ZytoLight® SPEC IRF4,DUSP22 Dual Color Break Apart Probe

CE 0124
IVD

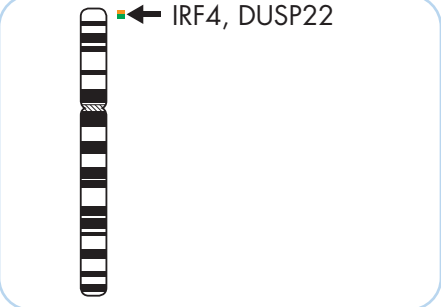
Background

The ZytoLight® SPEC IRF4,DUSP22 Dual Color Break Apart Probe (PL168) is intended to be used for the qualitative detection of translocations involving the human IRF4,DUSP22 gene region at 6p25.3 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.

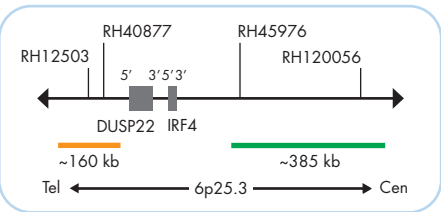
Probe Description

The ZytoLight® SPEC IRF4,DUSP22 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 6p25.3** (chr6:557,233-940,968) proximal to the IRF4,DUSP22 breakpoint region.
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~4.5 ng/µl), which target sequences mapping in 6p25.3** (chr6:114,722-273,908) distal to the IRF4,DUSP22 breakpoint region.
- Formamide based hybridization buffer



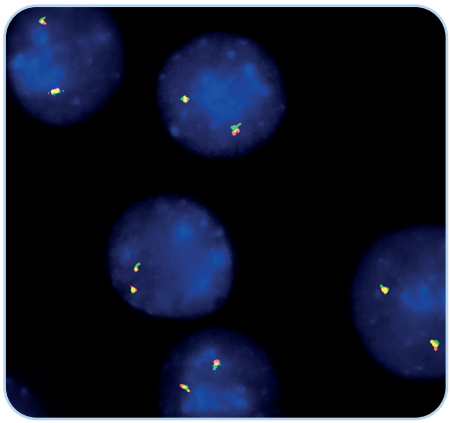
Ideogram of chromosome 6 indicating the hybridization locations.



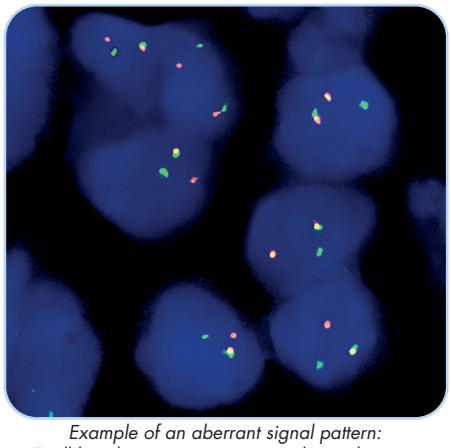
SPEC IRF4, DUSP22 Probe map (not to scale).

Results

In an interphase nucleus lacking a translocation involving the 6p25.3 band, two orange/green fusion signals are expected representing two normal (non-rearranged) 6p25.3 loci. A signal pattern consisting of one orange/green fusion signal, one orange signal, and a separate green signal indicates one normal 6p25.3 locus and one 6p25.3 locus affected by a translocation.



SPEC IRF4, DUSP22 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: T-cell lymphoma tissue section with translocation affecting the 6p25.3 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-2210-50	ZytoLight SPEC IRF4,DUSP22 Dual Color Break Apart Probe CE 0124 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

** 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*