

ZytoLight® SPEC ERG Dual Color Break Apart Probe



Background

The ZytoLight® SPEC ERG Dual Color Break Apart Probe (PL95) is intended to be used for the qualitative detection of translocations involving the human ERG gene at 21q22.2 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).

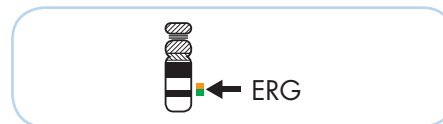
The product is intended for professional use only. All tests using the product should be performed in a certified, licensed anatomic pathology laboratory under the supervision of a pathologist/human geneticist by qualified personnel.

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.

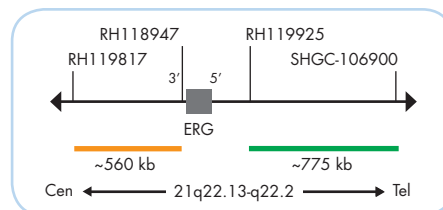
Probe Description

The ZytoLight® SPEC ERG 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 21q22.2** (chr21:40,078,039-40,850,582) distal to the ERG breakpoint region.
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~4.5 ng/µl), which target sequences mapping in 21q22.13-q22.2** (chr21:39,171,790-39,733,849) proximal to the ERG breakpoint region.
- Formamide based hybridization buffer



Ideogram of chromosome 21 indicating the hybridization locations.



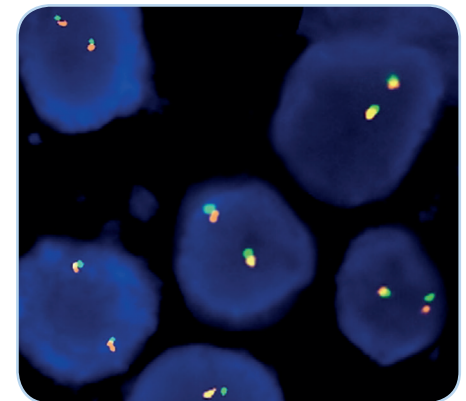
SPEC ERG Probe map (not to scale).

Results

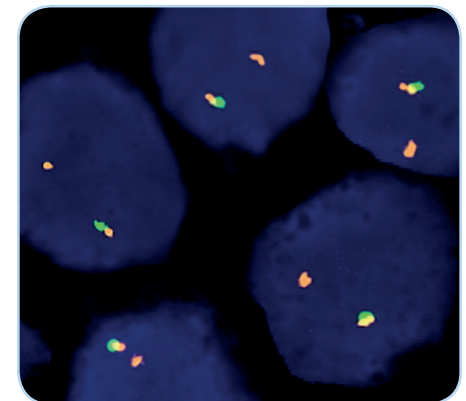
In an interphase nucleus of a normal cell lacking an aberration involving the 21q22.13-q22.2 band, two orange/green fusion signals are expected representing the two normal (non-rearranged) 21q22.13-q22.2 loci.

One 21q22.13-q22.2 locus affected by a 21q22.2 deletion resulting in the TMPRSS2-ERG fusion is indicated by the loss of one green signal.

A signal pattern consisting of one orange/green fusion signal, a separate green, and a separate orange signal indicates an ERG translocation without involvement of TMPRSS2 (e.g. SLC45A3-ERG).



SPEC ERG 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: Prostate cancer tissue section with interstitial deletion of the chromosomal region 21q22.2 resulting in the TMPRSS2-ERG fusion as indicated by the loss of one green signal.

Prod. No.	Product	Label	Tests* (Volume)
Z-2138-200	ZytoLight SPEC ERG Dual Color Break Apart Probe CE IVD	●/●	20 (200 µl)
Related Products			
Z-2028-20	ZytoLight FISH-Tissue Implementation Kit CE IVD		20
Incl. Heat Pretreatment Solution Citric, 500 ml; Pepsin Solution, 4 ml; Wash Buffer SSC, 560 ml; 25x Wash Buffer A, 100 ml; DAPI/DuraText-Solution, 0.8 ml			

* 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