

ZytoLight® SPEC CBF B Dual Color Break Apart Probe



Background

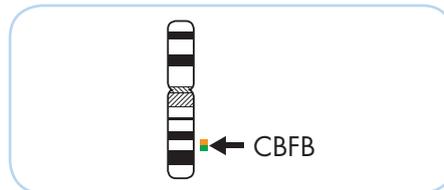
The ZytoLight® SPEC CBF B Dual Color Break Apart Probe (PL165) is intended to be used for the qualitative detection of translocations involving the human CBF B gene at 16q22.1 in cytologic specimens by fluorescence *in situ* hybridization (FISH). The probe is intended to be used in combination with the 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.

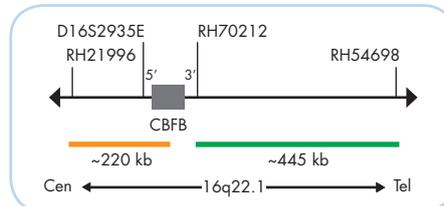
Probe Description

The ZytoLight® SPEC CBF B 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 16q22.1** (chr16:67,161,347-67,605,304) distal to the CBF B breakpoint region.
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~4.5 ng/μl), which target sequences mapping in 16q22.1** (chr16:66,882,262-67,102,895) proximal to the CBF B breakpoint region.
- Formamide based hybridization buffer

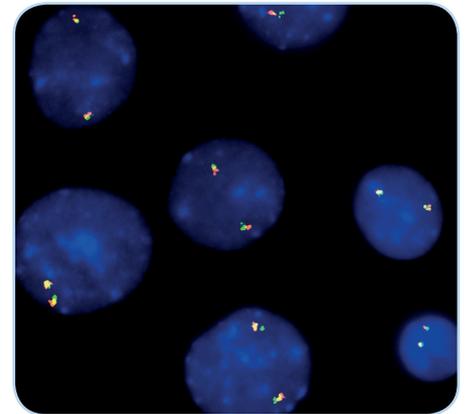


Ideogram of chromosome 16 indicating the hybridization locations.



Results

In an interphase nucleus of a normal cell lacking a translocation involving the 16q22.1 band, two orange/green fusion signals are expected representing two normal (non-rearranged) 16q22.1 loci. A signal pattern consisting of one orange/green fusion signal, one orange signal, and a separate green signal indicates one normal 16q22.1 locus and one 16q22.1 locus affected by a translocation. In case of a deletion distal to the CBF B breakpoint region a single orange signal can be expected.



SPEC CBF B Dual Color Break Apart Probe hybridized to normal interphase cells as indicated by two orange/green fusion signals per nucleus.

Prod. No.	Product	Label	Tests* (Volume)
Z-2207-50	ZytoLight SPEC CBF B Dual Color Break Apart Probe CE IVD	●/●	5 (50 μl)
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