ZytoLight® SPEC IGL Dual Color Break Apart Probe

CE IVD

Background

The ZytoLight® SPEC IGL Dual Color Break Apart Probe (PL241) is intended to be used for the qualitative detection of translocations involving the human IGL locus at 22q11.22 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.

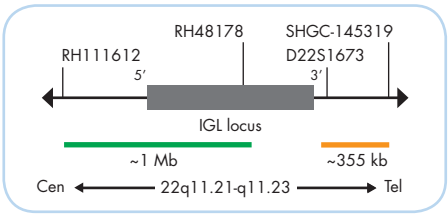
The probe is intended to be used as an aid to the differential diagnosis of various cancers and therapeutic measures should not be initiated based on the test result alone.

Probe Description

The ZytoLight® SPEC IGL Dual Color Break Apart Probe is composed of:

- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~10.0 ng/µl), which target sequences mapping in 22q11.21-q11.22** (chr22:21,931,816-22,942,402) proximal to the IGL breakpoint region.
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~4.5 ng/µl), which target sequences mapping in 22q11.22-q11.23** (chr22:23,324,781-23,679,042) distal to the IGL breakpoint region.
- Formamide based hybridization buffer

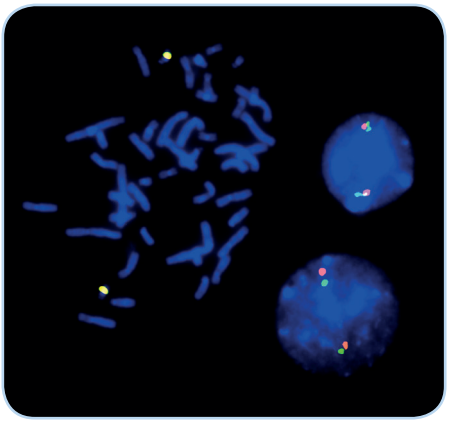
Ideogram of chromosome 22 indicating the hybridization locations.



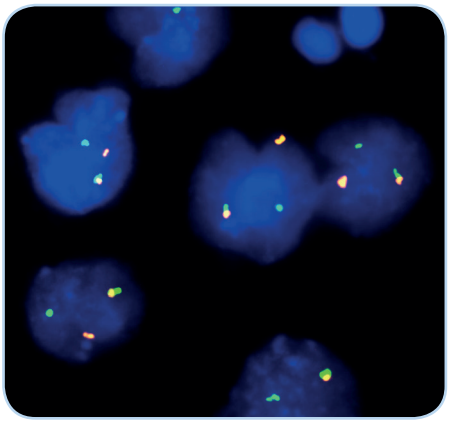
SPEC IGL Probe map (not to scale).

Results

In an interphase nucleus lacking a translocation involving the IGL locus at 22q11.22, two orange/green fusion signals are expected. A signal pattern consisting of one orange/green fusion signal, one orange signal, and a separate green signal indicates one normal IGL locus and one IGL locus affected by a translocation.



SPEC IGL Dual Color Break Apart Probe hybridized to normal interphase cells as indicated by two orange/green fusion signals in each nucleus and to metaphase chromosomes of a normal cell.



Example of an aberrant signal pattern: Cell line with an IGL translocation affecting the 22q11.21-q11.23 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-2286-50	ZytoLight SPEC IGL Dual Color Break Apart Probe CE IVD	●/●	5 (50 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-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*