ZytoLight® SPEC JAK2 Dual Color Break Apart Probe

CE IVD

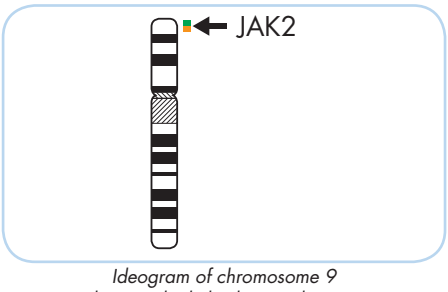
Background

The ZytoLight® SPEC JAK2 Dual Color Break Apart Probe (PL248) is intended to be used for the qualitative detection of translocations involving the human JAK2 gene at 9p24.1 in cytologic specimens by fluorescence *in situ* hybridization (FISH). The probe is intended to be used in combination with the ZytoLight® FISH-Cytology Implementation Kit (Prod. No. 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.

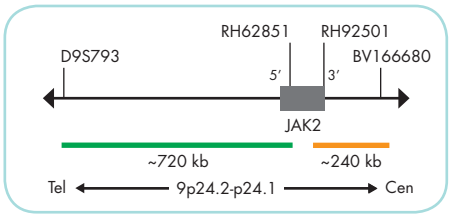
Probe Description

The ZytoLight SPEC JAK2 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 9p24.1-24.2** (chr9:4,311,843-5,031,620) distal to the JAK2 breakpoint region.
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~4.5 ng/µl), which target sequences mapping in 9p24.1** (chr9:5,088,700-5,328,239) proximal to the JAK2 breakpoint region.
- Formamide based hybridization buffer



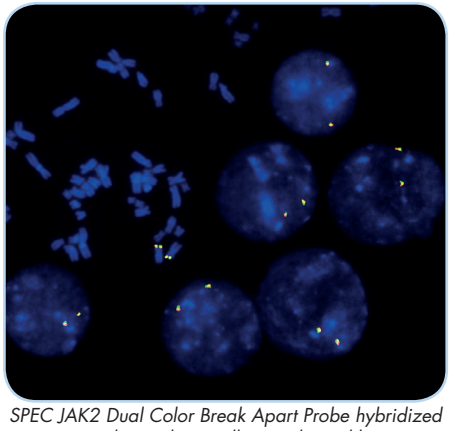
Ideogram of chromosome 9 indicating the hybridization locations.



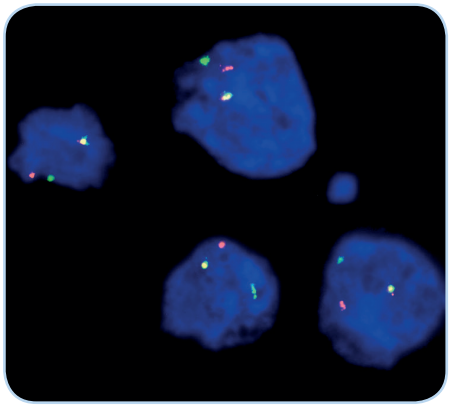
SPEC JAK2 Probe map (not to scale).

Results

In an interphase nucleus of a normal cell lacking a translocation involving the 9p24.2-p24.1 bands, two orange/green fusion signals are expected representing two normal (non-rearranged) 9p24.2-p24.1 loci. A signal pattern consisting of one orange/green fusion signal, one orange signal, and a separate green signal indicates one normal 9p24.2-p24.1 locus and one 9p24.2-p24.1 locus affected by a translocation.



SPEC JAK2 Dual Color Break Apart Probe hybridized to normal interphase cells as indicated by two orange/green fusion signals per nucleus and to metaphase chromosomes of a normal cell.



Example of an aberrant signal pattern: Bone marrow smear with translocation of the JAK2 gene as indicated by one non-rearranged orange/green fusion signal, one orange and one separate green signal.

Prod. No.	Product	Label	Tests* (Volume)
Z-2294-50	ZytoLight SPEC JAK2 Dual Color Break Apart Probe CE IVD	●/●	5 (50 µl)
Related Products			
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*