by one orange signal and a separate green signal, respectively.



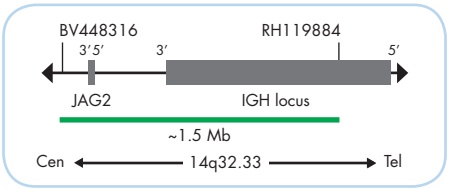
SPEC CCND1/IGH Dual Color Dual Fusion Probe hybridized to normal interphase cells as indicated by two orange and two green signals in each nucleus.



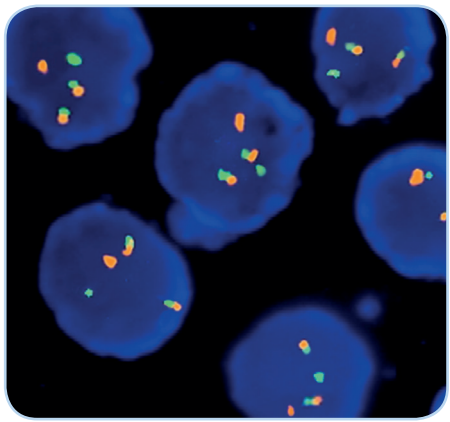
Ideograms of chromosomes 11 (above) and 14 (below) indicating the hybridization locations.



SPEC CCND1 Probe map (not to scale).



SPEC IGH Probe map (not to scale).



Example of an aberrant signal pattern: Section of an iliac crest biopsy with translocation affecting the CCND1/IGH loci as indicated by one separate orange signal, one separate green signal, and two orange/green fusion signals.

Prod. No.	Product	Label	Tests* (Volume)
Z-2125-50	ZytoLight SPEC CCND1/IGH Dual Color Dual Fusion Probe CE IVD	/●	5 (50 µl)
Z-2125-200	ZytoLight SPEC CCND1/IGH Dual Color Dual Fusion 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/DuraTect-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/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. 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*