

# ZytoLight® SPEC TFE3 Dual Color Break Apart Probe



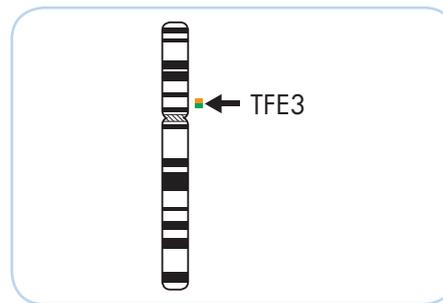
## Background

The ZytoLight® SPEC TFE3 Dual Color Break Apart Probe (PL66) is intended to be used for the qualitative detection of translocations involving the human TFE3 gene at Xp11.23 in formalin-fixed, paraffin-embedded specimens, such as renal cell carcinomas (RCC), 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 RCC and therapeutic measures should not be initiated based on the test result alone.

## Probe Description

The ZytoLight® SPEC TFE3 Dual Color Break Apart Probe is composed of:

- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~4.5 ng/µl), which target sequences mapping in Xp11.23\*\* (chrX:48,287,169-48,792,674) distal to the TFE3 breakpoint region.
- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~10 ng/µl), which target sequences mapping in Xp11.23\*\* (chrX:48,906,685-49,509,699) proximal to the TFE3 breakpoint region.
- Formamide based hybridization buffer



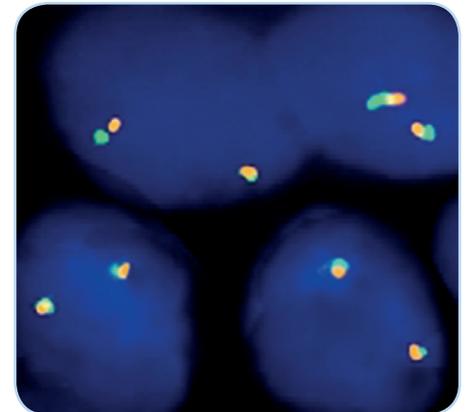
Ideogram of chromosome X indicating the hybridization locations.



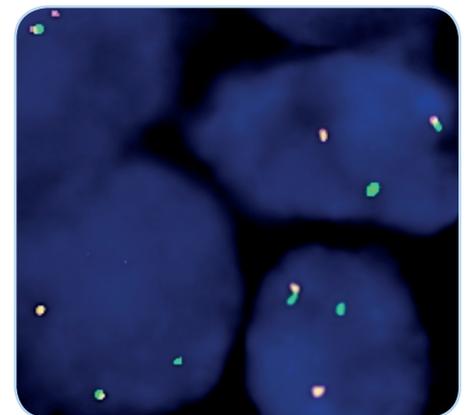
SPEC TFE3 Probe map (not to scale).

## Results

In a female interphase nucleus lacking a translocation involving the Xp11.23 band two orange/green fusion signals are expected representing two normal (non-rearranged) Xp11.23 loci. In a normal male interphase nucleus one orange/green fusion signal is expected representing one normal (non-rearranged) Xp11.23 locus. One separate green and separate orange signal indicate one Xp11.23 locus affected by a translocation.



SPEC TFE3 Dual Color Break Apart Probe hybridized to normal interphase cells as indicated by two orange/green fusion signals per nucleus.



Renal cell carcinoma section with translocation affecting the Xp11.23 locus as indicated by one non-rearranged green/orange fusion signal, one separate green signal, and one separate orange signal.

| Prod. No.               | Product  | Label | Tests* (Volume) |
|-------------------------|--|-------|-----------------|
| Z-2109-50               | ZytoLight® SPEC TFE3 Dual Color Break Apart Probe CE IVD   | ●/●   | 5 (50 µl)       |
| Z-2109-200              | ZytoLight® SPEC TFE3 Dual Color Break Apart Probe CE IVD   | ●/●   | 20 (200 µl)     |
| <b>Related Products</b> |  |       |                 |
| Z-2028-5                | ZytoLight® FISH-Tissue Implementation Kit CE IVD<br>Incl. Heat Pretreatment Solution Citric, 150 ml; Pepsin Solution, 1 ml; Wash Buffer SSC, 210 ml; 25x Wash Buffer A, 50 ml; DAPI/DuraText-Solution, 0.2 ml  |       | 5               |
| Z-2028-20               | ZytoLight® FISH-Tissue Implementation Kit CE IVD<br>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 |       | 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